Contents

Class - 1

Collect Information of Key persons at hospitals, pharmacies and dealers:

The healthcare supply chain plays a critical role in ensuring timely access to essential medications, medical equipment, and supplies for patients. Smooth operations within this chain rely on the coordinated efforts of various key personnel across different sectors: hospitals, pharmacies, and dealers.

Hospitals:

Hospital Administrator/CEO:

Oversees the overall management and operations of the hospital.
Sets budget and strategic direction to ensure adequate resources are procured and allocated efficiently.
Plays a crucial role in establishing relationships with suppliers and ensuring compliance with regulations.

Chief Medical Officer (CMO):

Leads the medical staff and oversees patient care quality.
Implements quality control measures and ensures medications and equipment meet safety standards.
Collaborates with department heads to ensure optimal utilization of resources.

Department Heads:

Manage specific departments like Surgery, Nursing, Pharmacy, and Radiology.
Oversee inventory levels within their departments and anticipate needs for medications, equipment, and supplies.
Place timely orders and communicate requirements to procurement teams.

Physicians:

Diagnose and treat patients, prescribing medications based on their expertise and familiarity with potential drug interactions.
Play a vital role in determining the type and quantity of medications needed for patient care.

Nurses:

Provide bedside care to patients, administering medications according to prescribed dosages.
Monitor patient condition for adverse reactions to medications and report any concerns.

Pharmacist:

Licensed professional responsible for dispensing medications accurately and safely.
Verifies prescriptions, counsels patients on medication use, and monitors for potential drug interactions.
Manages pharmacy inventory, ensuring adequate stock levels and timely procurement of new supplies.

Pharmacy Technician:

Assists pharmacists with dispensing medications, maintaining inventory records, and providing patient information.
Plays a crucial role in ensuring efficient pharmacy operations and timely medication delivery.

Wholesaler:

Supplies pharmacies with medications and medical supplies in bulk quantities.
Maintains a diverse inventory and ensures timely deliveries to meet pharmacy needs.

Dealers:

Medical Equipment Dealer:

Sells medical equipment and supplies to hospitals and clinics.
Provides technical expertise and ensures proper installation, maintenance, and calibration of equipment.
Plays a vital role in ensuring the functionality and safety of medical equipment used in patient care.

Pharmaceutical Sales Representative:

Promotes pharmaceutical products to doctors and pharmacies.
Provides information about new medications, their benefits, and potential side effects.
Contributes to the adoption of new medications and advancements in healthcare.

Additional Roles:

Researchers: Develop new medications, medical devices, and technologies that improve patient care and treatment outcomes.
Logistics/Supply Chain Specialists: Optimize transportation routes and schedules to ensure timely delivery of medications and supplies.
Regulatory Agencies: Oversee the safety and efficacy of medications and medical devices, ensuring adherence to quality standards and regulations.

Importance of Collaboration:

Effective communication and collaboration among these key personnel are critical for smooth operations within the healthcare supply chain.
Hospitals need to clearly communicate their needs to pharmacies and dealers.
Pharmacies rely on timely deliveries from wholesalers and accurate prescriptions from physicians.
Medical equipment dealers require clear specifications from hospitals and proper training for healthcare professionals.
By working together effectively, these individuals ensure the efficient flow of medications and supplies, ultimately contributing to better patient care and improved healthcare outcomes.

Roles	Responsibilities
Hospital Administrator/CEO	• Overssees overall hospital operations. • Sets budget and strategic direction. • Ensures compliance with regulations.
Chief Medical Officer (CMO)	• Leads medical staff and oversees patient care quality. • Implements quality control measures. • Makes treatment decisions in collaborations with physicians.
Department Heads	• Manage specific departments (e.g. Surgery, Nursing, Pharmacy). • Oversee inventory levels and resource allocation within their departments. • Place timely orders for medications, equipment and supplies.
Physicians	• Diagnose and treat patients. • Prescribe medications based on expertise and drug interactions.

Nurses	• Provide bedside care to patients. • Administer medications according to prescribed dosages. • Monitor patient condition for adverse reactions.

Table: Bridge the roles and responsibilities for patient care and improved healthcare conditions.

This list provides a starting point for further research on specific roles and their responsibilities within the healthcare supply chain.

Patient Care:

- Ensures timely access to essential medications, medical equipment, and supplies.
- Delays or shortages can directly impact treatment effectiveness and patient outcomes.

Cost Optimization:

- Streamlines processes, minimizes waste, and potentially reduces overall healthcare costs.
- Efficient logistics and inventory management can lead to significant cost savings.

Improved Efficiency:

- Enables healthcare providers to focus on patient care rather than logistical challenges.
- Well-coordinated supply chains ensure smooth operations and better resource utilization.

Resilience:

- Adapts to changing circumstances and unexpected disruptions.
- A robust supply chain can mitigate the impact of emergencies and shortages.

Innovation:

- Facilitates the timely delivery of new technologies and treatments to patients.
- Efficient distribution networks support the adoption of advancements in healthcare.

Visual Options:

- Consider using an image depicting a connected network of hospitals, pharmacies, and suppliers.

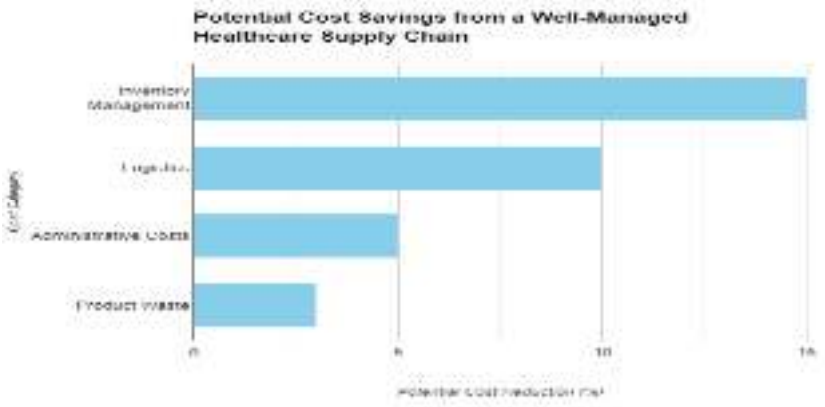

Figure: Healthcare supply chain

Pharmacy management system features:

There are different types of computer systems used by pharmacists.

Web-based ordering systems. Often provided by drug wholesalers, these systems allow pharmacists to order medications on a wholesaler's website.

Perpetual inventory systems
The use of perpetual systems (digital or not) is required by federal law for Schedule II controlled substances, and involves recording the quantity of medications continuously as the prescription is filled and dispensed. This way, the medication is automatically removed from inventory and you always have updated stock information.

Automatic dispensing systems
These are machines that automatically count and dispense pills for a pharmacist. Some complex systems even print the label and apply it to the bottle.

A PMS usually performs the functions of a perpetual inventory system and provides additional features and integrations to manage all other processes.

Inventory management
Inventory management processes in the pharmacy are saddled with paperwork and manual checks. Order forms are filled out manually and sent to manufacturers via fax, barcodes are scanned daily to update stock information, unclaimed prescriptions must be put back in stock, and so forth. Of course, not all of these processes can be automated due to federal laws and the technical limitations of your suppliers, but a PMS is able to handle some routine tasks.

Stock organization and counting. Medication counts are done regularly, but even that can't help in the situation where drug amounts are counted incorrectly or not updated in the system on time. A PMS can keep a detailed log of your inventory that can be easily filtered by the required storage conditions and expiration date, allowing you to prevent dangerous errors.

Medication ordering
A PMS uses reorder points or par levels set up by the pharmacy to generate automatic orders. The system calculates how many items are needed to raise the stock level and adds this quantity to the order. The orders are then sent via an electronic data interchange (EDI) method.

Reporting
A PMS generates reports allowing pharmacists to easily determine the better performing wholesalers and vendors and understand what factors come into play when ordering medications. This can help them better prepare for the flu season when certain drugs are in demand, and automatically calculate par levels.

E-prescribing
The process of e-prescribing involves the electronic creation and transmission of a prescription between a prescriber and a pharmacy. Using an EHR or more particularly a computerized provider order entry (CPOE) system, a doctor creates a medication order and sends it to a patient's pharmacy via secure connection. The pharmacy can then communicate that the order was received and filled, and even notify if the patient hasn't picked up their medication. Renewal requests can also be made in a couple of clicks.

This eliminates paperwork and helps ensure that the order is never lost or misunderstood -- the dosage is always accurate since the possibility of human error is minimized.

Compounding
Compounding features are tightly intertwined with inventory management and prescribing, so they're often presented as one solution. There are several ways in which a PMS can ensure accuracy in the process of drug dosing.

Scale integration
A PMS will be able to connect to scales and automatically log weight, even sending alerts when the weight is out of tolerance range.

Batch support and multi-batch compounding
Software can easily create compound batches, manage their quantities, and organize them. You can also combine batches into one prescription with all information detailed to easily track them down.

Automatic compound pricing and billing
The system will calculate prices for your compound items based on average wholesale prices of the ingredients.

Medication therapy management
In a previous article, we talked about the importance of patient engagement, particularly in a hospital setting and during patient-doctor interaction. The pharmacy environment presents even more capabilities to influence patients' adherence habits and consequently improve customer relationships. This set of services provided by pharmacists is known as Medication Therapy Management.

MTM includes such processes as:
• Creating a medication treatment plan
• Resolving drug-related problems
• Providing patient education and training

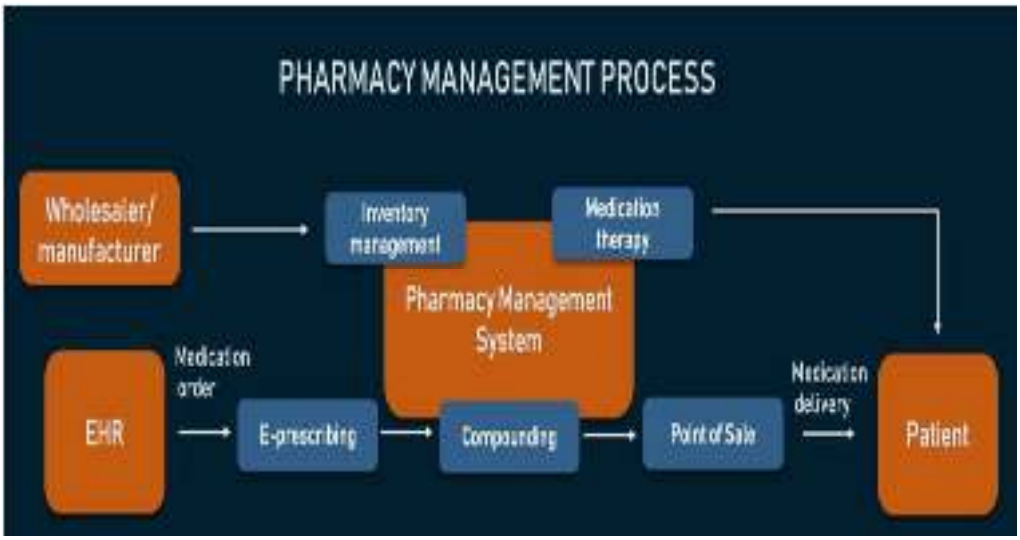

Figure: Pharmacy Management Process

Conclusion:
Understanding the key roles within the healthcare supply chain is vital for ensuring a well-functioning system that ultimately delivers optimal patient care. From hospital administrators setting strategic direction to nurses administering medications, each player contributes significantly. Hospitals rely on department heads to manage resource allocation, physicians to diagnose and prescribe, and pharmacists to dispense medications accurately. Pharmaceutical sales representatives and medical equipment dealers play crucial roles in introducing new technologies and ensuring equipment functionality. Appreciating the interconnectedness of these sectors reveals the intricate dance of communication and collaboration that keeps the supply chain moving. Each role, from hospitals to pharmacies and dealers, forms a vital link in the chain, ensuring the timely flow of medications and supplies that ultimately empowers healthcare professionals to deliver quality care to patients.

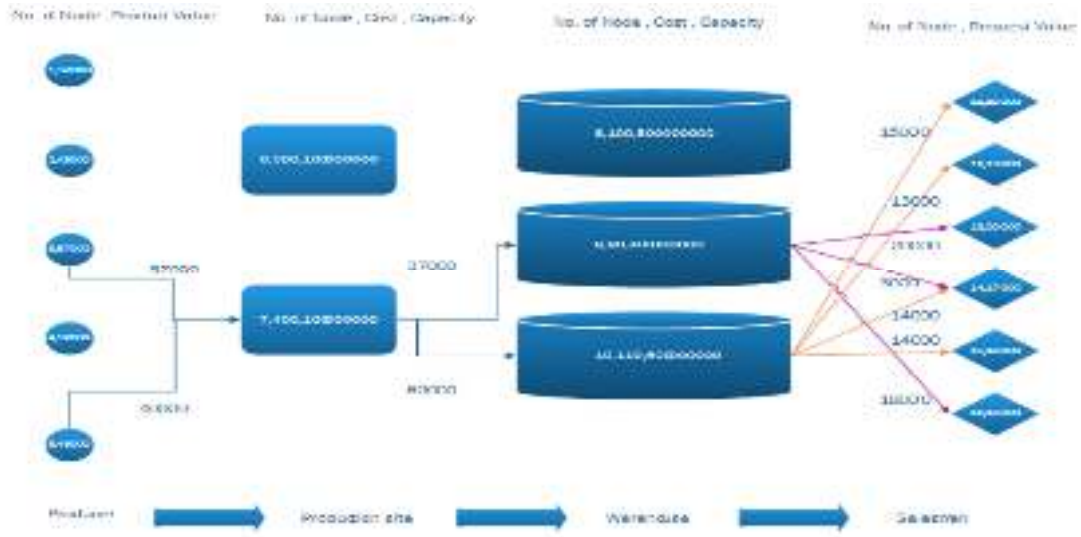

Figure: An example configuration of healthcare supply chain network

This diagram depicts the various entities involved in the healthcare supply chain and their interconnected relationships:

- **Hospitals:** Represent the central point of care, where patients receive medical services and utilize medications and equipment.
- **Pharmacies:** Dispense medications prescribed by physicians and maintain close communication with hospitals regarding inventory needs.
- **Dealers:** Supply medical equipment and technologies to hospitals, ensuring proper installation, training, and maintenance.
- **Wholesalers:** Act as intermediaries, providing pharmacies with bulk quantities of medications and medical supplies.
- **Manufacturers:** Develop and produce medications, equipment, and other essential healthcare products.
- **Regulatory Agencies:** Oversee the safety, quality, and efficacy of medications and medical devices.
- **Research Institutions:** Drive innovation by developing new drugs, technologies, and treatment approaches.

Class - 2

Healthcare Schemes

Public Health is a state subject; hence, the responsibility of providing medical assistance to patients of all income group is of respective State/ UT Governments. However, National Health Mission (NHM) – a flagship programme of the Ministry with its two Sub-Missions, National Rural Health Mission (NRHM) and National Urban Health Mission (NUHM), supports States /UTs to strengthen their health care systems so as to provide universal access to equitable, affordable and quality health care services.

The schemes launched under NHM are available free of cost to all income groups visiting in Public Health Facilities at sub district and district level are given below:

The following programmes/ schemes are run by government under National Health Mission:

Reproductive, Maternal, Neonatal, Child and Adolescent health

- Janani Shishu Suraksha Karyakaram (JSSK)
- Rashtriya Kishor Swasthya Karyakram (RKSK)
- Rashtriya Bal Swasthya Karyakram (RBSK)
- Universal Immunisation Programme

- Mission Indradhanush (MI)
- Janani Suraksha Yojana (JSY)
- Pradhan Mantri SurakshitMatritva Abhiyan (PMSMA)
- Navjaat Shishu Suraksha Karyakram (NSSK)
- National Programme for Family planning
- LaQshya' programme (Labour Room Quality Improvement Initiative)

National Nutritional Programmes

- National Iodine Deficiency Disorders Control Programme
- MAA (Mothers' Absolute Affection) Programme for Infant and Young Child Feeding
- National Programme for Prevention and Control of Fluorosis (NPPCF)
- National Iron Plus Initiative for Anaemia Control

Communicable diseases

- Integrated Disease Surveillance Programme (IDSP)
- Revised National Tuberculosis Control Programme (RNTCP)
- National Leprosy Eradication Programme (NLEP)
- National Vector Borne Disease Control Programme (NVBDCP)
- National AIDS Control Programme (NACP)
- Pulse Polio Programme
- National Viral Hepatitis Control Program (NVHCP)
- National Rabies Control Programme
- National Programme on Containment of Anti-Microbial Resistance (AMR)

Non-communicable diseases

- National Tobacco Control Programme (NTCP)
- National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases & Stroke (NPCDCS)
- National Programme for Control Treatment of Occupational Diseases
- National Programme for Prevention and Control of Deafness (NPPCD)
- National Mental Health Programme
- National Programme for Control of Blindness & Visual Impairment (NPCB&VI)
- Pradhan Mantri National Dialysis Programme (PMNDP)
- National Programme for the Health Care for the Elderly (NPHCE)
- National Programme for Prevention & Management of Burn Injuries (NPPMBI)
- National Oral Health programme

Support under NHM to States/UTs includes provision of a host of free services such as maternal health, child health, adolescent health, family planning, universal immunisation programme, and for major diseases such as Tuberculosis, HIV/ AIDS, vector borne diseases like Malaria, Dengue and Kala Azar, Leprosy etc.

Other major initiatives include Janani Shishu Suraksha Karyakram (JSSK) (under which free drugs, free diagnostics, free blood and diet, free transport from home to institution, between facilities in case of a referral and drop back home is provided), Rashtriya Bal Swasthya Karyakram (RBSK) (which provides newborn and child health screening and early interventions services free of cost for birth defects, diseases, deficiencies and

developmental delays to improve the quality of survival), implementation of Free Drugs and Free Diagnostics Service Initiatives and PM National Dialysis Programme.

Mobile Medical Units (MMUs) & Telemedicine are also being implemented with NHM support to improve healthcare access particularly in rural areas.

- The Ayushman Bharat Programme launched last year provides for holistic and integrated health care and is the principal vehicle for achieving Universal Health Coverage (UHC).
- It's Health and Wellness Centre component (AB-HWC) provides essential primary and community health services such as maternal, neonatal and child health services including immunization and nutrition, thus fostering human capital development during children's critical early years. These centres also provide services to prevent and manage common NCDs and major communicable diseases.
- The other component, AB-Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) provides free and cashless care to about 500 million poor and deprived people for secondary and tertiary hospitalization care.
- To enhance the facilities for tertiary care of cancer, Strengthening of Tertiary Care for Cancer Scheme is being implemented to support setting up of State Cancer Institutes (SCI) and Tertiary Care Cancer Centres (TCCC) in different parts of the country. Oncology in its various aspects has focus in case of new AIIMS and many upgraded institutions under Pradhan Mantri Swasthya Suraksha Yojna (PMSSY).
- Financial assistance to patients living below poverty line for life threatening diseases under the schemes such as Rashtriya Arogya Nidhi (RAN), Health Minister's Cancer Patient Fund (HMCPF) and Health Minister's Discretionary Grant (HMDG) is also provided.
- Affordable Medicines and Reliable Implants for Treatment (AMRIT) Deendayal outlets have been opened with an objective to make available drugs and implants for cardiovascular diseases (CVDs), Cancer and Diabetes at discounted prices to the patients.

Services at Ayushman Bharat – Health and Wellness Centres (AB-HWCs) are free and universal to all individuals residing in the service area.

Under Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana (AB-PMJAY), the State/ UT wise number of hospital admissions is given below:

Status as on 24.06.2019		
Sl. No.	**State**	**No of Hospital Admissions**
1	Andaman And Nicobar Islands	22
2	Andhra Pradesh	135,346
3	Arunachal Pradesh	652
4	Assam	47,631
5	Bihar	48,711
6	Chandigarh	835
7	Chhattisgarh	564,568
8	Dadra And Nagar Haveli	12,081
9	Daman and Diu	4,465
10	Goa	1,415
11	Gujarat	487,636
12	Haryana	27,811
13	Himachal Pradesh	19,145
14	Jammu And Kashmir	19,303
15	Jharkhand	184,760

16	Karnataka	197,799
17	Kerala	531,740
18	Lakshadweep	-
19	Madhya Pradesh	96,029
20	Maharashtra	139,906
21	Manipur	3,289
22	Meghalaya	15,404
23	Mizoram	13,422
24	Nagaland	945
25	Sikkim	122
26	Tamil Nadu	239,438
27	Tripura	17,505
28	Uttar Pradesh	119,204
29	Uttarakhand	49,815
30	West Bengal	17,636
Grand Total		

Table: Statewise statistics of Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana

AB-PMJAY provides health coverage of up to Rs 5.00 lakh per family per year to 10.74 crore poor, deprived families as per Socio Economic Caste Census (SECC) database. Details of the entitlement criteria are given below:

- Ayushman Bharat - PMJAY is an entitlement-based scheme with entitlement to be decided on the basis of deprivation and occupational criteria in the SECC database.
- The different categories in rural area include:

Automatically included households (based on fulfilling any of the 5 parameters of inclusion):

- Households without shelter.
- Destitute, living on alms.
- Manual scavenger families.
- Primitive tribal groups.
- legally released bonded labour

Total of (a) to (e) = 15.95 lakh

Standard Deprivation Parameter	Households
Only one room with kucha walls and kucha roof (D1)	2.38 crore
No adult member between the ages of 16 to 59 (D2)	65.33 lakh
Female-headed households with no adult male member between the ages of 16 to 59 (D3)	69.43 lakh
Disabled member and no able-bodied adult member (D4)	7.20 lakh
SC/ST households (D5)	3.87 crore
No literate adult above 25 years (D6)	4.22 crore
Landless households deriving a major part of their income from manual casual labour (D7)	5.40 crore

Total deprived Households targeted for PM-JAY who belong to one of the six deprivation criteria amongst D1, D2, D3, D4, D5 and D7	8.03 crore

Table: Standard deprivation Parameter

For urban areas, 11 defined occupational categories are entitled under the scheme. Targeted Urban Household categories proposed to be included in PM-JAY: 2.33 crore.

Sl. No.	Worker Category	Households
1	Rag picker	23,825
2	Beggar	47,371
3	Domestic worker	6,85,352
4	Street vendor/ Cobbler/hawker / Other service provider working on streets	8,64,659
5	Construction worker/ Plumber/ Mason/ Labor/ Painter/ Welder/ Security guard/ Coolie and another head-load worker	1,02,35,435
6	Sweeper/ Sanitation worker / Mali	6,06,446
7	Home-based worker/ Artisan/ Handicrafts worker / Tailor	27,58,194
8	Transport worker/ Driver/ Conductor/ Helper to drivers and conductors/ Cart puller/ Rickshaw puller	27,73,310
9	Shop worker/ Assistant/ Peon in small establishment/ Helper/ Delivery assistant / Attendant/ Waiter	36,93,042
10	Electrician/ Mechanic/ Assembler/ Repair worker	11,99,262
11	Washer-man/ Chowkidar	4,60,433
Total Targeted Urban Households		2.33 crore

Table: Worker category along with households

Total families covered under PMJAY

Sl. No.	Categories	Households (number in crore)
1	i) Rural (based on deprivation criteria)	8.03
	ii) Rural (automatically included)	0.16
2	Urban	2.33
3	Such number of families that are currently enrolled under RSBY but not in the targeted SECC data	0.22
Total		10.74

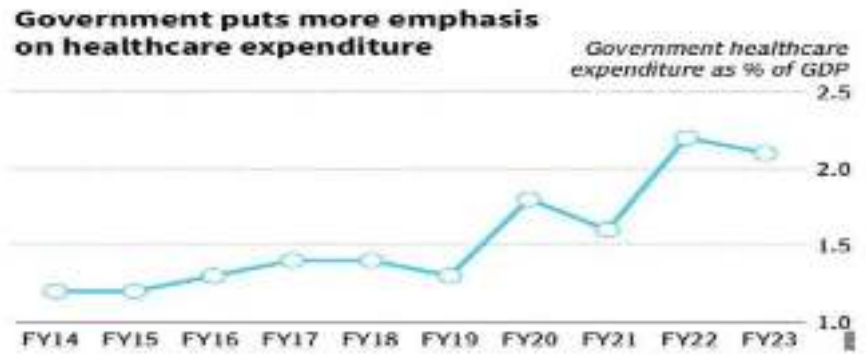

Figure: Role of Government on healthcare expenditure

- Post Covid, the government healthcare expenditure has increased from 1.2-1.4 percent to 1.6-2.2 percent of GDP.

- Average revenue per occupied bed day (ARPOB) increased from ₹34,277 to ₹49,836 during FY20-H1 FY24.
- India has one of the lowest per capita bed counts in the world.

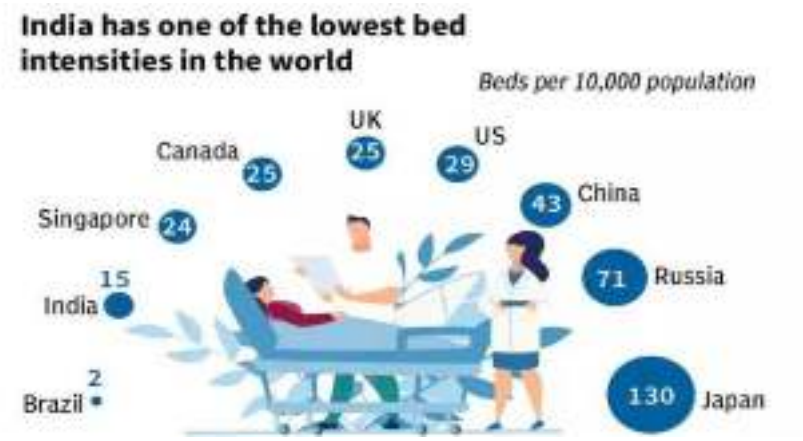

Figure: Bed intensities across the world

Healthcare Sector of India:

- Healthcare Sector: It comprises hospitals, medical devices, clinical trials, outsourcing, telemedicine, medical tourism, health insurance and medical equipment.
- India's healthcare delivery system is categorised into two major components – public and private.
- Public Sector: It comprises limited secondary and tertiary care institutions in key cities and focuses on providing basic healthcare facilities in the form of Primary Healthcare Centres (PHCs) in rural areas.
- Private Sector: The private sector provides the majority of secondary, tertiary, and quaternary care institutions with a major concentration in metros, tier-I, and tier-II cities.
- Medical Tourism: India ranks 10th in Medical Tourism Index (MTI) for 2020-2021 out of 46 destinations in the world.
- Future Projection: The hospital sector in India was valued at INR 7940.87 Bn in FY21 in terms of revenue & is expected to reach INR 18,348.78 Bn by FY 2027, growing at a CAGR of 18.24%.

The Indian medical tourism market was valued at US$ 2.89 billion in 2020 and is expected to reach US$ 13.42 billion by 2026.

Major Challenges Faced by Healthcare Sector in India:

Lack of infrastructure: India has been struggling with deficient infrastructure in the form of lack of well-equipped medical institutes.

- The government mandated that private medical colleges must be built on at least five acres of land hence, they were built in rural areas, where there was a lack of adequately qualified, full-time doctors due to living conditions, besides low pay scales.
- The National Medical Commission (NMC) has put forward the idea to do away with the requirement of minimum five acres of land.

Shortage of Efficient and Trained Manpower: There is a severe shortage of trained manpower, this includes doctors, nurses, paramedics and primary healthcare workers.

- The doctor-to-patient ratio remains low, which is merely 0.7 doctors per 1,000 people whereas the World Health Organisation (WHO) average is 2.5 doctors per 1,000 people.

Population Density and Demographics: The sheer size and diversity of the population pose unique challenges in providing healthcare services to all.

- Aging population and the associated increase in chronic diseases add to the healthcare burden.

High out-of-pocket Expenditure: While public hospitals offer free health services, these facilities are understaffed, poorly equipped, and located mainly in urban areas leaving no alternatives but to access private institutions and incurring high out-of-pocket expenses in healthcare.

Disease Burden: High prevalence of communicable diseases (such as tuberculosis) and the increasing burden of non-communicable diseases (like diabetes, cardiovascular diseases) pose a dual challenge.

- Every year, roughly 5.8 million Indians die from heart and lung diseases, stroke, cancer and diabetes.

Lack of Diagnostic Services: The penetration of diagnostic services in India is mainly concentrated around metros and big cities.

- Shortage of hygiene infrastructure, lack of awareness, limited access to facilities, lack of trained medical personnel, dearth of medicines and good doctors are the challenges faced by more than 70 percent of India's population living in rural areas.

Public-Private Partnership Issues: Challenges in fostering effective collaboration between the public and private sectors in healthcare.

- Ensuring that the private healthcare sector serves the larger public health goals.

Measures Needed for India to become Global Healthcare Provider:

- Increase in Public Spending: India's healthcare spending is 3.6% of GDP, including out-of-pocket and public expenditure.
- India spends the least among BRICS countries: Brazil spends the most (9.2%), followed by South Africa (8.1%), Russia (5.3%), China (5%).
- Infrastructure Development: Invest in building and upgrading healthcare infrastructure, including hospitals, clinics, and research facilities.
- Healthcare Education and Training: Strengthen medical education and training programs to produce skilled healthcare professionals.
- Research and Innovation: Foster a culture of research and innovation in healthcare. Provide incentives for pharmaceutical and biotech companies to conduct research and develop new treatments.
- Telemedicine and Digital Health: Promote the use of telemedicine and digital health solutions to increase access to healthcare services, especially in rural areas.
- Regulatory Reforms: Streamline and simplify regulatory processes to facilitate faster approval of drugs, medical devices, and healthcare technologies.
- Ensure a transparent and efficient regulatory framework.
- Public-Private Partnerships (PPPs): Encourage collaborations between the government, private sector, and non-profit organizations to leverage resources and expertise.
- Health Insurance and Financing: Implement and expand health insurance schemes to provide financial protection to citizens.
- Develop innovative financing models to fund healthcare projects and initiatives.

- Disease Prevention and Health Promotion: Focus on preventive healthcare measures to reduce the burden of diseases.
- Quality Standards and Accreditation: Establish and enforce stringent quality standards for healthcare services.
- Encourage healthcare facilities to obtain international accreditation to enhance their credibility.
- Medical Tourism Promotion: Develop and promote medical tourism by offering high-quality healthcare services at competitive prices.
- Improve visa and travel infrastructure to attract patients from other countries.

Recent steps Taken by the Government for the Growth of Healthcare Sector:

- National Digital Health Mission (NDHM): Launched in 2020, NDHM aims to create a digital health ecosystem, including health IDs for citizens and the establishment of a national digital health infrastructure.
- Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB-PMJAY): AB-PMJAY, launched in 2018, is a national health protection scheme that provides financial protection to over 100 million families for secondary and tertiary care hospitalization.
- National Health Policy 2017: The National Health Policy outlines the government's vision to achieve the highest possible level of health and well-being for all and emphasizes preventive and promotive healthcare.
- Health and Wellness Centers (HWCs): The government is working towards transforming primary health centers into HWCs to provide comprehensive primary healthcare services, including preventive and promotive care.
- Pradhan Mantri Swasthya Suraksha Yojana (PMSSY): PMSSY aims to enhance tertiary care capacities and strengthen medical education in the country by setting up new AIIMS (All India Institutes of Medical Sciences) institutions and upgrading existing government medical colleges.
- Research and Development Initiatives: The government has been encouraging research and development in healthcare, including support for the development of vaccines, drugs, and medical technologies.
- National Medical Commission (NMC) Act: The NMC Act, passed in 2019, aims to bring reforms in medical education and practice by replacing the Medical Council of India (MCI) and promoting transparency and accountability.
- Jan Aushadhi Scheme: The Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) aims to provide quality generic medicines at affordable prices through Jan Aushadhi Kendras.

Way Ahead

- There is a need to adopt technology wherever possible to streamline the operational and clinical processes for healthcare facilities in order to manage efficient patient flow.
- In addition, there is the challenge to think beyond the obvious and promote virtual care protocols, and telehealth services, which can be leveraged to reduce the patient-load burden to a large extent.
- To sum it up, there is an urgency to make healthcare service and service providers more transparent operationally.
- This will help ensure people and processes can be made easily accountable to provide better healthcare services.

Class - 3

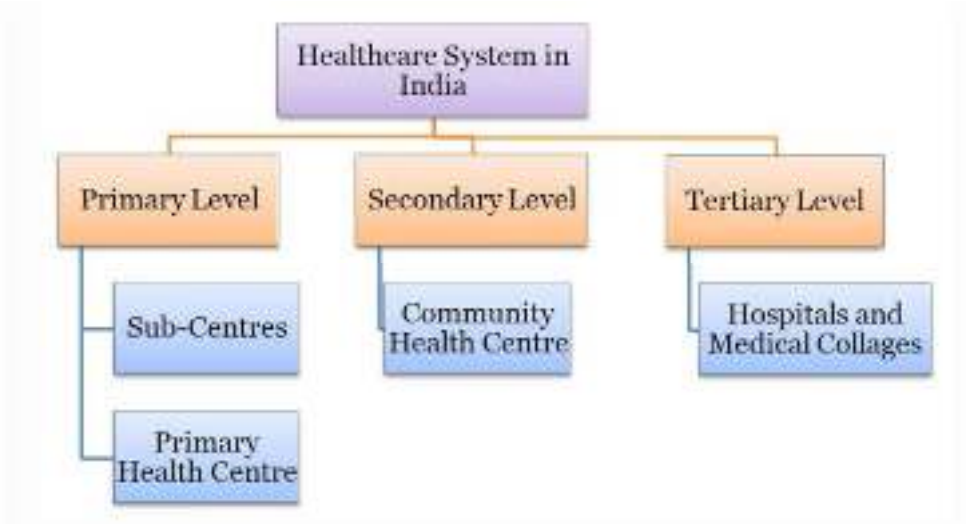

Figure: Healthcare System in India

The healthcare industry is a complex system of inter-connected entities. Each of these entities has disjoint information systems to manage patient data and records. The current IT solutions in healthcare systems have several challenges such as sharing and accessing medical records across several stakeholders while still maintaining security and privacy of these records. Thisglobal problem on how to create, maintain, and share sensitive medical records and clinical data among various stakeholders without sacrificing data privacy and integrity is still unresolved. In fact, existing healthcare records are decentralized, disjointed, non-uniform, and fragmented in nature. Here, you can see the presentation a Blockchain-based framework, called DASS-CARE, that supports decentralized, accessible, scalable, and secure access to healthcare services including medical records. Such framework will greatly facilitate the process of real time access and updates without compromising security, integrity and confidentiality of patient data. Our objective is multifold. First, improve the quality of healthcare and lower the cost of delivery. Second, enhance medical records management including electronic health records unification. Finally, provide users with the ability to view their medical records regardless of their history, a task that is difficult to accomplish under the current fragmented systems.

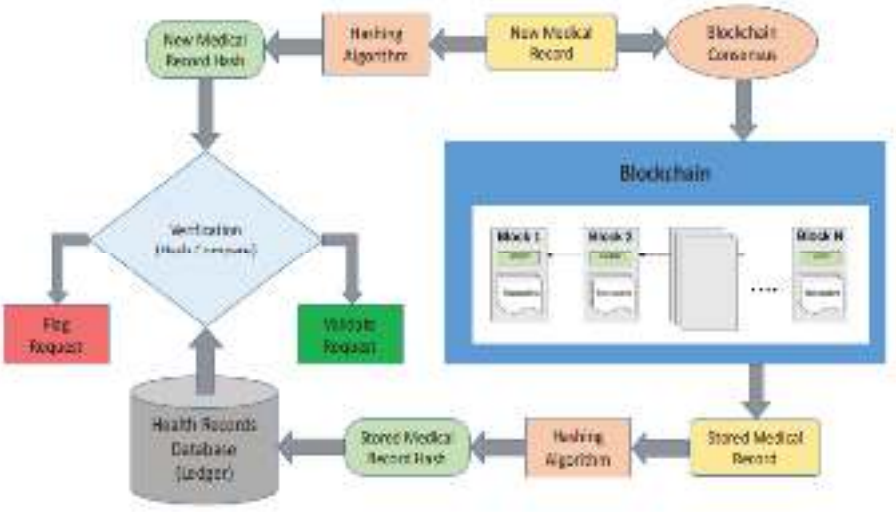

Figure: Proposed DASS-CARE framework: Health records validation process using Blockchain

Figure: Roles in Blockchain-based model: Use case Diagram

Figure: Inclusive Healthcare system

As seismic as the future trends that are expected to profoundly impact every industry over the next decade and their predicted applications to healthcare are, none of them will be effective on their own in moving towards inclusive health systems. To achieve this goal, they will need to happen in harmony – to be driven, or at least directed, by local health leaders working to bridge global and community actors into a coherent model of their future health ecosystem. This will require integration at two levels.

First, the integration of local communities with health systems and global platforms. Engaging communities in health promotion, prevention and care is the single most important factor enabling the inclusive vision described in Healthcare Horizons. At a global level, technology will be key to unlocking this, but it will require planning, investment and coordination from health leaders to ensure that the global players entering this space do not fragment and cherry pick patients. At the system level, the energy of local communities will need to be harnessed and to ensure equity their needs fully understood. But to make this happen integration must be accompanied with empowerment, entrusting communities with influence in the evolution of health systems.

Second, integration of health services themselves – physical and virtual, primary and secondary – so that patients can seamlessly move between different tiers of support with continuity of care and interoperable data acting as an engine for predictive and proactive healthcare. This is where changes to the health workforce and to information flows become most vital.

What kind of health system could this create? The above diagram that follows is one that may, at first, be familiar in its core, but has several layers and key distinctions from the reality of most healthcare systems today.

Social Security Benefits:
India's social security system is composed of a number of schemes and programs spread throughout a variety of laws and regulations. Keep in mind, however, that the government-controlled social security system in India applies to only a small portion of the population.

Furthermore, the social security system in India includes not just an insurance payment of premiums into government funds (like in China), but also lump sum employer obligations.

Generally, India's social security schemes cover the following types of social insurances:

- Pension;
- Health Insurance and Medical Benefit;
- Disability Benefit;
- Maternity Benefit; and
- Gratuity.

While a great deal of the Indian population is in the unorganized sector and may not have an opportunity to participate in each of these schemes, Indian citizens in the organized sector (which include those employed by foreign investors) and their employers are entitled to coverage under the above schemes.

The Code on Social Security, 2020
Foreign companies should note that when The Code of Social Security, 2020 – one of the four new labor codes introduced by the Ministry of Labor and Employment – comes into force, it will subsume the following enactments:

- The Employees' Compensation Act, 1923;
- The Employees' State Insurance Act, 1948;
- The Employees' Provident Funds and Miscellaneous Provisions Act, 1952;
- The Employment Exchanges (Compulsory Notification of Vacancies) Act, 1959;
- The Maternity Benefit Act, 1961;
- The Payment of Gratuity Act, 1972;
- The Cine- Workers Welfare Fund Act, 1981;
- The Building and Other Construction Workers Welfare Cess Act, 1996; and
- The Unorganised Workers' Social Security Act, 2008

Rules for the new labor codes on industrial relations, social security, and occupational safety health & working conditions (OSH) are likely to be finalized by the end of January, according to Labor Secretary Apurva Chandra. If that is the case, it may result in implementation of the labor codes by April 1, 2021 – which was the deadline put by the labor ministry. However, this timeline is subject to change, depending on interventions made by key stakeholders and lobby groups and other exigencies, such as the impact of the ongoing pandemic.

The Labor Secretary was also quoted in the media saying that the draft model standing orders for the manufacturing, mining, and service sectors will be finalized by February. These draft orders set the standards for service conditions and employees' conduct in the respective sectors and were notified on December 31, 2020 to seek feedback (within a period of 30 days from the date of notification).

Health Insurance and Medical Benefit

India has a national health service, but this does not include free medical care for the whole population. The Employees' State Insurance (ESI) Act, 1948 created a fund to provide medical care to employees and their families, as well as cash benefits during sickness and maternity, and monthly payments in case of death or disablement for those working in factories and establishments with 10 or more employees. (As on March 31, 2019, the total number of ESI beneficiaries was over 130 million, with coverage extending to over 120,00,000 factories and business establishments.)

Coverage under the ESI scheme has been extended to hotels, shops, cinemas and preview theatres, restaurants, newspaper establishments, and road-motor transport undertakings. The scheme has also been extended to private educational and medical institutions that have employed 10 or more employee. This is applicable in certain states and union territories only.

The ESI scheme offers benefits to both the workers and their dependents in case of any unfortunate eventualities at work. Under the ESI Act, employees or workers employed at the above-mentioned categories earning wages up to INR 21,000 per month (up to INR 25,000 per month in case of person with disability) are entitled to this social security scheme.

Eligible workers contribute 0.75 percent of their salary towards the ESI while the employer pays 3.75 percent – making a total contribution of 4.5 percent. These new rates are effective from July 1, 2019. (Earlier these rates stood at 1.75 percent and 4.75 percent, respectively.) The company or establishment can apply for an ESI registration within 15 days from the time the ESI Act becomes applicable to that entity. The Employees' State Insurance (Central) Amendment Rules, 2017 was notified on January 20, 2017 detailing new maternity benefits for women who have insurance. As of March 31, 2019, 51,20,000 women have benefitted from the scheme.

Further, daily wage earners earning an average wage of up to INR 137 are exempted from payment of contribution. Employers, however, are mandated to contribute their own share in respect of these employees.

Sickness benefit under ESI coverage is 70 percent of the average daily wage and is payable for a maximum of 91 days in a year. To qualify for sickness benefit, the insured worker is required to contribute for 78 days in a contribution period of six months. There are provisions for extended sickness benefits and corresponding eligibility criteria.

ESI also provides disablement benefit, which is applicable from day one of entering insurable employment for temporary disablement benefit. In case of permanent disablement benefit, it is paid at the rate of 90 percent of wage in the form of monthly payment, depending upon the extent of loss of earning capacity as certified by a Medical Board.

Besides sickness and disability pay outs, the ESI provides for dependents' benefits (DB). The DB paid is at the rate of 90 percent of the wage in the form of monthly payment to the dependents of a deceased insured person – in cases where the death has occurred due to employment injury or occupational hazards.

Other benefits that are offered with ESI are:

- Medical benefits;
- Maternity benefits;
- Unemployment allowance;

- Confinement expenses;
- Funeral expenses;
- Physical rehabilitation;
- Vocational training; and
- Skill upgradation training under Rajiv Gandhi Shramik Kalyan Yojana (RGSKY).

A one-time relaxation has been extended to employers who could not file the return of ESI contribution for the contribution period from April 1, 2020 to September 30, 2020 due to the extenuating circumstances faced by enterprises last year. The new deadline to file this return is January 15, 2021. This does not impact employees contributing to and receiving benefits from the ESI. Also, no further relaxations have been provided for older or newer contribution periods.

Disability Benefit

The Employee's Compensation Act, 1923, formerly known as the 'Workmen's Compensation Act, 1923', requires the employer to pay compensation to employees or their families in cases of employment related injuries that result in death or disability.

In addition, workers employed in certain types of occupations are exposed to the risk of contracting certain diseases, which are peculiar and inherent to those occupations. A worker contracting an occupational disease is deemed to have suffered an accident out of and in the course of employment, and the employer is liable to pay compensation for the same. Injuries resulting in permanent total and partial disablement are listed in parts I and II of Schedule I of the Employee's Compensation Act, while occupational diseases have been defined in parts A, B, and C of Schedule III of the Employee's Compensation Act.

Last year, the central government changed the wage amount to be considered for calculation of compensation to workers under the Employee's Compensation Act, 1923 vide notification S.O.71 (E) dated January 3, 2020. Now, it will be INR 15,000 (US$205), according to the notification by the Ministry of Labor and Employment. The previous wage amount considered for the calculation of compensation was just INR 8,000 (US$109).

Compensation calculation depends on the situation of occupational disability:

(a) Death

50 percent of the monthly wage multiplied by the relevant factor or an amount of INR 120,000 (US$1,640), whichever is more.

(b) Total permanent disablement

60 percent of the monthly wage multiplied by the relevant factor or an amount of INR 120,000 (US$1,640), whichever is more.

The relevant factor for computation is mentioned in Schedule IV of the Employee's Compensation Act.

Maternity Benefit

The Maternity Benefit (Amendment) Act, 2017 came into force on April 1, 2017, and increases some of the key benefits mandated under the previous Maternity Benefit Act of 1961. The amended law provides women in the organized sector with paid maternity leave of 26 weeks, up from 12 weeks, for the first two children. For the third child, the maternity leave entitled will be 12 weeks. India now has the third most maternity leave in the world, following Canada (50 weeks) and Norway (44 weeks).

The Act also secures 12 weeks of maternity leave for mothers adopting a child below the age of three months as well as to commissioning mothers (biological mothers) who opt for surrogacy. The 12-week period in these cases will be calculated from the date the child is handed over to the adoptive or commissioning mother.

In other provisions, the law mandates that every establishment with over 50 employees must provide crèche facilities within easy distance, which the mother can visit up to four times a day. For compliance purposes, companies should note that this particular provision will come into effect from July 1, 2017.

The Maternity Benefit (Amendment) Act introduces the option for women to negotiate work-from-home, if they reach an understanding with their employers, after the maternity leave ends.

Under the pre-existing Maternity Benefit Act of 1961, every woman is entitled to, and her employer is liable for, the payment of maternity benefit at the rate of the average daily wage for the period of the employee's actual absence from work. Apart from 12 weeks of salary, a female worker is entitled to a medical bonus of INR 3,500 (US$47.85).

The 1961 Act states that in the event of miscarriage or medical termination of pregnancy, the employee is entitled to six weeks of paid maternity leave. Employees are also entitled to an additional month of paid leave in case of complications arising due to pregnancy, delivery, premature birth, miscarriage, medical termination, or a tubectomy operation (two weeks in this case).

In addition to the above, the 1961 Act states that no company shall compel its female employees to do tasks of a laborious nature or tasks that involve long hours of standing or which in any way are likely to interfere with her pregnancy or the normal development of the fetus, or are likely to cause her miscarriage or otherwise adversely affect her health.

Changes expected under The Code on Social Security, 2020

Inspector cum facilitators will be hired for the purpose of ensuring the rules of the Act are being upheld. They will be able to get information from employers about their female employees, regarding the kind of work they do and the wages they are paid, as well as enquire about any complaints they may have.

Inspector cum facilitators will allow offending employers a period of time to begin complying with the rules of the Act by way of a written statement. If they do so, no action will be taken against them.

It will be ensured that female employees who work in the unorganized sector are able to establish their identities via their Aadhaar number.

Employers who withhold maternity rights from their female employees will be fined INR 50,000 (approx. US$683) or be imprisoned for at least six months or both.

If a female employee is denied maternity rights and she is part of a trade union under the Trade Unions Act of 1926, she is eligible to file a complaint with them that will be heard in any court of competent jurisdiction. However, only the denied employee and the inspector cum facilitator can approach the court for help.

Gratuity

The Payment of Gratuity Act, 1972 directs establishments with 10 or more employees to provide the payment of 15 days of additional wages for each year of service to employees who have worked at a company for five years or more.

Gratuity is provided as a lump sum payout by a company. In the event of the death or disablement of the employee, the gratuity must still be paid to the nominee or the heir of the employee.

The employer can, however, reject the payment of gratuity to an employee if the individual has been terminated from the job due to any misconduct. In such a case of forfeiture, there must be a termination order containing the charges and the misconduct of the employee.

Gratuity is calculated through the formula mentioned below:

Gratuity = Last Drawn Salary × 15/26 × Tenure of Service, where:

The ratio 15/26 represents 15 days out of 26 working days in a month.

Last Drawn Salary = Basic Salary + Dearness Allowance.

Tenure of Service is rounded up or down to the nearest full year. For example, if the employee has a total service of 10 years, 10 months and 25 days, 11 years will be factored into the calculation.

Gratuity is exempt from taxation provided that the amount does not exceed 15 days' salary for every completed year of service calculated on the last drawn salary (subject to a maximum of INR 2 million). It is important to note that an employer can choose to pay more gratuity to an employee, which is known as ex gratia and is a voluntary contribution. Ex-gratia is subject to tax.

When turning 65, applying for Medicare benefits can be a daunting and confusing task. From understanding the different parts of Medicare to determining eligibility, there are many things to consider when applying for Medicare. However, with the right guidance and knowledge, the process can be made simpler. In this section, we will provide you with an in-depth guide to applying for Medicare benefits.

1. Determine Eligibility: The first step in applying for Medicare is to determine your eligibility. You are eligible for Medicare if you are 65 years or older, have been a permanent resident of the United States for at least five years, or have a qualifying disability. You may also be eligible for Medicare if you have end-stage renal disease (ESRD) or amyotrophic lateral sclerosis (ALS).
2. Understand the Different Parts of Medicare: Medicare is divided into four parts: Part A, Part B, Part C, and Part D. Part A covers hospital stays, hospice care, and skilled nursing facility care. Part B covers doctor's visits, preventive care, and medical equipment. Part C is also known as Medicare Advantage and offers an alternative way to receive Medicare benefits through private insurance companies. Part D covers prescription drugs.
3. Choose Your Coverage: Once you've determined your eligibility and understand the different parts of Medicare, it's time to choose your coverage. You can choose to enroll in Original Medicare (Part A and Part B) or a Medicare Advantage plan (Part C). If you choose Original Medicare, you may also want to consider enrolling in a Medicare Supplement plan to help cover out-of-pocket costs.
4. Apply for Medicare: You can apply for Medicare online, by phone, or in person at your local Social Security office. If you are already receiving Social Security benefits, you will automatically be enrolled in Medicare Parts A and B.
5. Keep Track of Deadlines: Its important to keep track of Medicare enrollment deadlines to avoid late enrollment penalties. You can enroll in Medicare during your Initial Enrollment Period (IEP), which is the seven-month period that begins three months before the month you turn 65. If you miss your IEP, you may have to pay a late enrollment penalty.

In summary, applying for Medicare can be a complex process, but understanding the different parts of Medicare, determining eligibility, and choosing the right coverage can make it easier.

Benefits are important aspects of employee benefits that are often overlooked. Understanding how these two benefits works is crucial in planning for your future and financial wellbeing. Social Security is a federally funded program that provides retirement, disability, and survivor benefits to eligible individuals. Medicare, on the other hand, is a federal health insurance program that provides coverage to individuals who are 65 years and older, as well as those with certain disabilities.

1. Social Security Tax

- Social Security Tax is a payroll tax that is deducted from an employee's paycheck.
- The tax rate is currently at 12.4%, with half being paid by the employer and the other half paid by the employee.

- The tax is calculated based on the employee's earnings, up to a certain limit. In 2021, the limit is $142,800.
- The funds collected from the Social Security tax are used to pay for retirement, disability, and survivor benefits.

2. Medicare Benefits
- Medicare benefits are available to individuals who are 65 years and older, as well as those with certain disabilities.
- The program has four parts: A, B, C, and D.
- Part A covers inpatient hospital care, skilled nursing facility care, hospice care, and home health care.
- Part B covers doctor visits, outpatient care, and preventive services.
- Part C, also known as Medicare Advantage, is an alternative to Original Medicare and is offered by private insurance companies.
- Part D covers prescription drugs.
- The cost of Medicare depends on several factors, including income and the type of coverage selected.

Understanding Social Security tax and Medicare Benefits is crucial in planning for your financial future. These benefits can help ensure that you have a stable source of income during your retirement years and provide you with access to necessary healthcare services. By taking the time to understand these benefits, you can make informed decisions that will benefit you in the long run.

Strategies for maximizing PIA and Medicare benefits:

When it comes to maximizing your Primary Insurance Amount (PIA) and Medicare benefits, there are a variety of strategies you can employ depending on your unique situation. Whether you're just starting to think about retirement or have already made the transition, it's important to understand how your PIA and Medicare benefits work together to provide you with the coverage and support you need.

One key strategy is to delay claiming your Social Security benefits until you reach full retirement age or beyond. By doing so, you can increase your PIA, which is based on your highest 35 years of earnings. This can result in a higher monthly benefit payment and a larger overall payout over the course of your retirement.

Another important factor to consider is your Medicare coverage. While Medicare Part A is typically free for most beneficiaries, Part B and Part D come with monthly premiums that can vary depending on your income and other factors. To maximize your Medicare benefits, it's important to shop around for the right plan that meets your needs and fits your budget.

In addition to these strategies, there are a number of other steps you can take to maximize your PIA and Medicare benefits, including:

1. Working with a financial advisor or retirement planner to develop a comprehensive retirement plan that takes into account your unique needs and goals.
2. Staying up-to-date on changes to social Security and medicare policies, as well as any other relevant legislation that could affect your benefits.
3. Taking advantage of programs and resources designed to help retirees with healthcare costs, such as the Medicare Savings Programs and Extra Help.
4. Exploring alternative sources of income, such as part-time work or rental properties, to supplement your retirement savings and increase your overall financial security.

By following these strategies and taking a proactive approach to your retirement planning, you can maximize your PIA and Medicare benefits and enjoy a comfortable and secure retirement.

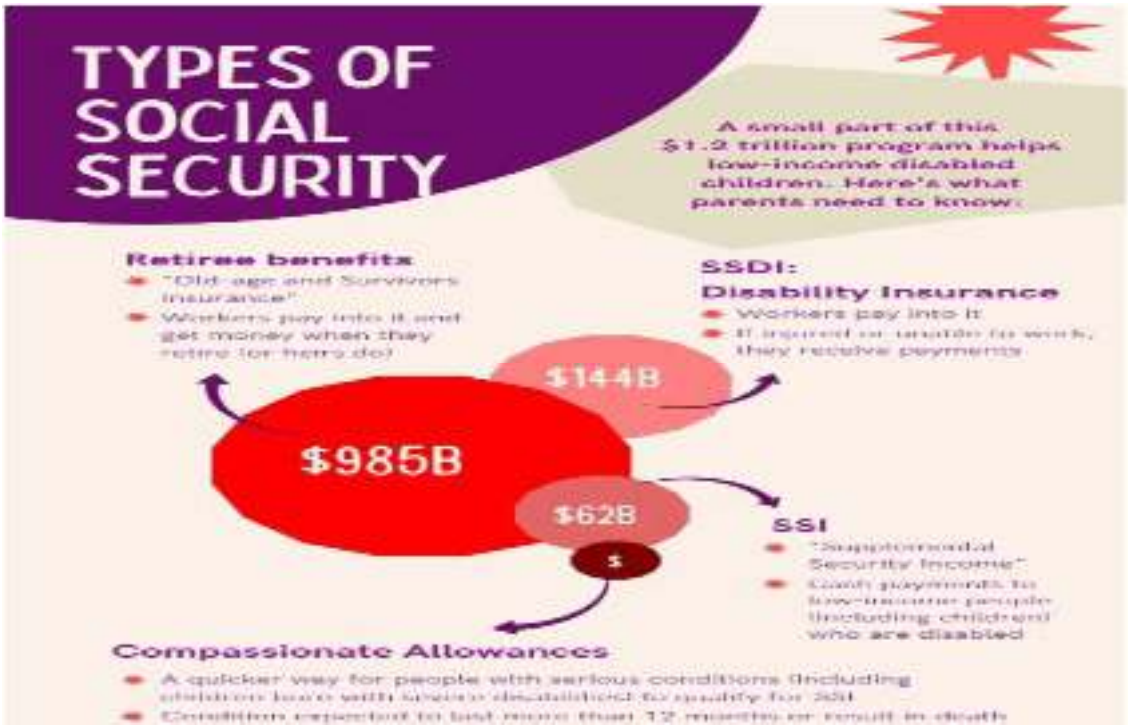

Figure: Types of Social Security

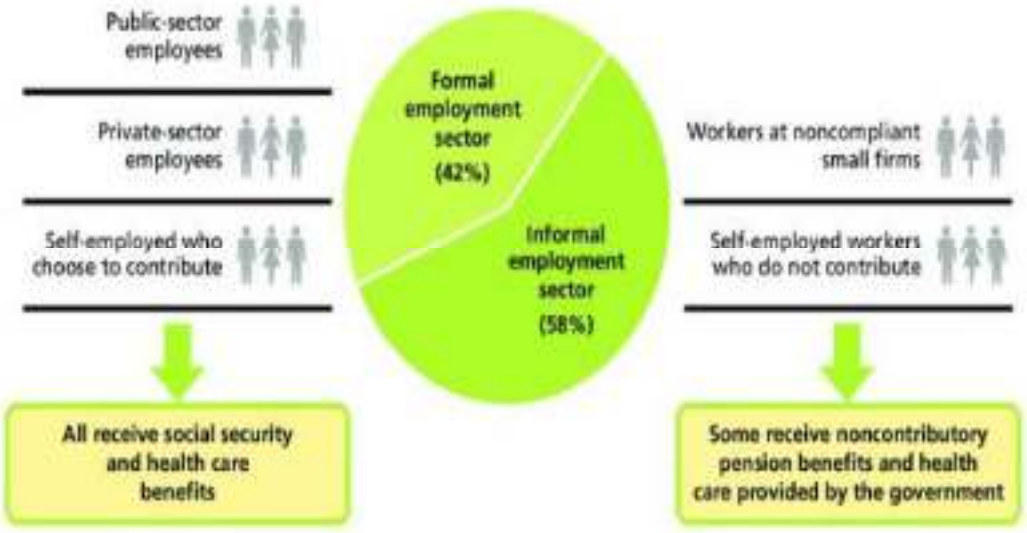

Figure: Social security and healthcare benefits

Class – 4

Figure: Social security globe

Healthcare is both a service and an industry. As such it needs to be regulated so that the government's requirements are properly enforced.

Regulation is an important entity in healthcare and healthcare insurance. The role of regulatory bodies is to protect healthcare consumers from health risks, provide a safe working environment for healthcare professionals, and ensure that public health and welfare are served by health programs. Regulation works at all levels, and the regulatory standards are developed by government and private organizations as well.

Regulations are necessary to standardize and supervise healthcare, ensuring that healthcare bodies and facilities comply with public health policies and that they provide safe care to all patients and visitors to the healthcare system.

Regulatory agencies thus monitor individual and corporate healthcare practitioners and facilities; inform the government about changes in the way the healthcare industry operates; ensure higher safety standards; and attempt to improve healthcare quality and follow local, state, and federal guidelines.

Functions of a regulator

A regulatory system helps keep track of how well the healthcare system is complying with its contractual obligations and other legal requirements, protecting the public interest. It also lays down the standards for technical operations, safety and quality as required apart from the contracts themselves, and the penalties for non-compliance.

Cost-effectiveness, performance analyses, tariff evaluations, and regular reviews, as well as setting up mechanisms for settling disputes between parties, are all part of regulation. The regulatory body also advises the government on private-public partnerships in healthcare, helping to shape policies and other related matters.

Statutory vs. non-statutory bodies

Statutory bodies thus publish quality standards, offer accreditation, and offer continuing education and training for healthcare professionals. Regulatory bodies of this sort may regulate services or professionals.

In contrast to such governmental oversight, accreditation agencies offer another level of oversight which is voluntary but offers quality certification and rankings, incentivizing efforts to improve the quality of healthcare and promoting best practices. These are more indirect in their approach but intend to enhance patient care.

The pros and cons

Regulatory activities are aimed at building appropriate motives and attitudes, policies, and healthcare protocols, within facilities and systems. Some regulatory activities include regular inspections and measures to enhance good practice and a better clinical culture.

The flip side is that slavish imposition of regulations could fail to address real problems of attitude and a non-professional approach to healthcare, is not flexible enough to cope with challenges and changes in the industry and may promote a bureaucratic pattern of complying with rules mechanically rather than seeking the patient's welfare.

Some may perceive it as interference by an external authority that reduces the efficiency of work and intrudes on the smooth functioning of the clinical service, but regulatory oversight is designed to encompass a broader range of functions. This has led many individual and corporate observers to advocate for regulatory reform, leading to a simplified approach that clubs together regulations relating to similar services, and reduces the load on healthcare providers.

The main problems are multiple regulatory bodies that share the same aims; make for a complex and rapidly changing regulatory environment; and cause duplication of work, increasing the workload and creating frustration and negative relationships with the regulatory bodies.

Not only so, but the uncoordinated nature of the interactions between the various organizations and agencies that are involved in regulation can also both create confusion within the regulated body, and cause resources to be diverted from where they could be best used, to produce a semblance of improvement for the sake of the regulator.

Both the time and the energy, apart from the money spent, in producing a portfolio of the evidence required to satisfy the regulatory bodies, are concerning issues, detracting from rather than enhancing the quality of healthcare.

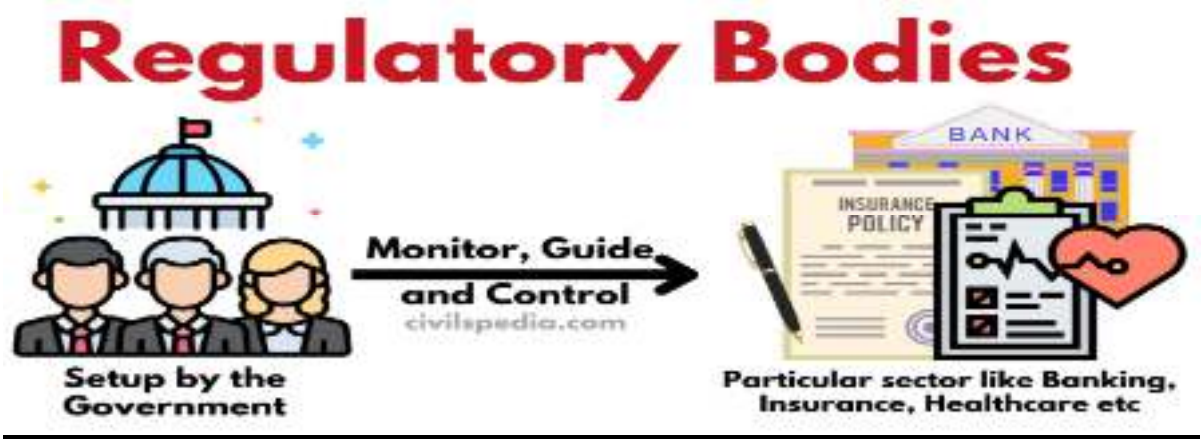

Figure: Regulatory Bodies (Source: civilspedia.com)

In the case of Natural Monopoly

A natural monopoly is a condition when an entire market is more efficiently served by one firm than by two or more firms.

In the case of a natural monopoly, regulation is necessary to protect consumer interests, control prices, and ensure the quality of service, as there is no competition in the market.

In India, the sectors such as transmission and distribution of electricity and railways are still natural monopolies.

Asymmetric Information

It is a situation when one party has more information than another. In India, asymmetric information is a significant reason for government intervention.

For example, in many sectors, like healthcare, insurance, and financial services, consumers may not possess the same expertise as service providers. Hence, regulation helps protect consumers by mandating disclosure requirements, ensuring transparency, and setting product quality and safety standards.

Presence of Externalities

Negative externalities refer to the costs or harms imposed on third parties not directly involved in a transaction or activity. When negative externalities exist, market forces alone may not be adequate to address the issue. In India, regulation is often implemented to address negative externalities in various sectors.

For example, Industries or activities that generate pollution or degrade natural resources often impose negative externalities on the environment and surrounding communities. India has implemented regulations governing air and water pollution, waste management, and environmental impact assessments to mitigate these externalities.

Check Anti-Competitive practices

Detecting and preventing anti-competitive practices is a crucial reason for regulation in India. For example,

- The regulation targets cartels and collusive behaviour, where competitors engage in agreements to fix prices, allocate markets, or rig bids, aiming to restrict competition and maximize their profits.
- Regulatory bodies monitor and address cases where a dominant firm exploits its market power to restrict competition, drive competitors out of the market, or engage in predatory pricing.
- Regulations govern mergers, acquisitions, and combinations that have the potential to reduce competition significantly.

Compliance officer
The designated role of a corporate compliance officer (CCO) is gaining prominence in many businesses.

The CCO serves as the point person who champions corporate integrity, accountability, and ethics.

With the time-intensive oversight involved in implementing and monitoring a compliance program, the CCO's sole focus is to stay on top of the ever-evolving regulatory landscape and make the necessary compliance decisions.

Establish and maintain your policies and procedures
It isn't enough to simply have policies and procedures. They need to address the specific compliance areas identified in the audit listed above.

Plus, they need to be reviewed regularly to stay current with the always-changing regulatory landscape. Again, that's why it's helpful to designate a CCO.

In addition to having targeted policies and procedure tied to compliance, a key component of policy management involves the need to track when employees have read and signed your policies.

This plays a huge role in being able to prove compliance down the road, if necessary. If you can show the employee knew the policy, read and acknowledged it, and violated it anyway, then the company's liability significantly decreases.

This provides a much strong position to act against that employee.

A policy management software like PowerDMS can help you easily maintain records of all of these policy signatures.

Regulatory compliance training
Just like having your policies and procedures tied to compliance issues, you want to "train to your policies."

If the policy is written to address specific compliance issues, then your training should reinforce that behavior and ensure employees comprehend what they are supposed to do.

Employees at every level need to adopt the philosophy that compliance is "everybody's business" – even if you have a designated CCO to oversee your corporate compliance program. (That's a key part of your training, as well.)

When your entire workforce understands the importance of compliance (and their role in making it happen), it distributes the knowledge broadly.

Compliance isn't about a handful of people who know the latest regulations and what that means for operations. Rather, everybody is up to speed on the latest changes and they've been trained on how it impacts them.

Continual improvement
Compliance is not a one-and-done program.

Your company needs to build in regular review periods and audits. Plus, your organization should seek input from subject-matter experts (ideally, the CCO) who can track regulatory changes and understand their impact on your business.

This allows you to continually assess the effectiveness of the program and be proactive in your actions.

It helps to automate this review process so nothing falls through the cracks. That's one of the powerful benefits of regulatory compliance software like PowerDMS.

It allows you to set workflows and reminders to route it to the appropriate people who need to review and make changes.

Now that you understand the critical importance of regulatory compliance (and the challenges you might face), you can use the above guidelines as your action plan.

These steps will help you create an effective regulatory compliance program in your business that protects your resources, your reputation, and your internal and external audiences.

Importance of Compliance with Regulatory Bodies

Compliance with regulatory bodies is crucial for businesses to operate legally and ethically. Regulatory bodies exist to ensure that businesses operate in a manner that is fair, safe, and in compliance with laws and regulations. These bodies set standards for industries, monitor compliance, and enforce penalties for non-compliance. In this section, we will explore the importance of compliance with regulatory bodies from different perspectives.

1. Customer Perspective

Customers rely on regulatory bodies to ensure that businesses provide safe and reliable products and services. Compliance with regulations helps to protect customers from harm and gives them confidence in the products they purchase. For example, the Food and Drug Administration (FDA) regulates food and drug safety in the United States. Compliance with FDA regulations ensures that products are safe for consumption and meet certain quality standards.

2. Business Perspective

Compliance with regulatory bodies is essential for businesses to avoid legal and financial penalties. Non-compliance can result in fines, legal fees, and damage to a company's reputation. Additionally, compliance can help businesses to gain a competitive advantage by demonstrating a commitment to ethical practices and high standards. For example, a company that complies with environmental regulations may be viewed more favorably by environmentally conscious consumers.

3. Societal Perspective

Compliance with regulatory bodies is important for the well-being of society as a whole. Regulations exist to protect the environment, public health, and safety. Compliance with these regulations helps to prevent harm to individuals and communities. For example, compliance with building codes and safety standards helps to prevent accidents and injuries.

4. Options for Compliance

There are several options for businesses to ensure compliance with regulatory bodies. One option is to hire compliance officers who are responsible for monitoring compliance with regulations. Another option is to outsource compliance to third-party companies that specialize in regulatory compliance. Additionally, businesses can use compliance software to automate compliance processes and monitor regulatory changes.

5. Best Option for Compliance

The best option for compliance depends on the size and complexity of the business, as well as the industry in which it operates. small businesses may find it more cost-effective to outsource compliance to third-party companies, while larger businesses may have the resources to hire in-house compliance officers. Compliance software can be a useful tool for any business to monitor regulatory changes and ensure compliance.

Compliance with regulatory bodies is essential for businesses to operate legally, ethically, and safely. Compliance benefits customers, businesses, and society as a whole. There are several options for ensuring compliance, and the best option depends on the size and complexity of the business.

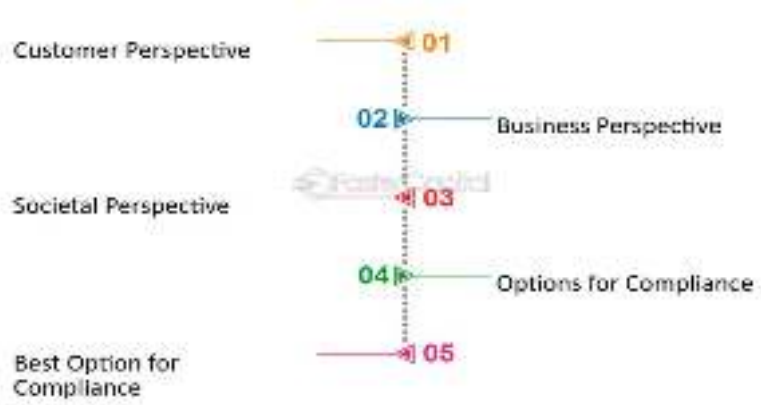

Figure: Perspectives of society in terms of regulatory bodies

(Source: https://fastercapital.com/content/Regulatory-bodies--Behind-the-Scenes--Regulatory-Bodies-and-their-Impact.html**)**

Importance of Regulatory Bodies

Regulatory bodies play a vital role in ensuring that industries operate in a safe and ethical manner. Without these bodies, industries would be left to self-regulate, which could lead to disastrous consequences for both consumers and the environment. In this section, we will discuss the importance of regulatory bodies and the impact they have on society.

1. Ensuring Safety

One of the primary functions of regulatory bodies is to ensure the safety of consumers. For example, the Food and Drug Administration (FDA) regulates the safety and efficacy of drugs and medical devices before they can be marketed to the public. Similarly, the National Highway Traffic Safety Administration (NHTSA) sets safety standards for automobiles and regulates recalls when defects are discovered. Without these regulatory bodies, consumers would be at risk of using unsafe products or driving unsafe vehicles.

2. Protecting the Environment

Regulatory bodies also play a crucial role in protecting the environment. The Environmental Protection Agency (EPA) regulates emissions from industry and sets standards for air and water quality. Without the EPA, industries would be free to pollute the air and water without consequence, leading to serious health and environmental consequences.

3. Promoting Fair Competition

Regulatory bodies also promote fair competition in industries. For example, the Federal Trade Commission (FTC) regulates advertising and marketing practices to ensure that companies do not engage in false or deceptive practices that could harm consumers. Similarly, the Securities and Exchange Commission (SEC) regulates

financial markets to prevent insider trading and other fraudulent practices. Without these regulatory bodies, companies could engage in unfair practices that would harm both consumers and other companies.

4. Balancing Industry Interests with Public Interests

Regulatory bodies also play a crucial role in balancing industry interests with public interests. For example, the Federal Communications Commission (FCC) regulates the telecommunications industry to ensure that consumers have access to affordable and reliable communication services. The FCC also regulates the use of the public airwaves to prevent interference and ensure that the airwaves are used in the public interest. Without the FCC, telecommunications companies could prioritize their own interests over the public interest.

Figure: Industry interests with respect to Public interests

(Source: https://fastercapital.com/content/Regulatory-bodies--Behind-the-Scenes--Regulatory-Bodies-and-their-Impact.html)

Practical solutions for real-world problems

ISO, the International Organization for Standardization, brings global experts together to agree on the best way of doing things – for anything from making a product to managing a process. As one of the oldest non-governmental international organizations, ISO has enabled trade and cooperation between people and companies the world over since 1946. The International Standards published by ISO serve to make lives easier, safer and better.

Figure: Role of ISO

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Class – 5

Life science Industry: -

The Life Sciences industry refers to all of the organizations and companies whose work is centred around research & development, Manufacturing, Marketing of products and services focused on living things (animals, plants, human beings.)

The life sciences industry comprises companies operating in the research, development and manufacturing of pharmaceuticals, biotechnology-based food and medicines, medical devices, biomedical technologies, nutraceuticals, cosmeceuticals, food processing, and other products that improve the lives of organisms

Examples

a. Companies operating in the research, development and manufacturing of pharmaceuticals,

b. Biotechnology-based food and medicines,

c. Medical devices,

d. Biomedical technologies,

e. Nutraceuticals,

f. Cosmeceuticals,

g. Food processing, and

h. other products that improve the lives of organisms.

Pharmaceutical Industry

The **pharmaceutical industry** is an industry in medicine that discovers, develops, produces, and markets pharmaceutical drugs for use as medications to be administered to patients (or self-administered), with the aim to cure and prevent diseases, or alleviate symptoms.

Pharmaceutical companies may deal in generic or brand medications and medical devices. They are subject to a variety of laws and regulations that govern the patenting, testing, safety, efficacy using drug testing and marketing of drugs.

Indian Pharmaceutical Industry is third largest in terms of Volume and 13th largest in terms of value. Often hailed as the 'pharmacy of the world,' the Indian pharmaceutical industry is booming. The pharmaceutical industry in India is currently valued at $50 Bn. India is a major exporter of Pharmaceuticals, with over 200+ countries served by Indian pharma exports.

Top 10 Pharma Companies by Market Cap In India

- Sun Pharmaceutical Industries Ltd.
- Cipla Ltd.
- Dr Reddy's Laboratories Ltd.
- Mankind Pharma Ltd.
- Torrent Pharmaceuticals Ltd.

- Zydus Lifesciences Ltd.
- Lupin Ltd.
- Alkem Laboratories Ltd.

Types of Pharmaceutical Companies

In the pharmaceutical business, companies can be categorised into many types of Pharmaceutical Companies based on their primary focus and operations within the industry. Mentioned below are the different types of pharmaceutical companies:

1. Prominent Pharmaceutical Firms

In the realm of pharmaceuticals, we have prominent companies known for their extensive range of medications and healthcare offerings. These well-established entities, like Pfizer, house sizable research teams and operate numerous production facilities, enabling them to create and supply a wide assortment of pharmaceutical products.

2. Research and Innovation-Centric Enterprises

Smaller organization's in the pharmaceutical sector are dedicated to research and development. They frequently partner with larger pharmaceutical companies to conduct clinical trials and play a role in the identification of novel drugs and treatment methods ultimately benefiting the society.

3. Generic Drug Manufacturers

Generic drug manufacturers play a crucial role in the pharmaceutical sector, particularly after the expiration of **drug patents**. These companies excel in the efficient mass production of generic medications. While they don't prioritise extensive R&D, they specialize in providing cost-effective alternatives to patent-expired medicines.

4. API Producers

In the pharmaceutical arena, **Active Pharmaceutical Ingredient manufacturers** have a key role in crafting biomolecules, bulk compounds, and a range of Active Ingredients utilized by pharmaceutical producers. Furthermore, they engage in the manufacturing of serums, vaccines, and other healthcare goods, making substantial contributions to the pharmaceutical supply chain.

5. Pharma Marketing and Distribution Companies

Pharma marketing offers various avenues for individuals looking to venture into the pharmaceutical sector. Two notable options include establishing a marketing company or owning a pharma franchise distribution unit. The choice between these options depends on individual preferences, as both are potentially lucrative ventures. Notably, a pharma franchise enjoys substantial marketing support from its parent pharmaceutical company.

Pharma distribution plays a vital role in the pharmaceutical supply chain and encompasses various sub-categories, such as **stockist, wholesaler, distributor, and sub-stockist**

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6. Pharma Retail Companies

The pharma retail sector is among the many types of pharmaceutical companies that offers a diverse range of opportunities, including:

1. **Medical and Drug Stores, Pharmacy:** Retail outlets focused on offering medications and related healthcare products.

2. **Retail Stores for Medical Devices:** These stores specialise in providing medical devices and equipment.

3. **Retail Stores for Surgical Products:** Retailers in this category supply surgical and medical equipment.

4. **Cosmetic and Dietary Supplement Stores:** These stores cater to customers seeking cosmetic products and dietary supplements.

Various Departments in a Pharmaceuticals Organization: -
Below is a quick overview of the departments that are typically found within the company:

- Production (Manufacturing)
- Quality
- Marketing
- Supply Chain Management.
- Research and Development
- Other

Production (Manufacturing)
As mentioned above, pharmaceutical companies are essentially manufacturing companies. So, Production would have the highest portion of employment within the company. A typical percentage of total company employment is between 30% and 50% depending on the stage of the company.
The Production (Manufacturing) department deals with all stages of pharmaceutical product manufacture, from producing active ingredients through the completion of finished products (packaging).
The following is the breakdown of department activities:

Upstream activities
Upstream activities are the early stages of biopharmaceutical processing from cell bank until the cell culture process. There are certain target proteins as the output of the cell culture process.

Downstream activities
Downstream activities are the stages that include separation and purification to achieve the required drug substance.

Fill Finish / Packaging
This is the final stages of the manufacturing process when the active product is prepared to its final form, then being filled, and sealed within specific primary and secondary containers. Aseptic techniques and detailed labeling play critical roles in these activities.

Quality
Quality is the function within the company that monitors all production-related activities, ensuring that they meet standards and predefined expectations. Depending on the stage of the company, the quality unit can be up to 30% of total company employment.
The following is the breakdown of department activities:

Quality Assurance
This is the main function where the focus is to maintain predefined process standards and expectations. The main mindset that is sometimes missed is that quality assurance is supposed to be preventative by nature ("Right the First Time"), instead of corrective. Most of the time we got caught up in corrective mindset due to high number of errors.

Quality Control
It is the function within biopharmaceutical company where the focus is on ensuring the products are produced as designed by testing product samples and ensuring proper monitoring of the production area and utilities.

Validation
Some companies have Validation function separated from Quality. Validation is one of the key functions, especially in the early stage of the company, as this function creates an evidence trail showing a process and system that leads to a consistent result that can be reproduced throughout the life of the company.

Regulatory Affairs
This function deals with all the matters related to outside regulations that must be complied with before the company can sell their medicine to the public.

Supply Chain Management in Pharmaceutical Industry: -
A distribution channel comprises of Manufacturers, Wholesalers, Retailers and the Consumers. Manufacturers produce products and leave the selling activities to the wholesalers and retailers. The retailers act as a connecting link between the Suppliers with the Consumers. Retailers include both the business houses and the individuals. They help in the transfer of goods from the wholesalers or from the manufacturers directly to the consumers. The figure given below shows the distribution channel.

Figure showing the channel of Distribution

Manufacturer —-> Wholesaler —-----> Retailer —------> Final Consumer

Sales and Marketing in Pharmaceutical Industry: -

Sales and Marketing both are closely related to each other.and are aimed to increase revenue of organisation. In small organisation there is not so much difference in sale and marketing but in big organisation there is lot of difference in sales and marketing and they have specialised people to handle both departments independently.

SALES
A sale is agreement between seller and buyer of the particular money, goods and services.

MARKETING
A Marketing refers to a activities a company undertakes to promote the buying and selling of a product or a service. Pharmaceutical marketing involves the actions to create a demand for goods and sales promotion. And pharmaceutical marketers use the elements of marketing mix which are 7Ps (Product, Place, Price, Promotion, Physical, People and Process) to meet and exceed the expectations of customers.

DIFFERENCE BETWEEN SALES AND MARKETING

- Marketing means generating leads or prospects and sales means converting leads or prospects into purchases and orders.
- Sales is a short term for finding customer and convert into exchange. where as marketing is a long-term process of building a name or brand in market.
- Marketing is directly related to need of customer and sale is not related to customer need.
- Marketing is responsible for brand and promotion where as sale is not related to promotion of brand.

Difference of Pharmaceuticals Selling AND FMCG Selling:-
Pharmaceutical marketing deals with the supply or availability of drug or medicinal products used for diagnosis, prevention or treatment of specific medical conditions (Diseases). FMCG market deals with the supply or availability of consumer products of the routine use.

Class - 6

Medical Sales Representatives.
In ethical Marketing practice, product promotion is directed towards doctors.

Medical Representatives, also known as medical sales representatives or pharmaceutical sales representatives, are those who sell and promote pharmaceuticals, medical equipment, and prescription drug products. Medical Representative (MR) plays an important role in the promotion process by directly meeting the physicians and promoting the brands.

In other terms, a Medical Representative (MR) is a point of communication between pharmaceutical companies and health professionals such as doctors and other institutional key persons.

A Medical Representative's primary responsibility is to promote and sell the company's products.

JOB of Medical Representatives: -

- A medical or pharmaceutical corporation appoints a medical representative to market and sell its products. He or she serves as the company's representative and is in charge of the company's branding.
- He/she promotes the goods to potential buyers on behalf of his/her company in such a way that they purchase it.
- The Medical Representative is also in charge of promoting and making medical items available to the intended audience. He or she can advertise the products, hold seminars, or hold meetings with various healthcare professionals to market them.
- Each medical representative is given a monthly target to meet within a certain amount of time.
- It is essential for them to keep track of monthly sales for future reference as well as examine his performance.
- Every medical representative's ultimate goal is to sell as many products as possible. Although his/her position is not solely sales-related, he/she is also responsible for after-sales customer assistance.
- Obtaining feedback from his clientele is one of his main responsibility. It will assist him in improving his future work performance.
- The Medical Representative must establish positive relationships with pharma professionals such as doctors, nurses, and other health care professionals.
- Because the Medical Representative promotes the pharma company's brand, he or she must have a pleasant personality and excellent communication skills.
- The Medical Representative must have complete knowledge of the pharmaceutical product so that he or she can effectively describe it to healthcare professionals.

QUALIFICATION: -

To be a Medical Representative, you don't need any specific qualifications. No one can stop a person who has fundamental intelligence, common sense, and a desire to succeed. However, if he has a rudimentary understanding of human anatomy, bioscience, and a sales background, he will have an advantage.

To become a medical representative, one must have completed their 12th standard or equivalent with Physics, Chemistry and Biology. A Bachelor's degree in Pharmacy or B. Sc. degree in a relevant field is a must to become a medical representative

Some pharmaceutical companies prefer B. Pharmacists and Para Medical School graduates. Also, individuals with a science background, such as PCMB (Physics, Chemistry, Biology, and Mathematics), are preferred over arts and commerce students since they understand things more easily

Role of Medical Representative

Product Knowledge and Expertise

A fundamental requirement for a medical representative is an in-depth understanding of the products they represent. They need to comprehend the scientific aspects, mechanisms of action, benefits, and potential side

effects of these products. This expertise enables them to provide accurate information to healthcare professionals and address any inquiries or concerns

Communication and Relationship Building
Effective communication is at the core of the role of a medical representative. They engage with healthcare professionals, including doctors, pharmacists, and hospital staff, to convey the value of the products they promote. By fostering meaningful relationships, they establish credibility and trust, which can influence healthcare professionals' decision-making.

Promotion and Sales
Medical representatives are tasked with promoting pharmaceutical products and medical devices to healthcare professionals. This involves presenting the features, benefits, and evidence supporting the efficacy of these products. Through persuasive communication, they aim to secure product prescriptions or recommendations from healthcare professionals.

Market Insights and Feedback
They are on the frontline of the pharmaceutical industry, interacting with healthcare professionals regularly. They gather valuable insights into market trends, competitor activities, and healthcare professionals' preferences. This feedback is relayed to the pharmaceutical company, guiding strategic decisions and product enhancements.

Continuous Education
Staying updated with the latest medical advancements, clinical studies, and industry regulations is crucial for a medical representative. They often engage in ongoing training to enhance their knowledge and ensure they can address any queries posed by healthcare professionals.

Ethical Considerations
Upholding ethical standards is paramount for medical representatives. They must provide accurate and unbiased information about products, avoiding exaggerated claims or misinformation. Ethical conduct ensures that healthcare professionals receive reliable information for their decision-making processes.

Time Management and Planning
Medical representatives typically manage a diverse territory, which requires effective time management and planning skills. They schedule visits to various healthcare facilities, ensuring they can engage with a wide range of professionals within their assigned area.

Data Collection and Reporting
Keeping detailed records of interactions, feedback, and the impact of their efforts is essential. Medical representatives compile data that provides insights into the effectiveness of their strategies and the reception of products by healthcare professionals.
In any setting, the process of selling involves getting in touch with potential customers, recognizing their requests, convincing them that your products or services are more pleasant than those of competitors and can best please the customer. Drug reps increase drug sales by influencing physicians, and they do so with finely titrated doses of friendship. They sometimes deliver lectures in medical work places or at a hotel or conference venue.
Normally, medical sales executives have their own regional area of responsibility and plan how and when to target health professions. Medreps should be able to keep up with the latest clinical data supplied by the company and interpreting, presenting and discussing these data with health care providers during their periodic visits.
They should also maintain update knowledge about competitor products and articles published regarding them.

Being smart, dedicated, good psychologist, well groomed, having soft skills with good personality and a high Emotional Quotient (EQ), would be part of their success towards their performance.
Factors contributing to a drug selection are comprised of product quality, safety, effectiveness, price, availability, company reputation, packaging attraction, patient affordability and satisfaction.

MEDICAL REPRESENTATIVE CAREER GROWTH

Medical Representative can get elevated to higher positions in the sales, as Area Manager, Regional Manager, Zonal Manager, and National Sales Manager.
From above the National Sales Manager position, the next promotion is General Manager- Sales & Marketing, then VP- Sales & Marketing, President and last but not least, Managing Director.
In Pharma Industry, there are numerous examples of the once Medical representative who have reached the Managing Director Position in their career.

MEDICAL REPRESENTATIVE PROMOTION

Ideally, Medical Representative should get promoted to the next position within 2-3 years of joining the field.
However, there are many Medical Representatives who get stuck to the same position for more than 5 years, or some even more than 10 years. Thereafter, their further promotions or positions also get delayed.
It is advisable for any Medical Representative to strive to get promoted within 2-3 years by constantly discussing this with their up lines.

MEDICAL REPRESENTATIVE FUTURE SCOPE IN INDIA

Medical Representatives' future in India is very bright, provided they keep doing their job of increasing prescriptions and helping the Pharma Corporations increase the Market Share of their brands.
Pharmaceutical Brand Marketing is In-Direct Selling, in that case, Doctors act as an Influencer. On his prescription, every sale of the strip or bottle is sold. Doctors prescribe the brand, only if the Medical Representative of the Pharma Corporate keeps visiting the Doctor. Thus, the job of Medical representatives would always be in demand and the future of Medical Representative's Job is going to be brighter in India.

Class - 7

COMMUNICATION

Communication is simply the act of transferring information, ideas, thought and feelings from one place, person or group to another.
Every communication involves
1.(at least) one sender,
2. message and
3. (at least) recipient.
This may sound simple, but communication is actually a very complex subject.
The transmission of the message from sender to recipient can be affected by a huge range of things (known as Barriers of Communication). These include our emotions, the cultural situation, the medium used to communicate, and even our location. The complexity is why good communication skills are considered so desirable by employers around the world: accurate, effective and unambiguous communication is actually extremely hard.

Types of Communication: -
Verbal Communication and Non-Communication

Verbal communication:
Verbal communication involves the exchange of thoughts, feelings and ideas using spoken words. Its effectiveness depends upon various aspects, including the choice of words, tone and clarity of speech.
It is a two-way process in which the speaker transmits information while the listener comprehends and interprets the message.

Non-verbal communication:
Verbal communication is oral communication. It's when we speak aloud. And it's a two-way process. Meaning it takes both a sender (the person talking) and a receiver (the person listening/receiving the message).
Nonverbal communication can include facial expressions, hand gestures and body language. We often mix verbal and nonverbal communication when we're trying to express ourselves or convey a message to others.

Non-verbal communication:
A substantial portion of our communication is nonverbal. In fact, some researchers suggest that the percentage of nonverbal communication is four times that of verbal communication, with 80% of what we communicate involving our actions and gestures versus only 20% being conveyed with the use of words.
Every day, we respond to thousands of nonverbal cues and behaviors, including postures, facial expressions, eye gaze, gestures, and tone of voice. From our handshakes to our hairstyles, our nonverbal communication reveals who we are and impacts how we relate to other people.

Types of Non-verbal Communication

1. Facial expressions
2. Gestures
3. Para linguistics (such as loudness or tone of voice)
4. Body language
5. Proxemics or personal space
6. Eye gaze, haptics (touch)
7. Appearance
8. Artifacts (objects and images)

Facial Expressions
Facial expressions are responsible for a huge proportion of nonverbal communication. Consider how much information can be conveyed with a smile or a frown. The look on a person's face is often the first thing we see, even before we hear what they have to say.
While nonverbal communication and behaviour can vary dramatically between cultures, the facial expressions for happiness, sadness, anger, and fear are similar throughout the world.

Gestures
Deliberate movements and signals are an important way to communicate meaning without words. Common gestures include waving, pointing, and giving a "thumbs up" sign. Other gestures are arbitrary and related to culture.
For example, in the U.S., putting the index and middle finger in the shape of a "V" with your palm facing out is often considered to be a sign of peace or victory. Yet, in Britain, Australia, and other parts of the world, this gesture can be considered an insult.

Nonverbal communication via gestures is so powerful and influential that some judges place limits on which ones are allowed in the courtroom, where they can sway juror opinions. An attorney might glance at their watch to suggest that the opposing lawyer's argument is tedious, for instance. Or they may roll their eyes during a witness's testimony in an attempt to undermine that person's credibility.

Para linguistics

Para linguistics refers to vocal communication that is separate from actual language. This form of nonverbal communication includes factors such as tone of voice, loudness, inflection, and pitch.

For example, consider the powerful effect that tone of voice can have on the meaning of a sentence. When said in a strong tone of voice, listeners might interpret a statement as approval and enthusiasm. The same words said in a hesitant tone can convey disapproval and a lack of interest.

Body Language and Posture

Posture and movement can also provide a great deal of information.

Research on body language has grown significantly since the 1970s, with popular media focusing on the over-interpretation of defensive postures such as arm-crossing and leg-crossing, especially after the publication of Julius Fast's book *Body Language*.

While these nonverbal communications can indicate feelings and attitudes, body language is often subtle and less definitive than previously believed.

Proxemics

People often refer to their need for "personal space." This is known as proxemics and is another important type of nonverbal communication.

The amount of distance we need and the amount of space we perceive as belonging to us are influenced by several factors. Among them are social norms, cultural expectations, situational factors, personality characteristics, and level of familiarity.

Eye Gaze

The eyes play a role in nonverbal communication, with such things as looking, staring, and blinking being important cues. For example, when you encounter people or things that you like, your rate of blinking increases and your pupils dilate.

People's eyes can indicate a range of emotions, including hostility, interest, and attraction. People also often utilize eye gaze cues to gauge a person's honesty. Normal, steady eye contact is often taken as a sign that a person is telling the truth and is trustworthy. Shifty eyes and an inability to maintain eye contact, on the other hand, is frequently seen as an indicator that someone is lying or being deceptive.

Haptics

Communicating through touch is another important nonverbal communication behavior. Touch can be used to communicate affection, familiarity, sympathy, and other emotions.

Gender differences also play a role in how people utilize touch to communicate meaning. Women tend to use touch to convey care, concern, and nurturance. Men, on the other hand, are more likely to use touch to assert power or control over others.

Appearance

Our choice of clothing, hairstyle, and other appearance factors are also considered a means of nonverbal communication.

These first impressions are important, which is why experts suggest that job seekers dress appropriately for interviews with potential employers.

Mode of Communication: -

Formal Communication:
Formal Communication refers to communication that takes place through legal channels in an organization. That kind of communication takes place between managers or employees of the same class or between high and low and vice versa. It may be oral or written but a complete record of that communication is kept in the organization.

Informal Communication:
Informal communication is defined as any communication that occurs outside of the official channels of communication. Informal communication is often referred to as the 'vine' as it spreads throughout the organization and on all sides regardless of the level of authority.

What are Communication Barriers: -

A communication barrier is anything that comes in the way of receiving and understanding messages that one sends to another to convey his ideas, thoughts, or any other kind of information. These various barriers of communication block or interfere with the message that someone is trying to send.
There are numerous barriers to effective communication that can come in the way. It happens because the message sent by the sender might not be understood exactly as it is meant to be. It can get distorted during the communication exchange.

These different types of communication barriers can come at any stage in the process of communication. It can come because of the bias or stereotyping and generalization that exists in the workplace.

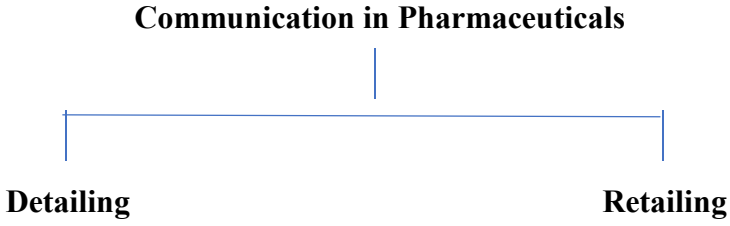
Few common Communication Barriers
One sometimes wants to connect with one thing, but he is actually saying something else that he did not intend. This type of event in communication behaviour is known as the "Arc of Distortion". The distortion may be the result of some error in any of the communication channels. These barriers to communication are also known as "barriers".
Some of the barriers to communication:

- Lack of proper style, feedback.
- Content is not related to customer requirements.
- Failure to maintain dual communication.
- Bad weather.
- Lack of horizontal flow of ideas.
- Availability of technical coordinators.
- Semantic Problems.
- Lack of leadership.
- Lack of enthusiasm.
- Lack of support from heads of institutions.

Common communication barriers in the Healthcare Industry: -

1. Medical words
2. Language differences
3. Cultural differences

4. Disabilities and other challenges
5. Low health literacy
6. Complexity of health topics
7. Lack of time



Pharmaceutical detailing.
Pharmaceutical detailing is a 1:1 marketing technique pharmaceutical companies use to educate a physician about a vendor's products, hoping that the physician will prescribe the company's products more often.
OR in other words, Detailing can be defined as the presentation of selling point in the most logical sequence.

Pharmaceutical Retailing.
Pharmaceutical RETAILING can be defined as the activities performed at Retailers level to generate information to make our presentation effective and to make our sales call successful.

Class – 8

PHARMACEUTICALS DETAILING

What is pharmaceutical detailing?
Pharmaceutical detailing is a 1:1 marketing technique pharmaceutical company use to educate a physician about a vendor's products, hoping that the physician will prescribe the company's products more often.
OR in other words, Detailing can be defined as the presentation of selling point in the most logical sequence.
Detailing is the selling with the persuasion of the highest order.

The benefits of pharmaceutical detailing
Pharmaceutical detailing has a number of benefits for the pharmaceutical company.

Increased sales.
Pharmaceutical detailing can result in increased pharmaceutical sales because a pharmaceutical sales representative is able to provide information about the product that may influence the physician to prescribe the product.

Compliance with FDA regulations.
Detailing helps pharmaceutical companies comply with FDA regulations by providing information about products that must be included on the label.

Improved patient outcomes.
Detailing also provides information about a product that may improve patient outcomes. This includes information about dosing, side effects and interactions with other medications.

Characteristics of Detailing:-
Detailing would always be clear, concise, logical a would enlightened the doctor on

A. WHAT IS THE PRODUCT?
B. WHAT IS THE PRODUCT USED FOR?
C. WHAT THE PRODUCT WILL DO?
D. HOW IS THE PRODUCT BETTER?

WHY SHOULD A DETAILING HAVE TO BE AN AUDIO VISUAL?

	RECALL AFTER 3 HOURS	RECALL AFTER 3 DAYS
ONLY TELL	70%	10%
ONLY SHOW	72%	20%
TELL AND SHOW	85%	65%

You would notice that the recall value when you tell and show is more than 3 times after 3 days as compared to only showing and 6 times to only saying.

The TOOL is known as "VISUAL AID"

4 Steps of Effective Detailing:-

Introduction:
Always give the doctor your full name, the company you represent, the name of your product and what it is used for. Don't assume the doctor remembers who you are or whom you represent from the few brief greetings shouted at her through the office window. And don't presume that she knows your product or what it does, even if you've left enough literature to fill a small library. In short, you had better start from scratch.

Product introduction:
Now is your chance. Go for it. Time to explain, in detail, what your product does, why it is the best and how the doctor can use it in her practice. Make it brief but informative. Remember: features and benefits. If you don't give that doctor a reason to use your drug, you've wasted her time and yours.

Probing:
Quickly, ask if there are any questions. Answer if needed.

Close:
Finally, close and ask for the sale. Everything leading up to this moment is just for show. Now is your chance to earn your pay. Get a commitment!

6 PRINCIPLES OF EFFECTIVE DETAILING

1. TEXT (content)
2. DELIVERY (manner in which you speak)
3. MODULATION (vary the tone /pitch of the voice)
4. Synchronisation (what you tell and what you show)

5. Handling of visual aid pointer
6. Detailing close

QUALITIES OF A GOOD DETAILER (6 C's)

1. Must be clear
2. Must be complete
3. Must be confident
4. Must eliminate competition
5. Must carry conviction (firm belief)
6. Must end with a close.

STAGES OF DETAILING (aida)

- To gain the doctor's ATTENTION and retain it till the meeting ends.
- To stimulate his INTEREST in listening to our message in our product
- To arouse a DESIRE in him to use our product.
- And thus, provoke ACTION, i.e to prescribe the product.

Class – 9

RETAILING

Retailing can be defined as the activity we perform at Retailers level to generate information to make our presentation to the doctors more effective.

In other words, retailing is the art of collecting information from retailers and using this information effectively to make the sales call successful.

Before we proceed further, we must take into cognizance 3 aspects:

1. Who are Retailers
2. What is the importance of Retailers for MSR.
3. What information's MSR collect from Retailers and How.

What are Retail Pharmacies?

Retail pharmacists (often known as chemists or community pharmacists) supply and sell medicine and medical-related products to the general public and medical practitioners, as well as other goods such as toiletries, cosmetics.

In the context of the Indian pharmaceutical industry, the supply chain side looks a little like this:

Role and Importance of Retail Pharmacies:

Accessibility:
Retail outlets provide essential access to medications for consumers, ranging from over-the-counter (OTC) products to prescription drugs.

Consumer Engagement:
Retailers can engage directly with consumers, offering counselling, medication management services, and health screenings, thus playing a critical role in public health.

Marketing Channel:
Retail environments serve as a marketing channel for pharmaceutical companies, particularly for OTC and consumer health products.
In-store displays, promotions, and pharmacist recommendations can influence consumer purchasing decisions.

To understand this process of Retailing well, we will discuss this topic under the following heads-

- Why there is a need to collect information from retailers?
- How to collect specific information from retailers?
- How to utilize the information for call planning?

A. Need to collect information from retailers:
Pharmaceuticals selling is quite different from other types of selling. Let us see why it is so, with the help of following example:-

- A consumer sales representative selling to a super market Manager will know at the end of his interview/discussion whether he is getting an order or not.
- An Industrial Sales Representative selling to a Purchase Manager will know at the end of his interview/discussion whether he is getting a contract or not.
- An Insurance Sales Representative will be reasonably certain at the end of his interview whether the prospect will buy the policy or not.

In all these instances, the Sales Representative in question will get to know the results/feedback of his sales interview right at the end of it,
But in case of Medical Sales Representative, we seldom get to know the exact outcome of the sales call, because most doctors promise to prescribe but a few of them keep up to their promise,

- How to collect "specific information"
- What do you mean by "Specific Information"

B. How to collect "specific information"
Specific information means the quantified data of prescriptions received and products sold by the retailer within a specified time and who were doctors who contributed to the prescriptions and sales.

Step 1- In this step we should decide on the details which we would like to follow up:

1. Whether Dr. X prescribed product A
2. Whether Dr. Y prescribed product B
3. Whether Dr. Z prescribed product C

These types of questions are asked to find out whether doctors who gave specific commitments during our previous visit really kept up their promise
(This implies that we must know specific commitments obtained from doctors during our previous visits).
In fact, the early part of our interview with retailer every time should be spent in verifying whether the doctor prescribed what they promised to prescribe. Since each retailer in the town will be catering to only three to four doctors we must seek for information only about these doctors from the retailer.

Step 2- Deciding on the product group or product about which we would like to collect information.

1. One that is critical to our performance
2. Or it might be important to our area's team performance
3. Or it might be important to our region's sales performance
4. Or it could be that our competitor is doing so well with his product that we want a crack at him,

Ideally, we must choose an important product group every month to collect data on from our entire Territory. Such a specific effort will help us to create a fund or a bank of information that will help us to plan our work and to use our promotional materials effectively.

Step 3

- To collect purchase details of this product/ product group. Just a day prior to our visit to a particular Town or territory, we should visit our stockist to find out the details of purchases (of the product about which we are going to seek information) made by retailers. This step will help us to access, the authenticity of information given to us by the retailer.
- Having prepared ourselves to visit the retailers to collect the information, let us see how we have to proceed
- Proceed when we are face-to-face with the retailer.

The first part of our interview should be to find out the effect of our earlier visit. This is achieved by asking very direct questions

The response will be yes or no. If the response ***is YES,*** two more questions may be asked.

- How many prescriptions did you receive OR
- How many STRIPS did you SELL?

Step 4

In the next part of the interview, our AIM should be able to make the retailer speak about quantified data. For example-

- Which brand of painkillers do you mostly sell in your counter
- Which is the highest moving brand
- How many strips do you sell per day
- Who is the maximum prescriber of the brand?
- How many prescriptions do you get per day

C. How to utilize the information for call planning:

A mere collection of data from retailers will lead MSR nowhere. We shall have to process and analyse the information. For example

- Who are our major competitors?
- Who are the doctors contributing to the sales of our product?

- Who are the doctors contributing to the sales of the competitor's product?
- How should I communicate to the concerned doctor?

WE MUST REMEMBER THAT, VERY NATURE OF THE PHARMACEUTICAL BUSINESS IS DYNAMIC, NOTHING REMAINS THE SAME IN THE MARKETPLACE FOR A LONG TIME.

- New products are being introduced and old products are being withdrawn or off focus.
- New doctors come to the town,
- New companies/Divisions come to the market.
- Pricing changes in off-patented products, etc.

Retailers are vital to the success of NSR because they are the one who provide him with relevant business informations. It is unto the respective MSR to make use of retailer as an important business ally, who can keep us on the road to Success as an MSR.

Class - 10

COMMUNICATION

UNIQUENESS OF PHARMACEUTICALS SELLING:

- Pharmaceutical selling is different.....entirely different from the usual "selling."
- The primary difference is that the person who is in fact paying for the drugs is not the decision-maker.
- The decision-making authority is someone else... the doctor. The patient or the end user, in turn is the doctor's customer.
- So basically, two customers need to be satisfied, the doctor as well as the patient.
- The job of a pharmaceutical salesperson is also very interesting in the sense that he has nothing to "sell" to his customer on the spot, nor can he deliver a live demonstration. He has to sell the concept, the research, the features and benefits and the scientific knowledge, a job much more difficult than is perceived.
- But still, there are thousands and thousands of pharmaceutical sales people worldwide doing a fine job and satisfying their ever-demanding customers. The role of a pharmaceutical salesperson has shifted over the years from a typical salesperson to that of a consultant or a facilitator. Knowledge has made the difference.

SKILLS: -

Selling is a multifaceted and demanding line of work. To be a successful sales person, it demands several skills. The list of skills a pharma sales man should possess is lengthy, to make it crisp few important skills are mentioned below.

1. Communication skill
2. Product Knowledge
3. Recognizing Systems and Process
4. Objection Handling
5. Identifying Buying signals
6. Negotiating and Closing.

4 PILLARS OF COMMUNICATION SKILL

A. Effective Listening: -

Listening, without your thoughts wandering or planning your response, is an act of caring. It is immediately felt and it builds the rapport and connection that speaking does not.

Too many salespeople believe that listening well is simply repeating back what they have heard in order to prove that they heard what was said. Besides annoying your prospect, it can be done without truly listening for the meaning and without really understanding. It is simply a tactic, not true listening.
I had a great mentor in sales that won more deals with fewer spoken words than I ever imagined possible. If there were an effectiveness measurement for revenue to words spoken, he would surely be one of the most effective salespersons. He was a brilliant listener, asking questions and then sitting quietly and listening, prompting the client with more questions only when they were completely finished speaking. He asked clarification questions when necessary. Then, when he gathered all of the information he needed, he neatly summarized the points for confirmation.

Practice the art of listening by first controlling your desire to speak.
Care deeply about what the other person is saying, so that you don't have to repeat everything back. Stop planning what you will say next, and be open to the idea that you don't already have the right solution just because you have seen their challenges before. Prompt for more information to clarify the meaning and to acquire a deeper understanding. Then, neatly summarize all of that you have heard to confirm you understand.

Most of all, care enough to pay attention.

B. Effective Speaking:

In pharma selling what we speak will make a strong impact on customer mind and if it suits to the necessity of customer, the conversation would be productive. For a successful conversation Probing the customer is a key skill

C. PROBING:

The first key to a successful sales call.
Ideally, a pharmaceutical representative's sales call with a physician should consist of opening, probing, proving and closing. From a sales perspective, probing and closing are probably the two that best determine success. Ironically, if you ask physicians what parts of the interview process they often find objectionable, the answer is likely to also be probing and closing.
In this article, I will focus on effective probing, while a future article will deal with successful closing. I define probing as the art of obtaining information, establishing needs and uncovering objections in a non-confrontational, collegial atmosphere. Probing is specifically designed to obtain information – both positive and potentially negative – about a product, allowing the representative to tailor presentation that will optimize sales success.

BE CAREFUL WHEN CHOOSING YOUR WORDS:

- Never condemn what they are using.

AVOID SAYING	BETTER TO SAY
Potent	**Effective**
Safe	**Tolerable**
The Best	**Good Choice**
Cheap	**Economic/Affordable**
I think	**Fact is**
Your objection	**Your concern**

D. BE NON-AGGRESSIVE:

If I had to name a major factor that separates the successful from the average reps, that factor would be the ability to probe. Doctors, as a rule, especially in geographical areas where prescription information is limited, are guarded about their prescribing habits. If a doctor is using product X, that physician does not want to be told by the representative for product Y that he or she is doing something wrong. Typically, most reps would not be aggressive enough to tell a physician directly that he or she was prescribing an "inferior" product, but in the physician's mind, this is a possibility he or she would like to avoid. The more the sales representative appears to use an aggressive, business-oriented approach or style, with the mandate to "sell" something, the more likely his or her message is to be viewed with

Open Question: Invites an extended doctor response, it should start with What, When, Why, Where, Who & How

Closed Question: Invites a "Yes" or "No" reply from the doctor, to start with Do, Will, Is, Should

Choice Question: Give the doctor two or more positive options in order to rule out a negative "No" response.

Benefit tag questioning: Benefit is presented in the form of a statement supported by a Feature and followed by a Closed Question

Tag on questioning: Tag on questions are used when the doctor makes a positive statement that you want to reinforce

Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024

On March 12, 2024, the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers (DoP), unveiled the revised Uniform Code for Medical Device Marketing Practices (UCPMP 2024) with a view towards providing a set of guidelines that would mitigate unethical ensure transparency, integrity, and accountability

India does not have a specific law at present that regulates promotion and marketing of drugs and medical devices by companies before health care practitioners ("HCPs"). Advertisement of drugs and medical devices to end consumers, on the other hand, is heavily regulated. The Central Government had published a set of guidelines in December 2014 called "Uniform Code of Pharmaceutical Marketing Practices" ("UCPMP") as guidance to the industry for promotion and marketing of drugs and medical devices.

However, these guidelines are voluntary and do not have the force of law, at present. The government is contemplating a separate code for promotion of medical devices called Uniform Code for Medical Device Marketing Practices ("UCMDMP"). However, the code has not yet been finalized.

Until UCMDMP is officially published, the UCPMP should be treated as the official guidance for promotion of medical devices by medical devices companies. Accordingly, in the paragraphs below, the reference to the word "drug" should be considered as a reference to "medical device" as well.

Important and Relevant Clauses pertaining to MSR:

The medical representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties. They must comply with all relevant requirements of the Code.

The medical representatives must not employ any inducement or subterfuge to gain an interview. They must not pay, under any guise, for access to a healthcare professional.

Relationship with Healthcare Professionals

Gifts: No gift should be offered or provided for personal benefit of any healthcare professional or family member (both immediate and extended) by any pharmaceutical company or its agent i.e. distributors, wholesalers, retailers, etc. Similarly, no pecuniary advantage or benefit in kind may be offered, supplied, or promised to any person qualified to prescribe or supply drugs, by any pharmaceutical company or its agent i.e. distributors, wholesalers, retailers, etc.

Travel: Companies or their representatives, or any person acting on their behalf, should not extend travel facilities inside or outside the country, including rail, air, ship, cruise tickets, paid vacations, etc., to healthcare professionals or their family members (both immediate and extended) for attending conferences, seminars, workshops etc., unless the person is a speaker for a CME Program.

Hospitality: Companies or their representatives, or any person acting on their behalf, should not extend hospitality like hotel stay, expensive cuisine, resort accommodation etc., to healthcare professionals or their family members (both immediate and extended) unless the person is a speaker for a CME program.

Monetary Grants: Companies or their representatives should not pay cash or monetary grant to any healthcare professional or their family members (both immediate and extended) under any pretext. Where any item missing, the Code as per the Indian Medical Council (MCI)

Class - 11

Regulatory Authorities and Government Policies:

Regulatory Authorities are government-created institutions that regulate, supervise, and govern diverse industries like insurance, finance, education, and healthcare. Each sector in India has its Regulatory Authority. They may be independent or act under executive supervision. For example, food safety is the responsibility of the FSSAI, just as financing of rural development is the responsibility of the NABARD. Telecom Regulatory Authority of India (TRAI), National Housing Bank (NBH), National Green Tribunal (NGT), and others are instances of regulatory entities.

In a regulatory or supervisory role, a Regulatory Authority of India is a public entity or governmental body accountable for exercising independent control over specific areas of human activity. They are in place to ensure that safety and norms are adhered to.

Regulatory Bodies in India:

At present, there are many regulatory agencies in our country. However, below is the list of essential regulators of India.

Sl No	Regulatory Authority	Area	Activities
1	NABARD (National Bank for Agricultural and Rural Development)	Financing of rural development	To build a financially strong rural India by financing, refinancing, planning, and monitoring rural development.
2	SEBI (Securities and Exchange Board of India)	Securities and stock market	The securities market must be controlled, and the interest and rights of the investors must be safeguarded.
3	RBI (Reserve Bank of India)	Banking, Finance, and Monetary Policy	Among other responsibilities, RBI regulates all banking and financial operations.
4	TRAI (Telecom Regulatory Authority of India)	Telecommunication	To introduce rules and norms to boost the efficiency and flexibility in delivering telecom services.

5	IRDAI (Insurance Regulatory and Development Authority of India)	Insurance	Monitoring and development of the insurance and reinsurance sector of India.
6	SIDBI (Small Industries Development Bank of India)	Financing small, medium, or microscale industries	To provide a loan or financial aid to small and micro industries in India for their development.
7	NHB (National Housing Bank)	Housing finances	To finance housing developments, either nationally or at the regional level.
8	CBFC (Central Board of Film Certification)	TV/Film certification, censorship	To certify films that are publicly exhibited.
9	FSSAI (Food Safety and Standards Authority of India)	Food and beverage	To ensure food safety, the processing, production, distribution, and marketing of foodstuffs are all controlled and monitored.
10	FSDC (Financial Stability and Development Council)	Financial sector development	It deals with the financial rules and regulations in the financial sector of India.
11	BIS (Bureau of Indian Standards)	Certification and standards	To develop and establish product standards, thus aiding the economy by supplying high-quality commodities.
12	BCCI (Board of Control for Cricket in India)	Cricket	To control, monitor, and enhance the standards of cricket in India. It is also responsible for protecting the values of the sport.
13	NASSCOM (National Association of Software and Service Companies)	Information Technology	To make the trade in software and services more flexible, and also support the development of software technology.
14	National Green Tribunal	Law	To effectively and timely resolve issues related to environmental preservation and forest conservation. It also deals with recovering damages to an individual or property due to environmental law violations.
15	CCI (Competition Commission of India)	Competition	To promote healthy competition and flexibility of trade in the Indian market. It is also responsible for minimising practices that have a negative impact on competition.

Table: Enlisted Regulatory Bodies in India

Apart from the above fifteen important regulators of our country, there are several other regulatory agencies as well, such as:

- Atomic Energy Regulatory Board (AERB)
- Insolvency and Bankruptcy Board of India (IBBI)
- Central Drugs Standard Control Organisation (CDSCO)
- Project Exports Promotion Council of India (PEPC)
- Organisation of Plastic Processors of India (OPPI)
- Manufacturers' Association for Information Technology (MAIT)
- Indian Stainless-Steel Development Association (ISSDA)
- Indian Chemical Council (ICC)
- Association of Mutual Funds in India (AMFI)
- Pension Fund Regulatory and Development Authority (PFRDA)
- Advertising Standards Council of India (ASCI)
- Express Industry Council of India (EICI)
- Engineering Export Promotion Council of India (EEPC)
- Federation of Indian Export Organisation (FIEO)
- Indian National Shipowners' Association (INSA)
- Functions of Regulatory Authorities

Functions:

A Regulatory Authority is a government entity or agency accountable for implementing the rules and regulations in various sectors. It is among its functions to apply norms, restrictions, or limitations, establish the standard for operations, and enforce or ensure conformance in these areas. The following are the primary responsibilities of a regulatory authority.

- Remedial measures
- Regulations and instructions
- Review and evaluation
- Enforcement
- Licensing/Inspection
- Guarantee that the market is fair and transparent, especially after liberalisation.
- Provides private investment with functional autonomy and protects them from any intrusion.

Importance of Regulatory Authorities:

- The Indian economy was spared the effects of the global financial crisis owing to the RBI's, SEBI's, and IRDAI's strict foreign investor regulations.
- The TRAI has safeguarded customers from profit-driven cell phone companies.
- The strict monetary policy of the RBI has allowed it to battle inflation.
- The CCI has aided in dismantling the cement mafia, which purposely maintained high prices and restricted competition.

The Regulatory Maze: Two examples:

As a result of this network of oversight bodies, those individuals and organizations subject to regulation must turn to multiple competing authorities for guidance. Two examples illustrate this dynamic.

The path to practicing medicine is paved with an array of regulatory hurdles implemented by an assortment of bureaucracies. A potential physician must attend a medical school that has received accreditation by a private

body, take a national examination administered by another nongovernmental organization, obtain licensure from a state medical board, complete a hospital residency that is funded and governed by the federal Medicare program, achieve certification from a private specialty board, and obtain clinical privileges at a hospital that may operate as either a private or public entity. To receive payment for services and actually earn a living, it is often also necessary for a physician to qualify for participation in Medicare and in the network of a managed care organization (MCO).

The path to marketing a new drug is similarly cumbersome. A pharmaceutical company must start by protecting its invention with a patent that is issued by the federal Patent and Trademark Office (PTO). It must then receive permission to conduct clinical testing from the federal Food and Drug Administration (FDA), which, for many products, culminates in review of the results by an advisory committee composed of private scientists. After approval for marketing is received in the form of a New Drug Approval (NDA), the manufacturer must adhere to marketing restrictions contained in the NDA.

Next, in order to sell the drug widely, the manufacturer must obtain a place for it on the formularies of private pharmacy benefit management companies (PBMs), which administer reimbursement plans. Ideally, the drug will also be included in the standards of care promulgated by private medical specialty societies.

After all of these steps, the drug still cannot be sold unless it is prescribed by physicians and is dispensed by pharmacists who are subject to licensure and a range of other regulatory requirements.

The Logic Behind Regulatory Complexity:

Is this complexity of health care regulation merely a result of a series of historical accidents and bureaucratic turf wars, or does it serve a purpose? The system's intricacy may make it inefficient, but it actually fits quite well with the American temperament. It is driven by an interplay of competing forces that seek to have their interests represented.

Different levels of government vie with one another for supremacy, as they have since the founding of the republic. This system of checks and balances makes it less likely that any one level, federal or state, will become too powerful, and it ensures that the overall system will receive input from each. The regulatory structure also reflects a form of public–private partnership. Private organizations, such as the Joint Commission and medical speciality boards, which are composed of professionals who actually work in the field, inject technical expertise. These organizations are balanced by government agencies, which provide a more disinterested external perspective that is presumably less subject to economic self-interest.

In essence, the system benefits by receiving regulatory input from varying perspectives. State and local agencies are often closest to the actual provision of health care and the most sensitive to regional needs. Federal oversight is usually necessary to provide national coordination, for example, to prevent physicians who have been disciplined by a medical board from gaining licensure in another state. Private organizations offer the deepest expertise in the clinical aspects of care.

System Shortcomings:

This explanation is not meant to suggest that the system is without its share of shortcomings, because some of them are substantial. Critics charge that private regulatory bodies are often more interested in safeguarding the reputation and economic status of their industries and professions than in protecting the public. State regulators, particularly those in smaller jurisdictions, may be subject to excessive influence by those they are supposed to oversee. Federal agencies may be slow, bureaucratic, and inefficient.

Moreover, in some areas of regulation, the division of authority is not clearly outlined, a drawback that has led at times to chaotic results. A prime example is the oversight of health insurance. States take the lead in regulating insurance, but the federal government pre-empts some state authority over employer-sponsored health coverage under the Employee Retirement Income Security Act of 1974 (ERISA). The lines of responsibility are not clearly defined in the law, and they have been subject to a series of equally confusing court decisions.

Consequences of the Regulatory Statement:

Despite the complicated and inefficient nature of its oversight, American health care has flourished over the past hundred years. Rather than hindering its progress, the complex system of regulation, for all of its flaws, may actually have served to support and nurture the overall enterprise.

Consider, for example, the public confidence that is engendered in the competence of physicians through licensure requirements and in the safety and efficacy of prescription drugs through the FDA approval process. These programs enhanced overall respect for major elements of the health care system and greatly expanded markets for the goods and services that they provide. Regulatory programs that include major funding components, such as Medicare and research support administered by the National Institutes of Health (NIH), serve an additional role of creating a financial base for key sectors of the industry.

Viewing the system in this way may help to provide perspective for those who have to navigate it. It is also important to consider the underlying nature of the system, with both its positive and negative elements, in evaluating proposals for reform.

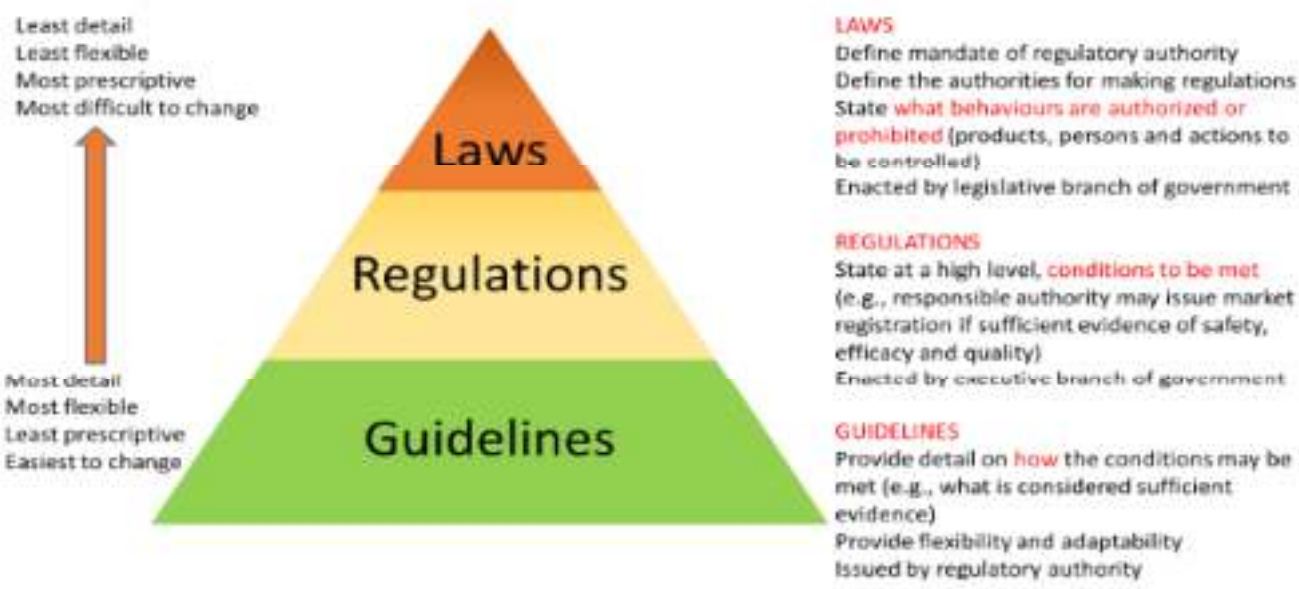


Figure: Architecture of a regulatory framework

Core components of regulatory compliance in healthcare:

Regulatory healthcare compliance is divided into four main categories, which are further divided into sub-categories. Let us have a look at all the categories and subcategories of regulatory healthcare compliance.

A. Policies and procedures

There are two sub-categories for policies and procedures

1. Developing effective policies

Effective policies and procedures are the foundation of regulatory compliance in healthcare. Healthcare organizations must develop clear, comprehensive, and up-to-date policies that align with regulatory requirements. This includes defining processes for patient care, data security, billing, and other critical aspects of healthcare operations.

2. Ensuring proper documentation

Proper documentation of policies and procedures is essential. Healthcare providers should maintain records of policy creation, revisions, and distribution. Documentation helps demonstrate compliance efforts and provides a reference for staff members to follow.

B. Training and Education

Training and education of the employees is an integral part of regulatory compliance in healthcare. It is an ongoing process rather than a one-time exercise.

1. Employee training

Healthcare organizations should provide comprehensive compliance training for all employees, including clinical staff, administrative personnel, and support staff. Training should cover relevant regulations, policies, and procedures to ensure that everyone understands their compliance responsibilities.

2. Ongoing education

Compliance is an evolving field, and regulations change over time. Ongoing education is crucial to keep staff informed about the latest compliance requirements and best practices. Regular training sessions, workshops, and updates help maintain a culture of compliance.

C. Risk assessment and management

Every activity brings risks. There were 11 reported healthcare data breaches of more than 1 million records in 2022 and a further 14 data breaches of over 500,000 records (HIPAA Journal). This makes risk assessments and management paramount.

1. Identifying compliance risks

Healthcare organizations should conduct regular risk assessments to identify potential compliance vulnerabilities. This involves evaluating processes, practices, and external factors that could pose compliance risks. Risk assessments help prioritize areas for improvement.

2. Mitigation strategies

Once compliance risks are identified, healthcare organizations should implement mitigation strategies. This may involve process improvements, policy revisions, or additional training to address specific risks. Mitigation strategies aim to reduce the likelihood of non-compliance.

D. Monitoring and auditing

Monitoring and auditing regularly is a step that cannot be missed. It consists of two sub-steps.

1. Regular audits and self-assessments

Healthcare organizations should conduct regular internal audits and self-assessments to evaluate compliance with policies and regulations. Audits may be conducted by dedicated compliance officers or teams. These assessments help identify compliance gaps and areas needing improvement.

2. Corrective action plans

When non-compliance is identified, healthcare organizations should develop corrective action plans to address deficiencies. These plans outline steps to remediate issues, prevent recurrence, and ensure ongoing compliance. Corrective actions may involve policy revisions, additional training, or process changes.

Effective regulatory compliance in healthcare requires a proactive approach that encompasses policies, education, risk management, and ongoing monitoring. By focusing on these core components, healthcare organizations can create a culture of compliance, reduce the risk of regulatory violations, and ultimately provide better care to patients while maintaining the trust of regulators and the public.

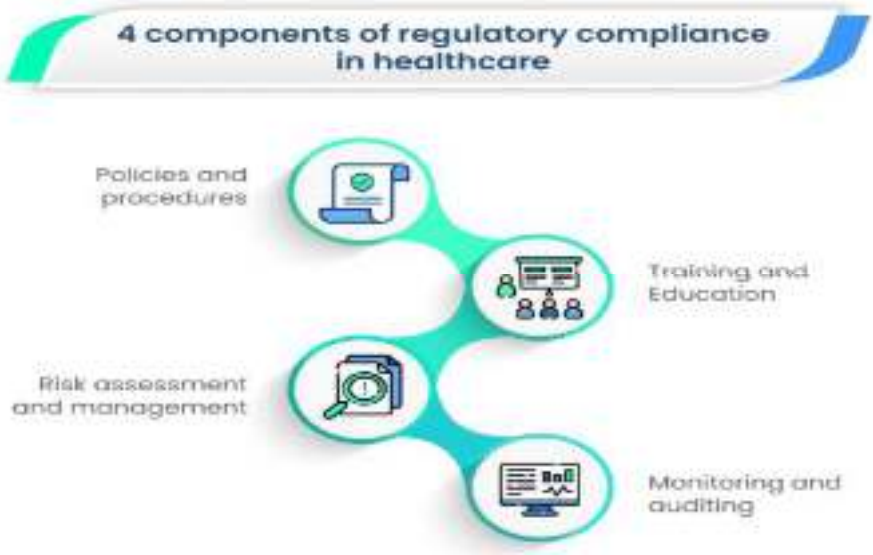


Figure: Four components of regulatory compliance

CDSCO Act:

The Central Drugs Standard Control Organisation (CDSCO) under Directorate General of Health Services,Ministry of Health & Family Welfare, Government of India, is the National Regulatory Authority (NRA) of India. Its headquarter is located at FDA Bhawan, Kotla Road, New Delhi 110002 and also has six zonal offices, four sub zonal offices,thirteen Port offices and seven laboratories spread across the country.

The Drugs & Cosmetics Act,1940 and rules 1945 have entrusted various responsibilities to central & state regulators for regulation of drugs & cosmetics. It envisages uniform implementation of the provisions of the Act & Rules made there under for ensuring the safety, rights and well-being of the patients by regulating the drugs and cosmetics. CDSCO is constantly thriving upon to bring out transparency, accountability and uniformity in its services in order to ensure safety, efficacy and quality of the medical product manufactured, imported and distributed in the country.

Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of New Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

Further CDSCO along with state regulators, is jointly responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera.

Figure: Homepage of CDSCO

Role of CDSCO in life science industry:

Biological products, or biologics, are medical products. Many biologics are made from a variety of natural sources (human, animal or microorganism). Like drugs, some biologics are intended to treat diseases and medical conditions. Other biologics are used to prevent or diagnose diseases. Examples of biological products include

- vaccines
- blood and blood products for transfusion and/or manufacturing into other products
- allergenic extracts, which are used for both diagnosis and treatment (for example, allergy shots)
- human cells and tissues used for transplantation (for example, tendons, ligaments and bone)
- gene therapies
- cellular therapies
- tests to screen potential blood donors for infectious agents such as HIV

Human Vaccines (Bacterial, Viral and Combination Vaccine) Veterinary Vaccines:

- Grant of NOC for issuance of Form 29 (manufacture of drugs for the purpose of Examination, test or analysis of vaccines)
- Approval of Clinical Trial.
- Grant of Marketing Authorization.
- Grant of Registration Certificate, Import License and Test Licence in Form 11.
- Approval of Form 28-D Licensing (Vaccines) under CLAA Scheme.
- Issuance of Export NOC and Permission under Rule 37.
- Approval of Post Approval Changes.

r-DNA Products:

- Approval of Clinical Trial.
- Grant of Marketing Authorization.
- Grant of Registration Certificate, Import License and Test Licence in Form 11.
- Approval of Form 28-D Licensing (r-DNA) under CLAA Scheme.
- Issuance of Export NOC and Permission under Rule 37.
- Approval of Post Approval Changes.

Veterinary Vaccines:

- Grant of NOC for issuance of Form 29 (manufacture of drugs for the purpose of Examination, test or analysis of Veterinary vaccines)
- Grant of NOC for field trials.
- Grant of Marketing Authorization.
- Grant of Registration Certificate, Import License and Test Licence in Form 11.
- Approval of Form 28-D Licensing (Veterinary Vaccines) under CLAA Scheme.
- Issuance of Export NOC and Permission under Rule 37.
- Approval of Post Approval Changes.

Figure: Biologics of CDSCO

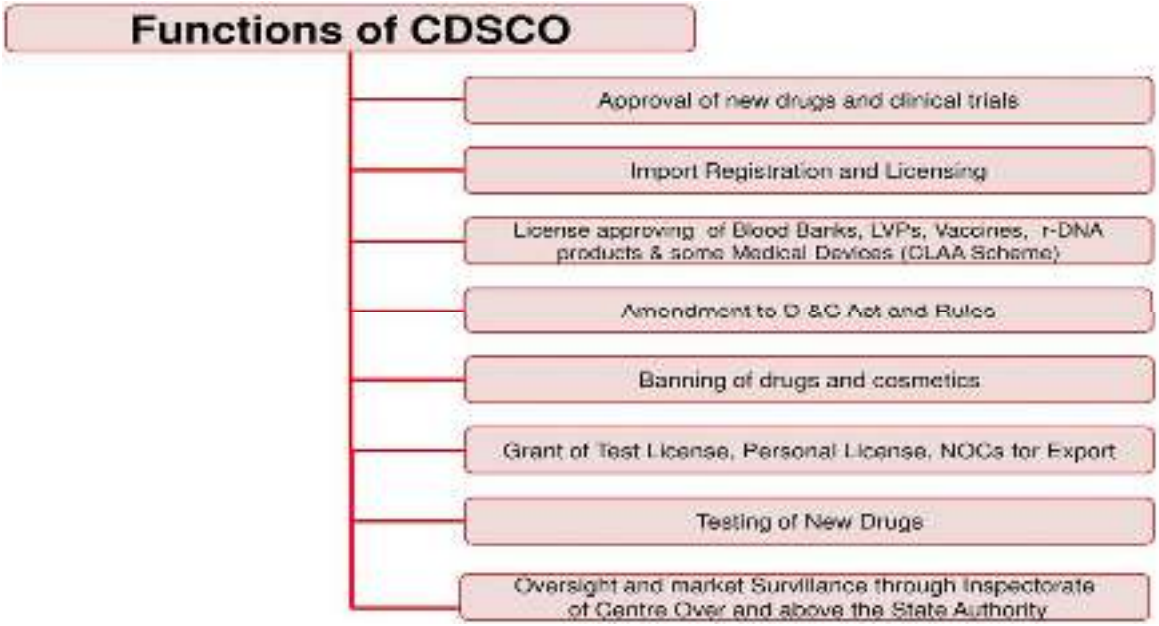


Figure: CDSCO functionality

NPPA Act:

National Pharmaceutical Pricing Authority (NPPA) was constituted vide Government of India Resolution dated 29th August, 1997 as an attached office of the Department of Pharmaceuticals (DoP), Ministry of Chemicals & Fertilizers as an independent Regulator for pricing of drugs and to ensure availability and accessibility of medicines at affordable prices.

NPPA's role as a Regulator is to work towards a Healthy Nation by making medicines accessible and affordable while creating an enabling environment for the Indian Pharmaceutical Industry to develop into a world leader. NPPA administers 'Pharma Sahi Daam' and 'Pharma Jan Samadhan' platforms for information on medicine prices and registering public grievances. The Integrated Pharmaceutical Database Management System 2.0 (IPDMS) is being implemented for online information collection from Pharma manufacturers.

Figure: Homepage of NPPA

NPPA is expanding outside Delhi, through the Price Monitoring and Research Units (PMRUs) at State levels. PMRU will function at the State level under the direct supervision of the State Drug Controller for increasing outreach of NPPA.

The primary function of PMRUs is to assist NPPA in monitoring of prices of drugs, ensuring availability of drugs and raising consumer awareness. They act as collaborating partners of NPPA with information gathering mechanism at the grass-roots level.

They will render necessary technical assistance to both the NPPA and the respective State Drug Controllers of States/ Union Territories. PMRUs will also ensure that the benefits of the DPCO (revised from time to time) trickle down at the grassroots level. NPPA, under its Central Sector Scheme named Consumer Awareness, Publicity and Price Monitoring (CAPPM), has already set up of PMRUs in 31 States/ Union Territories.

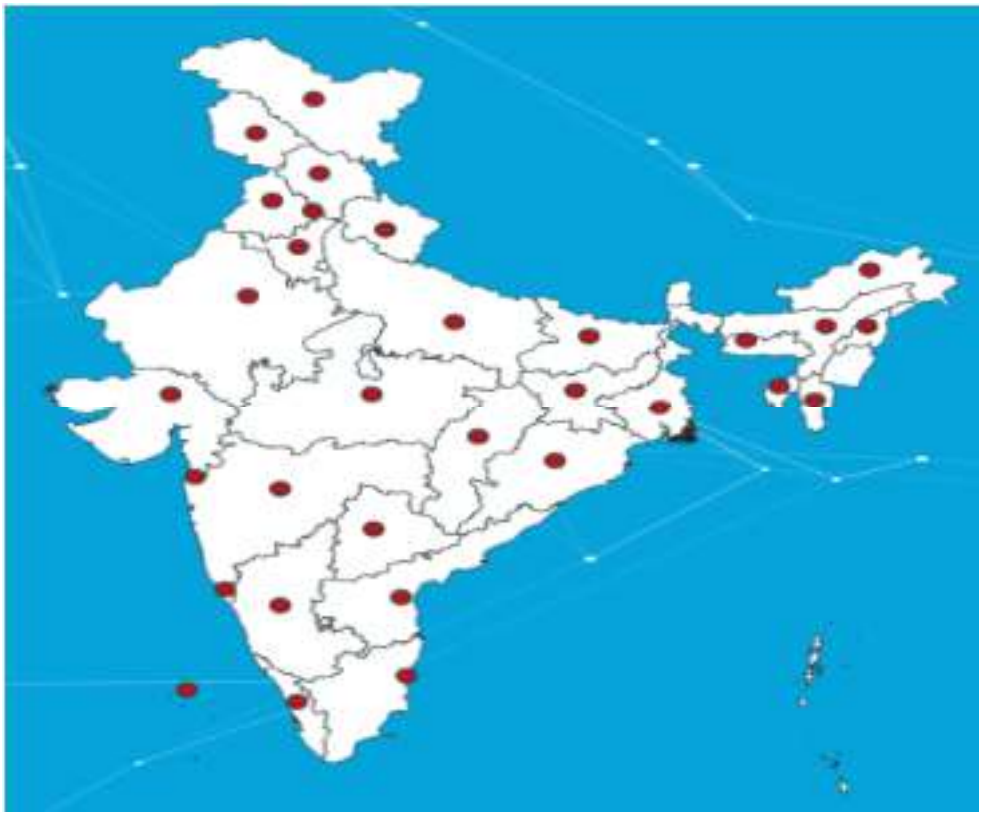


Figure: Map-wise distribution of NPPA

Figure: Flowchart of NPPA

National Pharmaceutical Pricing Authority

1	Name of the Authority	**National Pharmaceutical Pricing Authority**
2	Date of Establishment	**August 1997**
3	Address	**3rd/5th Floor, YMCA Cultural Centre Building,1, Jai Singh Road, New Delhi 110 001**
4	Telephone Fax	**23345118, 23345122, 23746652**

The National Pharmaceutical Pricing Authority was set up as an attached office of the Department of Chemicals and Petrochemicals (now Department of Pharmaceuticals since July, 2008) on 29th August 1997. It has been entrusted inter-alia, with the following functions

1. To implement and enforce the provisions of the Drugs Price Control Order (DPCO), 1995/2013 in accordance with the powers delegated to it.
2. To undertake and/or sponsor relevant studies in respect of pricing of drugs/formulations.
3. To monitor the availability of drugs, identify shortages, if any, and to take remedial steps.
4. To collect/maintain data on production, exports and imports, market share of individual companies, profitability of companies etc. for bulk drugs and formulations.
5. To deal with all legal matters arising out of the decisions of the Authority.
6. To render advice to the Central Government on changes/revisions in the drug policy.
7. To render assistance to the Central Government in the parliamentary matters relating to the drug pricing.

Figure: Snapshots of NPPA

Role of NPPA in the life science industry:

The National Pharmaceutical Pricing Authority was set up as an attached office of the Department of Chemicals and Petrochemicals on August 29, 1997. It is responsible for regulating the prices of drugs in the country and ensuring their availability, accessibility and affordability to every citizen of the country.

During the crisis of the ongoing COVID-19 pandemic in the country, NPPA has been actively responsible in capping the prices for various medicines, ventilators and other drugs which have been useful in treating the affected patients.

For the development of the coronavirus vaccine in India, the Government had launched Mission COVID Suraksha, wherein clinical development, manufacturing and licensing of Indian vaccines were promoted.

Functions of NPPA

Given below are the roles and responsibilities that are performed by the National Pharmaceutical Pricing Authority:

- To implement and enforce the provisions of the Drugs Price Control Order (DPCO), 1995/2013 in accordance with the powers delegated to it
- To undertake and/or sponsor relevant studies in respect of the pricing of drugs/formulations
- To monitor the availability of drugs, identify shortages, if any, and take remedial steps
- To collect/maintain data on production, exports and imports, market share of individual companies, the profitability of companies, etc., for bulk drugs and formulations
- To deal with all legal matters arising out of the decisions of the Authority
- To render advice to the Central Government on changes/revisions in the drug policy
- To render assistance to the Central Government in parliamentary matters relating to drug pricing

Significance of NPPA:

- It is important to fix the prices of certain important drugs so that they can be easily affordable and accessible to every citizen of the country, and the National Pharmaceutical Pricing Authority ensures the same. It mandates that no supplier can sell a drug at more than its Maximum Retail Price (MRP).

- NPPA played a very crucial role during the pandemic time in the country as many medical suppliers were selling drugs at higher prices, which were unaffordable for many. Thus, this authority fixed the prices so that they could be availed easily

NPPA Initiatives:
The National Pharmaceutical Pricing Authority (NPPA) is headquartered in New Delhi, and to increase its reach across the country, NPPA has set up a Price Monitoring and Resource Unit (PMRU) in various Indian States and Union Territories.
These PMRU's have been set up under the Consumer Awareness, Publicity and Price Monitoring (CAPPM) scheme. As of January 2021, there are 14 states/UTs where these PMRUs have already been set up. The pharmaceutical authority aims to set up a price monitoring unit in each and every state and union territory across India.
States/UTs with PMRU already set up – Kerala, Odisha, Gujarat, Rajasthan, Haryana, Nagaland, Tripura, Uttar Pradesh, Punjab, Andhra Pradesh, Mizoram and Jammu & Kashmir. The latest addition to this list is Karnataka and Goa, where the PMRU was set up in 2020.

THE MONOPOLIES AND RESTRICTIVE TRADE PRACTICES ACT, 1969
POLICY, PROVISIONS AND PERFORMANCE
The MRTP Act, 1969 has its genesis in the Directive Principles of State Policy embodied in the Constitution of India. Clauses (b) and (c) of Article 39 of the Constitution lay down that the State shall direct its policy towards ensuring:
(i) that the ownership and control of material resources of the community are so distributed as to best serve the common good; and
(ii) that the operation of the economic system does not result in the concentration of wealth and means of production to the common detriment.

Provisions Relating to Monopolistic, Restrictive and Unfair Trade Practices
Section 10 of the MRTP Act, 1969 empowers the MRTP Commission to enquire into monopolistic or restrictive trade practices upon a reference from the Central Government or upon its own knowledge or on information. The MRTP Act, 1969 also provides for the appointment of a Director General of Investigation and Registration for making investigations for the purpose of enquiries by the MRTP Commission and for the maintenance of a register of agreements relating to restrictive trade practices.
The MRTP Commission receives complaints both from registered consumers and trade associations, and also from individuals, either directly or through various Government Departments. Complaints regarding Restrictive Trade Practices or Unfair Trade Practices from an association are required to be referred to the Director General of Investigation and Registration for conducting a preliminary investigation in terms of Sections 11 and 36C of the MRTP Act, 1969and Regulation 119 of the MRTP Commission Regulations, 1974. The Commission can also order a preliminary investigation by the Director General of Investigation and Registration when a reference on a restrictive trade practice is received from the Central/ State Government, or when the Commission's own knowledge warrants a preliminary investigation. Enquiries are instituted by the Commission under relevant Sections of the MRTP Act, 1969 after the Director General of Investigation and Registration has completed the preliminary investigation and, as a result of the findings, submits an application to the Commission for an enquiry.

Monopolistic Trade Practices
Five enquiries under Section 10(b) were pending with the MRTP Commission at the beginning of the year 2005, while no fresh inquiry was instituted during the period April, 2005- December, 2005. All 5 enquiries were pending as on 31.12.2005.

Restrictive Trade Practices

Under Section 10(a)(i)
293 enquiries, including 267 brought forward from the previous year, were considered during April 2005-December 2005 of which 48 enquiries were disposed of during the said periodand the remaining 245 enquiries were pending with the Commission as on 31st December 2005.

Under Section 10(a)(ii)
Neither any enquiry was brought forward from the previous year nor any enquiry was instituted under this Section during the year.

Under Section 10(a)(iii)
39 enquiries including 37 brought forward from the previous year were taken up by the Commission during April 2005 to December 2005. One enquiry was disposed of during the period and the remaining 38 were pending with the Commission as of 31st December 2005.

Under Section 10(a)(iv)
58 enquiries were brought forward from the previous year and 3 fresh enquiries were instituted by the Commission during the year from April 2005 to December 2005. 6 enquiries were disposed of during the said period and 55 enquiries were pending with the Commission as on 31st December 2005.

Unfair Trade Practices
Provisions relating to Unfair Trade Practices were incorporated in the MRTP Act, 1969 in 1984. Unfair Trade Practices have been defined in Section 36A as trade practices which for the purpose of promoting the sale, use or supply of any goods or for the provision of any services, adopt one or more of the practices mentioned therein and thereby cause loss or injury to the consumers of such goods or services, whether by eliminating or restricting competition or otherwise.

Under Section 36B(a)
491 enquiries including 410 enquiries brought forward from the previous year were considered by the Commission during April, 2005 - December 2005. Of these, 54 enquiries were disposed of and the remaining 437 enquiries were pending as on 31st December 2005.

Under Section 36B(b)
Neither any enquiry under Section 36B (b) of the MRTP Act, 1984 was initiated nor any enquiry was brought forward during April, 2005- December, 2005.

Under Section 36B(c)
1 enquiry brought forward from the previous year before the Commission is still pending as of 31.12.2005.

Under Section 36B(d)
176 enquiries, including 169 brought forward from the previous year, were taken up by the Commission during April, 2005 - December 2005. Eight enquiries were disposed of and 168enquiries were pending with the Commission as on 31st December 2005.

Temporary Injunctions
Besides 143 applications pending under Section 12A with the MRTP Commission as on 1st April, 2005, 43 applications were received by the Commission during the period April, 2005 -December 2005. Out of 186

applications, 55 were disposed of and the remaining 131 applications were pending under Section 12A with the Commission as on 31st December, 2005.

Award of Compensation

During the period April, 2005 - December 2005, 1341 applications under Section 12Bincluding 1264 applications brought forward from the previous year were considered by the Commission. Of these, 126 applications were disposed of by the Commission during the period and the remaining 1215 applications were pending as on 31st December, 2005.

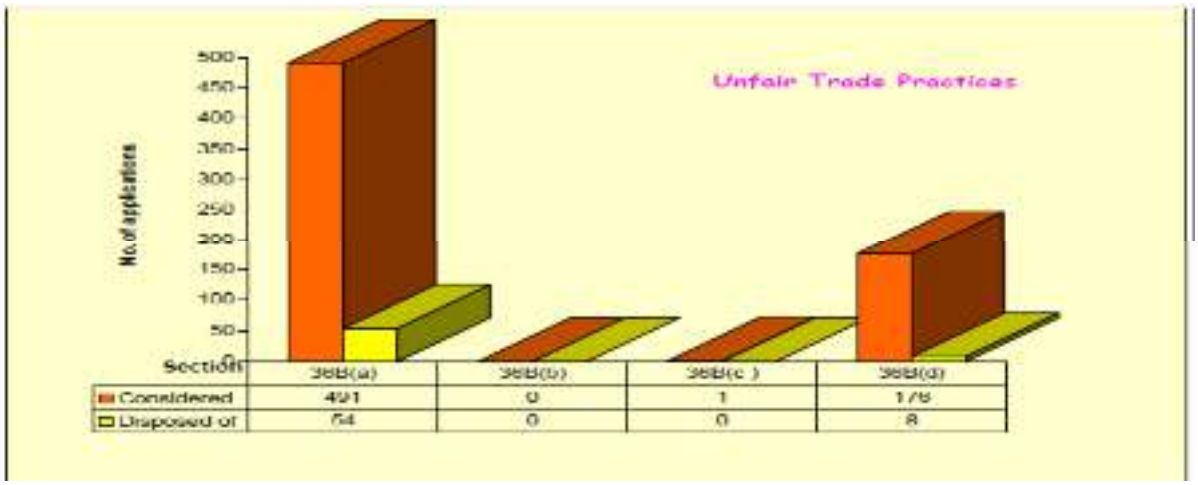


Figure: Unfair Trade Practices

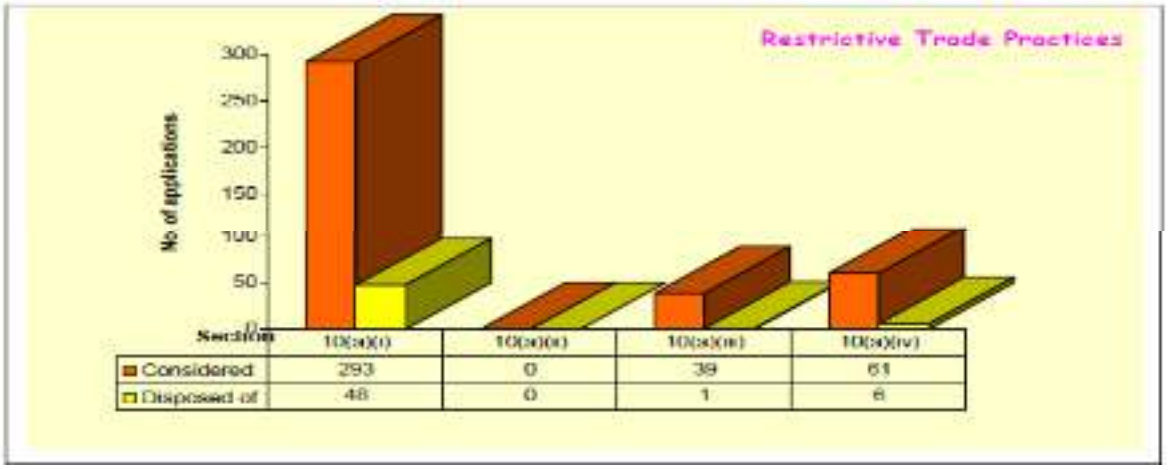


Figure: Restrictive Trade Practices

The Monopolies and Restrictive Trade Practices (MRTP) Act, 1969 was revoked and replaced by the Competition Act, 2002. The MRTP Act was enacted to deal with monopolistic, restrictive and unfair trade practices, but due to certain limitations, the Competition Act was introduced, which changed the focus from curbing monopolies to promoting competition.

Figure: MRTP act vs Competition act

Both the acts apply to the whole of India, except the state of Jammu and Kashmir. While the old Act belongs to the pre-liberalisation period, the new Act, came into force after liberalization. The arrangement and language of the new act are much simpler than the old one.

In other words, the Competition Act is an improvement over the MRTP Act. So, there are vast differences between the two regarding scope, focus, purpose, etc.

BASIS OF COMPARISON	MRTP ACT	COMPETITION ACT
Meaning	MRTP Act, is the first competition law made in India, which covers rules and regulations relating to unfair trade practices.	Competition Act, is implemented to promote and keep up competition in the economy and ensure freedom of business.
Nature	Reformatory	Punitive
Dominance	Determined by firm's size.	Determined by firm's structure.
Focuses on	Consumer interest at large	Public at large
Offenses against principle of natural justice	14 offenses	4 offenses
Penalty	No penalty for offense	Offenses are penalized
Objective	To control monopolies	To promote competition
Agreement	Required to be registered.	It does not specify any provision relating to registration of agreement.
Appointment of Chairman	By the Central Government	By the Committee consisting of retired

Table: Key Differences Between the MRTP Act and the Competition Act

The fundamental points of difference between the MRTP Act and the Competition Act are given as follows:

The MRTP Act is a competition law, that was created in India, in 1970 to prevent concentration of economic power in a few hands. On the other hand, the Competition Act emerged as an improvement over the MRTP act to shift the focus from controlling monopoly to initiating competition in the economy.

The MRTP Act is reformatory in nature, whereas the Competition Act is punitive.

In the Monopolies and Restrictive Trade Practices (MRTP) Act, the dominance of a firm is determined by its size. On the other hand, the dominance of a firm in the market is determined by its structure in the case of the Competition Act.

The MRTP Act focuses on the interests of consumers. Conversely, the Competition Act focuses on the interest of the public at large.

In the MRTP Act, there are 14 offences, which are against the rule of natural justice. On the contrary, there are only four offences listed out by the Competition Act that violate the principle of natural justice.

The MRTP Act does not specify any penalty for offences, but the Competition Act states a penalty for the offence.

The basic motto of the MRTP Act is to control monopolies. As against this, the Competition Act intends to initiate and sustain competition.

The Monopolies and Restrictive Trade Practices (MRTP) Act, requires that the agreement be registered. In contrast, the Competition Act is silent on the registration of agreements.

In the MRTP Act, the appointment of the chairperson was made by the Central Government. On the contrary, in the Competition Act the appointment of the chairperson was done by a Committee that comprises retired.

The healthcare supply chain plays a critical role in ensuring timely access to essential medications, medical equipment, and supplies for patients. Smooth operations within this chain rely on the coordinated efforts of various key personnel across different sectors: hospitals, pharmacies, and dealers.

Class - 12

Hospitals:

Hospital Administrator/CEO:

- Oversees the overall management and operations of the hospital.
- Sets budget and strategic direction to ensure adequate resources are procured and allocated efficiently.
- Plays a crucial role in establishing relationships with suppliers and ensuring compliance with regulations.

Chief Medical Officer (CMO):

- Leads the medical staff and oversees patient care quality.
- Implements quality control measures and ensures medications and equipment meet safety standards.
- Collaborates with department heads to ensure optimal utilization of resources.

Department Heads:

- Manage specific departments like Surgery, Nursing, Pharmacy, and Radiology.
- Oversee inventory levels within their departments and anticipate needs for medications, equipment, and supplies.
- Place timely orders and communicate requirements to procurement teams.

Physicians:

- Diagnose and treat patients, prescribing medications based on their expertise and familiarity with potential drug interactions.
- Play a vital role in determining the type and quantity of medications needed for patient care.

Nurses:

- Provide bedside care to patients, administering medications according to prescribed dosages.
- Monitor patient condition for adverse reactions to medications and report any concerns.

Pharmacist:

- Licensed professional responsible for dispensing medications accurately and safely.
- Verifies prescriptions, counsels' patients on medication use, and monitors for potential drug interactions.
- Manages pharmacy inventory, ensuring adequate stock levels and timely procurement of new supplies.

Pharmacy Technician:

- Assists pharmacists with dispensing medications, maintaining inventory records, and providing patient information.
- Plays a crucial role in ensuring efficient pharmacy operations and timely medication delivery.

Wholesaler:

- Supplies pharmacies with medications and medical supplies in bulk quantities.
- Maintains a diverse inventory and ensures timely deliveries to meet pharmacy needs.

Dealers:

Medical Equipment Dealer:

- Sells medical equipment and supplies to hospitals and clinics.
- Provides technical expertise and ensures proper installation, maintenance, and calibration of equipment.
- Plays a vital role in ensuring the functionality and safety of medical equipment used in patient care.

Pharmaceutical Sales Representative:

- Promotes pharmaceutical products to doctors and pharmacies.
- Provides information about new medications, their benefits, and potential side effects.
- Contributes to the adoption of new medications and advancements in healthcare.

Additional Roles:

- **Researchers:** Develop new medications, medical devices, and technologies that improve patient care and treatment outcomes.
- **Logistics/Supply Chain Specialists:** Optimize transportation routes and schedules to ensure timely delivery of medications and supplies.
- **Regulatory Agencies:** Oversee the safety and efficacy of medications and medical devices, ensuring adherence to quality standards and regulations.

Importance of Collaboration:

- Effective communication and collaboration among these key personnel are critical for smooth operations within the healthcare supply chain.
- Hospitals need to clearly communicate their needs to pharmacies and dealers.
- Pharmacies rely on timely deliveries from wholesalers and accurate prescriptions from physicians.
- Medical equipment dealers require clear specifications from hospitals and proper training for healthcare professionals.

By working together effectively, these individuals ensure the efficient flow of medications and supplies, ultimately contributing to better patient care and improved healthcare outcomes.

Role	Responsibilities
Hospital Administrator/CEO	• Oversees overall hospital operations. • Sets budget and strategic direction. • Ensures compliance with regulations.
Chief Medical Officer (CMO)	• Leads medical staff and oversees patient care quality. • Implements quality control measures. • Makes treatment decisions in collaboration with physicians.
Department Heads	• Manage specific departments (e.g. Surgery, Nursing, Pharmacy). • Oversee inventory levels and resource allocation within their departments. • Place timely orders for medications, equipment and supplies.
Physicians	• Diagnose and treat patients. • Prescribe medications based on expertise and drug interactions.
Nurses	• Provide bedside care to patients. • Administer medications according to prescribed dosages. • Monitor patient condition for adverse reactions.

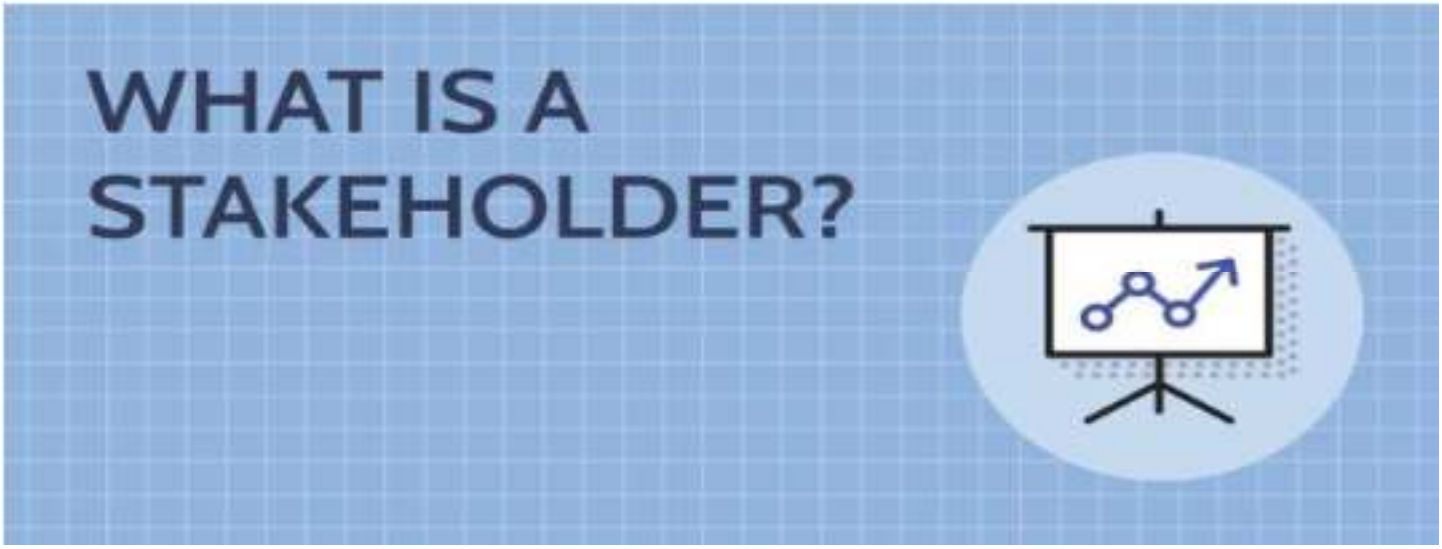


Figure: Stakeholder concept

A stakeholder is a party that has an interest in a company and can either affect or be affected by the business. The primary stakeholders in a typical corporation are its investors, employees, customers, and suppliers.

However, with the increasing attention on corporate social responsibility, the concept has been extended to include communities, governments, and trade associations.

Figure: Definition of a Stakeholder

Understanding Stakeholders:

Stakeholders can be internal or external to an organization. Internal stakeholders are people whose interest in a company comes through a direct relationship, such as employment, ownership, or investment.

External stakeholders are those who do not directly work with a company but are affected somehow by the actions and outcomes of the business. Suppliers, creditors, and public groups are all considered external stakeholders.

Example of an Internal Stakeholder:
Investors are internal stakeholders who are significantly impacted by the associated concern and its performance. If, for example, a venture capital firm decides to invest $5 million in a technology startup in return for 10% equity and significant influence, the firm becomes an internal stakeholder of the startup.
The return on the venture capitalist firm's investment hinges on the startup's success or failure, meaning that the firm has a vested interest.

Example of an External Stakeholder:
External stakeholders, unlike internal stakeholders, do not have a direct relationship with the company. Instead, an external stakeholder is normally a person or organization affected by the operations of the business. When a company goes over the allowable limit of carbon emissions, for example, the town in which the company is located is considered an external stakeholder because it is affected by the increased pollution.
Conversely, external stakeholders may also sometimes have a direct effect on a company without a clear link to it. The government, for example, is an external stakeholder. When the government initiates policy changes on carbon emissions, the decision affects the business operations of any entity with increased levels of carbon.

Issues Concerning Stakeholders:
A common problem that arises for companies with numerous stakeholders is that the various stakeholder interests may not align. In fact, the interests may be in direct conflict. For example, the primary goal of a corporation, from the perspective of its shareholders, is often thought to be to maximize profits and enhance shareholder value.
Since labor costs are unavoidable for most companies, a company may seek to keep these costs under tight control. This is likely to upset another group of stakeholders, its employees. The most efficient companies successfully manage the interests and expectations of all their stakeholders.

Stakeholders vs. Shareholders:
Shareholders are only one type of stakeholder. All stakeholders are bound to a company by some type of vested interest, usually for the long term and for reasons of need. A shareholder has a financial interest, but a shareholder can also sell their stock in the company; they do not necessarily have a long-term need for the company and can usually get out at any time.
For example, if a company is performing poorly financially, the vendors in that company's supply chain might suffer if the company limits production and no longer uses its services. Similarly, employees of the company might lose their jobs. However, shareholders of the company can sell their stock and limit their losses.

What Are the Different Types of Stakeholders?
Examples of important stakeholders for a business include its shareholders, customers, suppliers, and employees. Some of these stakeholders, such as the shareholders and the employees, are internal to the business. Others, such as the business's customers and suppliers, are external to the business but are nevertheless affected by the business's actions. These days, it has become more common to talk about a broader range of external stakeholders, such as the government of the countries in which the business operates, or even the public at large.

What Is an Example of a Stakeholder?
In the event that a business fails and goes bankrupt, there is a pecking order among various stakeholders in who gets repaid on their capital investment. Secured creditors are first in line, followed by unsecured creditors, preferred shareholders, and finally owners of common stock (who may receive pennies on the dollar, if anything at all). This example illustrates that not all stakeholders have the same status or privileges. For instance, workers in the bankrupt company may be laid off without any severance.

What Are the Stakeholders in a Business?

Stakeholders in a business include any entity that is directly or indirectly related to how a company operates, whether it succeeds, or if it fails. First the owners of the business. These can include actively-involved owners as well investors who have passive ownership. If the business has loans or debts outstanding, then creditors (e.g., banks or bondholders) will be the second set of stakeholders in the business. The employees of the company are a third set of stakeholders, along with the suppliers who rely on the business for its own income. Customers, too, are stakeholders who purchase and use the goods or services the business provides.

Why Are Stakeholders Important?

Stakeholders are important for a number of reasons. For internal stakeholders, they are important because the business's operations rely on their ability to work together toward the business's goals. External stakeholders on the other hand can affect the business indirectly.

For instance, customers can change their buying habits, suppliers can change their manufacturing and distribution practices, and governments can modify laws and regulations. Ultimately, managing relationships with internal and external stakeholders is key to a business's long-term success.

Are Stakeholders and Shareholders the Same?

Although shareholders are an important type of stakeholder, they are not the only stakeholders. Examples of other stakeholders include employees, customers, suppliers, governments, and the public at large. In recent years, there has been a trend toward thinking more broadly about who constitutes the stakeholders of a business.

The Bottom Line

Stakeholders are individuals, groups or any party that has an interest in the outcomes of an organization. Stakeholders can be internal or external and range from customers, shareholders to communities and even governments.

Figure: Distribution of Stakeholders by type and background (https://doi.org/10.1186/1472-6882-11-71)

Note:

Complementary and alternative medicine (CAM) is a treatment that falls outside of mainstream healthcare. These treatments range from acupuncture and homeopathy to aromatherapy, meditation and colonic irrigation.

CAM therapies include a wide variety of botanicals and nutritional products, such as herbal and dietary supplements, and vitamins. These products do not have to be approved by the Food and Drug Administration (FDA) before being sold to the public. Also, a prescription isn't needed to buy them.

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Class - 13

Describe the drug distribution system of pharmaceutical, vaccines, ayurvedic and homeopathic products:

Pharmacokinetics is the study of a drug moiety or a compound as it moves through the body after its administration. It involves the processes of drug absorption, bioavailability, clearance, and distribution. [1] Although these processes are theoretically separate, from a practical standpoint, in vivo, they are all interconnected. After the drug is absorbed from the site of administration, it is distributed to extracellular fluids. [2] High reserves of plasma protein-bound drugs can cause prolonged effects by creating a sustained release mechanism. [3] Drug distribution is the disbursement of an unmetabolized drug as it moves through the body's blood and tissues. The efficacy or toxicity of a drug depends on the distribution in specific tissues and in part explains the lack of correlation between plasma levels and the effects that are seen. Based on the molecular structure, drugs have variable distribution in different types of tissues such as fat, muscle, and brain. Unlike other tissues, the brain and testes are unique, as they contain membrane barriers making a drug significantly less susceptible to distribution. [4] Based on lipid and non-lipid solubility, drugs can be classified as lipophilic or hydrophilic described below.

Lipophilic (Fat Soluble):

- Nonpolar compounds
- Easily diffuses across lipid bilayers of cell membranes
- Rx can be administered topically
- Free diffusion across the blood-brain barrier
- Biotransformed in the liver
- Excreted through the bile duct

Hydrophilic (Water Soluble):

- Polar compounds

- Cross lipid bilayers via facilitated transport (passive chemical diffusion across a cell membrane by ion channels or carriers)
- Eliminated by the kidneys

Issues of Concern:
Drug distribution is impacted by several factors related to the drug and the body. The drug-related factors include blood and tissue binding proteins, pH, and perfusion. The body-related factors include body water composition, fat composition, and diseases (e.g., volume depletion, burns, third spacing).

Clinical Significance:
As people age, the overall body water reduces. However, intracellular water remains relatively stable from the first month of life to adulthood. Higher doses of drugs per kilogram of weight are required in younger children as they have a higher percentage of water. [5] Lipophilic drugs are more likely to distribute to areas of high lipid density. [6] Body fat varies with age, gender and genetics. Many drugs are bound to plasma proteins, and the most important drug-binding proteins include albumin and globulins. The concentration of these proteins varies with age, nutritional status, and disease.
Understanding drug distribution and pharmacokinetics (PK) is important for all clinicians prescribing medication, along with understanding the fundamentals of protein binding. [7] Only free and unbound drugs will pass from vascular spaces to tissues, where a drug-receptor interaction will occur as well as the effect of the drug. Protein binding is not only affected by the concentration of protein but also by the pH, metabolic abnormalities (hyperglycemia, uremia), and the presence of other chemicals that will compete for protein binding.
Competition for plasma binding can influence drug effects. For example, Aspirin and Warfarin are known to compete for the same plasma protein binding site. Administering both drugs at the same time will increase the unbound drug, thereby potentiating their effects and potentially lead to bleeding risk. [8] For a drug to be effectively eliminated by the kidney, the drug must be metabolized from a lipophilic molecule into a polar molecule. The liver produces a polar metabolite of the drug, using two unique sets of reactions known as phase I metabolism and phase II metabolism. [9]
Phase I metabolism involves what is known as the cytochrome P-450 system (CYP enzyme). CYP alters a drug in such a way so that it will be more amenable to combining with polar molecules. These reactions involve basic chemistry principles such as oxidation, reduction, or hydrolysis. Phase II metabolism is the process of adding a polar moiety to the drug, such as sulfate, acetate, or glucuronate. The addition of a polar moiety to a drug makes the drug water-soluble and available for excretion by the kidney.

Phases of Biotransformation:
Phase I reaction: The drug is first transformed into a polar metabolite via oxidation by the cytochrome P-450 system → allows phase II to occur.
Phase II reactions: Involves the coupling of the metabolite with glucuronic acid, acetyl groups, sulfates, amino acids, or glutathione.

Types of Drug Kinetics:
Zero-order kinetics: The rate of metabolism/elimination remains constant and is independent of the concentration of a drug.
First-order kinetics: The rate of metabolism/elimination is directly proportional to the plasma concentration of the drug.
Half-life (T1/2): The time required for a drug's plasma concentration to reach half of its initial value.
After 4 half-lives > 90% of the drug is eliminated.
Drug clearance: The measure of the rate of drug elimination → the plasma volume that can be completely cleared of the drug in a given period of time.

Additionally, uraemia not only affects protein binding, but kidneys also play a significant role in drug absorption, distribution, metabolism, and excretion (ADME). Renal dose adjustment is essential in moderate to severe renal failure. Important strategies for managing and drug dosing must be adjusted accordingly, and the risks must be weighed against the benefits. [10] Several factors impact drug distribution. These factors include the concentration of drug transporters in blood, pH, perfusion, body water composition, body fat composition, and most certainly disease conditions (e.g., volume depletion, burns, third spacing). The majority of protein binding is relevant only when the drug is more than 90 percent protein bound. In the hypoalbuminemia state, which occurs in malnutrition and inflammation, there is a higher concentration of the unbound drugs. Body composition and metabolic factors also affect drug distribution. For example, during the last trimester of pregnancy, plasma volume expands, so there is an overall diluting effect on plasma proteins. There is also a change in adipose tissue. Additionally, pregnant women are frequently excluded in clinical trials related to drugs. [11] In a critically ill patient, drug distribution also changes due to deranged physiology, protein binding changes, fluid shifts, pH changes, and vascular organ perfusion. [12] Thus it could be useful to monitor drug levels in these conditions if possible.

The cytochrome P-450 system is a family of heme-containing enzymes found in the liver and intestinal tract. There are multiple forms of CYP enzymes. Some drugs can either induce or inhibit specific isoforms of the enzyme, affecting the ADME of a drug. A clinician must be aware of potential drug-drug interactions with CYP enzyme inducers and inhibitors and naturally occurring compounds that can alter the actions of CYP enzyme. Naturally occurring compounds include grapefruit juice, nicotine-containing products, and St. John's wort. [13], [14]
Below is a list of the major drugs that inhibit and induce the cytochrome P-450 system, as well as dugs that are a major substrate of the enzyme:

CYP1A2
Inhibitors: amiodarone, cimetidine, ciprofloxacin, fluvoxamine
Inducers: carbamazepine, phenobarbital, rifampin, tobacco
Substrates: caffeine, clozapine, theophylline

CYP2C9
Inhibitors: amiodarone, fluconazole, fluoxetine, metronidazole, ritonavir, trimethoprim/sulfamethoxazole
Inducers: carbamazepine, phenobarbital, phenytoin, rifampin
Substrates: carvedilol, celecoxib, glipizide, ibuprofen, irbesartan, losartan

CYP2C19
Inhibitors: fluvoxamine, isoniazid, ritonavir
Inducers: carbamazepine, phenytoin, rifampin
Substrates: omeprazole, phenobarbital, phenytoin

CYP2D6
Inhibitors: amiodarone, cimetidine, diphenhydramine, fluoxetine, paroxetine, quinidine, ritonavir, terbinafine
Inducers: none
Substrates: amitriptyline, carvedilol, codeine, donepezil, haloperidol, metoprolol, paroxetine, risperidone, tramadol

CYP2E1
Inhibitors: none

Inducers: ethanol, isoniazid, tobacco
Substrates: acetaminophen, theophylline, verapamil

CYP3A4 and CYP3A5
Inhibitors: clarithromycin, diltiazem, erythromycin, grapefruit juice, itraconazole, ketoconazole, nefazodone*, ritonavir, telithromycin, verapamil
Inducers: carbamazepine, Hypericum perforatum, phenobarbital, phenytoin, rifampin
Substrates: alprazolam, amlodipine, atorvastatin, cyclosporine, diazepam, estradiol, simvastatin, sildenafil, verapamil, zolpidem
Below is an additional list of common drug-drug interactions involving the cytochrome P-450 system that clinicians should be aware of:
Drug: amiodarone
CYP enzyme: CYP2C9 and CYP3A4 inhibitor
Drug-Drug Interaction: warfarin
Metabolizing Enzyme: CYP2C9
Side Effects: Increased risk of bleeding caused by increased warfarin level.
Drug: carbamazepine, phenobarbital, phenytoin
CYP enzyme: CYP3A4 inducer
Drug-Drug Interaction: Ethinyl estradiol-containing contraceptives
Metabolizing Enzyme: CYP3A4
Side Effects: Unplanned pregnancy caused by reduced estradiol level.
Drug: clarithromycin, erythromycin, telithromycin
CYP enzyme: CYP3A4 inhibitor
Drug-Drug Interaction: simvastatin, verapamil
Metabolizing Enzyme: CYP3A4
Side Effects: Myopathy or rhabdomyolysis caused by increased simvastatin level. Hypotension and QT interval prolongation caused by increased verapamil level.
Drug: diltiazem, verapamil
CYP enzyme: CYP3A4 inhibitor
Drug-Drug Interaction: prednisone
Metabolizing Enzyme: CYP3A4
Side Effects: Immunosuppression caused by increased prednisolone serum levels.
Drug: fluoxetine, paroxetine
CYP enzyme: CYP2D6 inhibitor
Drug-Drug Interaction: risperidone, tramadol
Metabolizing Enzyme: CYP2D6
Side Effects: Increased risk of extrapyramidal adverse effects caused by increased risperidone level.
Drug: Grapefruit juice
CYP enzyme: CYP3A4 inhibitor
Drug-Drug Interaction: buspirone
Metabolizing Enzyme: CYP3A4
Side Effects: Dizziness and serotonin syndrome caused by increased buspirone level.
Drug: metronidazole
CYP enzyme: CYP2C9 inhibitor
Drug-Drug Interaction: warfarin
Metabolizing Enzyme: CYP2C9
Side Effects: Increased risk of bleeding caused by increased warfarin level.

Drug: terbinafine
CYP enzyme: CYP2D6 inhibitor
Drug-Drug Interaction: amitriptyline
Metabolizing Enzyme: CYP2D6
Side Effects: Dry mouth, dizziness, and cardiac toxicity caused by a prolonged increase in amitriptyline and nortriptyline.
CYP = cytochrome P-450

The modern pharmaceutical supply chain is complex. With the advent of globalization and relaxed FDI norms in the emerging economies, Asia is fast becoming a magnet for pharmaceutical manufacturing companies. Medicines nowadays are made from ingredients that are sourced from different countries. The final product is packaged, repackaged and sold multiple times and in many countries. Now, more than ever, essential life-saving drugs change hands multiple times from the time it was manufactured till it reaches the patient. This creates increased possibility for falsified or substandard products to infiltrate the market. Participation of numerous stakeholders such as pharmaceutical manufacturers, wholesalers, distributors, customers, information service providers and regulatory agencies further complicates the process flow.
In most developed countries, all of the pharmaceutical supply chain is managed by the private sector apart from the regulatory role played by the government, but in developing countries, despite their vastly smaller tax base, the government manages this complex distribution chain. African nations have a government-owned-andoperated central medical store which manages the distribution of drugs, transporting goods around the country in a government-owned fleet. Inefficient supply chain management can lead to higher costs and drug stock-outs in an already burdened system. This drug scarcity in turn creates a vacuum for poor-quality products to fill, which leads to a host of life-threatening problems. Traditionally the process is managed manually which is marred by the following challenges:

- Lack of proper tracking & monitoring of drug indents
- Absence of a single platform for supplier and drug distributors
- Vulnerable data due to physical record-keeping
- Time-consuming process riddled with inaccuracies due to manual filling of data
- Lack of a digital payment gateway
- Unavailability of current stock position

The important features of this solution are:

- Profiling all the drug suppliers & equipment manufacturers
- Managing the procurement of drugs & equipment
- Generation of Purchase Order against tender/rate contract
- Automation of Inventory & Distribution Management and Indent Generation
- Rating Supplier and Quality Testing Labs
- Auto-calculation and disbursal of payments to suppliers & labs
- Disbursing stocks on the First Expiry First Out principle
- Generation of various analytical reports useful in strategic decision-making

The drug distribution and supply chain system ensures that all stakeholders are connected via a single entity, an informative and user-friendly interface. Adoption of e-Niramaya, a robust and dependable IT platform by the Odisha Government has reduced PO generation time by a massive 50% without compromising on data accuracy. The cumbersome task of providing 570 types of medicines, 83 surgical items, 107 anti-cancer items, 6 child

health items, 6 nutrition program, 28 malaria control programs, 5 items to fight against leprosy, etc. to the right people at the right time has been made possible through this unique system.

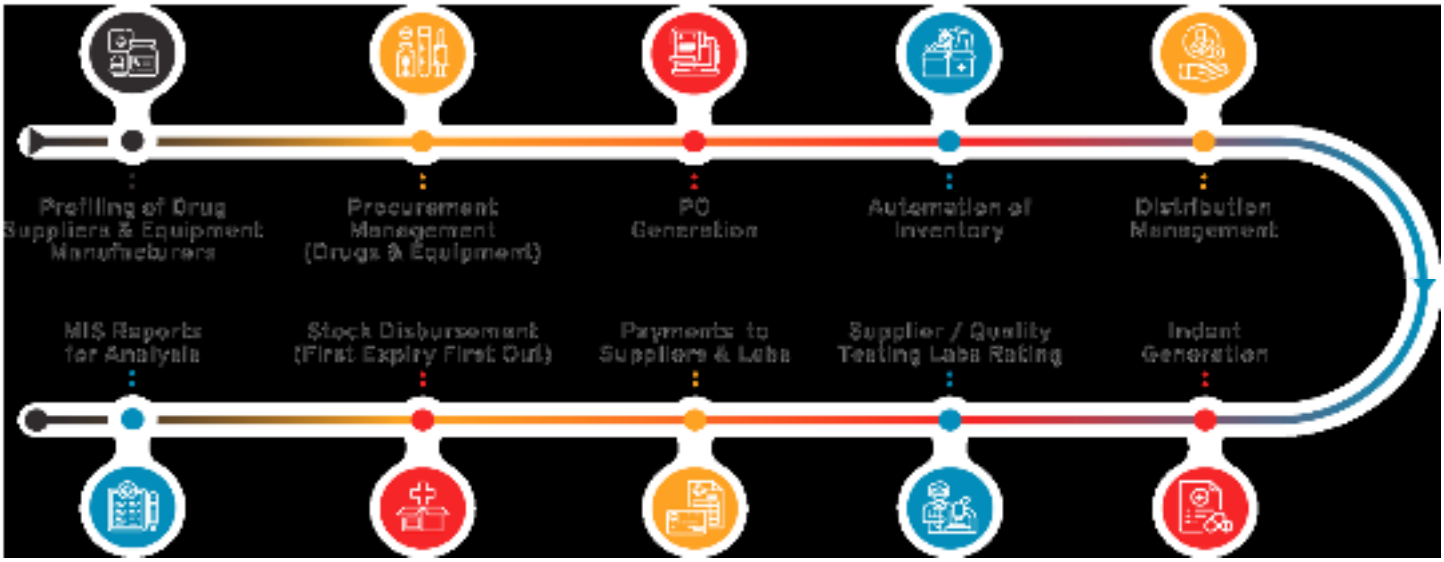

Figure: Steps of Drug distribution system in pharmaceuticals

The Republic of India accounts for around ten percent of the total production of drugs in the world. Also, more than 200 countries are dependent on India for their requirement of vaccines and generic medicines. The unpleasing news is that the World Health Organisation (WHO) has already indicated that thirty-five percent of the total counterfeit medication available around the world originates from India. Such a flow of fake medicines into the healthcare ecosystem puts patients' lives at risk. It also dents the profit-making of pharmaceutical companies, which ultimately pushes them to curtail their budget on medicine research and increase the cost of medicines. The situation in India is notably more difficult, as twenty-five percent of the domestic medicine market consists of counterfeit medicines. The WHO recently published a report mentioning that, in developing countries like India, one out of ten therapeutic items is unacceptable as it is counterfeit. This motivated us to come up with a solution to foolproof the existing drug distribution system so that every opportunity to introduce counterfeit medicines into the current system is thwarted.

Counterfeit medicines can be introduced into the market through various channels, where the local distributors and pharmacists are prominent. A pharmacist can buy counterfeit medicines at cheaper rates from unauthorized dealers and can make a bountiful amount. Similarly, a local distributor or regional distributor channel can be a source of counterfeit medicines, advertently or inadvertently.

Figure: A typical Drug Distribution system

The fake medicine market is flourishing at the cost of the patient's life, and the state machinery is incapable of preventing or thwarting this immoral business of counterfeit medicines. The profit-making is enormous in comparison to investment in the business of fake medicines, which is a potent source of motivation to the phoney medicine mafias, and the lack of reliable and efficient vigilance system further encourages this wrongful business. There are multiple other problems associated with the Indian medicine market apart from the menace of counterfeit medicine. Patients are many times unaware of whether the medicines they are receiving from the retailer are the same as prescribed by their doctor. In a country where only one physician is available for around 10,000 citizens, going back to the doctor and getting the purchased medicines verified is impractical. Another critical problem is the selling of the same medication multiple times to admitted patients at private hospitals.

It has been reported that some hospitals ask attenders of the patients to buy unnecessary medicines, and later, the hospital staff smuggles these unused medicines back to the hospital-controlled pharmacy shops. In this way, hospitals charge heavily to the payers and providers and make medical facilities unaffordable to the people. This becomes possible due to the absence of any reliable measures to record the sale of medicines uniquely.

Another major problem is the sale of narcotic drugs by the retailer to the buyer without any prescription from a physician. Though preventive steps are taken by the government machinery to curb this practice, none of the initiatives have been proven effective yet.

Smuggling of medicines from the government hospitals and selling them at cheaper costs in the medical market is a bigger problem, which prohibits the real beneficiary from receiving free or subsidized medicines. In the end, the availability of counterfeit vaccines that are administered to newborn babies puts the health and life of generation at stake.

Though various hospitals in India have implemented their local EHN to manage and streamline processes, undergoing treatments to patients and their pharmacy shops, the genuineness of the drugs purchased by the patients is still doubtful. Similarly, various pharmaceutical industries have implemented large IT systems for the seamless running of their internal processes. Still, the end customer has no access to such systems through which heor she can check required to record the drug-related information right from its manufacturing through distributors and retailers to the patient. Such a ledger will help to track the authenticity of the medicine and will keep an overall inventory check on the produced medicines until the lifecycle of the medicine ends. One primary concern while implementing such an extensive system arises out of the trust. A centralized server or system cannot be trusted to manage such transactions of medicines. The problem with such a centralized system is that it offers a single point of failure, which is undesirable when implementing such a large-scaleinformation-intensive network. The solution lies in realizing the above requirements on adecentralized system using sufficient cryptographic measures to ensure the security andimmutability of the medicinal data records. Fortunately, blockchain technology exists tooffer a decentralized platform and secure the ledger maintained on various computer nodes.

The underlying methodology is explained by taking an example of a typical Indian pharmaceuticaldistribution system. At the very first step, a drug is manufactured at a genuineproduction hub, which is followed through proper distribution channels to many regionaldistributors spread across the country and abroad. After that, the regional distributors sendthe cartons to the local distributors. Finally, the local distributor handover the batch ofmedicines to the number of pharmacy shops and hospitals which fulfill the demands of thepatients. This drug distribution ecosystem is shown in previous figure. Here at the time of production and packaging of the drug (tablets, syrup bottles, injections, capsules.), the proposed system requires affixing a unique QR code with every saleable unit, sub-packets, and wholesale cartons.

The QR code contains information such as the drug composition, manufacturer name and license, manufacturing date, expiry date, batch number, total quantity produced in this batch, and logistic partner information. QR coding is the essential step of the proposed system, which prevents the introduction of fake medicines into the supply

chain. The handover of medicine at various distribution points is recorded on the blockchain only after the receiver verifies the authenticity of the medicine.

The process followed in the blockchain-based implementation of the proposed system, to deter the production and penetration of counterfeit medicines into the market, is explained as a five-step process:

1. Suppose a registered drug manufacturing unit produces 100 cartons of a particular medicine in a batch. Since each carton is produced in the same batch, it will bear the same batch number. However, a unique carton number will also identify each carton. Similarly, every carton will have uniquely identified sub-packets, and so on. This information is recorded on the ledger maintained over a blockchain network.
2. The same manufacturing unit handovers the produced 100 cartons to its registered logisticpartner. At this point of interaction, the logistic partner will verify the authenticityof the cartons and accept the consignment only after the cartons are declared authentic. This ledger on the blockchain will now be updated with this new handover. In case ifthe logistics include more logistic partners, the same process of ledger update will befollowed for each handover. This step will ensure the consistency of the consignmentflow throughout the supply chain.
3. The regional distributors will receive the drug consignments from the logistic partnersafter the shipment is verified for authenticity. Note that at this stage, the varying quantityof drug consignments will be received by different regional distributors. The ledger willalso update itself with every new handover. This step will ensure that the authentic drugin the right quantity is distributed over the supply chain network.
4. The regional distributors will hand over the desired quantity of drugs to the local distributors, which will distribute the same to the pharmacists and hospitals. Both of thesehandovers also get registered on the blockchain-based ledger.
5. At the lower end of the hierarchy, the customer will ask for the required medicine froma pharma-shop and will check the authenticity using QR code imprinted on the medication. The customer will refuse to buy medicine if the authenticity of the medicine is notverified. Once the patient purchases the medicine, the same transaction will be updatedin the ledger. At this juncture, the sold medicine has completed its supply chain lifecycle.

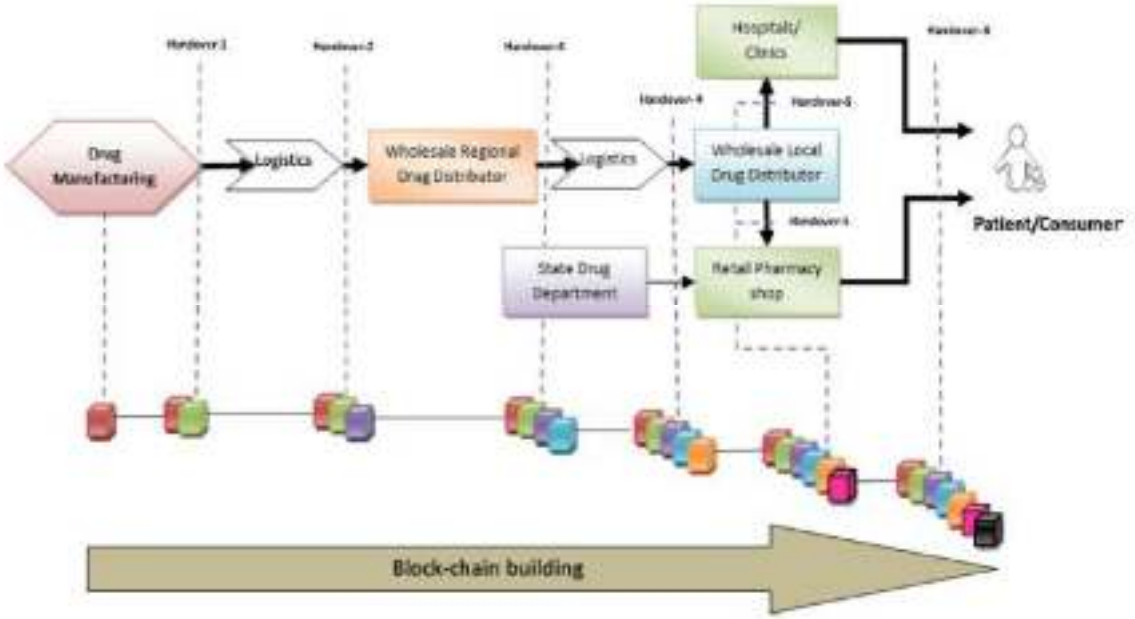

Figure: Proposed system based on Blockchain

A vaccine is a material that induces an immunologically mediated resistance to a disease but not necessarily an infection. Vaccines are generally composed of killed or attenuated organisms or subunits of organisms or DNA encoding antigenic proteins of pathogens. Sub-unit vaccines though exceptionally selective and specific in reacting with antibodies often fail to show such reactions in circumstances such as shifts in epitopic identification center of the antibody and are poorly immunogenic. However, the selectivity and specificity of sub-units of the

causative organism like proteins, carbohydrates can be exploited for producing strong and prolonged immune responses by catering them to the immune system in such a way that a specific and strong immune response is induced. These epitopes may also allow the generation of vaccines not only against infectious diseases, but also against chronic diseases such as hepatitis C or cancer.

In order to induce an effective protective immunity, these vaccines require boosting with agents called "adjuvants." Adjuvants are believed to act by forming complexes with the agent to be delivered from which immunogens are slowly released.
Vaccine delivery systems (e.g., emulsions, microparticles, immune-stimulating complexes ISCOMs, liposomes).
Immunostimulatory adjuvants: Conserved molecular patterns of pathogens stimulate immunity as they are identified by pattern recognition receptors like "Toll" receptors located mainly on B-cells, dendritic cells of mammals (e.g., unmethylated CpG-containing DNA).
Adjuvants potentiate the immunostimulatory property of the antigen while being non-immunogenic, nontoxic, and biodegradable by themselves.
Aluminium salts such as aluminium hydroxide, aluminium phosphate; oil emulsions such as Freund's incomplete adjuvant; particulate matter such as ISCOMs; synthetic polynucleotides are other types of adjuvants.

VACCINE DELIVERY SYSTEM:
Delivery of antigens from oil-based adjuvants such as Freunds [1] adjuvant leads to a reduction in the number of doses of vaccine to be administered, but due to toxicity concerns like inductions of granulomas at the injection site, such adjuvants are not widely used. FDA-approved adjuvants for human use are aluminium hydroxide and aluminium phosphate in the form of alum. Hence, search for safer and potent adjuvants resulted in the formulation of the antigen into delivery systems that administer the antigen in particulate form rather than solution form.

Class – 14

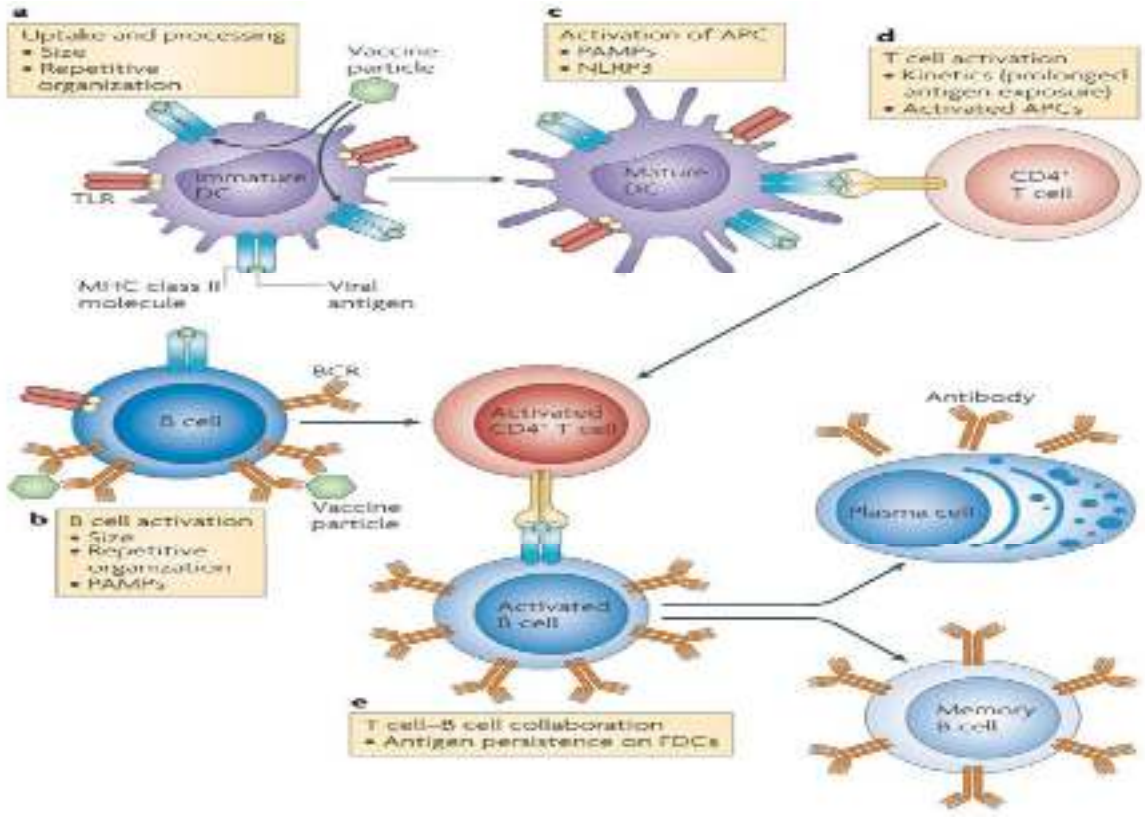

Figure: a | Antigen processing is facilitated if antigens are particulate and have a repetitive surface organization, which increases phagocytosis and the ability to activate complement and recruit other

molecules of the innate humoral immune system. b | B cell activation is also facilitated by antigens that have a repetitive surface organization (through cross-linking of the B cell receptor (BCR) and activation of complement), that are 20–200 nm in size (which allows them direct access to the lymphatic system) and that contain pathogen-associated molecular patterns (PAMPs). c | Activation of antigen-presenting cells (APCs) is facilitated by the recognition of PAMPs by Toll-like receptors (TLRs) or other pattern-recognition receptors (such as NOD-like receptor family pyrin domain-containing protein 3 (NLRP3)), or by other mechanisms. d | T cell activation is facilitated by the prolonged presence of antigen through depot-forming adjuvants or perhaps vaccination regimens. e | T cell–B cell collaboration is essential for the generation of antibody-producing plasma cells and memory B cells but not much is known about the factors that influence this interaction. It is likely that factors that increase the persistence of antigen on follicular dendritic cells (FDCs) would be beneficial. DC, dendritic cell.

Other reasons driving the development of vaccines as controlled drug delivery systems are as follows:

- Immunization failure with a conventional immunization regimen involving prime doses and booster doses, as patients neglect the latter.
- Vaccines delivery systems, on the other hand, allow for the incorporation of doses of antigens so that booster doses are no longer necessary as antigens are released slowly in a controlled manner.
- Control the spatial and temporal presentation of antigens to the immune system, thereby promoting their targeting straight to the immune cells.

Vaccine delivery systems can be classified as follows

Solid particulates: Solid particulate systems such as microspheres and lipospheres are being exploited for vaccine delivery [Table] based on the fact that the intestine is an imperfect barrier to small particulates. Antigens entrapped in such particulates, when taken up by M-cells, can generate immunity.

Delivery of vaccines by polymeric microparticles through different routes

Antigen	Polymer	Particle size (μm)	Route of delivery
B. pertussis fimbriae[8]	PLGA	0.8-5.3	IP, PO
B. pertussis hemagluttin	PLGA	1	IN
Diphtheria toxoid[15]	PLGA	30-100	IM
Influenza virus, formalinized	PLGA	2.2-10.8	SC AND PO
Tetanus toxoid[15]	PLA and PLGA	10-60	SC
Vibriocholera cell-free lysate	PLGA	1-10	PO AND IT

PLGA = Poly (lactic-co-glycolic acid); PLA = Poly (lactic acid); PS = Poly (styrene); PMMA = Poly (methyl methacrylate); IP = Intraperitoneal; IN = Intranasal; IM = Intramuscular; SC = Subcutaneous; PO = Peroral; IT = Intrathecal

Table: Delivery of vaccines of polymeric microparticles through different routes

Methods such as light microscopy, confocal microscopy, electron microscopy, extraction of polymer from tissue, followed by quantification by gel permeation chromatography, flow cytometry indicated that microparticulates of <10 μm in diameter can enter gut-associated lymphoid tissue (GALT) within 1 h of oral administration and can be used as antigen carriers for controlled-release vaccine applications.

Particle size: It is an important consideration while formulating microparticulate systems, as it influences their uptake and release and hence immune responses. Small (<10 μm) microspheres due to their large surface to mass ratio, are capable of facilitating extracellular delivery of antigen to the phagocytic accessory cells leading to faster release and increased antigen processing. Larger particles could not be phagocytosed by macrophages until they had disintegrated into smaller debris. A combination of larger and smaller particles might produce a pulsatile pattern for antigen release thus mimicking an immunization process involving prime and booster shots.

Liposomal Delivery Systems: Liposomes and their derivatives "lipoplexes" (liposome/DNA complexes), are hollow spherical constructs of phospholipid bilayers capable of entrapping hydrophilic moieties in the aqueous compartment and hydrophobic moieties in the lipid bilayers with cholesterol imparting rigidity to the bilayer. However, lipoplexes tend to aggregate during storage, due to neutralization of the positive charge on liposomes by the negative charge on DNA. This drawback is overcome by formulating liposomes/protamine/DNA (LPD). Protamine is an arginine-rich peptide. It condenses with DNA before DNA can complex with positive lipids thereby conferring stability to the preparation.

Viruses, proteins, glycoproteins, nucleic acids, carbohydrates, and lipids can be entrapped and targeted at the cellular and subcellular level for evoking immune responses.

Antigen	Result
BSA as a model antigen[14]	Increased IgG and sIgA after nasal administration of liposomes in mice
Diphtheria, tetanus, HAV, HBV and influenza[15]	Shows good immunogenicity and tolerance in humans
Hepatitis-A virus, formalin inactivated	Protective antibody levels in clinical trials, currently marketed in Europe
HIV-1, subunit from gp-120[16]	Induces humoral and cellular immunity after both oral and IM administration
P. falciparum circumsporozoite protein[17]	Cytotoxic T-cell lymphocytes and an antibody response inhibited sporozoite invasion of hepatoma cells *in vitro*
Vibrio cholera cell-free lysate	Liposome vaccines were effective orally and parenterally

Table: Current researches in liposomal delivery system

Immunostimulatory Complexes: ISCOMs are spontaneously formed spherical open cage-like complexes when saponin, cholesterol, phospholipid, and immunogen, usually protein are mixed together and have typically a diameter of 30-80 nm. ISCOMs combine certain aspects of virus particles such as their size and orientation of surface proteins, with the powerful immunostimulatory activity of saponins. Unlike other vaccine adjuvants, ISCOMs have shown to promote a broad immune response by simultaneously promoting high levels of antibody and strong T cell responses, including enhanced cytokine secretion and activation of cytotoxic T lymphocyte responses in a variety of experimental animal models and has now progressed to phase I and II human trials.

Brunham and Murdin describe a two-step immunization procedure against chlamydia infection by initial administration of Chlamydia protein followed by administration of a chlamydia protein in ISCOMs. Such Immunogenic compositions have utility as chlamydial vaccines and in diagnostic applications. Other ISCOM based vaccines are invented for infections by Moraxella, Helicobacter infections, Campylobacter infections.

ISCOM-based veterinary vaccine against equine influenza is commercially available.

Polymeric Nanoparticles: Polymeric nanoparticles because of their size are preferentially taken up by the mucosa-associated lymphoid tissue. They are extensively reviewed for nasal and oral delivery of vaccines. Limited doses of antigen are sufficient to induce effective immunization. Hence, the use of nanoparticles for oral delivery of antigens is suitable because of their ability to release proteins and to protect them from enzymatic degradation in the GIT.

Biodegradable PACA [23] nanoparticles have been shown to enhance the secretory immune response after their oral administration in association with ovalbumin in rats. PMMA nanoparticles [23] being very slowly degradable (30%-40% per year) appear to be particularly suitable for vaccine purposes because prolonged contact between antigen and immunocompetent cells favors persistent immunity. Nanoparticles labelled with MAb specific to M-cells increase the level of absorption of nanoparticulate vaccines and hence immune response.

Metal chelating polymers such as polyaminocarboxylic acids such as EDTA (ethylenediamine tetra-acetic acid), DTPA (diethylenetriamine-pentaacetic acid) form non-covalent complexes with antigenic epitopes and are useful in their controlled delivery in vivo.[24] The existence of at least one Histidine residue at the amino- or carboxyl-

terminus of a biologic molecule (e.g., protein, peptidic antigen, or fusion construct with His tag) is an important factor contributing to the binding of the biologic to the polymer as it results in improved specificity of binding of the biologic molecule to the metal ion in the metal affinity complex.

An effective prophylactic mucosal gene expression vaccine (GXV) [25] is made up of at least four different plasmid DNAs encoding corresponding RSV antigens, coacervated with chitosan to formulate nanospheres. When given by the intranasal route in a murine model of RSV infection, nanospheres resulted in significant induction of RSV-specific antibodies, nasal IgA antibodies, cytotoxic T lymphocytes, and IFN-gamma production in the lung and splenocytes resulting in the reduction of viral titres. Other nanocarrier types that have been used as multivalent vaccine constructs include metallic oxide particles, polysaccharide-based spermine, alginate capsules (which are natural polymers) and synthetic biocompatible and biodegradable poly (d, l-lactide-co-glycolide) copolymer.

Inorganic Nanoparticle: Inorganic nanoparticles have largely been used as imaging contrast agents or photothermal therapy in cancer. Recent interest has been directed toward the development of inorganic nanoparticles as vaccines in preclinical settings. Most inorganic materials have a smaller particle size, improved stability, controlled tunability, enhanced permeability, high drug loadings, and a triggered release profile, which is ideal for antigen delivery as a vaccine. These newer generations are typically constructed with an inorganic core and an organic outer shell to afford hybrid inorganic nanomaterials. In this section, we briefly review the recent development of these inorganic nanoparticles in vaccines as both carriers and adjuvants.

Nanoparticles	Antigens	Diseases	Size (nm)	Shape
Gold	West Nile virus envelope protein	West Nile virus	20–40 (spherical) 40 × 10 (rod) 40 × 40 × 40 (cubic)	Spherical, rod, and cubic
	Foot-and-mouth disease virus peptide	Foot-and-mouth	8–50	Spherical
	CpG oligodeoxynucleotide	H1N1 IAV	12	Spherical
	Streptococcus pneumoniae type 14 capsular polysaccharide	Streptococcus pneumonia	N/A	N/A
	B. thailandensis E264 lipopolysaccharide with Hc fragment of tetanus toxin	Burkholderia mallei	30	Spherical
Iron Oxide	M. tb fusion protein	M. tb	<20	Spherical
	Merozoite surface protein 1 (rMSP1)	Malaria		
	Mannose and HBxAg	HBV	60	Spherical
Mesoporous silica	Soluble Worm Antigenic Preparation Antigen	*Schistosoma mansoni*	39	Spherical
	Porcine circovirus type 2 opening reading frames (PCV2-ORF2) proteins	Post-weaning multi-systemic wasting syndrome	200	Spherical

Table: Inorganic nanoparticles tabular representation

Emulsion delivery system: Emulsions are heterogeneous liquid systems that may be water-in-oil emulsions, oil-in-water emulsions, or more complex systems such as water-in-oil-in-water multiple emulsions, microemulsions, or nanoemulsions. Antigens are dissolved in a water phase and emulsified in the oil in the presence of an appropriate emulsifier. The controlled release characteristics of an emulsion are determined by factors such as viscosity of oil phase, oil-to-water phase ratio and emulsion droplet size. For example, high oil content can cause unnecessary injection site irritation and too large a droplet size can result in a physically unstable product thereby reducing its shelf life. Squalene O/W emulsion containing influenza vaccine was approved in Italy in 1997 and in several additional countries in 2000.

Huang et al., [22] developed a novel emulsion-type vaccine delivery system of the amphiphilic bioresorbable polymer poly (ethylene glycol)-block-poly(lactide-co-epsilon-caprolactone) (PEG-b-PLACL) using ovalbumin as a model antigen. Results from physicochemical characterization studies and in vitro release studies showed that PEG-b-PLACL-emulsified formulations are composed of homogenous fine particles and are stable, reproducible and hence are advantageous over vaccines prepared with conventional adjuvants. In vivo studies in mice have shown that antigen-specific antibody titers and T-cell proliferative responses, as well as the secretion of IFN-gamma, were significantly enhanced for ovalbumen-PEG-b-PLACL-based emulsions.

Exosome based Delivery systems: Exosomes are cell-derived components composed of proteins, lipid, genetic information, cytokines, and growth factors. They play a vital role in immune modulation, cell-cell communication, and response to inflammation. Immune modulation has downstream effects on the regeneration of damaged tissue, promoting survival and repair of damaged resident cells, and promoting the tumor microenvironment via growth factors, antigens, and signaling molecules. On top of carrying biological messengers like mRNAs, miRNAs, fragmented DNA, disease antigens, and proteins, exosomes modulate internal cell environments that promote downstream cell signaling pathways to facilitate different disease progression and induce anti-tumoral effects. In this review, we have summarized how vaccines modulate our immune response in the context of cancer and infectious diseases and the potential of exosomes as vaccine delivery vehicles. Both pre-clinical and clinical studies show that exosomes play a decisive role in processes like angiogenesis, prognosis, tumor growth metastasis, stromal cell activation, intercellular communication, maintaining cellular and systemic homeostasis, and antigen-specific T- and B cell responses. This summarizes the advancement of exosome-based vaccine development and delivery, and this comprehensive review can be used as a valuable reference for the broader delivery science community.

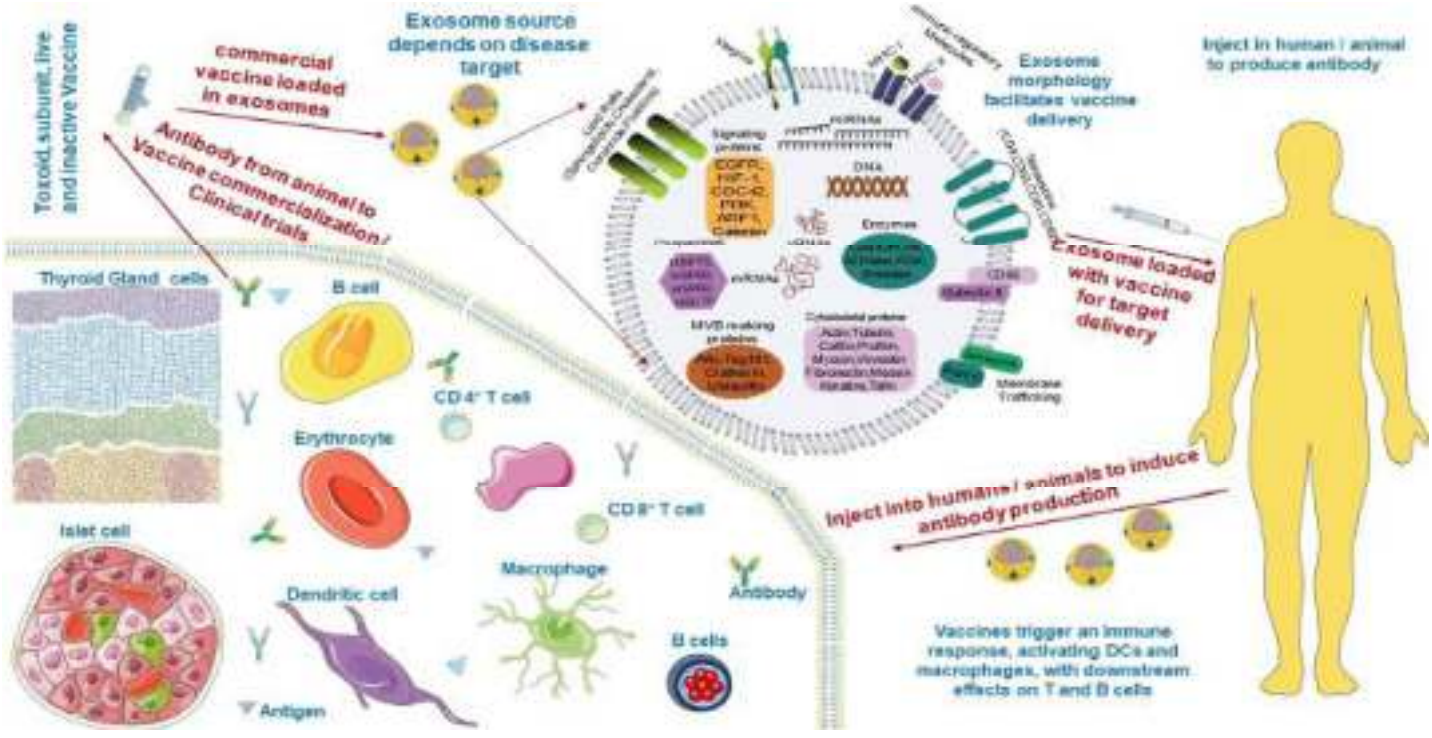

Figure: Sources of exosome-based delivery

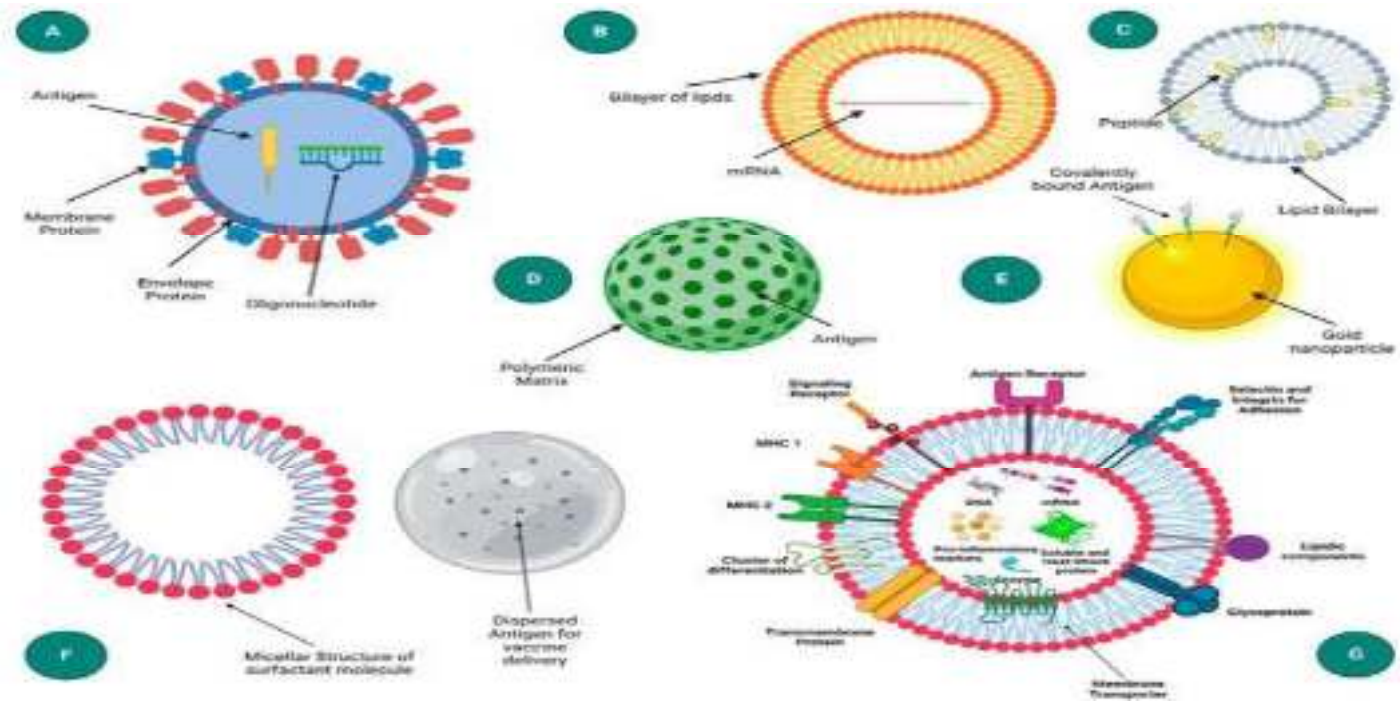

Figure: Schematic representation of different nanoparticle-based delivery system: (A) virus-like particle, (B) liposome, (C) ISCOM (Immune-stimulating complexes), (D) polymeric nanoparticle, (E) inorganic nanoparticle, (F) emulsion, and (G) exosome.

The key properties of viruses that are responsible for eliciting potent immune responses may be used as a framework for rational vaccine design. These important immunogenic properties of viruses include their size, geometry, an ability to induce innate immunity with appropriate conditioning of the adaptive immune responses and an ability to replicate, leading to characteristic antigen kinetics and distribution. New-generation vaccines aim to harness these properties.

To induce potent immune responses, vaccines of viral size are preferable, as only particles in the nanometre range can reach lymph nodes and directly interact with B cells. The antigenic epitopes should be displayed on the nanoparticles in an ordered and highly repetitive way to optimally activate B cells and fix components of the innate humoral immune system (natural antibodies, complement and pentraxins). To further enhance antibody responses and induce more protective IgG2a (mouse) and IgG1 (human) antibodies, vaccines should be co-delivered with particular TLR ligands. To ensure maximal B cell stimulation together with minimal nonspecific side effects, TLR ligands should be linked to or packaged into the vaccine particles.

Nanoparticle-sized vaccines are also preferable for the induction of T cell responses, as size limits the ability of particles to reach the appropriate DC subsets in lymphoid organs. Linkage of the particles to TLR ligands will facilitate licensing or activation of DCs, which is essential for the induction of T cell responses. Nevertheless, the induction of strong T cell responses in humans even with nanoparticle-based vaccines has remained difficult and it remains to be established whether a combination of different innate stimulators or creation of long-lived antigen exposure with new depot-forming formulations or vaccine regimens may be more successful.

In summary, vaccine carrier systems that mimic the size, geometry, replication kinetics and PAMPs of viruses may be one possible way to optimally harness viral properties without the risks associated with infection.

Class – 15

Ayurvedic Products:

For the grant of licence to manufacture Ayurvedic drugs for sale or distribution, an application in form 24-D is made to the Licensing Authority appointed by the state government in this behalf. A licence is issued for manufacture in 25-D subject to the fulfilment licensing conditions such as compliance to GMP (Schedule T), competent technical persons, documented records and requirements with respect to products. The requirement

for safety and effectiveness evidence for issuance of product licence depends upon product type i.e. classical or propriety, ingredient such as presence or absence of Schedule E (1) ingredient, indication i.e. new or as per text, solvent for extraction i.e. aqueous or hydro-alcoholic etc.

Ayurveda is the sacred system of health care originated in India. It is gaining widespread acceptability due to more affordable, more closely corresponds to the patient's ideology, and less paternalistic than allopathic medicine. Earlier the practicing physicians used to prepare drug products by themselves for their patients. Today drug products are usually prepared and packed by manufacturer and made available to pharmacy or physician or health care systems for sale or distribution. Drug and Cosmetic Act 1940 (DCA) and Rules 1945 (DCR) have regulations for the manufacture of Ayurvedic drugs for sale or distribution. In addition to DCA, it is mandatory to comply all relevant laws such as Factory Act, Pollution Acts, GST registration etc. while manufacturing Ayurvedic drug for sale or distribution.

Factory means any premises engaged in "manufacturing process" employing 10 or more workers with the aid of power or, 20 or more workers without the aid of power. A person who runs a "factory" either in owned or rented premises shall be the "Occupier" and requires to obtain "factory" licence. State government may make rules regarding approval, licencing and registration of factories. The occupier of the factory is required to submit the application for the registration and grant of licence to state Chief Inspector (or Concern Inspector) along with required fee and documents such as ID proof of Occupier and Manager, list of Partners/Directors with their residential address, NOC from other partners or Board Resolution by Directors for nomination of occupier as per sections 2(n) and 7 of the Factories Act, 1948, proof/supporting documents of Occupier as Director/ Partner/ Proprietor of the factory, existing building plan, latest electricity bill as a proof of sanctioned load of electricity, proof of occupancy, flow chart of manufacturing process, list of raw materials used in manufacturing process, list of machineries installed in the premises etc. The application is scrutinized, followed by communication to applicant and inspection of premises. If factory conforms to the statutory requirements, the factory licence is granted for a period of one or five or ten years as per the application from the date of grant of licence. A licence granted under the provisions of Factories Act and Rules is required to be renewed for continuation of manufacturing activities. Licencing, registration process and requirement vary for state to state and place to place 1, 8, 9.

A 100 per cent pollution-free environment is a myth with operating factories and industries. Adequate and effective pollution control measures are required so that adverse effects on the environment are minimised. The three main laws relating to pollution are- The Water (Prevention and Control of Pollution) Act- 1974, The Air (Prevention and Control of Pollution) Act- 1981 and The Environment (Protection) Act-1986. There are numerous rules under these acts relating to different matters prohibiting industries from spread of pollution. As per the Water (Prevention and Control of Pollution) Act- 1974 and the Air (Prevention and Control of Pollution) Act- 1981, it is mandatory to obtain Consent to Establish (CTE) from respective state pollution control board, prior to commencement of construction or any similar activities to start the business. The process for obtaining CTE involves making an application in a prescribed format to respective pollution control board along with required documents and fee. It is followed by physical inspection and assessment of the environment management system proposed so as to meet the requirement prescribed. Once the industry or process plant is established along the required pollution control systems, the entrepreneur is required to obtain consent to operate (CTO) the unit. This consent is given for a particular period, which needs to be renewed regularly. In the present study an attempt has been made to understand the requirement for manufacture ofAyurvedic drugs at factory premises with reference to DCA 10, 11, 12, 13.

Application for licensing Ayurveda Drugs:

Manufacture of Ayurvedic drugs for sale or for distribution are permitted under the licence issued in Form 25-D by Licencing Authority (LA) appointed by state government in this behalf. The application for the grant or renewal of a licence is made in Form 24-D along with fee and documents such as declaration, site plan, key plan, ownership deed of the land, non-conviction affidavit, organization chart, authorized signatory, list of machineries, list of books, SOPs, proof of the premises, MOA, documents regarding medicines etc. which vary state to state

or area to area to the LA appointed by state government. The LA consult the experts appointed in this behalf and grant licence only when the conditions of licencing are fulfilled for a period of five years from the date of issuance of the license. Fig. 1 shows the steps for licensing of Ayurvedic firms. For renewal of a licence, application is made to LA in Form 24-D and the certificate of renewable is issued from LA in Form 26-D. The conditions which are to be fulfilled for licencing include- GMP, competent technical staff and maintain of records. LA verify the requirements as per schedule T and issue the Good Manufacturing Practices (GMP) certificate in form 26 E-I, simultaneously along with grant or renewal of licence in form 25-D. There is also the provision for loan licence. A loan licence means a licence which a LA may issue to an applicant who does not have his own arrangements for manufacture but intends to avail himself of the manufacturing facilities owned by a licence in Form 25-D. Table 1 enlist Forms No. related with Ayurveda manufacturing units under DCR. These forms are applicable for Siddha and Unani for same purpose 3, 14, 15.

Sl. No.	Form No.	Application / Certificate
1.	FORM 24D	Application for the grant / renewal of a licence to manufacture for sale of Ayurvedic/ Siddha or Unani drugs.
2.	FORM 25D	Licence to manufacture for sale of Ayurvedic (including Siddha) or Unani drugs
3.	FORM 26D	Certificate of renewal of licence to manufacture for sale of Ayurvedic / Siddha or Unani drugs
4.	FORM 24E	Application for grant or renewal of a loan licence to manufacture for sale Ayurvedic (including Siddha) or Unani Drugs
5.	FORM 25E	Loan Licence to manufacture for sale Ayurvedic (including Siddha) or Unani Drugs
6.	FORM 26E	Certificate of renewal of loan licence to manufacture for sale of Ayurvedic / Siddha or Unani Drugs
7.	FORM 26E-I	Certificate of Good Manufacturing Practices (GMP) to manufacture of Ayurveda, Siddha or Unani drugs
8.	FORM 26E2-I	Free Sale Certificate
9.	FORM 26E2-II	Free Sale Certificate (Under Loan License)
10.	FORM 26 E3	Non-Conviction Certificate
11.	FORM 35	Form in which the Inspection Book shall be maintained
12.	Schedule TA	Form for record of utilization of raw material by Ayurveda or Siddha or Unani licensed manufacturing units during the financial year

Table: Forms under Drug and Cosmetic Rules related to manufacturing of Ayurvedic Drugs

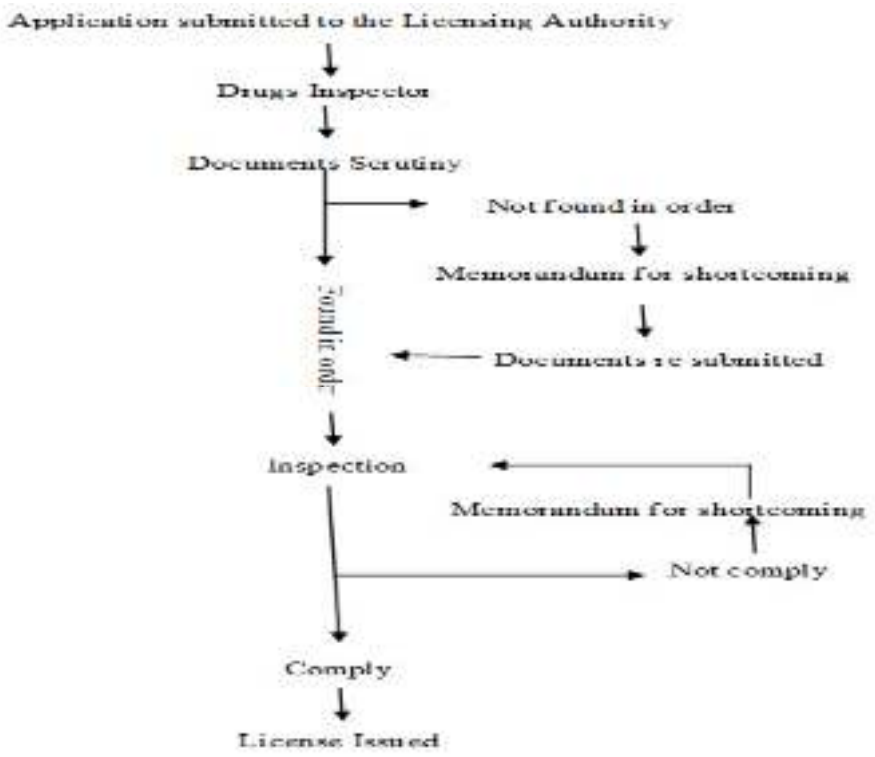

Figure: Steps of licensing for Ayurveda products

Good Manufacturing Practice:

GMP is the system for ensuring manufactured products are free from unexpected contamination, complies quality standards, safe for use and have expected therapeutic efficacy. GMP covers all aspects of production; from the starting materials, premises and equipment to the training and personal hygiene of staff. There must be system to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process- each time a product is made. DCR require the compliance to GMP for grant or renewal of license to manufacture any Ayurveda drug. Schedule "T" of DCR prescribes the GMP guidelines. Part-I of the schedule prescribes general requirement of GMP whereas part-II enlist recommended machinery and space for manufacturing and quality control (Table 2). There is supplementary guidelines in part-II for manufacturing of mineral/metal based formulations in Schedule "T".

PART-I	PART-II
General Requirements: A. Location and surroundings B. Buildings C. Water Supply D. Disposable of Waste E. Container's Cleaning F. Stores G. Working space. H. Health Clothing, Sanitation & Hygiene of Workers I. Medical Services J. Machinery and Equipments K. Batch Manufacturing Records L. Distribution Records M. Record of Market Complaints N. Quality Control. **Requirement for Sterile Product:** A. Manufacturing Areas: B. Precautions against contamination and mix	A. List of recommended machinery, equipment and minimum manufacturing premises required for the manufacture of various categories of Ayurvedic, Siddha system of medicines B. List of machinery, equipment and minimum manufacturing premises required for the manufacture of various categories of Unani system of medicines C. List of equipment recommended for in-house quality control section D. Supplementary guidelines for manufacturing of Rasaushadhies or Rasamarunthukal and Kushtajat (herbo-mineral-metallic compounds) of Ayurveda, Siddha and Unani medicines

Table: Schedule T

All workers employed in the factory shall be free from contagious diseases and there should be adequate facilities for first aid and medical examination of workers at the time of employment and periodical check-up once a year. Adequate facilities for personal cleanliness such as clean towels, soap and scrubbing brushes shall be provided. The uniform shall include cloth or synthetic covering for hands, feet and head wherever required. Workers will also be provided facilities for changing their clothes and to keep their personal belongings. Batch manufacturing record (BMR) of medicines shall provide an account of the list of RM and their quantities obtained from the store, tests conducted during the various stages of manufacture, in process record of various shodhana, bhavana, burning in fire, specific grindings, record of date, manpower, machine and equipment used, details of transfer of manufactured drug to the finished products store including dates, quantity, packaging, testing report of the FG and any other records as required. These records shall be duly signed by production and quality control personnel respectively. The FG transferred from the production area shall be stored in the FG stores within an area marked "Quarantine". After the quality control have approved the correctness of FG in all aspect then it will be moved to "Approved Finished Goods Stock" area and goods shall be dispatched as per marketing requirements from this area only with records of sale and distribution of each batch. The record shall be maintained up to the date of expiry of the batch. A register shall be maintained to record all reports of market complaints and shall enter all data received on such market complaints; investigations carried out by the manufacturers regarding the complaint as well as any corrective action initiated to prevent recurrence of such market complaints shall also be recorded.

Sl No	Category of Medicine	Space required	Machinery/ Equipment Recommended
1	Anjana/Pisti	100 sq. feet	Mechanised / Motorized Karel, End Runner / Ball–mill, Sieves/ Shifter.
2	Churna / Nasya / Manjan / Lepa / Kwath Churn	200 sq. feet	Grinder / Disintegrator / Pulveriser, Powder mixer, Sieves / Shifter.
3	Pills / Vati / Gutika / Matirai and Tablets	100 sq. feet	Ball Mill, Mass mixer / Powder Mixer, Granulator, Drier, Tablet Compressing Machine, Pill / Vati Cutting Machine, Stainless Steel Trays / Container for storage., Sugar coating pan & Polishing pan in case of sugar-coated tablets, Mechanised chattoo for mixing guggulu where required.
4	Kupi Pakava/Ksara/ Parpati/ Lavana Bhasma Satva / Sindura Karpu/Uppu / Param	150 sq. feet	Bhatti, Karahi/Stainless steel Vessels/Patila, Flask, Multani Matti / Plaster of Paris, Copper Rod, Earthen container, Gaj Put Bhatti, Mufflefurnace (Electrically operated), End/Edge Runner, Exhaust Fan, Wooden / S.S. Spatula.
5	Kajal	100 sq. feet	Earthen lamps for collection of Kajal, Triple Roller Mill, End Runner, Sieves, S.S. Patila, Filling/ packing and manufacturing room should be provided with exhaust fan and ultra violet lamps
6	Capsules	100 sq. feet	Air Conditioner, De-humidifier, Hygrometer, Thermometer, Capsule filling machine, Chemical balance.
7	Ointment/Marham Pasai	100 sq. feet	Tube filling machine, Crimping Machine, Ointment Mixer, End Runner/ Mill (Where required), S.S. Storage Container S.S. Patila.
8	Pak/Avaleh/Khand/ Modak/Lakayam	100 sq. feet	Exhaust fan fitted and fly proof Bhatti section, Iron Kadahi /S.S. Patila, S.S. Storage container
9	Panak, Syrup / Pravahi KwathManapaku	150 sq. feet	Tincture press, Exhaust fan fitted and fly proof Bhatti section, Bottle washing machine, Filter press / Gravity filter, Liquid filling machine, P.P. Capping Machine.

10	Asava / Arishta	200 sq. feet	Same as mentioned above., Fermentation tanks, Distillation plant and containers where necessary, Filter Press
11	Sura	100 sq. feet	Same as mentioned above, Distillation plant, Transfer pump.
12	Ark / Tinir	100 sq. feet	Maceration tank, Distillation plant, Liquid filling tank with tap, Gravity filter/Filter press, Visual inspection box.
13	Tail/Ghrit/Ney	100 sq. feet	Bhatti, Kadahi / S.S. Patila, S.S. Storage containers, Filtration equipment, filling tank with tap, Liquid filling machine.

Table: List of Recommended Machinery, Equipment And Minimum Manufacturing Premises Required For The Manufacture Of Various Categories Of Ayurvedic Medicines

Every licensee is required to provide a facility for a quality control (QC) section in his own premises or through a government-approved testing laboratory. The test shall be as per the Ayurvedic pharmacopoeia standard and where the tests are not available, the test should be performed according to the in-house specification or other information available. Preferably for the quality control section, there will be a separate expert. The QC section requires 150 sq. feet area, reference books and reference samples for identification of raw drugs, controlled samples of finished products of each batch will be kept till the expiry date of the product. Manufacturing records should be maintained for the various processes.

CHEMISTRY SECTION

1. Alcohol Determination Apparatus (complete set)
2. Volatile Oil Determination Apparatus.
3. Boiling Point Determination Apparatus.
4. Melting Point Determination Apparatus.
5. Refractometer.
6. Polarimeter.
7. Viscometer.
8. Tablet Disintegration Apparatus.
9. Moisture Meter.
10. Muffle Furnace.
11. Electronic Balance.
12. Magnetic Stirrer.
13. Hot Air Oven.
14. Refrigerator.
15. Glass/Steel Distillation Apparatus.
16. LPG Gas Cylinders with Burners.
17. Water Bath (Temperature controlled.)
18. Heating Mantles/ Hot Plates.
19. TLC Apparatus with all accessories (Manual)
20. Paper Chromatography apparatus with accessories.
21. Sieve size 10 to 120 with Sieve shaker.
22. Centrifuge Machine.
23. Dehumidifier.
24. pH Meter.
25. Limit Test Apparatus.

PHARMACOGNOSY SECTION

1. Microscope Binoculor.
2. Dissecting Microscope.
3. Microtome.
4. Physical Balance.
5. Aluminium Slide Trays.
6. Stage Micrometer.
7. Camera Lucida (Prism and Mirror Type).
8. Chemicals, Glassware etc.

Table: List of equipment recommended for In-house Quality Control Section

Competent Technical Staff:

The manufacture of Ayurvedic drugs shall be conducted under the direction and supervision of competent technical staff consisting at least of one person, who is a whole-time employee and who possesses the qualifications as shown in Table below. Documents required for approval of competent staff include- degree, registration, biodata, experience, affidavit, photographs, appointment letter and consent letter etc. which vary state to state or area to area.

Sl. No.	Qualification	From where	*Experience
1	Degree in Ayurveda medicine or Ayurvedic pharmacy	Conferred by a university, a state government or statutory faculties, councils and boards of Indian systems of medicines recognized by the central government or a state government.	-----
2	Diploma in Ayurveda medicine	Granted by a state government.	-----
3	Graduate in pharmacy or pharmaceutical chemistry or chemistry or botany.	University recognized by the central government.	At least 2 years'
4	Vaid	Registered in a state register of practitioners of indigenous systems of medicines.	At least 4 years'
5	Qualification as pharmacist in Ayurvedic system of medicine.	As may be recognized by the central government	Not less than 8 years'

*Experience in the manufacture of Ayurvedic drugs.

Table: Required qualifications for competent technical staff

Guidelines for Product Permission:

As defined in clause (a) of section 3 of DCA, "Ayurvedic drug includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in, the authoritative books". More than 54 books are listed as authoritative books for Ayurveda in the first schedule of DCA. Ayurvedic drug defined above are of textual reference and in day-to-day language they are called classical medicine. Use of any prefix or suffix with the name of any classical formulation is not permitted except as described in the authoritative books. A formulation without any specific name, described in the authoritative books may be named on the basis of the ingredients of the formulation. Sub-clause (i) of clause (h) of section 3 of DCA defines patent and proprietary drug in relation to Ayurveda as "all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books". The name of any Ayurvedic falling under classical medicine shall not be used for naming any patent or proprietary medicine relating to Ayurvedic except for single plant-ingredient based Ayurvedic formulation licensed or to be licensed as patent or proprietary medicine. In DCR, patent or proprietary medicines have been categories under four broader categories. The newly added categories are- Balya/Poshak, Saundarya Prasadak and Aushadh Ghana. Formulations having ingredients mentioned in books of first schedule of the DCA and recommended for promotional and preventive health called Balya/Poshak/ Positive health Promoter whereas formulation having ingredients mentioned in books of First Schedule of DCA and recommended for oral, skin, hair and body care are Saundarya Prasadak.

Aushadh Ghana (Medicinal plant extracts - dry/wet) are extract obtained from plant mentioned in books of first schedule including aqueous or hydro-alcohol. In addition to efficacy, safety is the prime requirement for medicinal product. Schedule E(1) separately lists poisonous substances under Ayurvedic, Siddha and Unani system of medicine. If ingredient of Schedule E(1) is present in medicinal product for internal use of human then their container must be labelled conspicuously with the word 'Caution: To be taken under medical supervision' both in English and Hindi language. Evidence-based studies are becoming essential for establishing the safety and efficacy of drug products. DCA has given to attention toward safety and efficacy of drug products while issuing product permission. For issue of licence to the medicine with respect to Ayurvedic drug, the conditions relating to safety study and the experience or evidence of effectiveness shall be such as specified Table below. Documents

required for licensing the product include- affidavit, formulation, label, trial report, testing protocol, proof and product proforma etc. which vary state to state or area to area 2, 3, 5, 6.

For Issuance of Licence For Ayurvedic Drugs						
Sl. No.	Category	Ingredients	Indications	Safety	Experience/Evidence of Effectiveness	
					Published Literature	Published Literature
Classical Ayurvedic drugs						
1	-as such	As per text	As per text	Not required	Required	Not required
2	-any change in dosage form.	As per text	As per text	Not required	Required	Not required
3	- to be used for new indication	As per text	New	Not required	If required	Required
Patent or Proprietary Ayurvedic drugs						
4	-with no ingredients of Schedule E (1) of D & C Act	As per text	Textual Rationale	Not Required	Of ingredient	Pilot study as per relevant protocol for Ayurveda
5	-with any of the ingredients of Schedule E (1) of D & C Act	As per text	Existing	Required	Required	Required
Aushadh Ghana extract of medicinal plant (dry/wet)						
6	Aqueous extract	As per text	As per text	Not required	Required	Not required
7	Aqueous extract for new indication.	As per text	New indication	Not required	Required	Required
8	Hydro-alcoholic extract.	As per text	As per text	Not required	If required	Not required
9	Hydro-alcoholic for new indication	As per text	New indication	Required	If required.	Not required
10	Other than Hydro/ hydro-alcoholic extract.	As per text	As per text	Required Acute, Chronic, Mutagenicity and teratogenicity.	Required	Required

Table: Safety study and effectiveness evidence

For issue of licence with respect to Balya and Poshak medicines the person who applied for licence is required to submit the- (i) photo-copy of the textual reference of ingredients used in the formulation as mentioned in the book of 1st schedule; (ii) conduct safety studies in case the product contains of any of the ingredients as specified in the Schedule E (1), as per the guidelines for evaluation of Ayurveda Siddha and Unani Drugs formulations; (iii) for textual indications the safety and effectiveness study is not required. Same are the requirement with respect to Saundarya Prasadak. For licencing of proprietary medicine scientific data-based shelf life or date of expiry based on real time stabilities of medicine in accordance with the guidelines prescribed in the Ayurvedic Pharmacopoeia of India, Part-I, volume-viii is also required to be submitted. In an order Ministry of AYUSH has ordered to all State Licencing Authority to consider and accept the accelerated stability data for fixing the shelf life for grant of license and renewal of licence 3, 4.

A licence issued in Form 25-D by Licencing Authority is required to manufacture any Ayurvedic drug for sale or distribution. The conditions of licencing are GMP, competent technical staff, documented information and

records, quality control through in-house or government approved lab, safety study and/or proof of effectiveness for product permission. The manufacturer has to comply other regulatory requirement related with factory, environment and business.

Figure: Indian Market scenario in Ayurveda

Rising health concerns due to the side effects of western drugs and the growing awareness about the benefits of natural and organic medicines represent one of the key factors bolstering the market growth in India. In addition, the increasing popularity of ayurvedic products as a safe and healthy alternative to synthetic chemicals and pharmaceuticals is propelling the market growth in the country. Apart from this, the easy availability of ayurvedic products through online and offline distribution channels, coupled with the increasing affordability and easy accessibility of products across both urban and rural regions of the country are fuelling the market growth. Moreover, the Government of India (GOI) is undertaking favorable initiatives to support the ayurvedic product industry. For this, the government is organizing exhibitions, trade fairs, and roadshows for the promotion of ayurveda. The government is also investing in different programs to increase the visibility, acceptability, and usage of ayurvedic products in the health system. This, along with the increasing investments in various research and development (R&D) activities for developing new formulations, improving manufacturing processes, and incorporating modern technology into ayurvedic product development is creating a favorable market outlook. Besides this, various strategies to globalize and promote ayurveda with the health system and the increasing number of visitors coming to India to seek ayurvedic treatments and products are offering lucrative growth opportunities to ayurvedic product manufacturers. Other factors, such as changing dietary patterns, increasing prevalence of lifestyle diseases, such as diabetes, obesity, and hypertension, and various incentives and subsidies provided to drug manufacturers and entrepreneurs, are projected to stimulate the growth of the in the country.

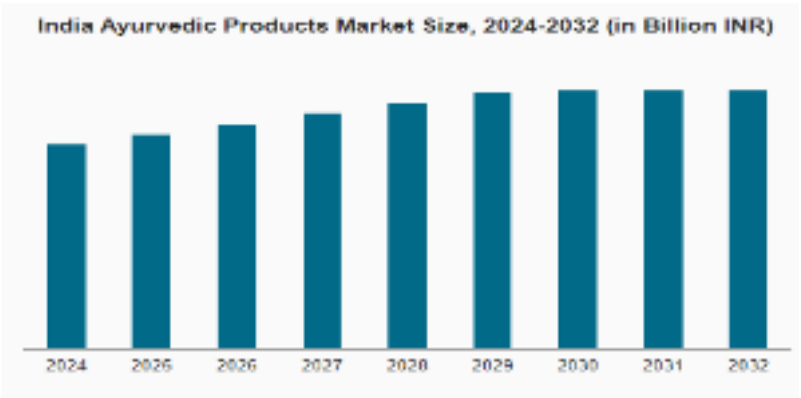

Figure: Trends of Ayurvedic Products

Class – 16

Homoeopathic Products:

Homeopathy has been the cause of much debate in the scientific literature with respect to the plausibility and efficacy of homeopathic preparations and practice. Nonetheless, many consumers, pharmacists, physicians, and other health care providers continue to use or practice homeopathic medicine and advocate its safety and efficacy. As drug experts, pharmacists are expected to be able to counsel their patients on how to safely and effectively use medications, which technically includes homeopathic products. Yet many pharmacists feel that the homeopathic system of medicine is based on unscientific theories that lack supporting evidence. Since consumers continue to use homeopathic products, it is necessary for pharmacists to have a basic knowledge of homeopathy and to be able to counsel patients about its general use, the current state of the evidence and its use in conjunction with other medications.

This guidance describes how we intend to prioritize enforcement and regulatory actions for homeopathic drug products marketed in the United States without the required FDA approval. As discussed below, FDA has developed a risk-based approach under which the Agency intends to prioritize enforcement and regulatory actions involving certain categories of such products that potentially pose a higher risk to public health. The Agency anticipates that many homeopathic drug products will fall outside the categories of drug products that FDA intends to prioritize for enforcement and regulatory action as described in Section III below. For the purposes of this guidance, we define a "homeopathic drug product" as a drug product that is labeled as "homeopathic," and is labeled as containing only active ingredients and dilutions (e.g., 10X, 20X) listed for those active ingredients in the Homeopathic Pharmacopeia of the United States (HPUS). In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidance's describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not required.

FDA Enforcement Policy:

FDA is not required, and generally does not expect, to give special notice that a drug product may be subject to enforcement action. In the listing that follows, we clarify our general approach to prioritizing our enforcement and regulatory actions with regard to homeopathic drug products marketed in the United States without the required FDA approval. However, this guidance is intended to provide notice that any homeopathic drug product that is being marketed illegally is subject to FDA enforcement action at any time.

In developing a risk-based approach, FDA has identified certain categories of homeopathic drug products marketed without the required FDA approval as potentially posing higher risks to public health. FDA generally intends to prioritize enforcement and regulatory actions withrespect to premarket approval requirements involving homeopathic drug products that are marketed without the required FDA approval that fall within the following categories:

- Products with reports of injury that, after evaluation, raise potential safety concerns. For example, MedWatch reports or other information submitted to the Agency can indicate or signal a potential association between the product and an adverse event, medication errors, or other safety issues.
- Products that contain or purport to contain ingredients associated with potentially significant safety concerns. For example, potentially significant safety concerns are raised by products that contain or purport to contain: o An infectious agent with the potential to be pathogenic;

✓ A controlled substance, as defined in the Controlled Substances Act, 21 U.S.C. 802; o Multiple ingredients that, when used in combination, could result in possible interactions, synergistic effects, or additive effects of the various ingredients; or,

✓ Ingredients that pose a risk of toxic, or other adverse effects, particularly when the ingredients are concentrated or in low dilution presentations (e.g., 1X, 2X, or 1C), or are not adequately controlled in the manufacturing process.

- Products for routes of administration other than oral and topical. For example, injectable drug products and ophthalmic drug products in general pose a greater risk of harm to users because the routes of administration for these products bypass some of the body's natural defenses. In particular, contaminated injectable and ophthalmic products can pose serious risks to the patient.
- Products intended to be used for the prevention or treatment of serious and/or life-threatening diseases or conditions. Unapproved products for serious and/or life-threatening diseases or conditions raise public health concerns, in part, because they may cause users to delay or discontinue medical treatments that have been found safe and effective through the new drug application (NDA) or biologics license application (BLA) approval processes.
- Products for vulnerable populations. For example, patient populations such as immunocompromised individuals, infants and children, the elderly, and pregnant women may be at greater risk for adverse reactions associated with a drug product, even if it contains only small amounts of an ingredient, due to the varying ability of individuals in these populations to absorb, metabolize, distribute, or excrete the product or its metabolites. These populations may also be at greater risk of harm as a result of foregoing the use of medical treatments that have been found safe and effective through the NDA or BLA approval processes or under the OTC Drug Review.
- Products with significant quality issues. For example, products that are contaminated with foreign materials or objectionable micro-organisms, and/or are made in facilities with significant deviations from CGMP, pose a significant safety risk to patients.

Essential Drug List recommendation:

For homoeopathy, several clinical trials have been performed for the cure of ailments. The meta-analyses regarding the same has been tabulated below:

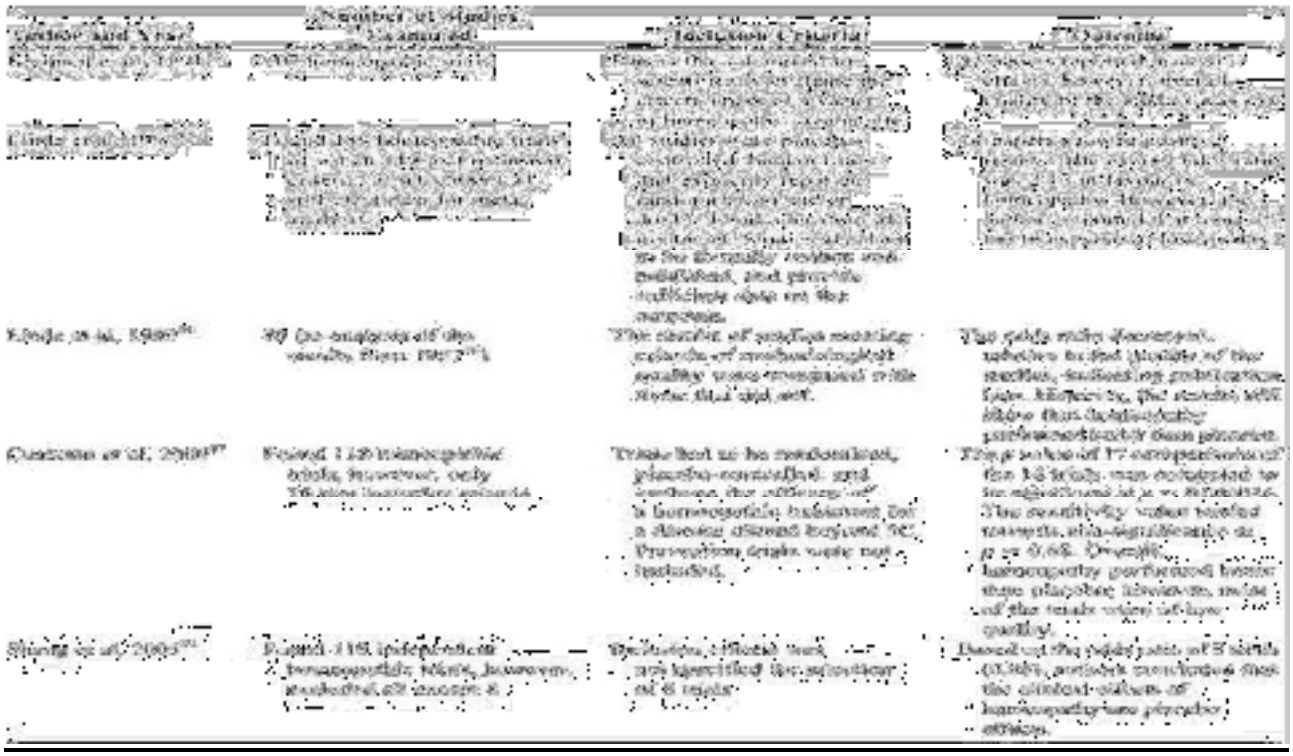

Table: Meta analyses of homeopathy trials

Pharmacists' knowledge regarding Homeopathy:

It does not appear to make sense for pharmacists to attempt to learn about homeopathic medicine in detail. However, we argue that some basic knowledge is required for pharmacists to meet their duty of care. It is recommended that pharmacists learn the main principles of homeopathy, as outlined above; the law of similars,

individualized therapy based on symptoms, and the use of very small doses. Pharmacists should also be aware that the data assessing the efficacy of homeopathy are mixed—there are rigorous, reproducible studies that show homeopathy is effectiveand equally scientifically sound studies that show it is not. A similar situation exists with respect to in vivo studies of homoeopathic products used to treat plants and animals. Pharmacists should also be aware that there is currently no plausible mechanism of action postulated for homeopathy; even homeopathic doctors do not claim to know how it works. Furthermore, pharmacists should be aware that, unless the product is contaminated, there are generally no direct adverse health effects or drug interactions associated with using homeopathic. However, an aggravation may sometimes occur, meaning that the symptoms worsen before they resolve. This is seen as a positive effect by homeopaths because it indicates that the body's own healing mechanism is engaging. Finally, pharmacists should be aware that patients may alter or discontinue using conventional medications if they perceive that their health is improving due to homeopathy.

With these items in mind, pharmacists should be able to differentiate between homeopathic and non-homeopathic dietary supplements; assist the patient in evaluating the scientific homeopathic literature before selecting a product, and identify patients who should not be self-medicating with homeopathic drugs and need referrals to a homeopathic practitioner or medical doctor.

Pharmacists must be aware of the scientific literature and decide for themselves if the data are sufficient for them to endorse the use of homeopathic preparations in their practices. To fulfill their obligations to their patients and their profession, pharmacists should at least have a basic understanding of homeopathic principles and the nature of remedies. The fact that homeopathic medicines are regulated as drugs in both Canada and the United States underscores the importance of this. As accessible, critical, science-based health care professionals, pharmacists should evaluate the research on homeopathy without bias, and then convey the facts to their patients and other health professionals.

Class – 17

Pharmaceutical Supply Chain (PSC):

Pharmaceutical supply chain (PSC) consists of multiple stakeholders including raw material suppliers, manufacturers, distributors, regulatory authorities, pharmacies, hospitals, and patients. The complexity of product and transaction flows in PSC requires an effective traceability system to determine the current and all previous product ownerships. In addition, digitizing track and trace process provides significant benefit for regulatory oversight and ensures product safety. Blockchain-based drug traceability offers a potential solution to create a distributed shared data platform for an immutable, trustworthy, accountable and transparent system in the PSC. Here, an overview of product traceability issues in the PSC and envisage how blockchain technology can provide effective provenance, track and trace solution to mitigate counterfeit medications etc. have been discussed.Two potential blockchain based decentralized architectures, Hyperledger Fabric and Besu to meet critical requirements for drug traceability such as privacy, trust, transparency, security, authorization and authentication and scalability. Two potential blockchain architectures for drug traceability has been compared. The proposed blockchain architectures provide a valuable roadmap for Health Informatics researchers to build and deploy an end-to-end solution for the pharmaceutical industry.

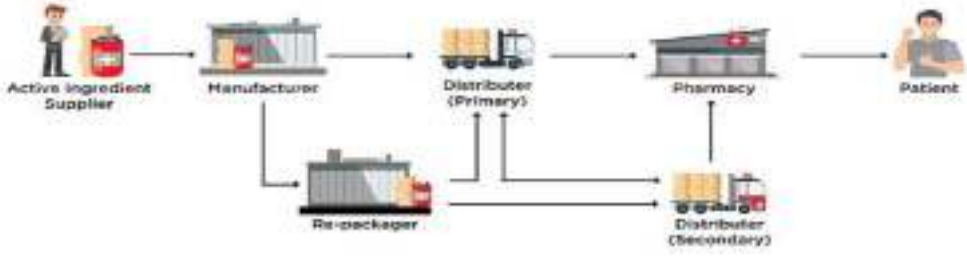

Figure: Drug supply chain stakeholders and their relationship

The drug distribution system is a meticulously choreographed dance between numerous stakeholders, each with a vital role to play in ensuring patients receive the right medications safely and efficiently. Let's delve deeper into the specific functions of these key players:

1. Manufacturers:

- Research and Development (R&D): These companies invest heavily in research to discover and develop new drugs. This involves extensive scientific exploration, clinical trials, and regulatory approvals.
- Manufacturing: Once a drug is approved, manufacturers set up large-scale production facilities adhering to strict quality control standards (e.g., Good Manufacturing Practices or GMP).
- Packaging and Labeling: Accurate labeling is crucial. Manufacturers ensure drug information, dosage instructions, and potential side effects are clearly communicated.
- Distribution Planning: They establish relationships with wholesalers and distributors to ensure medications reach pharmacies and hospitals efficiently.

2. Wholesalers and Distributors:

- Bulk Purchasing: Wholesalers buy drugs directly from manufacturers in bulk quantities, negotiating for better prices.
- Storage and Transportation: They maintain specialized warehouses with proper temperature and humidity controls to preserve medication integrity. They also manage secure transportation networks to get drugs to their destinations.
- Order Fulfillment: Wholesalers fulfill orders from pharmacies, hospitals, and other healthcare providers, ensuring timely and accurate deliveries.
- Inventory Management: They maintain efficient inventory control systems to prevent stockouts and ensure a steady supply of medications.

3. Regulatory Agencies (Government):

- Drug Approval Process: These agencies evaluate the safety and efficacy of new drugs through rigorous clinical trials and reviews. They only grant approval for medications that meet strict criteria.
- Safety Monitoring: Regulatory bodies actively monitor the drug distribution system for adverse drug reactions and potential drug shortages. They can issue recalls or safety warnings if necessary.
- Quality Control: They conduct inspections of manufacturing facilities and drug distribution channels to ensure compliance with quality standards.
- Counterfeit Prevention: They work to prevent counterfeit drugs from entering the market, which can pose serious health risks.

4. Healthcare Providers (Doctors, Nurses, Pharmacists):

- Prescription: Doctors diagnose patients and prescribe medications based on their specific needs. They consider factors like medical history, allergies, and potential drug interactions.
- Dispensing: Pharmacists dispense medications according to the doctor's prescription. They counsel patients on proper medication use, potential side effects, and storage instructions.
- Monitoring: Healthcare providers monitor patients' progress on medication and adjust treatment plans if necessary. They are also responsible for reporting any adverse reactions to the appropriate authorities.

5. Patients:

- Medication Adherence: Patients play a crucial role in their own health outcomes by taking their medications as prescribed. This includes understanding proper dosage, frequency, and potential side effects.

- Communication: Open communication with healthcare providers regarding any concerns or side effects is essential.
- Reporting: Patients can report adverse drug reactions to regulatory agencies or healthcare providers, helping improve the overall safety of the drug distribution system.

Additional Stakeholders:

- Pharmacy Benefit Managers (PBMs): These companies act as intermediaries between insurers and pharmacies, negotiating drug prices and managing pharmacy networks.
- Insurance Companies: They provide financial coverage for medications, influencing patient access and affordability.
- Research Institutions: Universities and research institutes play a critical role in drug development through pre-clinical and clinical trials.
- By working together effectively, this network of stakeholders can ensure a safe, efficient, and accessible drug distribution system that prioritizes patient well-being.

Figure: Overview of Pharma Industry

The pharmaceutical industry is a vital sector that is crucial in developing and providing medications to people worldwide. It involves various stages and processes to ensure safe and effective drugs reach those in need.

Understanding the value chain concept is important in comprehending how the pharmaceutical industry functions.

A value chain represents the activities involved in creating a product or service, from its initial development to its distribution and beyond.

In the pharmaceutical industry, the value chain encompasses all the steps needed to bring a drug from the research and development stage to its availability in pharmacies and hospitals.

We will focus on the drug makers, manufacturers, and distribution. The insurance aspect of the chain is a whole other can of worms we can discuss another day.

Understanding this value chain gives us insights into the different stages and the important players.

Why is it important to grasp the value chain in the pharma sector?

Well, it allows us to appreciate the complexity of the industry and the collaborative efforts required to develop, manufacture, and distribute medications.

It helps us understand how pharmaceutical companies work with regulatory authorities, healthcare professionals, and various stakeholders to ensure safe and effective drugs are available to patients.

Moreover, understanding the value chain helps us recognize the significance of each stage in the process, from research and development, where new drugs are discovered and tested, to manufacturing and production of these drugs on a larger scale, and finally to distribution and sales, where they reach the hands of patients in need.

Each stage has its challenges, regulations, and key players, all working together to ensure the availability of life-saving medications.

In the following sections, we will delve into the different components of the pharmaceutical industry's value chain and highlight some publicly traded companies involved in each part.

This exploration will provide a glimpse into the intricate workings of the industry and shed light on the diverse entities that contribute to the development and distribution of pharmaceutical products.

Role of CFA:

With the e-commerce boom and ever-expanding global market, CFA services play a crucial role in meeting customer expectations with efficient storage and transportation operations. CFA full form in logistics is Carrying and Forwarding Agent, who is primarily responsible for managing the storage, distribution, and transportation of products. They take responsibility for activities like inventory management, warehousing, freight forwarding, customs clearance, and shipping. All in all, CFA in supply chain management help ensure the smooth movement of goods from manufacturers to retailers and customers.

The difference between CNF, CFA, and third-party logistics (3PL) is as follows:

Figure: Overview of the difference between CNF, CFA & 3PL

Is your ultimate goal to be a manufacturer? That's easy, however, it's the delivery of your manufactured goods to the target customer or final point of sale that can interfere with your market reputation and customer satisfaction. So, how can you manage the delivery aspect when the core part of your business needs a lot more time and energy? Well, the solution is going for a competent supply chain, logistics, and distribution unit for your product.

Managing all aspects of a business can be difficult in such a competitive market. As a result, organisations seek third-party logistics to outsource their operational logistics.

On the other hand, different ways of handling logistics and distribution have emerged over time. Be it the Clearing and Forwarding agent (CNF) or Carrying and Forwarding Agent (CFA) or Third-party logistics (3PL), these modes have been brought into practice. Although their foremost function is to deliver the final goods to the customer's doorstep, each one is different in their core operations.

Clearing and Forwarding Agent (CNF):

CNF deals with the distribution of stock in a specific zone. The primary function of a CNF agent is to procure and maintain a large number of stocks to distribute further. The agent obtains stocks from the manufacturer and makes them available to the company's dealers and distributors.

Thereafter, the agent is responsible for pushing the sale to earn a certain percentage of the stock sold. For example, in the pharmaceutical business, a primary distributor procures medicine in bulk below the MRP from the manufacturer and then keeps a certain percentage of the margin in the order received by other distributors. By doing so, the agent is not only forwarding the stock but also clearing the procured stock.

Here, a CNF agent takes charge of all the inventory procured from the manufacturer, procures stocks as per the stock-keeping capacity (SKU), bridges the gap between the manufacturer and wholesaler, and acts as a representative of the company to other distributors.

A CNF agent's main role is to allocate the product to other distributors in a specific zone and link the gap between a manufacturer and other distributors. And in order to deliver the ordered product to distributors, they approach forwarding agents.

Figure: Clearing and Forwarding Agent

Carrying and Forwarding Agent (CFA):

A CFA agent is someone whose primary concern is to manage the storage and transportation of products from one point to another. These forwarding agents are responsible for bringing out the best carrier service providers – as air freighters, trucking companies, rail freighters, and ocean liners – for the client and then negotiating with the service provider to get the best price for transporting the stocks.

Further, after picking up the stocks from the manufacturer, supplier, or distributor, they will be stored at the CFA warehouse or secondary warehouse. The products are then loaded into the fleet according to the size of the order, by third-party logistics.

CFA agents are responsible for organizing methods to decide the fastest and safest mode of transportation of stocks to a designated destination.

Figure: Carrying and Forwarding Agent (CFA)

Third-Party Logistics (3PL):

Third-Party Logistics (3PL) is a one-time solution for all logistics solutions. It comes into play when a company outsources its logistics operations to an external company. It enables the accessibility of its product in the domestic as well as international marketplace. 3PL integrates all the logistic solutions under one roof, improving the supply chain operation. For instance, warehousing, transportation, inventory management, inventory forecasting, material procurement, picking and packing, order fulfilment, freight forwarding, customs brokerage & clearance, payment, documentation, shipment tracking, etc.

Figure: Third-Party Logistics (3PL)

Supply chain solution:

As we know, the supply chain is a prominent part of any production unit. In this case, the solution involves converting raw materials into finished products and then delivering those products to the target market. This may sound simple, but it's a complex process and in order to reduce the complexity, companies are approaching third-party logistics. Under the supply chain solution, the services provided by 3PL are packaging, assembling, labelling, licensing, housekeeping, and security of the stocks.

Figure: Supply Chain Solutions

Fulfilment Centre:

The greatest beneficiary from the fulfilment centre function of 3PL is the e-commerce business. Third-party logistics provides facilities for sourcing, quality checking, sorting, storing, picking, packing, and dispatch under the fulfilment centre as per the business requirement of a company. Along with this, third-party logistics reviews the requirement of a business and thereafter, analyses, plans, designs, and implements.

Figure: Fulfilment Centre

The Warehouse:

This function of 3PL has broadened the scope of companies to manage their logistics. These days, for any manufacturer or supplier to allocate a spare space for storing the final product is difficult, but now with the warehouse facility provided by 3PL, this hindrance can be overcome.

There are different kinds of storage spaces 3PL provides. For example, an organisation not willing to spend much on buying property can lease a warehouse for rent. Similarly, ready-to-move (RTM) warehouses, Built-in-suit (BTS) warehouses, customised warehouses, integrated warehouses, and in-city warehouse options are accessible through third-party logistics.

Figure: Warehouse

Transportation:

The foremost function that a 3PL performs is to actually execute the delivery and transport of goods from the warehouse to the endpoint. In addition, the carrier and fleet are selected based on a number of factors, including the size, cost, and destination of the shipment.

Figure: Transportation

Shipping:

A third-party logistics service provider also provides services to the shipping industry. It means they also manage logistics for companies that do business in the international market.

In order to operate, 3PL uses technology such as transportation management systems (TMS), and integrated management services. Additionally, 3PL attains freight data and matrix reports for better management.

Moreover, third-party logistics also comprises many advantages that compel companies to outsource their logistics to a third party. Some of the advantages include cost reduction, expert opinions and expertise, market expansion, scalability, customer satisfaction, and handling international logistics.

Figure: Shipping

CFA is a process comprising eight steps, as shown in the Table below. Data sources were mapped, and the concepts identified, deconstructed, and categorised. The concepts were then integrated and synthesised into a framework.

Phase	CFA phases [28]	Objective of phase as per CFA	Alignment with sections in this paper	Objectives of part
1	Mapping data sources	Map spectrum of multidisciplinary literature	Part 1: Investigation and discovery of sources and subsequent concept identification and categorization (section 4)	Systematic literature review to include investigation of key success factors of [illegible] from other industries
2	Reading and categorizing data	Read selected data and categorize by discipline and scale of importance		
3	Identifying and naming concepts	Read and reread data to discover concepts, and allow concepts to emerge from the literature		
4	Deconstructing and categorizing concepts	Identify the main attributes, characteristics, assumptions, and role of each concept. This is followed by categorizing the concepts		
5	Integrating concepts	Integrate and group together similar concepts to form one group of concepts	Part 2: Development of framework (process described in section 5)	Integrate and synthesize findings into a framework
6	Synthesis and resynthesis	Synthesize concepts into a framework. This is an iterative process, that includes repetitive synthesis and resynthesis		
7	Framework validation	Establish whether the framework makes sense	Part 3: Validating: Framework validation	Evaluate and modify the framework in three stages: Semi-structured interviews. Building interviews. Case studies. This is a continuous process of modifying the framework.
8	Rethinking framework	A multidisciplinary framework will always be dynamic, and needs to be revised		

Table: Overview of CFA and its implementation

What is CFA in pharma industry?

A Carrying and Forwarding Agent or CFA in pharma and FMCG industry is primarily responsible for prudent management and transportation of products from one end to the other. A CFA is an intermediary that bridges the gap between a manufacturer and a retailer or wholesaler. These CFA agents facilitate the receipt, custom clearance, and forwarding consignments at designated destinations. Moreover, they also organize and decide the mode of conveyance to ensure cost-efficient and timely delivery of the consignment.

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Class – 18

Distribution Cycle of C&F Agent in Pharma Company:

The distribution process begins when the manufacturer dispatches pharmaceuticals and other products. It ends when medicine consumption information or consumption of any other commodities reaches back to the unit.

The primary distribution activities are discussed below-

- Procurement of products: The distribution process intersects the procurement process when the pharma and FMCG products are ready to be delivered to the concerned facilities.
- Storage: Different pharma and FMCG products have vastly different requirements in terms of temperature, humidity, and lighting. The storage facility must ensure that each product is in line with its specific needs.
- As a significant CFA in pharma products, we take great care throughout the supply chain to keep products in optimal conditions. Our temperature-controlled storage facility keeps the space within specific environmental parameters.
- We provide enough space to store finished goods, inbound functions to prepare items for storage, and outbound functions that consolidate, pack, and ship orders accordingly.
- Delivery: The pharma and other commodities are handled cautiously while loading them into the heavy goods vehicle. Our team carries each product to the place of delivery under expert supervision. Also, we schedule deliveries systematically to provide punctual and economical service to our esteemed clients.
- Dispensing products: The distribution process achieves its purpose when pharmaceuticals and other FMCGs safely reach their final destination.

We are working towards providing top-notch services to all our premium clients, adhering to all their specifications.

With 3000+ distributors, whole-sellers, modern trade, retailers, direct patients, and hospitals across Northeast India, we dispatch over 10,000+ invoices & 2,50,000+ cases monthly.

What is a distributor?

A distributor is an intermediary entity between a producer of a product, or manufacturer, and a downstream entity in the distribution channel or supply chain. The downstream entity is typically a retailer or value-added reseller (VAR), but it can also be a wholesaler.

The distributor is an integral supply chain component, acting as an intermediary between the manufacturer and the downstream entity. The distributor bridges the gap between upstream and downstream entities while adding important services that help smooth the distribution process.

A distributor typically works with multiple manufacturers and multiple downstream entities. For each manufacturer, the distributor serves as an agent that enters into an agreement with the manufacturer to sell its products to retailers, VARs or wholesalers.

What is the difference between a distributor and a wholesaler?

Today's supply chains can include both distributors and wholesalers, and it's not always clear how they differ from one another. Some sources treat them as the same, but there are important distinctions in terms of the services they provide.

To appreciate these differences, it's important to understand how distributors and wholesalers fit into the overall supply chain ecosystem. The following diagram provides an overview of the basic supply chain execution and flow. Although this is a simplified representation of the process, it can help to conceptualize the main entities that make up a typical supply chain and how they fit together.

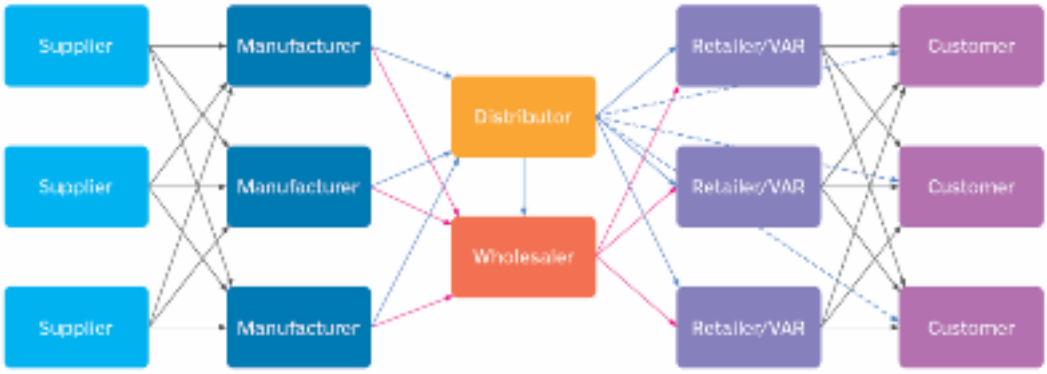

Figure: The distributor plays a pivotal role in moving products from the manufacturer to downstream entities

The distributor can play a pivotal role in moving products from the manufacturer to downstream entities. In a typical scenario, the supplier delivers materials to the manufacturer. The manufacturer uses these materials to build products, which it then ships to the distributor. The distributor delivers the products to the retailer or VAR, which then sells them to the customer.

Of course, supply chains are usually much more complex and might require supply chain management. Multiple suppliers can provide material for multiple manufacturers, a distributor can buy products from multiple manufacturers, and a retailer can sell products to multiple customers. A distributor might even sell products directly to customers.

In addition, the wholesaler might buy products directly from manufacturers -- as well as from other distributors -- and then sell the products to retailers. A manufacturer might also work with multiple distributors and wholesalers, and might even sell directly to retailers or customers.

Product delivery can also take forms other than what is reflected in the diagram, but it typically follows this pattern or something similar. This means that the wholesaler and distributor can both acquire products directly from the manufacturer, and then sell them to the retailer. It also means that the wholesaler and distributor roles are often confused.

Some of the confusion comes from the fact that a distributor performs some of the same functions as a wholesaler. However, the distributor's responsibilities are generally much more complex. In addition, the distributor takes a more active role with both the manufacturer and retailer, such as handling payment and procurement. The distributor also takes on more advanced capabilities. For example, manufacturers that lack the means to build out a channel strategy often outsource that work to distributors.

Distributors also frequently take a more proactive approach in educating resellers about new products by employing strategies such as presales training, roadshows or demos on behalf of manufacturers. Distributors

might also provide services around the procurement process, including contract negotiation, marketing or product warranties. In contrast, wholesalers primarily focus on buying products in large quantities, breaking them into smaller units and selling them at profit.

Introduction:

Distribution management is a crucial step in completing the supply chain cycle. Without effective and timely distribution, the efforts put in by the other departments, be it marketing or manufacturing, will not see the desired results. Distribution management in the supply chain is essential to ensure the right quality and quantity of materials are ordered and the right quantity of products is delivered at the right sale points. This will help in reducing excess costs in inventory and shipping.

Various companies can adopt different types of distribution management to adapt to their companies' specific needs and ensure that there is a seamless movement of goods/services.

You can make a scaling career in distribution management by pursuing supply chain management courses. You can also consider getting a certification in logistics planning and management.

Understanding Distribution Management:

Distribution management deals with more than moving products from point to point. It should be able to provide information to the management to study the customer database and trends. This will help to harness opportunities for the growth of the company. Many progressive companies use their distribution information to obtain market intelligence.

There are primarily two types of distribution: commercial distribution (sales) and physical distribution (logistics). The distribution cycle involves diversified functions such as customer service, warehousing, shipping, inventory management, packing, labelling, transporting, materials handling, and distribution to the final point, along with information gathering and integration.

Distribution management is the process of a bird's eye view and supervision of the movement of products/services from the manufacturer/vendor to the point of sale. It is a comprehensive term referring to many processes and activities. These are subsets of the supply chain: inventory, packing, warehousing, and multimodal logistics.

Effective distribution management is an important part of the business cycle for all stakeholders in the supply chain, such as distributors, agents, and wholesalers. Profit margins are an important part of business and depend on how fast they can reach their goods and services to customers.

Successful distribution management systems are required for businesses to remain alive and competitive and to bring a network of happy and loyal customers. As mentioned earlier, distribution management is a function of many parameters, namely, understanding the end user's needs, geographical locations, socioeconomic conditions, etc. The end user can be for different types of items. It can be for commodities or services. Supply chain management courses provide aspirants with the knowledge to handle a company's logistics and supply chain management.

Role of Distribution Management in Supply Chain Management:

The role of distribution management in supply chain management is diverse. Proper distribution management is important to the supply chain as it ensures that it is sustained and performs optimally. It helps to keep the company organised and effectively deliver goods and services. It helps retailers relieve and manage their storage spaces (warehouses) so more goods can be accommodated at any time.

Earlier, customers had to visit different shops to buy their products at different locations. In today's world, customers can choose all their products from one common shop location. Further, it now provides the facility and luxury of online shopping to deliver products to the doorstep. This is all because of improvements in distribution management. The supply chain management online course enables aspirants to master the digital technologies used in SCM to make data-driven decisions.

Proper distribution improves the face value of the company and its popularity. It also increases the company's profitability and helps its sustenance in the competitive world. Efficient distribution management using advanced software helps to gather information on the movement of various types of goods and services being handled at various stages. This helps in creating a database that assists in improving the business of the company and extending its consumer base. Real-time data availability helps in stock and sales visibility across the selling points in the supply chain. It will also help with auto-replenishment and maintenance of optimum stock to avoid a last-minute rush to procure goods. It helps to reduce the errors in delivery and time factor in delivering.

Advantages of Distribution Management:

Distribution management not only increases profitability but also reduces waste in a variety of ways, from less spoilage to lower warehousing expenses since items and goods can be distributed as needed ("just in time" inventory) rather than stored in larger quantities ("just in case" inventory).

Distribution management facilitates "one-stop shopping" and other conveniences and benefits, such as customer loyalty reward programmes, reduced shipping costs, and expedited delivery to clients. It also makes things simpler for purchasers.

Distribution Management as a Marketing Function:

The core tenet of distribution management as a marketing function is that it takes place in an ecosystem that also takes into account the following factors:

- A product is not only a physical thing; it can also be a concept, music, or knowledge.
- Price: This is the amount a product or service is worth to the vendor and the buyer. It can include tangible and intangible elements, such as the list price, financing options, discounts, and the likelihood that consumers and rivals would react favourably.
- Promotion is any kind of communication a seller uses to inform, convince, and/or remind customers and potential customers about the seller's products, services, reputation, beliefs, and social effects.
- Placement: This procedure ensures that products are offered, accessible, and visible to final consumers or business users in the target channels or customers where they purchase.

What Are the 4 Channels of Distribution?

Wholesaler:

In this route, products are delivered from producers to distributors. For instance, spirits producers sell their brands of alcohol to wholesalers.

Retailer:

Retailers receive products from manufacturers or wholesalers. For instance, high-end retailing chains like Neiman Marcus, Nordstrom, and Macy's receive distribution of brand-name designer clothing and accessories.

Distributor:

This route transports products from the manufacturer or source to a licenced distributor. An authorised Ford dealership, for instance, receives different Ford makes and models from a Ford factory for sale to customers or business fleets.

E-commerce:

This is the newest and most disruptive distribution method, in which products and services are digitally exhibited online before being delivered to the customer. As a fourth channel, e-commerce has sped up transformation.

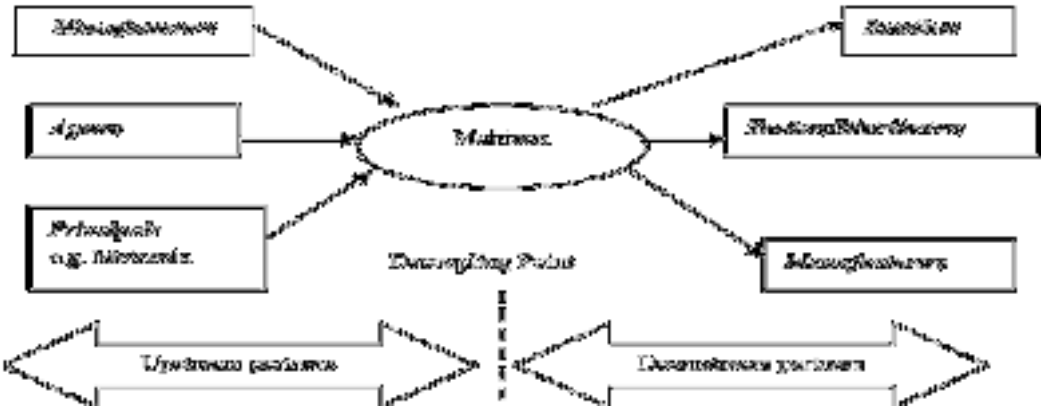

Figure: The upstream and downstream partners of Mobicon

In order to have a better picture to understand the role of distributor in the supply chain, we choose the electronicsindustry in Hong Kong since it is facing the problems of volatility demand, short product life cycle and fluctuationof supply price. In fact, the success of Hong Kong's electronics companies lays great emphasis on the quickresponse on customers' need by monitoring the product trends. Thus, a proper supply chain strategy should be aresponsive one which might rise a question of bypassing the distributor to achieve quick response. However, the factis that Hong Kong (and the Pearl River Delta area) is an important trading hub for electronic parts and components in the Asia-Pacific area. Apart from Chinese products, many items from Japan, Taiwan, the US and South Korea arere-exported via Hong Kong by distributors. From the study of HKTDC (2006), Hong Kong's electronics industry accounted for 48% of Hong Kong's total exports in 2005 and is th e largest export category of Hong Kong. This feature of having many distributors in such an industry is a great topic for us to research and generate someknowledge both beneficial for the industry and academic. Actually, the Pearl River Delta region is crowded with manufacturing plants. They come from different industriessuch as electronics, toys, watches, etc. Most of them need some electronics components to fabricate their productssuch as electronic toys, digital watches and consumer electronics. As China becomes the world factory, the PearlRiver Delta area is one of the main manufacturing areas of China. This situation forms the centralization ofindustries in one main area and creates a need for some electronics distributors to re-distribute the electronicscomponents so as to satisfy the different needs arising from different industries. Thus, Hong Kong, because of itslocation advantage, becomes the electronics distribution center to support the whole Pearl River Delta area as wellas the other Asian area. All the above factors enable Hong Kong to become the place postponement position to serve the downstream player.Moreover, inventories from upstream players are thus 'pooling' in this area for other postponement activities toenhance the supply chain performance.

After knowing the general picture of the Hong Kong's electronics industry, we choose an electronics distributor, Mobicon Group Limited (Mobicon), as an example to illustrate the distributors' roles in the supply chain. Thereason why we use Mobicon as our example study is that it is the first listed electronics distributor company in HongKong. In order to study the supply chain practices of Mobicon, we will make use of the concept of push-pullboundary to study how a distributor should do in an efficiency way to benefit the supply chain.

Class – 19

Role of Distribution in Supply Chain:

Distribution refers to the steps taken to move and store a product from the supplier stage to a customer stage in the supply chain.

Figure: Steps of Distribution

Distribution occurs between every pair of stages in the supply chain. Raw materials and components are moved from suppliers to manufacturers, whereas finished products are moved from the manufacturer to the end consumer.

Distribution is a key driver of the overall profitability of a firm because it affects both the supply chain cost and the customer value directly. The choice of distribution network can achieve the supply chain objective from low cost to high responsiveness.

Examples: Wal-Mart and Seven-Eleven Japan, have built the success of their entire business around outstanding distribution design and operation.

Dell distributed its PCs directly to end consumers, whereas companies such as HP distributed through resellers. Procter & Gamble (P&G) has chosen to distribute directly to large supermarket chains while obligating smaller players to buy P&G products from distributors. The process of designing a distribution network has two broad phases. In the first phase, the broad structure of the supply chain network is visualized. This stage includes decisions such as whether the product will be sold directly or go through an intermediary. The second phase then takes the broad structure and converts it into specific locations and their capability, capacity, and demand allocation. The appropriate choice of distribution network grows the supply chain surplus by satisfying customer needs at the lowest possible cost.

Figure: Strategies and Challenges Distributing Products

- Distributors bridge the gap between manufacturers or suppliers and end consumers. They facilitate the efficient flow of products or services, enabling companies to focus on their core strengths.
- They offer value-added services, such as marketing assistance and after-sales support, which benefit both suppliers and customers.
- There are various types of distributors, including wholesale, retail, and online distributors, each serving different segments of the market. They contribute to economic growth by providing access to financial products and services.
- Moreover, distributors support manufacturers through marketing, sales support, and supply chain management, resulting in cost savings and improved customer service.
- To succeed, distributors must build strong partnerships with suppliers, negotiate effectively, embrace technological advancements, and manage challenges like market competition, inventory, and regulatory compliance.
- In doing so, they can remain competitive, meet customer needs, and thrive in the ever-changing business landscape.

Role of Stockists in the Drug Distribution System:

Stockists, also referred to as wholesale distributors or regional distributors, are vital intermediaries within the drug distribution system. Their primary function lies in bridging the gap between pharmaceutical manufacturers and various healthcare providers at the local level. Here's a breakdown of their key roles, drawing on scientific literature:

1. Inventory Management and Local Availability:
Stockists maintain a diverse inventory of medications from multiple manufacturers, catering to the specific needs of their designated region. This ensures a readily available supply of essential drugs for pharmacies, hospitals, and clinics. Scientific literature highlights the importance of efficient inventory management by stockists.

2. Distribution and Logistics:
Stockists play a crucial role in the physical distribution of medications. They receive bulk orders from manufacturers and break them down into smaller quantities for individual healthcare providers. This facilitates efficient delivery and reduces transportation costs for manufacturers. Effective logistics management by stockists ensures timely delivery and proper storage conditions for temperature-sensitive medications, a critical factor for maintaining drug efficacy.

3. Market Access and Credit Facilitation:
Stockists act as a bridge between manufacturers and smaller healthcare providers, particularly in rural areas. They can offer credit facilities to pharmacies and clinics, allowing them to purchase essential medications. This financial support, as discussed in research by the Healthcare Distribution Alliance (HDA), is crucial for ensuring wider market access to medications in regions with limited financial resources.

4. Information Dissemination:
Stockists can serve as a valuable source of information for healthcare providers regarding new drug launches, product updates, and potential drug shortages. They can also provide training on proper medication storage and handling practices.

5. Regulatory Compliance:
Stockists are responsible for ensuring that all medications they distribute comply with relevant regulations regarding storage, transportation, and expiry dates. They play a role in maintaining the integrity of the drug supply chain.

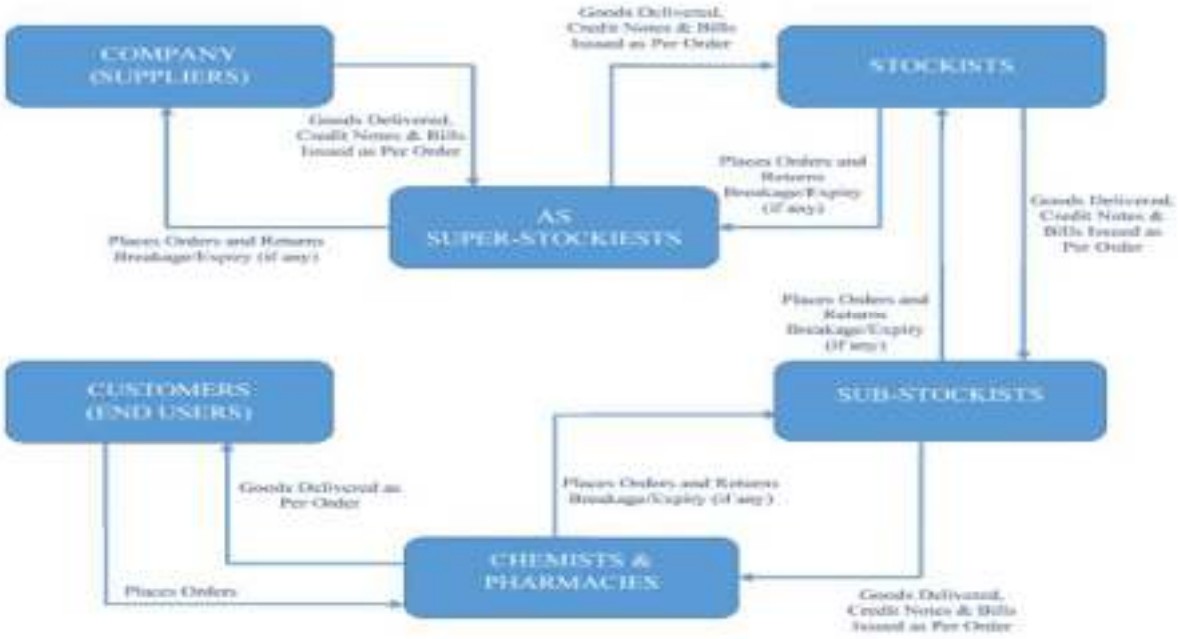

Figure: Network of a stockist in a pharma system

This network works in the following manner:

- Customer places orders to chemists and receives the goods as per prescription.
- Chemists place orders to stockists or sub-stockists and receive the goods from either stockists or sub-stockists.

- Stockists place orders to Super-Stockists and receive the goods as per order.
- Super-Stockists place orders to the Company and, in turn, receive the goods as per order.

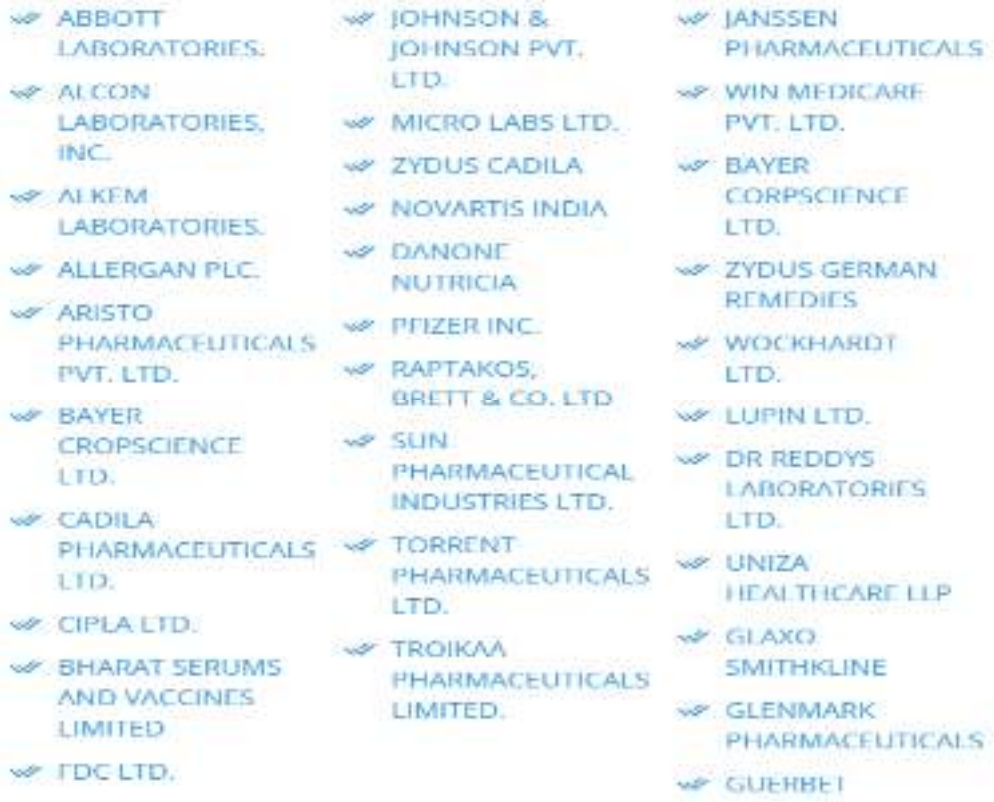

Figure: Distribution of a stockiest

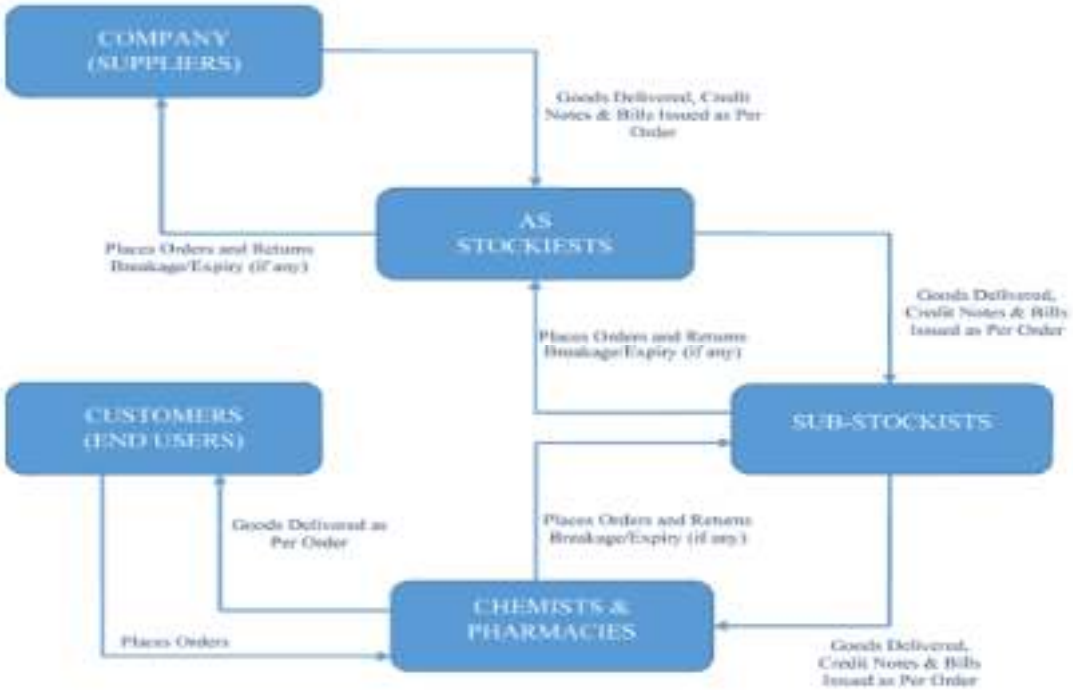

Figure: Business Process Operations from a stockiest

It has been followed using the following steps:

- Customer places orders to chemists and receives the goods as per prescription.
- Chemists' places orders to Stockists or Sub-Stockists and receives the goods from either stockists or sub-stockists.

- Sub-stockists' places orders to stockists (North Point) and receives the goods as per order.
- stockists' places orders to Company and in turn receives the goods as per order.

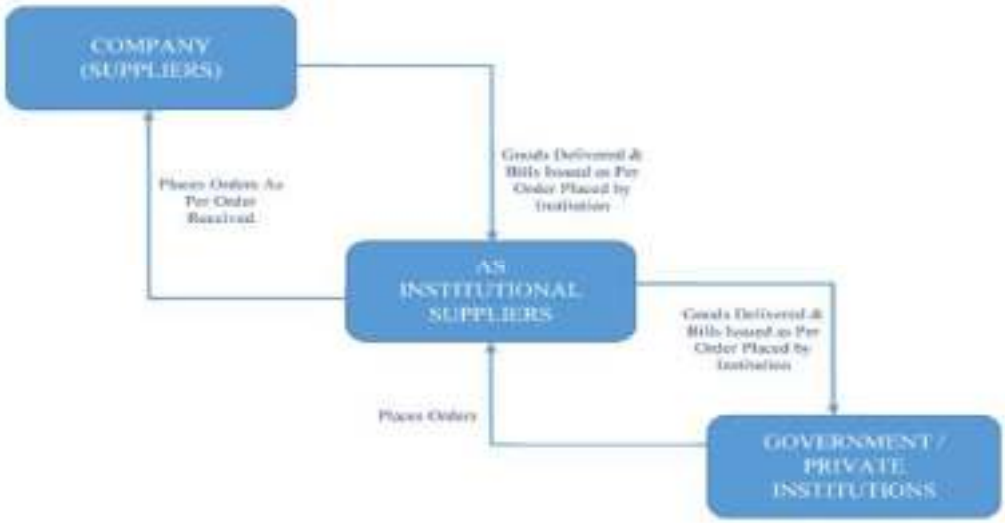

Figure: Institutional Supplier Distribution system

It has been performed using the following steps:

- Concerned Institution (Hospital, Nursing Home etc.) places orders to authorised distributor for the company it is associated with.
- Authorised distributor places the received order to Company as per requirement.
- Company Bills the goods as per requirement to Authorised distributor which in turn bills the received goods to the concerned institution.

Role of liasioning agents in the Drug Distribution System:

Medical Science Liaisons (MSLs) are therapeutic specialists with advanced scientific training. They are experts in communicating complex scientific and medical information toa variety of stakeholders. Their primary role is to build and foster strong relationships with key external experts in their shared therapeutic category. They provide a credible link to external stakeholders, helping bridge the communication between clinical development and commercial success. Additionally, MSLs are in a unique position to gather insights that inform business strategy in areas such as product development and market access. Demand for MSLs is strong and growing, globally driven by increasing stakeholder demands.

In an environment that requires transparent and compliant communications, MSLs are positioned to generate and disseminate complex scientific information to both internal and external stakeholders. MSLs work throughout a product's lifecycle, acting as scientific communicators and resources within the medical community, as well as scientific experts to internal teams. In this way, they help patients gain access to appropriate medicines and help see that products are utilized effectively. Collaboration within the regulations and required Codes of Practice is key to success.

While the term "liaison agent" appears occasionally within the drug distribution system, it doesn't represent a single, well-defined role. There are possibilities for liaison roles existing at various points in the system, but their specific duties can vary depending on the context. Here's a breakdown of some potential interpretations:

1. Internal Liaisons:

Within large pharmaceutical companies or distributors, liaison agents might facilitate communication and collaboration between different departments. For example, they could bridge the gap between manufacturing and sales teams, ensuring smooth order fulfilment.

2. Regulatory Liaisons:
Some companies might employ liaison agents to manage communication with regulatory agencies. These agents could help navigate the approval process, address regulatory inquiries, and ensure compliance with changing regulations.

3. Third-Party Liaisons:
In some cases, liaison agents might work for consulting firms or specialized companies. They could act as intermediaries between manufacturers, distributors, and healthcare providers, facilitating negotiations, resolving supply chain issues, or managing logistics for specific projects.

4. Advocacy Liaisons:
Patient advocacy groups may employ liaison agents to build relationships with pharmaceutical companies or distributors. These agents could advocate for patient access to specific medications or participate in discussions regarding pricing and affordability.

Challenges in Defining the Role:
The lack of a standardized definition for "liaison agent" within the drug distribution system makes it difficult to pinpoint their specific functions. Additionally, some of the tasks mentioned above might be handled by existing roles within companies, such as account managers, regulatory affairs specialists, or supply chain coordinators.

Importance of Communication and Collaboration:
Regardless of the specific title, effective communication and collaboration are essential throughout the drug distribution system. While the concept of a liaison agent focusing on these aspects holds merit, their specific duties may be integrated into existing roles depending on the organizational structure.

Example Medical Science Liaison job description (small pharmaceutical company):
Description
Position: Medical Science Liaison, Ophthalmology
Reports to: Senior Director, Field Medical
Location: Remote

Position Summary:
The MSL is a remote role focused on developing and maintaining peer-to-peer relationships with key medical experts. Thisrole will primarily support the company ophthalmology program. The MSL will collaborate with physicians and othermedical experts to support trial enrollment, provide program and protocol training and ensure that health careprofessionals have the most up to date information as the clinical development programs mature.

Key Responsibilities Include:

- Develop and maintain peer-to-peer collaborations and relationships with key medical experts in theophthalmology community.
- Support clinical development initiatives including site identification, trial recruitment, registry, and presentation offinal approved data.
- Collaborate with physicians on medical affairs initiatives including publications, advisory boards, medical educationopportunities, training, and speaker development.
- Serve as scientific peer-to-peer resource to external disease experts and internal stakeholders.
- Support the medical community with up-to-date medical information, robust disease expertise, and productinformation.
- Communicate clinical insights on new data to the company Medical Affairs and to inform medical strategy for thetherapeutic area.
- Train internal stakeholders on key scientific and medical topics in relevant therapeutic area.
- Develop an understanding of the regional landscape including specialties involved in care of patients.

- Maintain effective and appropriate communication among internal stakeholders while maintaining full compliancewith relevant requirements.
- Generate tactical regional plans to provide needs based, value-added support of the medical and scientificcommunity in-line with company goals.
- Uses systems to strategically map, identify, profile and prioritize thought leaders in line with the medical plan andgoals.
- Maintain accurate reporting and documentation of MSL activities.

Education, Registration & Certification:

- Bachelor's degree in chemistry, biology, pharmacy, or other medical-related discipline.
- Advanced degree preferred.

Experience:

- At least 5 years of experience in Medical Affairs or Medical Science role,
- Robust and current clinical development experience supporting drugs to treat rare diseases; prior ophthalmology experience preferred.
- Candidates must have well-established networks and active relationships with KOLs in the ophthalmology community.
- Candidate must have an understanding of compliance considerations and demonstrate the ability to work compliantly in a field-based role, within the medical organization, as well as across the commercial organization.

Skills, Knowledge & Abilities:

- Excellent oral and written communication skills.
- Energetically embraces responsibilities, demonstrates ability to achieve goals.
- Has strong initiative and functions well as part of a cross-functional team.
- Exhibits excellent time management.
- Demonstrated ability to work independently.
- Excellent verbal and written communication skills.
- Experience in a start-up environment preferred.
- Must be a proactive team player, flexible, and ability to work in ambiguous situations.

Other:

- Office is home-based.
- Travel within the region up to 75%.
- Required travel to medical meetings, team meetings, and other group meetings (will require some weekends).

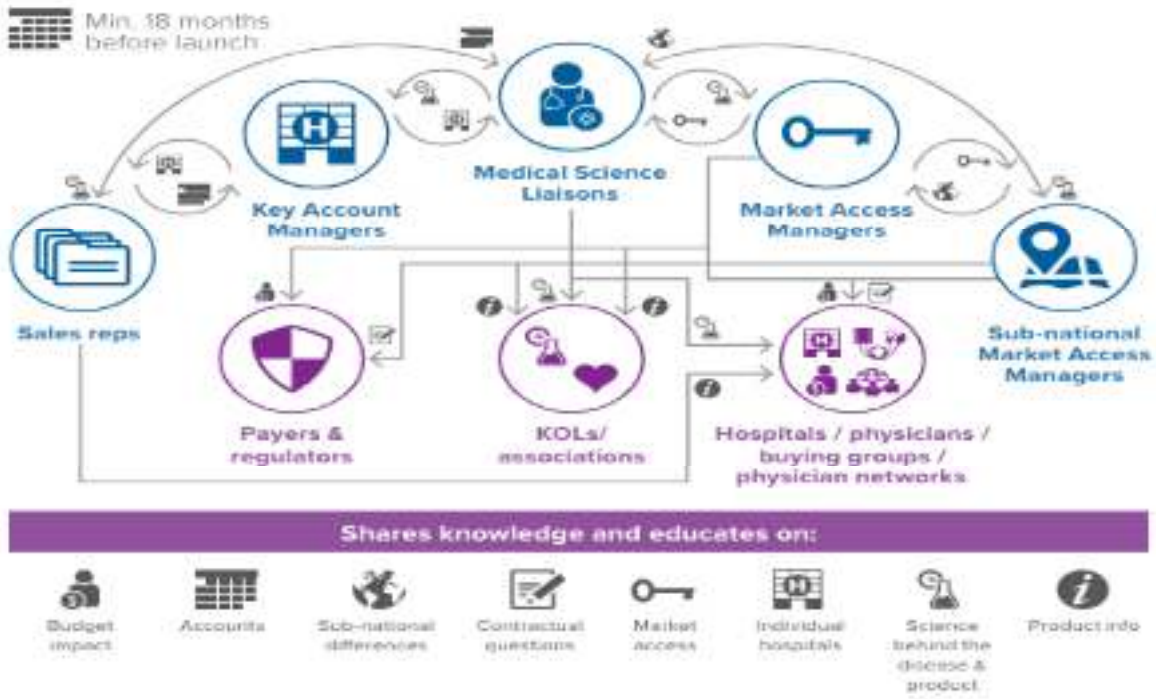

Figure: Helping to ensure information flow complies with local regulations

How MSLs differ from other team members:
Important differences between MSLs and other members of the team includethe following:

- Disseminates scientific data.
- Delivers scientific presentations and education relating to the therapy area, mode ofaction and clinical evidence.
- Develops medical plan and projects with Scientific Opinion Leaders (SOLs).
- Engages with external experts on the generation of scientific data, includinginvestigator-initiated studies.
- Scientific resource to internal stakeholders.

Sales representative:

- • Sells the product's benefits to encourage utilization of a brand.
- • Always limited to discussions within labeling.

Figure: Differentiation and interactions of Medical Affairs roles

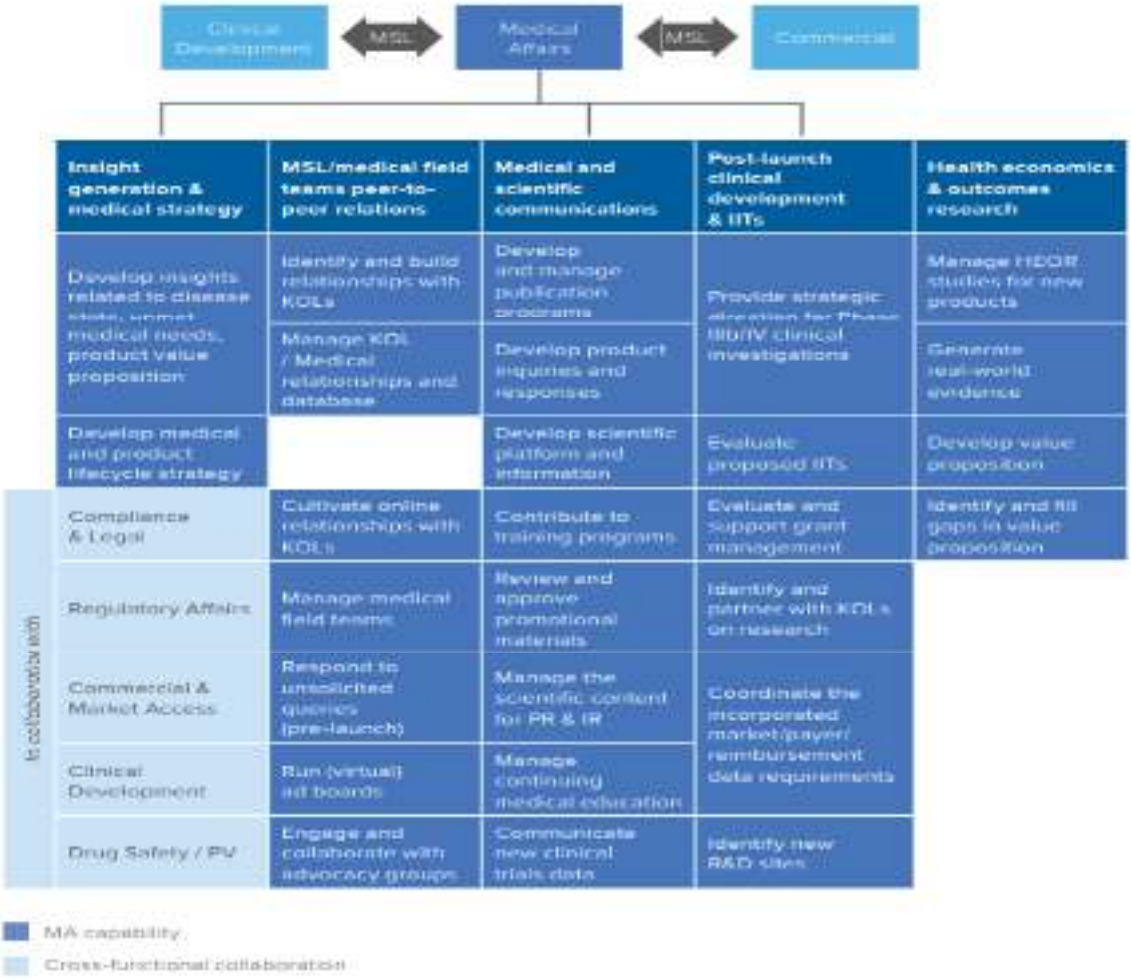

Figure: MSL resources and teams to meet specific needs

Figure: In-field practices for effective MSLs

Conclusion:

The medical liaisons play a pivotal role in medico marketing, facilitate late phase clinical research and pharmacovigilance, medical writing, mediate market research and product launch, training marketing and sales workforce, developing public-private opportunities, regulatory and legal responsibility. Communication and presentation, writing and problem solving, innovative thinking, commercial orientation, working independently, ability to teach and other relevant therapeutic expertise and skills are required. They should possess a scientific

qualification with pharmaceutical or medical or clinical experience; ability to process, understand and communicate high standard scientific information; excellent presentation skills; strong networking capabilities; understanding of clinical development, practices and regulations; excellent networking, communication and presentation skills; aware of ethical standards, clinical regulations and industry standards; adapt to business and strategic needs; cross-functional team working capabilities and managing multiple projects.

They should be updated with the latest medical or scientific information and trends through professional and scientific meetings, seminars or conferences. Relationship building and developing good public relations for long term with both internal and external clients; problem solving or resolving problems; innovative thinking and communicating information to consumers or media; working with healthcare professionals are some of their roles. They have to establish communication between corporate medical affairs field team of sales and marketing for short- and long-term goals, strategies and activities.

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Class – 20

Introduction

The purpose of this summary is to present key findings from recent technical and scientific data presentations in the pharmaceutical industry. These presentations cover various aspects such as drug development, clinical trials, regulatory updates, and novel therapeutic approaches.

Drug Development and Discovery

Recent presentations highlighted advancements in drug discovery techniques, including:

High-Throughput Screening (HTS): Improved methods for rapidly screening large compound libraries to identify potential drug candidates.

Structure-Based Drug Design (SBDD): Utilization of computational models to predict how small molecules interact with biological targets, enhancing the precision of drug design.

Biomarker Discovery: Identification of new biomarkers for disease states, which can guide personalized medicine approaches and improve patient outcomes.

Clinical Trials and Data
Key insights from clinical trial data were presented, focusing on:

Phase I-III Trials: Results from early to late-stage clinical trials, demonstrating the safety, efficacy, and optimal dosing of new therapeutics.

Real-World Evidence (RWE): Use of data from real-world settings to complement clinical trial findings, providing a broader understanding of drug performance in diverse patient populations.

Adaptive Trial Designs: Innovative trial designs that allow modifications based on interim results, improving efficiency and patient safety.

Regulatory Updates
Presentations on regulatory affairs provided updates on:

New Drug Applications (NDAs): Recent approvals and pending applications, highlighting the regulatory pathways and review processes.

Compliance and Safety Monitoring: Updates on pharmacovigilance practices, ensuring ongoing monitoring of drug safety post-approval.

Regulatory Harmonization: Efforts to standardize regulatory requirements across different regions, facilitating global drug development and approval.

Novel Therapeutic Approaches
Emerging therapeutic strategies were discussed, including:

Gene Therapy: Advances in delivering genetic material to treat or prevent diseases, with a focus on recent clinical successes and ongoing challenges.

Cell Therapy: Progress in using cellular products, such as CAR-T cells, for treating cancer and other diseases.

RNA-Based Therapies: Development of mRNA and RNA interference (RNAi) technologies for a range of therapeutic applications.

Case Studies
Case studies were presented to illustrate the application of these advancements in real-world scenarios:

Oncology: Development of targeted therapies and immunotherapies, with case studies showcasing successful treatments for various cancers.

Rare Diseases: Innovative approaches to treating rare and orphan diseases, highlighting the importance of accelerated approval pathways and patient advocacy.

Infectious Diseases: Efforts in vaccine development and antiviral treatments, particularly in response to emerging infectious threats.

Conclusion:

The presentations underscore the rapid pace of innovation in the pharmaceutical industry. Continued collaboration between researchers, clinicians, and regulatory bodies is essential to translate these scientific advancements into safe and effective therapies for patients worldwide.

The Pharmaceutical Industry: Navigating Innovation and Market Dynamics:
The pharmaceutical industry plays a critical role in advancing healthcare by developing life-saving drugs and therapies. However, it faces complex challenges related to drug pricing, regulatory frameworks, and market competition. Let's delve into key aspects of this dynamic sector:

1. Drug Development and Innovation

Drug Discovery: Pharmaceutical companies invest heavily in research and development (R&D) to discover new drugs. This involves identifying potential drug targets, conducting preclinical studies, and progressing to clinical trials.

Clinical Trials: Rigorous clinical trials evaluate drug safety, efficacy, and side effects. These trials are essential for regulatory approval and market entry.

Patents and Exclusivity: Patents protect innovative drugs, granting companies exclusive rights for a limited period. However, balancing exclusivity with affordability remains a challenge.

2. Pricing and Access

Rising Drug Costs: While innovation drives drug development, it also contributes to escalating drug prices. Balancing affordability and profitability is crucial.

Health Insurance and Access: Health insurance policies influence patient access to medications. Striking a balance between coverage and cost containment is essential.

Generic Drugs: Generic versions of brand-name drugs provide cost-effective alternatives once patents expire. Generic competition benefits consumers but affects pharmaceutical revenues1.

3. Market Dynamics

Global Competition: The pharmaceutical market is fiercely competitive. Companies vie for market share, often through mergers, acquisitions, and strategic alliances.

Market Entry Strategies: Companies choose between launching new drugs or extending existing product lines. Line extensions (LEs) allow leveraging existing brand recognition.

Strategic Delay: Some firms strategically delay introducing unpatented LEs to maximize profits. Balancing innovation and market timing is critical.

4. Marketing Strategies

Pharmaceutical Marketing: Effective marketing strategies are essential for product success. Companies employ various channels, including digital marketing, physician engagement, and direct-to-consumer advertising.

Research vs. Marketing Spending: Interestingly, pharmaceutical companies allocate more resources to marketing than R&D. This raises questions about priorities and resource allocation.

Here are a few examples of technical data presentations commonly found in the pharmaceutical industry:

Example 1: Efficacy and Safety of a New Oncology Drug:
Title: "Phase III Clinical Trial Results of XYZ-123: A Novel Targeted Therapy for Advanced Non-Small Cell Lung Cancer"

Objective: To present the efficacy and safety data from a Phase III clinical trial of XYZ-123.

Key Data Points:

- Patient Population: 500 patients with advanced non-small cell lung cancer (NSCLC).
- Study Design: Randomized, double-blind, placebo-controlled trial.

- Primary Endpoint: Overall survival (OS).

Results:

- Median OS for XYZ-123: 18.6 months (95% CI, 16.7-20.5)
- Median OS for placebo: 12.3 months (95% CI, 10.8-13.7)
- Hazard ratio: 0.65 (95% CI, 0.55-0.78; $p < 0.001$)
- Common adverse events: fatigue (45%), nausea (30%), neutropenia (25%)

Conclusion: XYZ-123 significantly improves overall survival in patients with advanced NSCLC with an acceptable safety profile.

Example 2: Biomarker Discovery in Alzheimer's Disease:
Title: "Identification of Novel Biomarkers for Early Detection of Alzheimer's Disease Using Proteomics"

Objective: To present findings from a study on the discovery of biomarkers for early detection of Alzheimer's disease (AD).

Key Data Points:

- Study Population: 200 individuals, including 100 with early-stage AD and 100 age-matched controls.
- Methodology: Proteomic analysis of cerebrospinal fluid (CSF) samples.

Key Findings:

- Identification of 5 novel protein biomarkers significantly elevated in early-stage AD patients compared to controls.
- Validation of biomarkers using ELISA showed high sensitivity (85%) and specificity (90%).
- Implications: These biomarkers could potentially be used for early diagnosis of AD, enabling earlier intervention and better management of the disease.

Example 3: Regulatory Update on Gene Therapy
Title: "Regulatory Pathways for Approval of Gene Therapies: Challenges and Opportunities"

Objective: To provide an update on the regulatory landscape for gene therapies.

Key Data Points:

Current Status: Overview of recent gene therapy approvals by FDA and EMA.

Challenges:

- Long-term safety monitoring requirements.
- Manufacturing and quality control complexities.

Opportunities:

- Expedited pathways such as Breakthrough Therapy Designation and Priority Review.
- Case study of a recently approved gene therapy for spinal muscular atrophy (SMA).

Conclusion: While gene therapies offer significant potential, navigating the regulatory pathways requires careful planning and adherence to stringent safety and efficacy standards.

Example 4: Advancements in mRNA Vaccine Technology
Title: "Next-Generation mRNA Vaccines: Enhancing Efficacy and Stability"

Objective: To discuss advancements in mRNA vaccine technology and their implications for future vaccine development.

Key Data Points:

Technology Improvements:

- Optimized mRNA sequences for increased protein expression.
- Enhanced lipid nanoparticle (LNP) formulations for better delivery and stability.

Preclinical Data:

- Increased immunogenicity observed in animal models.
- Improved thermostability allowing storage at higher temperatures.

Clinical Trials:

- Phase I trial results showing robust immune response with minimal adverse effects.
- Future Directions: Potential applications in infectious diseases, cancer, and personalized medicine.

Example 5: Real-World Evidence in Chronic Disease Management
Title: "Utilizing Real-World Evidence to Optimize Chronic Disease Management: Insights from the ABC Registry"

Objective: To present real-world evidence (RWE) on the management of chronic diseases from the ABC registry.

Key Data Points:

Registry Overview: Data collected from over 10,000 patients with chronic diseases such as diabetes and hypertension.

Findings:

- Treatment adherence rates and their impact on clinical outcomes.
- Comparative effectiveness of different treatment regimens.

Case Studies:

- Impact of patient education programs on medication adherence.
- Success of telehealth interventions in managing hypertension.

Conclusion: RWE provides valuable insights into the effectiveness of treatments in real-world settings, guiding better clinical decision-making and policy formulation.

The pharmaceutical industry is one of the most innovative and competitive industries in the world. The pharmaceutical industry according to report has made a jump from $40 billion in 2021 to an expected $130 billion in 2030, with projections hitting $450 billion by 2047. With an extensive range of products, it has to be competitive on multiple fronts, from research and development to marketing and sales.

Data science in pharmaceutical industry is extensively used to improve its operations through applications such as predictive modeling, segmentation analysis, machine learning algorithms, visualization tools, etc., which help improve decision-making processes. In this article, we have explained about data science in pharma, their use cases, opportunities, and more.

How is Data Science Used in Big Pharma?
Data science is used to improve the efficiency of drug development, sales, and marketing. It can help pharma companies understand their customers better and predict new trends in the market.

Data science in pharmaceutical industry can also help improve patient outcomes by analyzing data from clinical trials and other clinical studies to identify areas for improvement or new treatments. In addition, data scientists use machine learning algorithms that analyze large amounts of data at high speeds to make predictions about

future events based on historical patterns observed from past events (this is known as predictive modeling in pharma data science).

10 Use Cases for Data Science in Pharmaceutical Industry:
Here are the top use cases for Data Science in pharmaceutical industry:

- Utilizing Predictive Models for Drug Development
- Forecasting of Patient Flow/Demand
- Developing Data-Driven Decision Support Systems
- Facilitating Digital Sales and Marketing Efforts
- Medical Image Analysis
- Personalized Diagnosis and Treatment
- Calculating the Expected Life Cycle of Drug Patents
- Access to Real-Time Information via Health Apps
- Reduction of Drug Side Effects and Adverse Reactions
- Improving the Efficiency of Clinical Trials

1. Utilizing Predictive Models for Drug Development:
Predictive models are extremely helpful in drug development because they help to predict future results based on past observations. For example, if a patient has been using a certain medication for a long time and has not caused any side effects yet, then it might be safe for that patient to continue using this medication. On the other hand, if there is some new information about this patient's health that suggests that continuing with their current treatment might be dangerous (e.g., heart disease), then predictive models can determine which option will give them more benefit overall continuing with their current medication or switching over to another type?

These models in pharmaceutical data science help these companies understand their patients better and make better decisions about what kind of care they need to get healthier faster. This is done by pharmaceutical data scientists through advanced methods such as machine learning algorithms, and deep neural network models, along with regular old-fashioned regression analysis techniques from textbooks.

2. Forecasting of Patient Flow/Demand:

Figure: Forecasting of Patient Flow

Yet another use case of Data Science in the pharma industry is forecasting the patient flow and demand for a particular drug or medicine. This is an important use case as it helps pharmaceutical companies to determine the production rate and meet the market demand.

Existing data and surveys can help build models that can suggest the number of patients that will require the medication in upcoming days, weeks, or months. This helps the companies keep a check on their production pipeline. They can meet the existing and upcoming demands while minimizing wastage.

3. Developing Data-Driven Decision Support Systems:

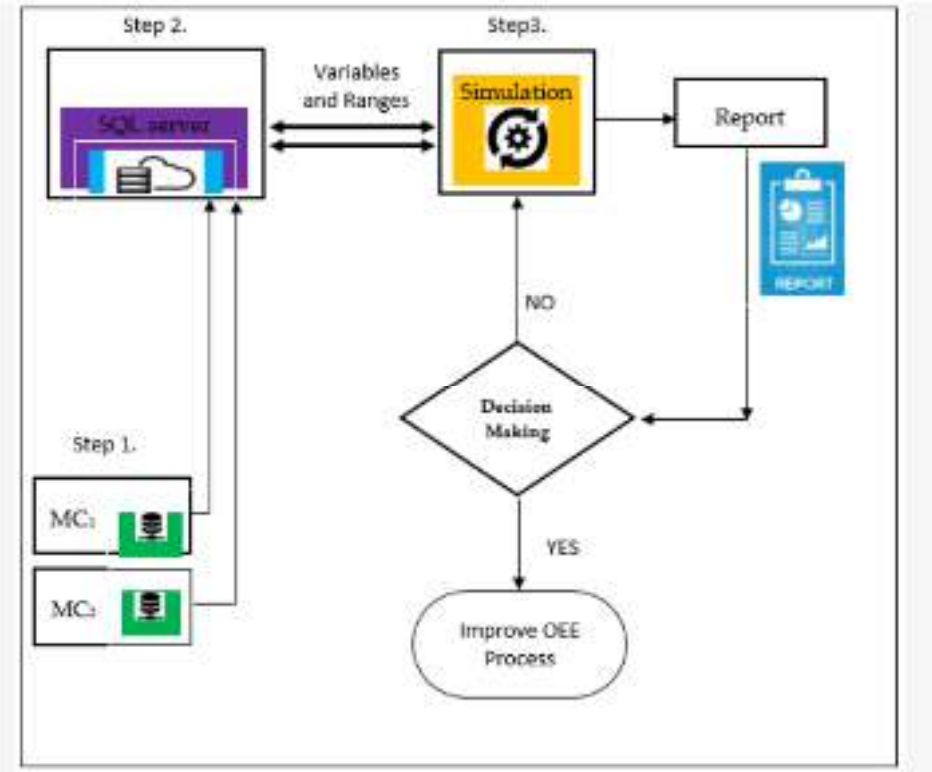

Figure: Data Driven Decision Support System

Data-driven decision support systems (DDDS) are an important part of the pharma industry, especially in clinical research and development. DDDS helps to improve decision-making by analyzing data and providing real-time insights about the effectiveness of a drug on different patient populations.

Data scientists analyze large amounts of information from various sources like clinical trials, regulatory documents, pharmacokinetic studies etc., to create a holistic view of how a drug works with different patient populations. They then use this information to inform clinical trial design decisions or generate new hypotheses for future research efforts.

4. Facilitating Digital Sales and Marketing Efforts:

Data science has become an important part of the pharmaceutical industry's digital marketing efforts. It's used to help companies understand their customers, who they are, and what they need. The data helps them develop new products or processes that will effectively reach these individuals.

Data scientists can also use their skillset to help with sales initiatives and other aspects of business-to-business (B2B) relationships using predictive analytics tools like predictive sales models and predictive bidding algorithms that determine when it's best for a company to buy from another company based on specific criteria such as price or quality levels for products being sold at different times during each day/week/month etc.

5. Medical Image Analysis:

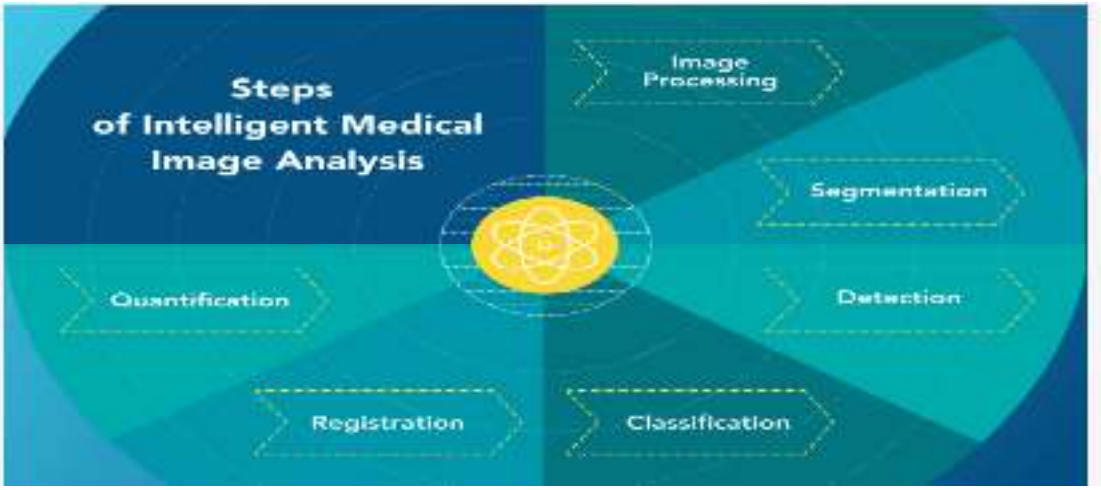

Figure: Medical Image Analysis

Another advanced and revolutionizing use case of Data Science in pharmaceutical industry is Medical Image Analysis. Analysing medical images has been proven to identify the tiniest microscopic defects.

With the help of Deep Learning techniques in Data Science, the software can be built to understand and interpret images like X-rays, MRIs, mammograms, etc.

These advanced techniques can also be used to study the growth of a certain microorganism, such as bacteria in the human body, which can further help pharmaceutical companies to design an effective drug that can counteract the observed growth pattern of that microorganism.

Before learning about these advanced techniques, one can first learn data science for pharmaceutical industry by opting for a course that teaches data science in pharmaceutical industry.

6. Personalized Diagnosis and Treatment:

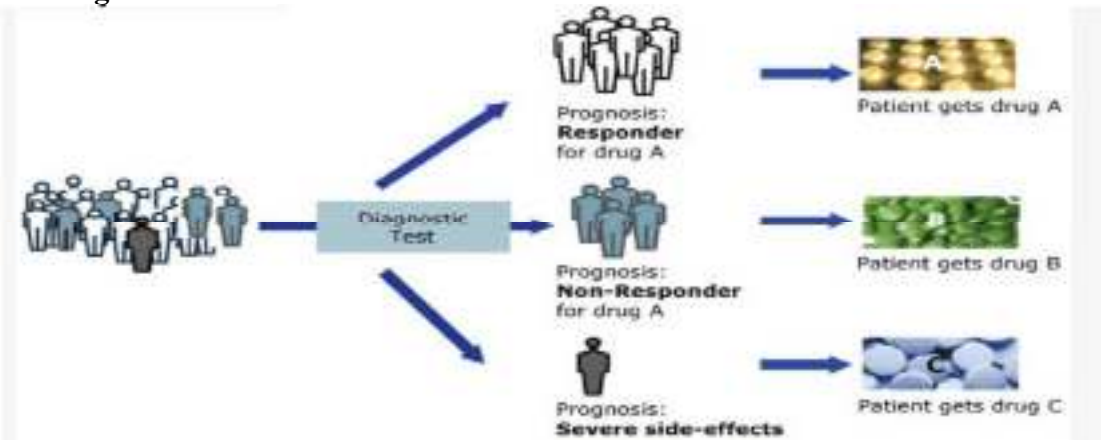

Figure: Personalized Diagnosis and Treatment

Personalized medicine is a buzzword in the healthcare industry, and it's something that has been talked about in the Data Science world for a while now. The concept of personalized diagnosis and treatment is not new, but its use in drug development has recently become more widespread.

This means that the doctors can already see what kind of drug will work best for each patient based on their individual symptoms and genetic makeup. This type of personalized care helps patients get better faster, saving money on unnecessary tests and procedures that aren't needed right away (or ever). It also means having fewer side effects—and therefore lesser overall health costs.

7. Calculating the Expected Life Cycle of Drug Patents:
A patent life cycle is a time between the date a patent application is filed and the date on which the patent expires. This can be used to determine how much money the company can make with the drug and whether it will be profitable with the help of Data Science in Pharma.

In order to calculate this, they need to know how long it takes for some other drug company to come up with an idea of its own. This can be determined up to a certain degree with the help of Data Science and Machine Learning using past data.

8. Access to Real-Time Information via Health Apps:

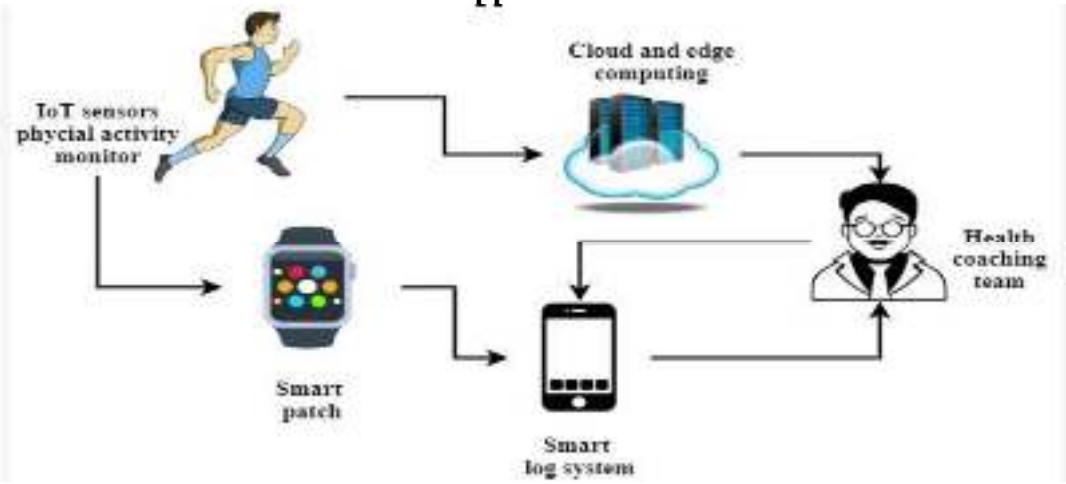

Figure: Accessing Real-Time Information

If you are a pharma company and want to use data science in your business, you must have access to real-time information on the health of your patients. This is possible by using health apps that gather real-time health data from the users.

These Health apps are available for almost all smartphones and tablets, so there's no need to buy special equipment or software before starting out with this type of data analytics solution.

For example, an app tracks your daily activities such as walking steps taken per day (or just minutes) and calories burned by burning off energy during exercise sessions at home or the workplace; how much time did it take from waking up until getting dressed? etc. It can then help keep track of what kind of exercise regimen works best for each individual user based on their specific needs.

Another example would be an app that allows users to track their blood pressure levels via an easy-to-use interface. This can help the user stay informed about any irregular levels that she needs to be worried about.

9. Reduction of Drug Side Effects and Adverse Reactions:
Drug side effects and adverse reactions are major causes of patient dissatisfaction. In the United States alone, over 30 million people suffer from drug-induced illnesses each year, which cost an estimated $200 billion in medical expenses and lost productivity.

Data science can help reduce these problems by reducing the likelihood that patients will experience them by using predictive models to identify high-risk patients prior to prescribing medications.

10. Improving the Efficiency of Clinical Trials:
Data science is helping to improve the efficiency of clinical trials by automating processes, increasing accuracy, and reducing costs.

As a result, it has become necessary for pharmaceutical companies to conduct more clinical trials in order to improve their products' efficacy and reduce their costs. The number of clinical trials conducted has increased by over 500% since 2000. This increase can be attributed largely to the increased demand for new drugs coupled with rising prices due to supply constraints.

In order to ensure that these new technologies are used as efficiently as possible, pharmaceutical companies need professionals who understand how data science works within their organizations and also know how this technology can help drive improvements across multiple departments such as quality control or research & development.

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Data Usage in the Pharmaceutical Industry:
Data usage in the pharmaceutical industry is a major trend. As we saw above, Data Science has been used for many different functions, such as sales, marketing, and customer service. It's also used for drug development and clinical trials.

To leverage Data Science properly, the pharmaceutical industry has at its disposal a huge variety of historical data with millions of records. This data is judiciously used in accordance with the health care standards and laws.

The use of data science in pharmaceutical industry is only possible because of the data that's available. From clinical trials to marketing and sales to image data, the pharmaceutical industry uses all kinds of it to utilize the power of Data Science, including Natural Language Processing, Machine Learning, and Deep Learning.

Collaboration Between Big Pharma and Big Data:
Proper collaboration between Big Pharma and Big Data has helped the industry reduce R&D costs, make clinical trials better, escalate drug discoveries, control drug reactions, and focus on sales and marketing.

The ability to collect and analyze data from many sources can help drug companies find new ways to treat diseases, but it also has the potential to improve patient outcomes. For example, one study found that when doctors used electronic health records (EHRs) in conjunction with genomic information about their patient's genetic makeup, they could identify which treatments were most effective for certain illnesses. This allows physicians and researchers alike to make better decisions about what kind of treatment options are best suited for each individual patient and ultimately helps ensure better care overall.

Using Predictive Analytics Models in Pharma:
Here are how predictive analytics models are being used in Pharma:

Predictive analytics models can be used to predict the probability of the occurrence of an event. They are also known as "predictive models" or "prediction engines" in the context of data science.

Predictive models allow you to make predictions about future events with high accuracy and confidence levels that is, they can provide information about what will happen next based on past observations or trends within your dataset (e.g., customer purchase history). Note that these predictions are not guaranteed but are backed by a significant degree of confidence.

Predictive models have become very common when it comes to applications of Data Science in pharmaceutical industry. They drive most of the decision-making process of the industry. These predictive models learn the patterns from pre-existing clinical data and can answer some questions based on response and input variables.

Various Machine Learning techniques are used to build these strong predictive models that can work efficiently with Big Data and help pharmaceutical brands forecast various trends. From predicting drug behavior in clinical trials to forecasting sales, predictive models are widely helpful in the pharmaceutical industry.

Opportunities in Pharmaceutical Data Science:

Data Science for Better Follow-up with Patients:
Data Science can help pharmaceutical companies to understand their customers better. By analysing patient interaction and visits with the doctor, Data Science can be used to understand the current relationship between the two.

This developed understanding can then be used to further improve doctor-patient interactions by suggesting better follow-ups with the patients to the doctors. Analyzing a patient's behavior such as visit frequency, lab tests, and drug history combined with her personal information and medical history can be used to understand the needs of a patient.

Conclusion:
The data science in pharmaceutical industry is evolving rapidly, and so must its methods of data analysis and analytics. There are many opportunities for companies to improve the efficiency of their processes, develop innovative new drugs, and decrease risks for patients. The future will bring more efficient processes, better patient outcomes, and increased profitability in this industry as organizations adopt new technologies like Machine Learning algorithms that can help them achieve these goals.

Understanding Pharmaceutical Marketing: Navigating the Complex Landscape of Healthcare Promotion:
For many business leaders, sales and marketing are interchangeable specialties with a singular goal: increasing revenue. However, sales and marketing teams should align together for a single objective. The truth is that they are distinct fields with differing strategies.

Marketers often prioritize brand equity and capturing customers' attention, while salespeople focus exclusively on immediate customer conversions. And more importantly, sales needs marketing to succeed.

This is especially true within the pharmaceutical industry. Digital marketing's rise makes it crucial for business leaders to grasp how marketing functions in the current landscape. And the best place to start is by answering a critical question: what is pharmaceutical marketing.

Overview of Pharmaceutical Marketing:
Pharmaceutical marketing, often referred to as pharma marketing. Pharmaceutical marketing is a set of activities to increase awareness of and loyalty to pharmaceutical brands and products.

Figure: Overview of Pharmaceutical Marketing

Although its primary objective is to increase product awareness. Along with driving demand, and ultimately influencing healthcare professionals and consumers to choose a particular brand over others.

Pharmaceutical marketing also aims to create a positive image of the drugs and the companies that manufacture them. It attempts to accomplish this by presenting scientific data, case studies, testimonials and other content persuasively.

To do this, pharma marketers activate various channels, including digital marketing, traditional marketing (TV and Print), branding, direct-to-consumer advertising, and events.

Target Audiences in Pharmaceutical Marketing:
However, to be successful at increasing product awareness and driving demand. Pharma marketers must first understand who their target audience is and how to reach them. So, who is the target audience for pharma marketing?

Healthcare Professionals: The primary target audience for pharma marketing is healthcare professionals (HCPs), including physicians, pharmacists, nurses, and other medical professionals. Pharmaceutical marketing aims to educate HCPs about the benefits and risks of various drugs. Their usage, administration, and to improve their prescribing behavior. Pharma companies can improve the chances of prescribing and selling their drugs by engaging with HCPs.

Patients: Additionally, pharma marketing targets patients and caregivers to promote products and create brand awareness. Direct-to-consumer marketing has become increasingly prevalent.

The Role of Digital and Mobile Marketing in Pharma:
While the target audience for pharma marketing is specific, pharma marketing strategies can vary. But they all have an underlying goal; to persuade the target audience to take action. The following are a few common channels pharma companies use to reach them.

Pharma Digital Marketing: With most people's lives centred around the digital space. Online marketing tactics have become increasingly popular among pharma companies.

They use interactive websites, social media, SEO, and targeted Ads to reach HCPs and patients. HCPs receive product info and data through newsletters, emails, digital catalog, and text messages. For patient-centred marketing, the goal is to make people aware of a brand and educate them about a health issue.

Digital marketing also offers valuable data to pharma companies. Which can help them understand the customer's needs better, make informed decisions, and create personalized marketing campaigns.

Pharma Mobile Marketing: Mobile technology has simplified its engagement by offering a direct channel of communication. This allows HCPs and patients to communicate with pharma reps at any time, on any device. Mobile technology also accelerates the time it takes to receive information. Rather than scheduling an in-person meeting, HCPs and patients can connect with reps at their convenience.

The Use of Direct-to-Consumer Advertising in Pharmaceutical marketing:
DTCA is a type of advertising that focuses directly on patients. DTCA promotes prescription drugs, medical devices, and health services. Supporters of DTCA say it can make people more aware of health issues and treatments, leading them to seek medical advice. Despite its criticisms, DTCA remains a popular marketing channel. Pharma companies that use it must be careful about creating accurate and informative advertisements.

Engaging Healthcare Professionals: Conferences and Events:
Pharma companies often sponsor and participate in medical conferences and events. These conferences and events provide education and networking opportunities for healthcare professionals to exchange new product information and data.

These conferences provide a platform to launch new products, engage with HCPs, and create a positive brand image. The conferences provide opportunities to showcase equipment, technologies, and services, and they offer an environment for networking and developing relationships with HCPs. For pharma companies, this is an opportunity. In these events they showcase their products and offer solutions to the challenges faced by HCPs.

Networking and Information Exchange in Pharma Industry:
Pharma companies often hold educational events for healthcare professionals to learn about their products and how to use them. These events allow HCPs to learn more about the product, its features and benefits, and how it can solve a specific health problem.

Events also allow pharma companies to demonstrate how their product can offer solutions to everyday healthcare issues. Webinars are also a cost-effective way of reaching HCPs and increasing brand awareness.

Figure: Network and Information exchange

The Role of Pharmaceutical Sales Representatives in Pharma Marketing:
Pharmaceutical sales representatives have been a crucial component of pharma marketing for decades. These representatives engage with HCPs directly to provide product information and samples. Training programs equip sales reps with the ability to understand the unique challenges and ideas in the healthcare industry.

They are knowledgeable about the latest products and trends in the market. They offer a personal touch, which digital marketing fails to provide. They can also offer responsive and timely solutions to individual HCPs' needs.

Navigating Regulatory Compliance in Pharmaceutical Marketing:
Pharmaceutical marketing poses several unique challenges that other industries do not face. Pharma marketers must balance the need for effective marketing with regulatory compliance, changing healthcare landscapes, public perception and trust, and ethical considerations. Here is a more detailed examination of each aspect.

Regulatory Compliance: Pharmaceutical companies must adhere to strict regulations designed to protect public health. Balancing the need for effective marketing with regulatory compliance requires a nuanced approach. Pharma marketers need accurate messaging and regulatory approval before launching campaigns to avoid misleading information. To adhere to regulations, pharma marketers must walk a fine line between promoting and providing truthful information.

Adapting to the Changing Healthcare Landscape:
The healthcare landscape is continually evolving, with advancements in medical technology and changes in treatment paradigms. Keeping marketing strategies aligned with emerging trends is crucial, and pharma marketers must stay updated with the latest developments. Doing so can ensure their marketing campaigns remain relevant and effective in a rapidly changing market.

Building Trust: Ethical Considerations in Pharmaceutical Marketing:
Keeping the public's trust is always hard for people who market medicines. This is especially true when there are problems with how much drugs cost, worries about safety, and questions about what is right and wrong.

Building and sustaining trust requires transparency and ethical marketing practices. Ethical pharmaceutical marketing involves providing true and accurate information to patients and healthcare professionals. Pharma marketers can also benefit from being transparent. They must communicate with stakeholders and respond to inquiries or concerns to rebuild trust.

Balancing Transparency and Promotion:
Striking a balance between providing necessary information about pharmaceutical products and avoiding overly promotional tactics is another critical consideration.

Patients and healthcare professionals should receive accurate, unbiased information to make informed decisions. That's why transparent communication about the benefits and risks of pharmaceutical products is essential. Concealing or downplaying potential side effects can erode trust and lead to ethical concerns.

Avoiding Unfair Competition:
Unfair competition practices, such as spreading misinformation about competitors' products, undermine the industry's integrity. Pharma marketers should always focus on the merits of one's own products rather than disparaging others.

The Crucial Role of Pharmaceutical Marketing in Advancing Healthcare:
There is no doubt that pharmaceutical marketing plays a pivotal role in promoting innovative medical solutions. The term "pharma marketing" often elicits varied responses, ranging from scepticism to admiration. Its significance lies in its ability to educate, inform, and connect stakeholders in the healthcare ecosystem. It is a dynamic and indispensable aspect of the healthcare industry, and it helps pharma companies succeed by achieving the following.

Figure: Crucial Role of Pharmaceutical Marketing in Advancing Healthcare

Pharma marketing is a conduit for disseminating critical information about pharmaceutical products, medical devices, and healthcare services. The healthcare world is always changing fast with new science. This makes it hard for doctors, nurses, and patients to keep up with new things. Marketing helps by making sure everyone knows the latest information about new treatments, medicines, and medical tools.

Pharmaceutical Marketing: Bridging Information Gaps:
Pharma marketing helps healthcare professionals learn how drugs work, their good effects, and their safety. Knowing this is important for selecting the correct treatments for patients, especially in areas with numerous new options.

Accelerating Patient Access to New Treatments:
One of the primary goals of pharma marketing is to facilitate timely and widespread access to innovative healthcare solutions. Through targeted promotional campaigns, pharmaceutical companies can raise awareness about breakthrough treatments and medications. This ensures that healthcare professionals receive information about new options for managing diseases and improving patient outcomes.

For patients, pharma marketing can be empowering. Awareness campaigns educate individuals about specific medical conditions and inform them about available treatment options. This knowledge enables patients to engage in more meaningful conversations with their healthcare providers. As they actively participate in treatment decisions, and, in some cases, advocate for their own health.

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Pharmaceutical Marketing and Research & Development:
Pharma marketing is integral to the economic sustainability of the pharmaceutical industry. By creating demand for innovative products, marketing efforts contribute to the financial resources needed for ongoing research and development. The revenue generated from successful marketing campaigns allows pharmaceutical companies to reinvest in creating new drugs, medical devices and therapies. The pharmaceutical market is very competitive. This makes companies work hard to create new and better products. They need to use good marketing to tell people about these new products. If they don't, they won't make enough money to pay for the research and tests needed to make new treatments

Educational Role of Pharma Marketing for Healthcare Professionals:
Healthcare professionals like doctors, and others need clear and complete information to choose the best care for their patients. Pharma marketing serves as an educational resource, providing healthcare professionals with insights into the latest clinical data, treatment guidelines, and emerging therapeutic approaches.

Through avenues such as medical conferences, seminars and digital platforms, pharmaceutical companies engage healthcare professionals in discussions about disease management and treatment options. This continuous exchange of information enhances the expertise of healthcare providers, contributing to improved patient care and outcomes.

Addressing Public Health Challenges Through Pharma Marketing:
Pharma marketing is important for public health. It helps people learn about how to prevent diseases, manage them, and know about treatments. Pharma companies start campaigns to teach people about health issues. This helps people act to lower the chances of getting sick.

For instance, they do campaigns on vaccines, handling diabetes, or mental health support. These campaigns add to public health work. Pharma companies use their large marketing networks to spread health information far and wide. This helps many different people learn more about how to prevent health problems.

Supporting Patient Assistance Programs:
Pharmaceutical companies often collaborate with advocacy groups and establish patient assistance programs to ensure that individuals with financial constraints can access essential medications. These programs, supported and promoted through marketing efforts, provide discounted or free medications to eligible patients, addressing socioeconomic disparities in healthcare access.

Pharma marketing supports programs that help people get healthcare. This means that those who need it can receive important treatments.

Pharmaceutical Marketing in the Era of Personalized Medicine:
The healthcare landscape is continuously evolving, marked by technological advancements, changing treatment paradigms, and a greater emphasis on personalized medicine. Pharma marketing plays a crucial role in helping

stakeholders navigate these dynamics by providing information about emerging therapies, diagnostic tools, and treatment modalities.

Through targeted educational campaigns, pharmaceutical companies prepare healthcare professionals and patients for the integration of novel technologies and treatment approaches into routine clinical practice. Being flexible is key in healthcare. It helps meet the changing needs of patients and the community.

The healthcare industry shall never doom with continuous researches for better medicines due to new challenges. The current Covid-19 pandemic wave all over the world stands a strong testimony for this sector. This unanticipated universal contagious disease is turning out to be a boon for the pharmaceutical sector in India as it continuously plays a vital role in supplying essential medical supplies to the world. The country is an active and substantive contributor to WHO demands of Diphtheria, Pertussis, BCG and Tetanus vaccines which accounts for nearly 40-70% as they are regarded as safe and high quality.

Why pharma exports from India?

The discovery of multiple effective and safe vaccines for various diseases including Covid-19 has provided the much-needed reputational boost to pharmaceutical products in India. As there is an unprecedented push to manufacture billions of doses this year, the pharma exports from India are set to reach new heights. India is seen as the epicentre for manufacturing pharmaceutical products due to the availability of various resources and low cost. The country is called "pharmacy to the world" and has always been a major exporter of medicines to Africa, Rwanda, the US, Zimbabwe and many other nations.

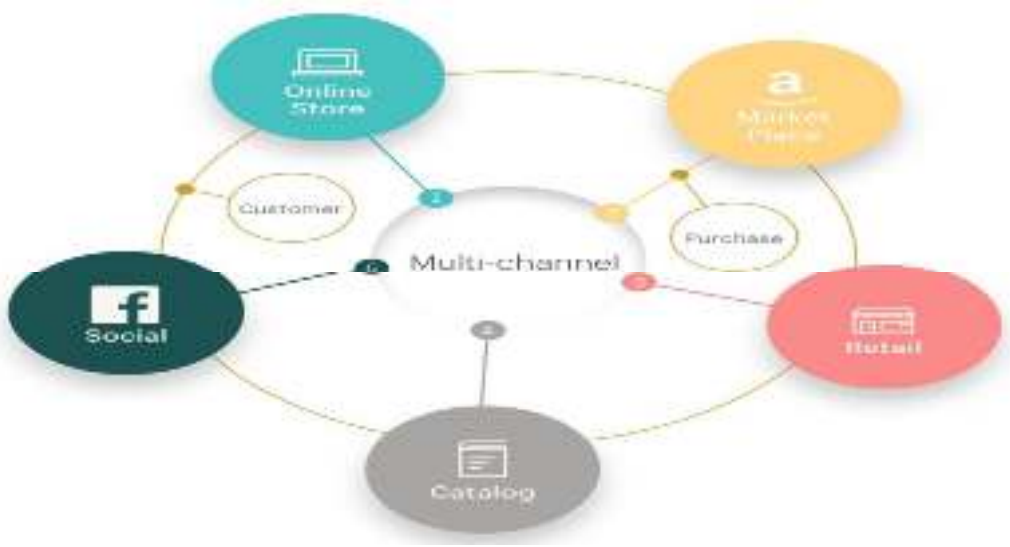

Figure: Marketing Strategies of Pharmaceutical Products in India

What medical tactics to use?

To increase the pharma exports from India as well as within the country, the pharmaceutical products in India need to be well advertised. The pharma companies in Mumbai and other states may face a wide number of challenges. Hence to have a customer-centric approach, the manufacturer of pharmaceutical products in India need to followsome tactics to attract the medical practitioners, and subsequently their patients which are:

- Identify your target customers
- Up-to-date and good social media presence
- Appropriate and well-designed leave-behinds for good remembrance
- Focus on problem more for easy acceptance of solutions
- Less information to arouse the curiosity of customers

Figure: Usage of Medical Tactics

Which marketing strategies to use?

The pharmaceutical products in India see a large margin of profits as they are driven by large foreign demands. As a result, the pharma exports from India guarantee a promising number to pharma companies in Mumbai and other places. To ensure the pharmaceutical products in India get their right value and large customer base, the manufacturers need to ascertain a few of the latest marketing strategies:

Unique promotions:

To promote pharmaceutical companies in Mumbai and other areas, the manufacturer and salesperson need to devise out-of-the-box promotional ideas such as hiring an influencer/celebrity or a reputed or a reputed practitioner, offering heavy discounts and personal aides for adverse effects.

Brand marketing:

Having an online presence; own website and active social media pages.

Transparency:

Being transparent to your customers can automatically turn them into your advertisers.

Generic Marketing:

Have and develop good professional relations with retailers that they sell your products for a maximum.

Upsell your products:

Suggesting another product to a customer when they already have one in their cart or shopping bag can assist to increase your sales.

The pharmaceutical companies in Mumbai andother regions can set new benchmarks for the world if they adopt technology to reach out to the doctors and end users. By using digital marketing and branding strategies, the sellers can reach the target audience easily and have a platform for discussing remedies for their patients along with the concerned medical professional. This will encourage people to approach doctors and even pharmaceutical suppliers.

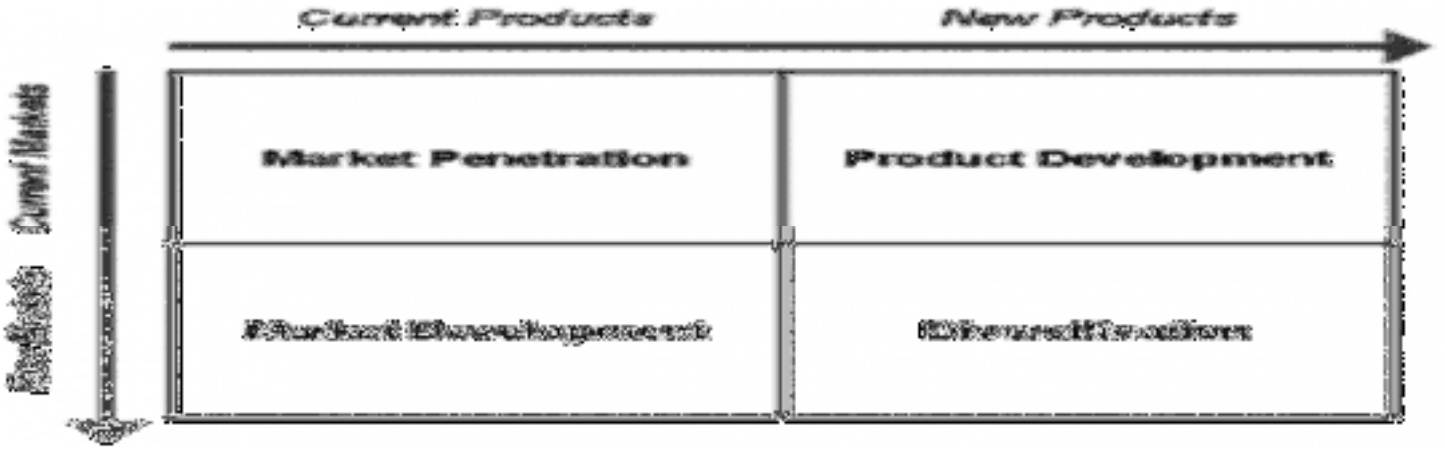

Figure: Marketing Strategies

Conclusion: The Future of Pharma Marketing

Even though pharma marketing is complex and always changing. Pharmaceutical marketing is a very important part of making progress in healthcare. From bridging information gaps and accelerating patient care to fostering research and development, the impact of pharma marketing reverberates across the entire healthcare ecosystem.

By serving as a conduit for knowledge, promoting preventive measures and supporting patient assistance programs. It contributes not only to the success of individual pharmaceutical products but also to the overarching goal of advancing public health. And as the healthcare industry continues to evolve, so will pharma marketing.

Class – 22

General Anatomy:

Let's begin with the basics of human body drawing. A well-proportioned figure, regardless of variations due to gender and such, is defined by the alignment of the joints, which is invariable (that is, we perceive something odd if it does vary). This is our groundwork for the proportions of a human body diagram. Draw your own chart with me as we go—it really helps with learning the material.

To learn how to draw a body, we start with the head. Start by drawing an oval or egg shape (pointy end down) for a head, and mark down eight measurements, the last one being the ground.

The measurement (ideal male height = eight heads) was set down during the Renaissance as an idealization of the human form. It's rather obvious that very few people are actually eight heads tall (even Northern Europeans, who served as the basis for this model, are closer to seven heads), but this is still the best model to start your anatomy drawing, as it makes it easier to grasp the alignments.

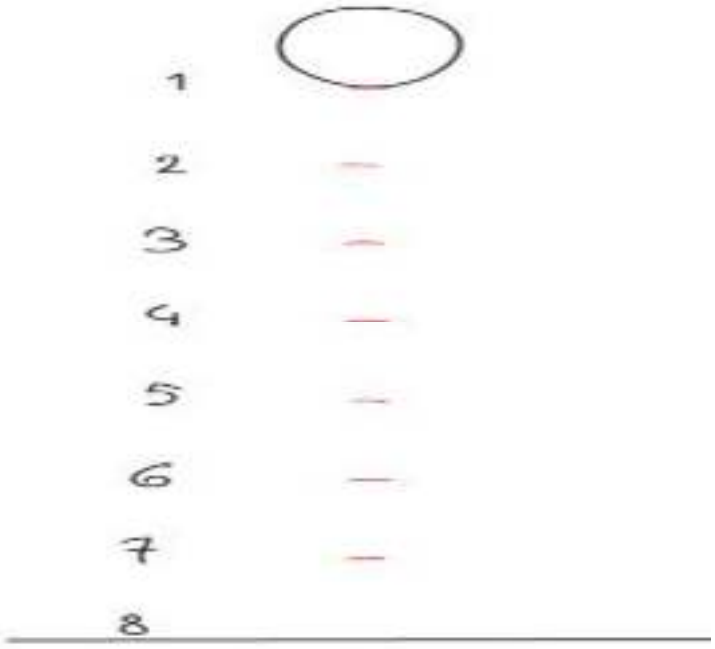

Figure: Human body drawing reference for the head

Learning anatomy is similar to building a house; if the foundation is strong then it will last for a lifetime. This subject is definitely difficult and filled to the brim with details, but the basics keep cropping up time and time again. You will constantly use them as reference when learning new anatomical concepts, thus mastering the fundamentals is essential.

So, what are these foundations? In the realm of anatomy, they include:

- Terminology, planes, body movements
- Regions of the body

- Organ systems
- Regional neurovasculature

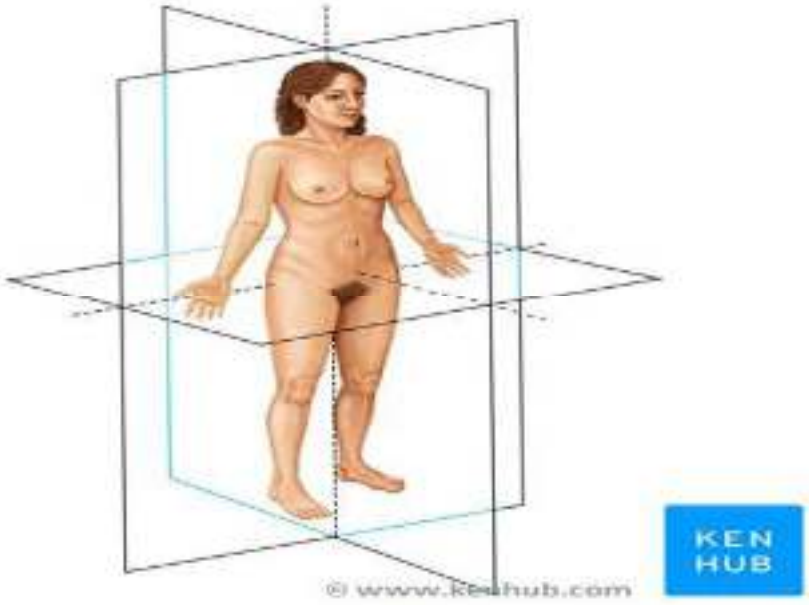

Figure: Anatomical position and body planes

Before we move to the specific terminology, a quick reminder that the wonderful thing about human anatomy terms, is that in many cases, the names of anatomy related content are incredibly helpful if you just understand that often the words can be broken down into different parts that have meanings.

Anatomical terminology	a list of terms that concern with the anatomy of the human body. it gathers the terms that pertain to the anatomical regions and specific structures, planes, directions and body movements
Anatomical planes	Imaginary planes that intersect the body, creating slices of inner body structures at different levels. Major planes: median (mid-sagittal), sagittal, frontal (coronal), transverse (axial).
Directional terms	Anatomical terms used to describe the position and relation between various structures (e.g. anterior, posterior, ventral, dorsal, proximal, distal, median, medial, lateral)
Movements	changing the position of a body part around a certain axis and in one of the anatomical planes (e.g. flexion, extension, abduction, adduction)
Anatomical regions	Areas of the human body defined by the landmarks provided by evident structures that are easily palpable or visible. major regions: head, neck, thorax, abdomen, pelvic, upper extremity, lower extremity
Human body systems	a group of organs that work together to perform one or more functions in the body. Systems: circulatory, respiratory, digestive, nervous, excretory, endocrine, reproductive, lymphatic , skeletal, and muscular systems

Table: Key Facts about the basic anatomy and terminology

Anatomical terminology:
The most basic anatomy concept, and equally the most important, is orientation. All structures and the relationships between them are referenced to the standard anatomical position. In this orientation, the person is considered to be standing upright, with the arms hanging by the side, palms facing forward, and thumbs pointing away from the body. The feet are slightly parallel, and toes oriented to the front. To compare the location of body parts relative to each other, anatomy uses some universal directional terms: anterior, posterior, ventral, dorsal, distal, proximal, medial, lateral, median, superior, inferior, external, internal, frontal, occipital, rostral, caudal, superficial, deep, central, peripheral, ipsilateral, contralateral, cranial, and cephalic.

Apart from the directional terms and relationships, you also need to know from which direction you're looking. This is provided by the three body planes and axes: coronal (frontal), sagittal, and transverse (axial).

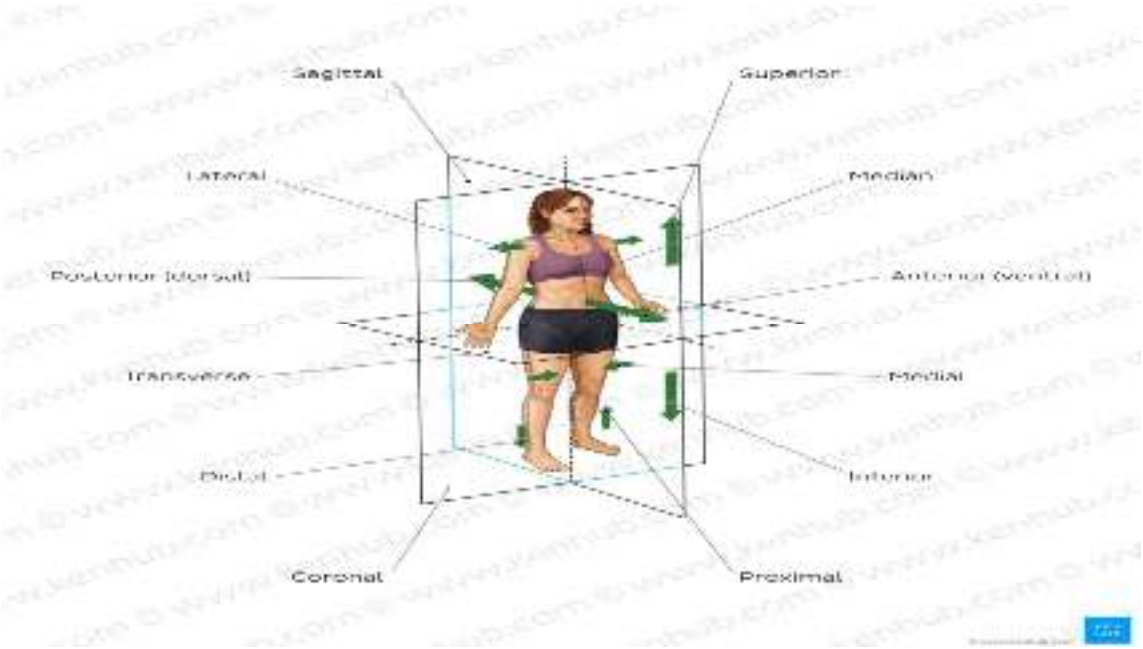

Figure: Directional terms and body planes

In terms of movements, the human body is capable of many of them. Depending on the type of joint in question (the synovial joint being the most flexible), there is: flexion, extension, abduction, adduction, protrusion, retrusion, elevation, depression, lateral (external) rotation, medial (internal) rotation, pronation, supination, circumduction, deviation, opposition, reposition, inversion, and eversion.

Anatomical regions:
The entire human body is divided into regions, an approach called regional anatomy. Each main area (head, neck, thorax, abdomen, upper, and lower extremities) is divided into several smaller regions that aid compartmentalisation.

Head regions	frontal, parietal, temporal, occipital, auricular, orbital, infraorbital, buccal, parotid, zygomatic, nasal, oral, and mental regions
Neck regions	submandibular, submental, carotid, muscular, lesser supraclavicular, occipital, omoclavicular, suboccipital triangles/regions
Posterior trunk regions	[illegible], supravesicular, interscapular, scapular, infrascapular, vertebral, lumbar, sacral, gluteal, and anal regions
Anterior trunk regions (thorax and abdomen)	presternal, pectoral, inframammary, hypochondriac, epigastric, lumbar, inguinal, umbilical, and pubic regions
Upper limb regions	infraclavicular, clavipectoral, axillary, deltoid, scapular, anterior arm, posterior arm, anterior forearm, posterior forearm, anterior cubital, posterior cubital, anterior carpal, posterior carpal, palm of hand, dorsum of hand
Lower limb regions	Femoral, anterior thigh, posterior thigh, anterior knee, posterior knee, anterior leg region, posterior leg region, calcaneal, retromalleolar, dorsum of foot, and sole of foot regions

Table: Anatomical regions of the Human Body

There are many regions in total, so here are some resources to help you learn more about each of them.

In addition to the regional approach, there is the surface anatomy approach. Here, the evident and palpable surface features of the body are described. There are common ones to both males and females, but also gender specific surface markers.

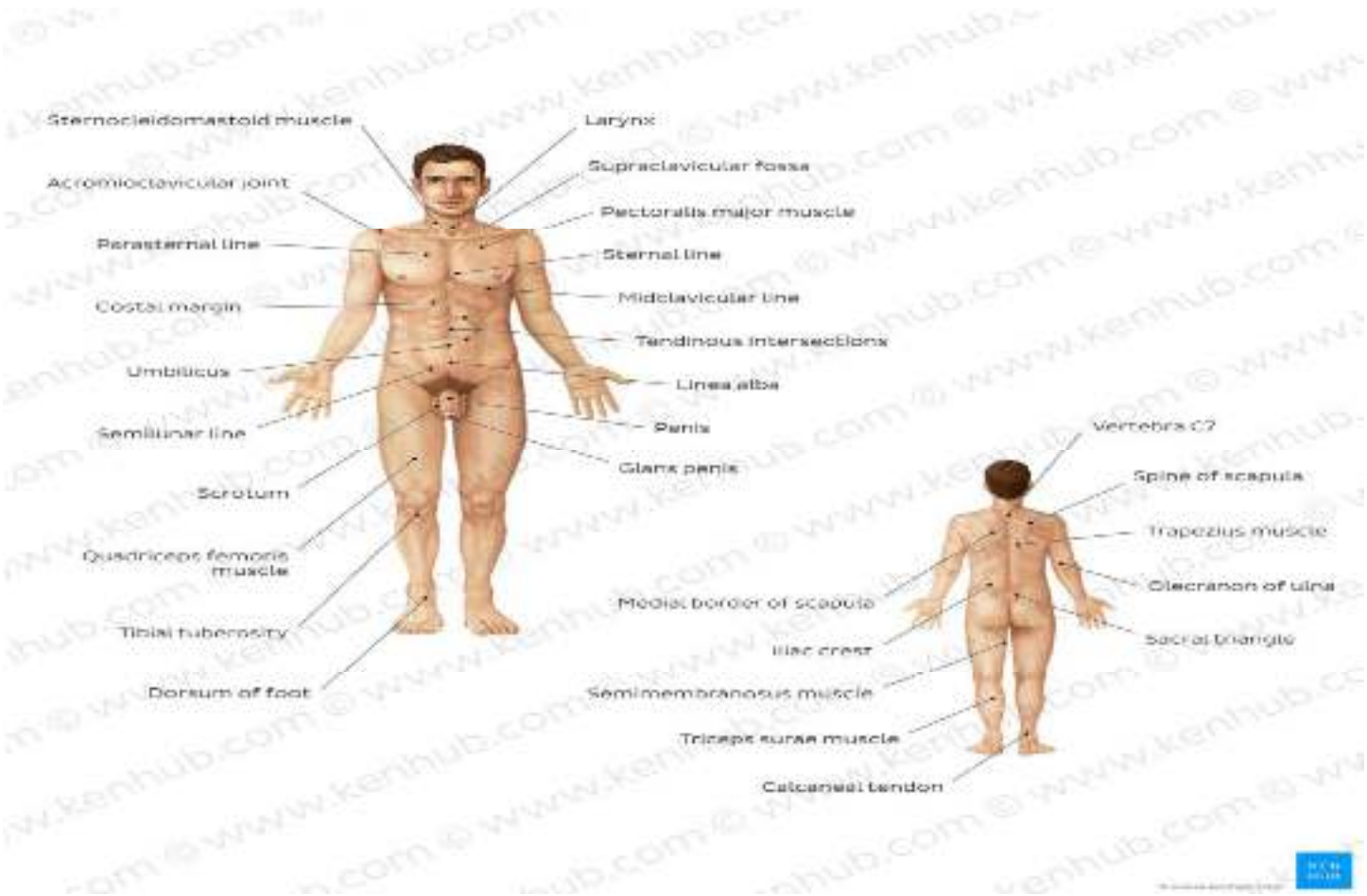

Figure: Male body surface anatomy (anterior and posterior views)

Underneath the surface of the body, there is another 'anatomical region'. This consists of the cavities of the human body which house many vital organs, neurovasculature, and anatomical structures. There are five major body cavities: cranial, thoracic, abdominal, pelvic, and vertebral cavities. Many of them are subdivided into smaller ones. In particular the thoracic cavity, it consists of the pleural, pericardial, and mediastinal cavities.

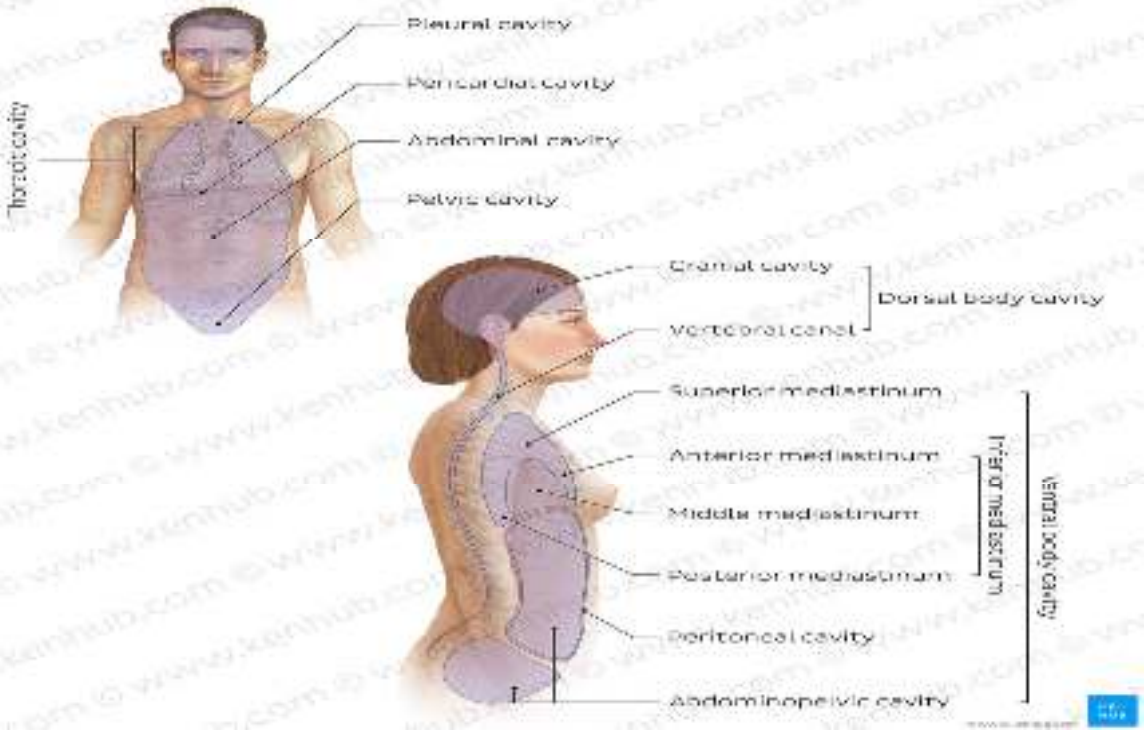

Figure: Cavities of the body (anterior view)

Class – 23

Basic Physiology:
Anatomy and physiology is the study of the body's systems and structures and how they interact. Anatomy focuses on the physical arrangement of parts in the body, while physiology studies the inner functioning of cells, tissues, and organs. This section will review the body's major systems: the musculoskeletal system, the circulatory system, the nervous system, the digestive system, the respiratory system, and the integumentary system.

Figure: Basics of Physiology

The Musculoskeletal System
The musculoskeletal system is a system of bones and muscles working together. The musculoskeletal system provides structure to the body, allows for movement, and physically protects the body's other systems.

- The skull consists of multiple flat bones that interlock and form a protective space for the brain. They also create the structure of the face and mouth with many attachments for the muscles that allow for all head movement.
- The spine is made of multiple interlocking vertebrae with a central channel for the spinal cord and exit points for the nerves. Like the skull, it protects the spinal cord and provides attachment points for both muscles and ribs.
- The thoracic cage or "rib cage" provides the rigidity of the chest, which is vital to the expansion and contraction of the lungs, making the rib cage vital to the respiratory system. It also serves to protect the vital organs within the chest.
- The pelvic girdle is one of the most complex anatomical structures in the body. It transfers the upper body's weight from the spine to the legs and has a massive number of attachment points for various large muscle groups of both the trunk and the legs.
- Like the pelvis, the limbs are complex and have many different joints and attachment points to allow for precise and varied movement.
- The muscles consist of bundles of smaller fibers (myofibrils) that are anchored to a bone via a tendon and have one or more nerves from the peripheral nervous system that allows for voluntary and involuntary contraction. All bodily movements stem from the muscles pulling against the bones across the joints. This

type of muscle is known as "Skeletal muscle" or "Striated" muscle due to the arrangement of the muscle fibers. There is another type of muscle in the body known as "smooth muscle", a component of many bodily systems. This form of muscle is loosely arranged and does not have the characteristic striations of the previously mentioned skeletal muscle.

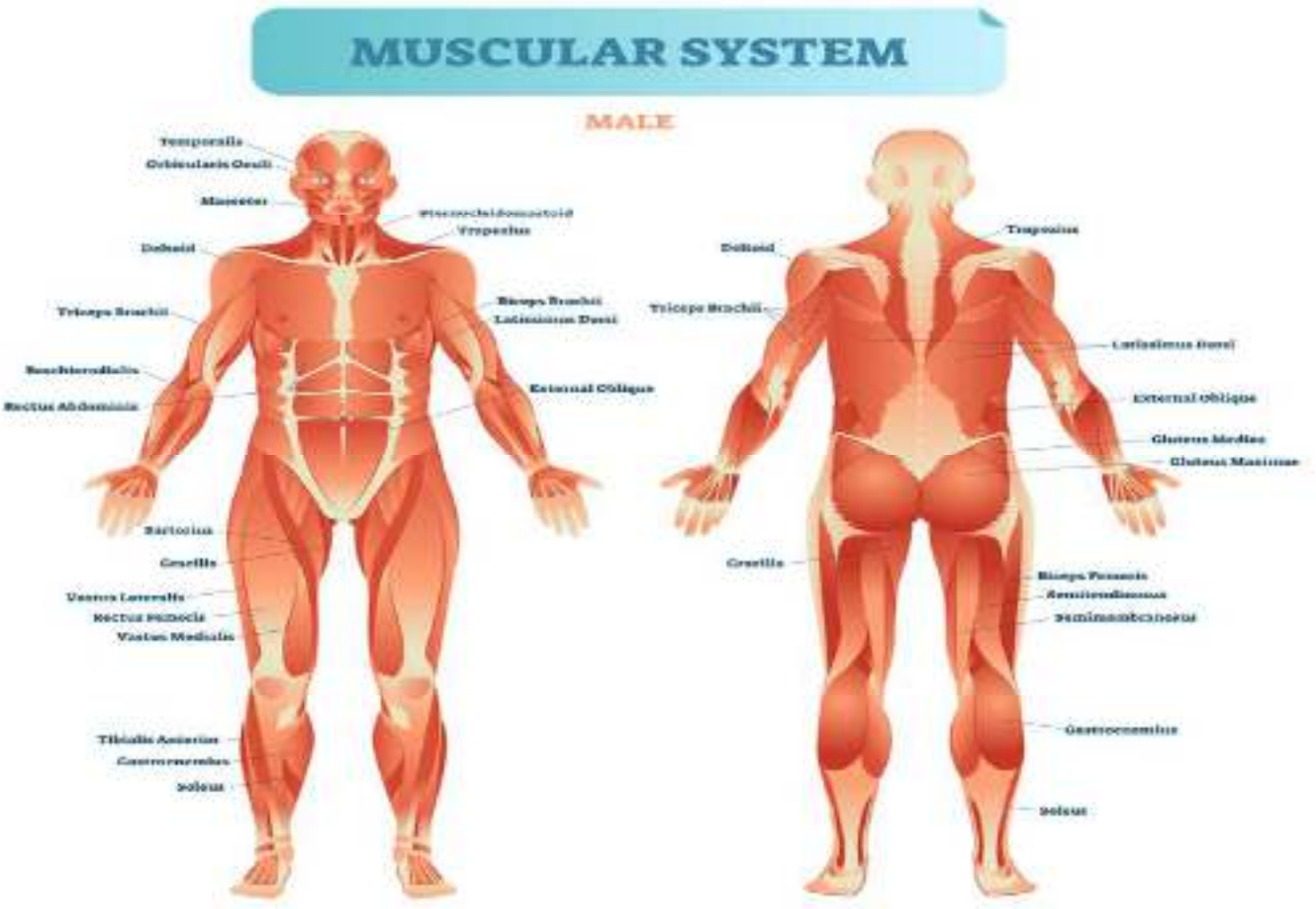

Figure: Muscular System of a Male

The Circulatory System:

The role of the circulatory system is to deliver oxygen and glucose to the cells of the body and then remove waste. It is comprised of the heart, blood vessels, and the blood itself. The anatomy and physiology of the circulatory system are extremely complex, but its essential elements can be broken down into a relatively simple framework.

The anatomy of the circulatory system is simple at a superficial level, it consists of a pump, pipes, and the fluid they carry.

- The heart is a four-chamber pump that fills with blood when it relaxes and propels it through the body when it squeezes. The chambers are separated by valves that prevent the backflow of blood. The coronary arteries run across the surface of the heart and
- provide oxygen to the muscle. Within the heart's muscle is a network of modified heart muscle cells that act almost like neurons, transferring electrical signals through the heart in a precise and structured manner.
- The blood vessels carry blood and regulate its flow to different areas of the body. The vessels are smooth muscle tubes that can expand and contract based on signals from hormones and the nervous system. Vessels are present in varying sizes, with the largest ones being near the heart and the smallest within the body's various tissues. There are different types of vessels; arteries, arterioles, veins, venules, and capillaries all have unique functions, which will be further reviewed in later sections.

- The blood is not traditionally considered to have anatomy, but know that it has many parts in the form of different cells, red blood cells, white blood cells, platelets, and a variety of proteins/hormones/chemicals all have different roles.

The Physiology of the circulatory system is complicated by the many types of cells in the heart and blood.

- The heart's muscle cells (cardiac myocytes) are unique in that they are electrically connected and do not require a nerve signal to contract. This allows them to beat in a rhythmic manner that allows for the effective pumping of blood. A collection of specially modified myocytes known as the SA node act as the pacemaker for a healthy heart, creating the electrical signals that spread through the myocytes and lead to a heartbeat. Other specialized myocytes act as fast pathways for these electrical signals, ensuring that the spread of electricity through the heart results in a coordinated and effective contraction.
- As mentioned above, the blood is a complex mix of cells and other compounds. The most relevant of these are red blood cells; these cells have a protein known as
- tissue in the body. White blood cells combat infection, and platelets help to block off any holes that form in the system.

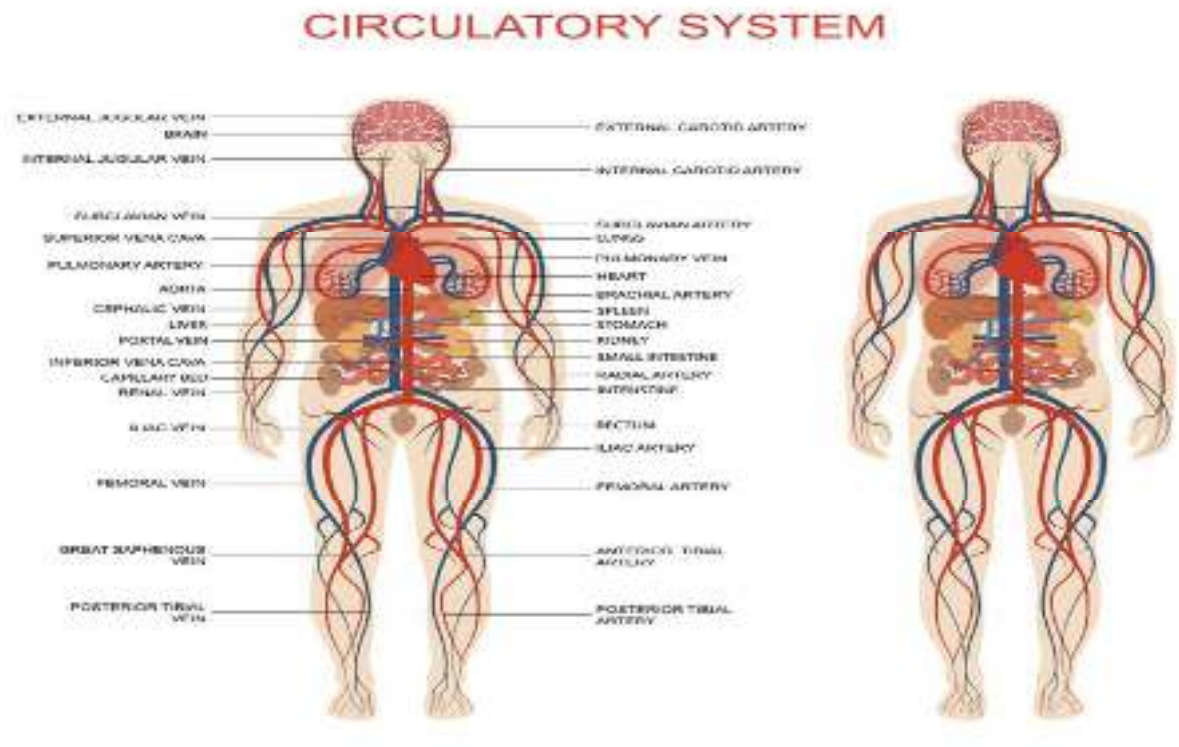

Figure: Human Circulatory system

The Nervous System:

The nervous system controls the entire body. It has fibers that run across every inch of the body, controlling muscles, organs, and glands; while returning information to the spinal cord and brain to allow them to make decisions. Neurons have several parts, dendrites that receive signals, axons that transmit them, and the cell body, which maintains the nerve cell.

The anatomy of the nervous system is divided into the central and peripheral systems, with the central nervous system acting as the control system for the body and the peripheral as communication lines that relay information to and from the central system.

The central nervous system (CNS) is made up of the brain and spinal cord; both of these structures are made up of a large number of neurons and support cells, with both large blood vessels and capillaries supplying the large amount of energy the neurons require.

The peripheral nervous system (PNS) is extensive and covers all areas of the body. These nerves have a myriad of functions controlling movement in the body, controlling the function of the organs, and returning sensory information from all across the body to the spinal cord and brain. The nerves of the PNS branch off of the spinal cord. The somatic nervous system (SNS), a branch of the PNS, is responsible for controlling voluntary muscle movements.

The autonomic nervous system (ANS) is a division of the peripheral nervous system (PNS) that controls and regulates the involuntary functions of the body. It plays a crucial role in maintaining internal homeostasis by regulating various physiological processes, such as heart rate, blood pressure, digestion, respiratory rate, and body temperature, among others. The ANS is responsible for coordinating responses to changes in the external and internal environments to ensure the body's proper functioning. It operates independently and continuously without conscious effort or control.

The ANS is further divided into two main branches:

1. Sympathetic Nervous System: The sympathetic nervous system is often referred to as the "fight or flight" system because it prepares the body to respond to stressful or threatening situations. When activated, it increases physiological arousal and mobilizes energy reserves to help the body deal with perceived threats.
2. Parasympathetic Nervous System: The parasympathetic nervous system is often referred to as the "rest and digest" system because it promotes relaxation and conserves energy. It is most active during restful states, such as when we are sleeping or after a meal, and works to restore balance after the sympathetic system's stress response.

The physiology of the nervous system surrounds the ability of nerves to transfer signals. They do so via "action potentials," which allow signals to transfer down the axon of the nerve and to receptors at their end.

The action potentials that neurons send are created by the opening and closing of voltage-sensitive ion channels on the neuron's surface. This results in a "wave" of electrical energy, which travels down the neuron and eventually releases neurotransmitters from the end of the neuron.

The variety of receptors present on neurons and muscles allows neurotransmitters to be released due to an action potential to affect other neurons by stimulating other action potentials; or causing the release of calcium which causes muscles to contract.

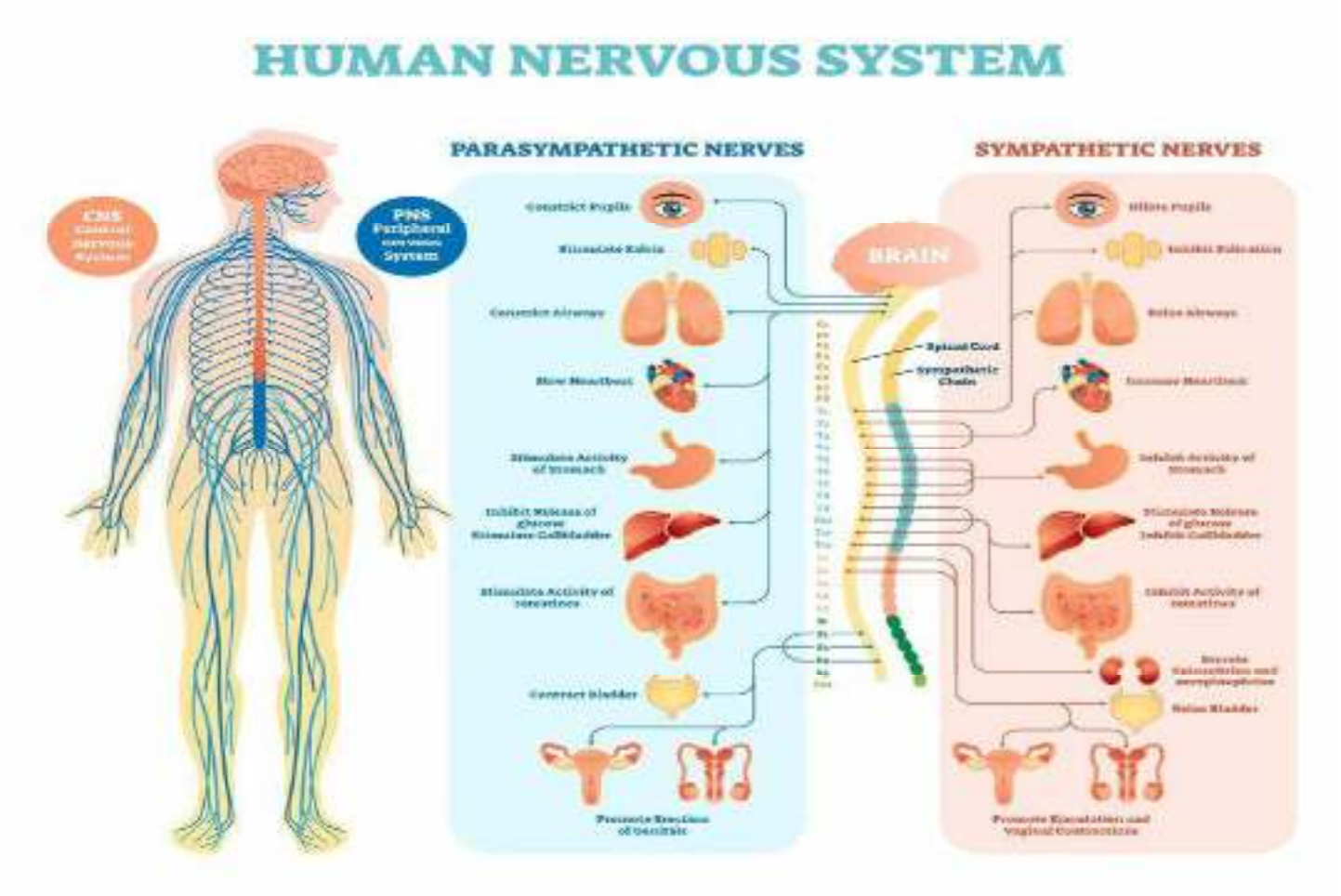

Figure: Human Nervous System

The Digestive System:

The digestive system exists to break down and absorb ingested material, allowing it to be used for energy and create new cells within the body.

You can divide the anatomy of the digestive system into the hollow and solid organs. The hollow organs convey food matter and process it, while the solid organs act as support systems, ensuring the process of digestion can proceed smoothly.

- The hollow organs are the oesophagus, stomach, and intestines: The oesophagus is the physical tube that connects the mouth to the stomach. The stomach both physically grinds up food and chemically digests it with acid. The intestines then absorb the nutrients and water from ground up food with help from liver bile and pancreatic enzymes.
- The solid organs are the liver and the pancreas: The liver serves the dual purpose of producing bile, which helps with the absorption of fats by the intestines and detoxifies the blood. The pancreas, like the liver, has a dual role. It produces enzymes that break down protein and hormones, balancing blood glucose.
- The physiology of the digestive system is heavily dependent upon the organ in question, and many have multiple roles. The hollow organs tend to be specialized in the mechanical breakdown and absorption of food. In contrast, the solid organs create and secrete substances that assist with the chemical breakdown of food.
- The stomach and intestines have a variety of special cells and receptors that work to detect their contents and absorb them.
- The liver cells, known as hepatocytes, produce bile from the body's waste, which helps absorb fat in the intestines. These same hepatocytes are filled with complex enzymes that break down countless toxins the body produces.

- The pancreas has several types of cells. Some secrete enzymes to break down proteins, while others are known as "islets," which secrete the hormones insulin and glucagon, which regulate the balance of glucose within the blood.

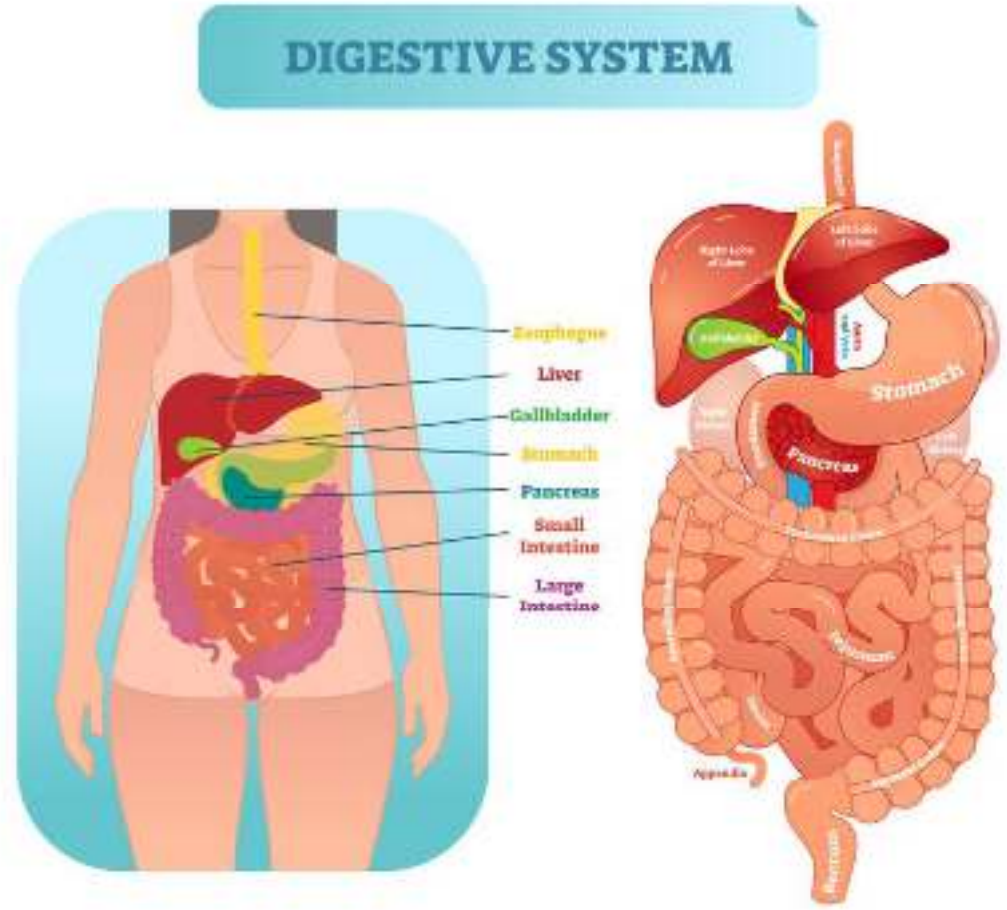

Figure: Human Digestive system

The Respiratory System:

The respiratory system is a close counterpart to the circulatory system. Its role is to bring oxygen from the air in contact with the blood inside microscopic capillaries. It interacts closely with the cardiovascular and musculoskeletal systems. Some of the largest blood vessels in the body are associated with the lungs, and the chest wall is vital in the inspiration and expiration of air.

The anatomy of the respiratory system is divided into the upper and lower respiratory tract. The division occurs at the level of the larynx. The upper respiratory tract consists of the nasopharynx and oropharynx. In comparison, the lower respiratory tract is made up of the trachea, bronchi, bronchioles, and lungs, with the movement of air through the system provided by the diaphragm.

The upper respiratory tract is responsible for the initial cleaning and warming of air before it is transmitted to the lower airways. The upper respiratory tract also carries food and fluids to the oesophagus and is instrumental in producing speech.

The larynx is a cartilage "box" that divides the GI and respiratory systems. It has a physical flap, "the epiglottis," that protects the airway from food and fluids. The rest of the larynx is specialized to allow for speech production; the vocal cords and various cartilages can change shape to allow air to pass over them to create speech.

The lower respiratory tract transfers air through a branching inverted tree made up of the trachea, bronchi, and bronchioles until it reaches the alveoli. These microscopic sacks have thin walls that are covered in thin-walled capillaries. These allow for blood to come in close contact with air.

The diaphragm is a sheet of muscle at the base of the lungs that pulls air into the airways by creating negative pressure in the chest. Remember that when the diaphragm contracts, air is drawn into the chest, which is known as inspiration.

The physiology of the respiratory system is best divided into the airways and the lungs.

- The airways have physiologic mechanisms that protect them from the countless viruses and bacteria in the environment. Countless mucus-secreting cells coat the inner nose/mouth, trachea, and bronchi/bronchioles in a protective layer that inhibits bacterial growth and traps inhaled contaminants. These mucosal cells are paired with cilial cells in the lower airway (trachea, bronchi, etc.) They are mobile and work to push mucus and contaminants up and out of the lower airways.
- The lung's chief physiologic function is the exchange of gases between the blood and the air. They do so through the incredibly thin walls of the alveoli, which allow diffusion to naturally move gases from areas of high concentration to those of low concentration.

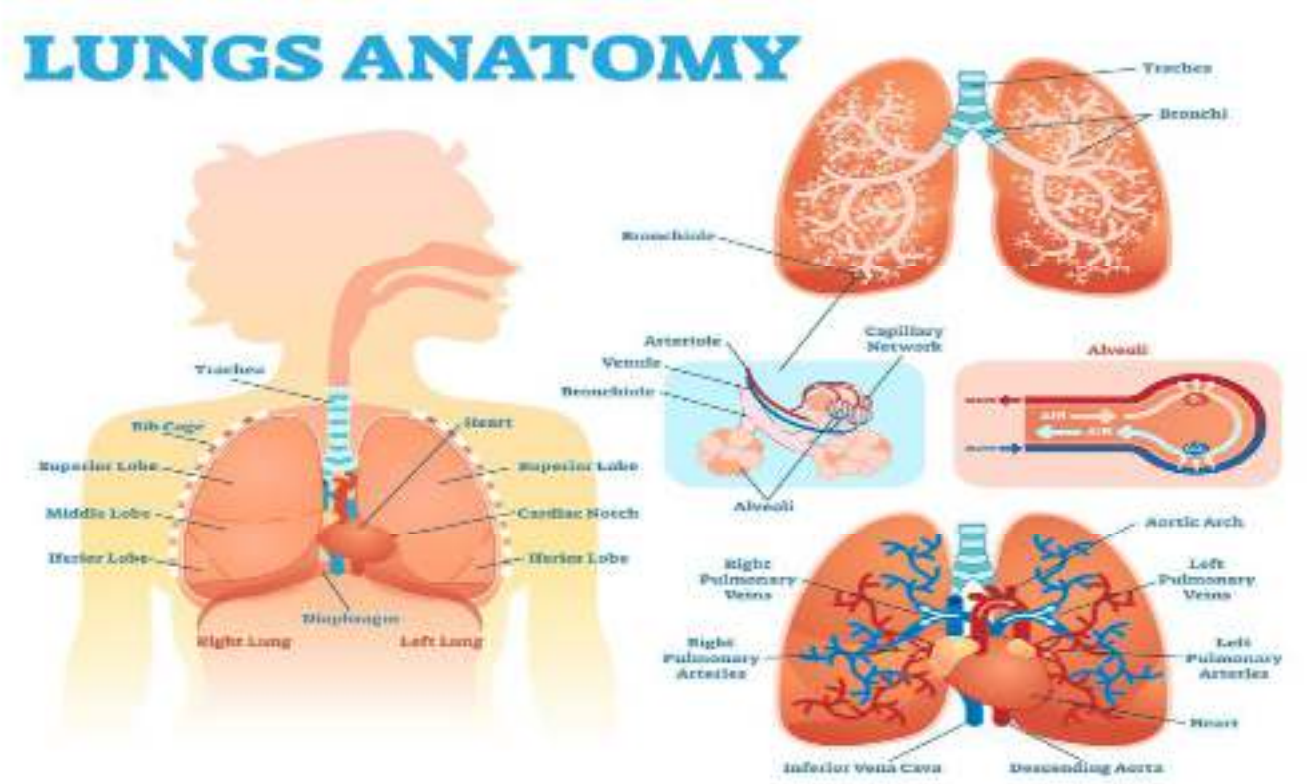

Figure: Human Lungs anatomy

The Integumentary System:

The integumentary system provides the physical barrier between the inner systems of the body and the outside world. It is vital to regulate the body's internal environment, holding in fluids, keeping out bacteria, and providing a regenerating layer that prevents permanent damage to the more fragile cells of the body.

The anatomy of the integumentary system is more complex than it would first appear. It has three main layers, the epidermis, dermis, and subcutaneous layers.

The epidermis is a thick layer of dead cells that acts as a "sacrificial layer" for the body. This layer of cells gradually rubs off and protects the more fragile layers below. The dermis is the living skin layer with cells that continuously multiply and divide; it holds nerves, blood vessels, sweat glands, and oil glands. The subcutaneous layer is one of the main areas of fat storage, also acting as a significant insulating layer for the body.

The physiology of the integumentary system is based on the continuously dividing stem cells in the dermis that create the thick epidermis. The dermis also contains countless capillaries, nerves, and glands that act to regulate the temperature through the mechanisms of vasoconstriction/vasodilation and diaphoresis (sweating).

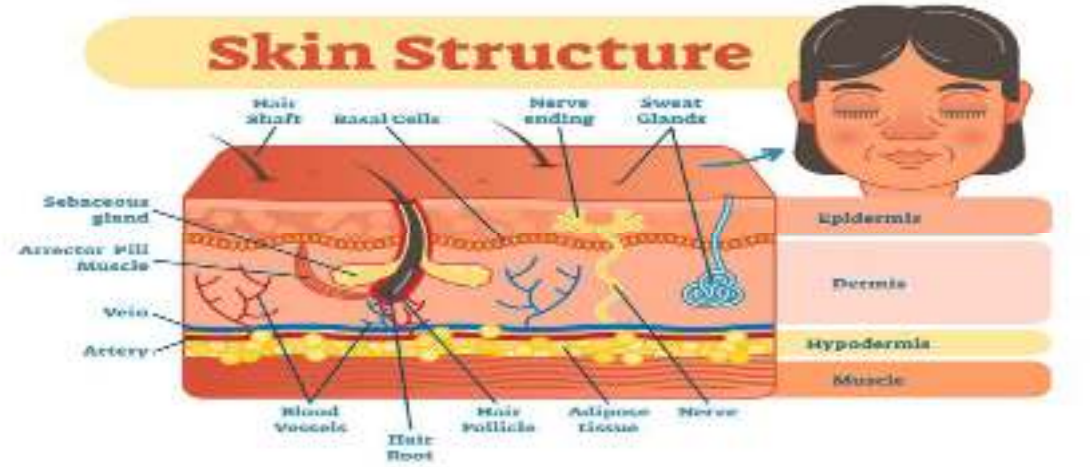

Figure: Human Integumentary system

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Class - 24

Introduction:

Opening Statement

Begin with a compelling opening statement to capture attention. Highlight the importance of the product in improving patient outcomes, streamlining processes, or addressing a significant healthcare challenge.

Example: “Good morning, esteemed colleagues. Today, we are excited to introduce a revolutionary product that promises to transform patient care and enhance the efficiency of healthcare delivery.”

Agenda Overview

Briefly outline what the presentation will cover. This helps set expectations and provides a roadmap for the audience.

Example: “We will cover the product’s features, benefits, clinical evidence, and implementation process. We will also discuss how it integrates with existing systems and the support we offer for a smooth transition.”

Background and Context

Industry Challenges

Discuss the current challenges in the healthcare industry that your product aims to address. Use data and statistics to highlight the urgency and relevance of these challenges.

Example: “The healthcare industry faces numerous challenges, including rising costs, increasing patient volumes, and the need for more efficient care delivery. According to a recent report, healthcare providers are under immense pressure to improve patient outcomes while managing limited resources.”

Product Introduction
Introduce your product, emphasizing its innovative aspects and how it addresses the identified challenges.

Example: “Introducing [Product Name], a state-of-the-art solution designed to enhance patient care, improve operational efficiency, and reduce costs. Our product leverages advanced technology to provide comprehensive support to healthcare professionals.”

Detailed Product Description
Key Features
Detail the main features of the product. Use visuals such as diagrams, screenshots, or videos to illustrate these features.

Example:

User-Friendly Interface: Describe how the product’s interface is intuitive and easy to navigate, reducing training time and enhancing usability.

Integration Capabilities: Explain how the product seamlessly integrates with existing electronic health records (EHR) systems and other healthcare technologies.

Advanced Analytics: Highlight the product’s ability to analyze patient data and provide actionable insights for better decision-making.

Clinical Evidence and Validation
Present clinical evidence and validation studies that support the product’s efficacy and safety. This is crucial for gaining the trust of healthcare professionals.

Example: “Our product has been rigorously tested in multiple clinical trials, demonstrating significant improvements in patient outcomes. A study conducted at [Institution Name] showed a 20% reduction in hospital readmissions and a 15% improvement in patient satisfaction scores.”

Benefits to Healthcare Professionals
Improved Patient Care
Explain how the product enhances patient care. Use case studies or testimonials from healthcare professionals who have successfully implemented the product.

Example: “Dr. Smith from [Hospital Name] reports that our product has significantly improved patient monitoring, allowing for timely interventions and better management of chronic conditions.”

Operational Efficiency
Discuss how the product streamlines processes and reduces the administrative burden on healthcare professionals.

Example: “With our product, healthcare providers can automate routine tasks, freeing up more time for patient care. A study at [Clinic Name] showed a 30% reduction in paperwork and a 25% increase in patient-facing time.”

Cost Savings
Highlight the cost-saving potential of the product, both in terms of direct savings and long-term financial benefits.

Example: “By reducing hospital readmissions and improving resource allocation, our product helps healthcare institutions save on operational costs. Over a year, [Hospital Name] reported savings of $500,000.”

Implementation and Support
Implementation Process
Outline the steps involved in implementing the product, from initial assessment to full deployment. Provide a timeline and highlight any support provided during this process.

Example: “Our implementation process includes a comprehensive assessment, customized deployment plan, and ongoing support. We work closely with your team to ensure a smooth transition, with minimal disruption to your operations.”

Training and Support
Detail the training programs and support services available to healthcare professionals. Emphasize your commitment to ongoing education and assistance.

Example: “We offer extensive training programs, including on-site training, webinars, and online resources. Our support team is available 24/7 to assist with any issues or questions that may arise.”

Integration with Existing Systems
Seamless Integration
Explain how the product integrates with existing systems, such as EHRs, laboratory information systems (LIS), and radiology information systems (RIS). Use technical diagrams to show integration points.

Example: “Our product is designed for seamless integration with major EHR systems, ensuring a unified workflow and eliminating the need for duplicate data entry. This integration enhances data accuracy and improves overall efficiency.”

Data Security and Compliance
Address concerns about data security and compliance with healthcare regulations, such as HIPAA. Provide details on encryption, data protection measures, and compliance certifications.

Example: “Data security is our top priority. Our product complies with HIPAA regulations and uses advanced encryption to protect patient information. We undergo regular security audits to ensure the highest standards of data protection.”

Case Studies and Testimonials
Real-World Success Stories
Share case studies and testimonials from healthcare institutions that have successfully implemented the product. Highlight specific outcomes and benefits achieved.

Example: “At [Hospital Name], our product helped reduce emergency room wait times by 40%, resulting in improved patient satisfaction and better resource management. Dr. Jones states, ‘This product has been a game-changer for our hospital, enabling us to provide faster and more effective care.’”

Conclusion
Summarize the main points of the presentation, reinforcing the product’s benefits and the value it brings to healthcare professionals.

Example: “In summary, [Product Name] offers numerous benefits, including improved patient care, enhanced operational efficiency, and significant cost savings. It is backed by robust clinical evidence and designed for seamless integration with existing systems.”

Call to Action
End with a strong call to action, encouraging healthcare professionals to take the next step, whether it’s scheduling a demo, requesting a trial, or contacting your sales team for more information.

Example: “We invite you to experience the benefits of [Product Name] firsthand. Schedule a demo today and see how our product can transform your practice. Thank you for your time and attention.”

Questions and Answers
Q&A Session
Allocate time for a Q&A session at the end of the presentation. Encourage healthcare professionals to ask questions and provide detailed answers.

Example: “We would now like to open the floor for questions. Please feel free to ask about any aspect of our product, its features, implementation, or clinical evidence.”

Additional Sections (if needed)

Market Analysis
Industry Trends
Discuss current trends in the healthcare industry and how your product is positioned to take advantage of these trends.

Example: “The increasing adoption of telemedicine and digital health solutions is transforming the healthcare landscape. Our product is designed to leverage these trends, providing innovative solutions that meet the evolving needs of healthcare providers.”

Competitive Landscape

Provide an analysis of the competitive landscape, highlighting how your product stands out from competitors.

Example: “While there are several products available in the market, [Product Name] stands out due to its unique combination of advanced features, user-friendly interface, and robust clinical validation.”

Technical Specifications
In-Depth Technical Details
For audiences interested in technical specifications, provide detailed information about the product’s architecture, technology stack, and performance metrics.

Example: “Our product is built on a scalable cloud platform, ensuring high availability and performance. It supports integration with HL7 and FHIR standards, enabling seamless data exchange with other healthcare systems.”

Future Roadmap
Product Development Plans
Share your plans for future development and enhancements to the product. This helps build confidence in your long-term commitment to innovation.

Example: “We are continuously working on enhancing our product, with upcoming features including AI-driven predictive analytics and expanded telemedicine capabilities. Our goal is to stay ahead of industry trends and provide cutting-edge solutions to our customers.”

Conclusion
Delivering a successful product presentation to healthcare professionals requires a well-structured approach that addresses their specific needs and concerns. By focusing on the product’s benefits, providing robust clinical evidence, and demonstrating a commitment to ongoing support and innovation, you can effectively communicate the value of your product and encourage adoption. Remember to engage your audience, use visuals to enhance understanding, and be prepared to answer questions comprehensively. With careful planning and execution, your presentation can make a lasting impact and drive interest in your product.

1. Lectures
Medical lectures educate an audience about a medical topic. They’re one of the most challenging presentations. According to the Learning Pyramid, lectures are the most passive learning techniques, which is also why they have the lowest retention rates.

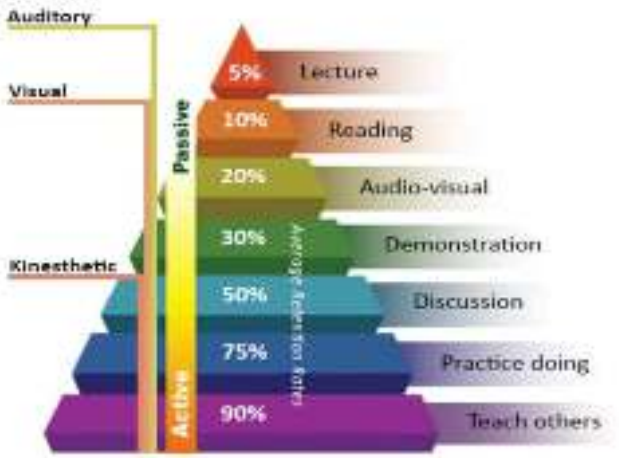


Figure: Applied Behavioral Science Learning Period

There are several settings for educational lectures, including:

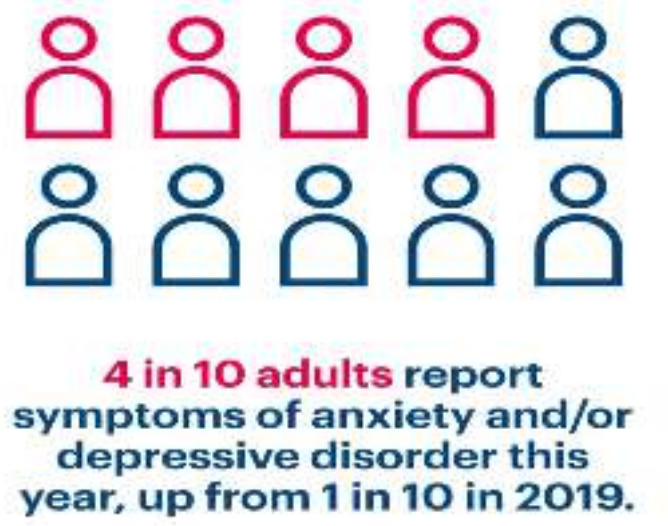
- Conferences
- Training
- University or school lectures

Medical lectures help students or an audience comprehend complex medical information and then turn what they learned into actionable strategies.

For example, you may teach students with little medical knowledge about a new medical concept. But they must understand the topic and be able to recall it for examinations.

- Be interactive: Use Q&As, activities, and open discussions.
- Hand out resources: Give physical booklets students can review after the presentation.
- Use multimedia: Add audio-visual elements like images, video, and audio clips.
- Use simple language: Your audience is learning, so they need simple language and plenty of definitions to understand the topic.
- Make it entertaining: Keep your audience's attention with a more engaging and entertaining presentation.

United Health Group incorporated imagery and movement to show rather than talk about mental health in 2022 to boost their engagement on the topic.



Figures: Symptoms of anxiety

2. Research presentations
The most information-heavy medical presentation is the research presentation. Research presentations share findings with experienced medical professionals, usually in conference settings. Some of the audience includes:

- Investigators
- Ph.D. students
- Medical professionals and experienced doctors

Research presentations can also be part of healthcare marketing. You may have to introduce a new process, pharmaceutical, or device to encourage other healthcare professionals to adopt it in their practices.

- Speak on a higher level: You're talking to a knowledgeable audience, so they expect a higher level of research.
- Back all facts with data: Use statistics and research to back all claims.
- Use power poses: Build authority with a confident presentation.
- Grab the audience's attention: Start your presentation by giving your audience a reason to care, like a problem you want to solve.
- Build up the conclusion: Structure the research in a natural, progressive order that builds up to your conclusion.
- Look at the future: Conclude with how the research findings will impact the future of medicine.

3. Case reports
Medical professionals must give oral case reports when transferring information between providers or a team. These presentations are very brief and often don't require visuals.

Sometimes a case is especially unique and offers educational value to others. In that case, presenters should transform their quick oral case reports into a longer presentation that incorporates data and visuals.

Tips for giving case reports
Case reports use a similar structure to oral patient presentations, except with more details about each point. You'll still want to pack as much information in a short presentation as possible.

- Begin the presentation with a patient overview: Start by introducing the patient, including all relevant demographic details in summarized graphics and lists.
- Present the history of the patient: Describe the patient's history, why they sought care, and the symptoms they presented in charts and visuals.
- Explore medical information: Dive into the medical details, like treatment and history, using a storytelling structure to connect the information.
- Offer a plan: Outline a treatment plan alongside proof.

Tips for preparing engaging medical presentations
Your medical presentations have highly complex topics rich with data. These topics can easily feel overwhelming or even boring if they don't have the right structure and appearance.

Here are three medical presentation tips we've learned to help you prepare and present high-quality medical presentations that engage AND inform.

Know your audience's knowledge level
Before building and presenting a medical topic, you must know your audience's knowledge level. A lecture to a class of first-year college students will sound far different from a presentation to doctors with 10+ years of industry experience.

Build a presentation around your audience's knowledge, so it's understandable yet challenging. By taking this extra step, you'll know what points need more explanation and what topics you can dig deeper into based on your audience's experience.

Build a structured story
A complex topic becomes easy to understand and follow if you use a storytelling structure. You might ask, "How can a lecture on a new treatment be a story?"

Any time you communicate, it's a story: You have the challenge to solve, potential solutions to try, and a final winner (like when presenting medical research). You can structure that story in a progressive order or by announcing one primary outcome and providing a list of proofs (like with patient case studies).

Focus on a goal
The goal of medical presentations can be educating, training, or persuading the audience, depending on the type of medical presentation. Knowing your goal guides which data is most relevant to bring your desired outcome.

Communicate at the speed of healthcare with Prezent
Whether you're preparing a lecture, research presentation, or case report, creating presentation slides is probably far down your priority list. The fast-paced healthcare industry has enough duties vying for attention. So how are you supposed to squeeze in hours to build an engaging presentation?

Prezent has your back. No need to sweat the details as we have already developed leading presentation templates perfect for data-driven presentations. Personalize to your audience's knowledge and presentation preferences with AI-powered technology. Save time and energy with access to 35,000+ custom-built slide templates designed with key business and pharma storylines in mind.

You'll have an engaging and clear presentation deck in minutes rather than hours. Take back your time and communicate efficiently with Prezent so you can focus on turning your ideas and insights into action.

Class – 25

What is the circulatory system?
Your heart and blood vessels make up the circulatory system. The main function of the circulatory system is to provide oxygen, nutrients and hormones to muscles, tissues and organs throughout your body. Another part of the circulatory system is to remove waste from cells and organs so your body can dispose of it.

Your heart pumps blood to the body through a network of arteries and veins (blood vessels). Your circulatory system can also be defined as your cardiovascular system. Cardio means heart, and vascular refers to blood vessels. The circulatory system provides blood to all the body's tissues so they can function.

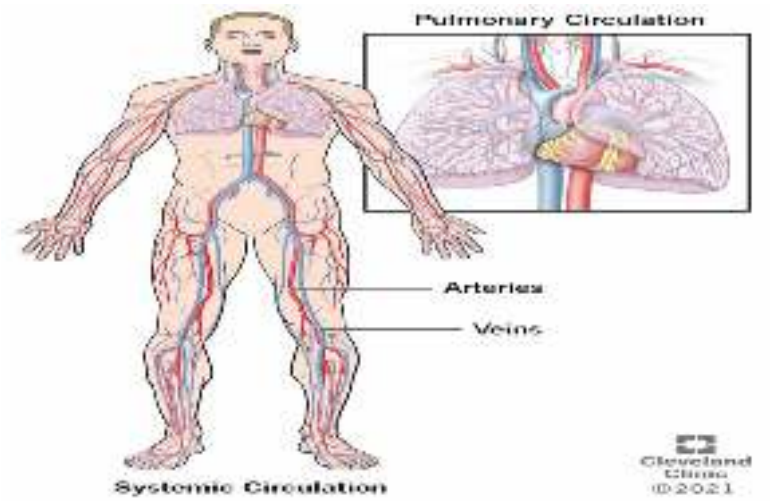


Figure: Circulatory System

Function
What does the circulatory system do?

The circulatory system's function is to move blood throughout the body. This blood circulation keeps organs, muscles and tissues healthy and working to keep you alive.

The circulatory system also helps your body get rid of waste products. This waste includes:

- Carbon dioxide from respiration (breathing).
- Other chemical byproducts from your organs.
- Waste from things you eat and drink.

How does the circulatory system work?
Your circulatory system functions with the help of blood vessels that include arteries, veins and capillaries. These blood vessels work with your heart and lungs to continuously circulate blood through your body. Here's how:

1. The heart's bottom right pumping chamber (right ventricle) sends blood that's low in oxygen (oxygen-poor blood) to the lungs. Blood travels through the pulmonary trunk (the main pulmonary artery).
2. Blood cells pick up oxygen in the lungs.
3. Pulmonary veins carry the oxygenated blood from the lungs to the heart's left atrium (upper heart chamber).
4. The left atrium sends the oxygenated blood into the left ventricle (lower chamber). This muscular part of the heart pumps bloods out to the body through the arteries.
5. As it moves through your body and organs, blood collects and drops off nutrients, hormones and waste products.
6. The veins carry deoxygenated blood and carbon dioxide back to the heart, which sends the blood to the lungs.
7. Your lungs get rid of the carbon dioxide when you exhale.

Anatomy:

What are the circulatory system parts?
The parts of your circulatory system are your:

- Heart, a muscular organ that pumps blood throughout your body.
- Blood vessels, which include your arteries, veins and capillaries.
- Blood, made up of red and white blood cells, plasma and platelets.

What are the circulatory system circuits?
Your circulatory system has three circuits. Blood circulates through your heart and through these circuits in a continuous pattern:

- The pulmonary circuit: This circuit carries blood without oxygen from the heart to the lungs. The pulmonary veins return oxygenated blood to the heart.
- The systemic circuit: In this circuit, blood with oxygen, nutrients and hormones travel from the heart to the rest of the body. In the veins, the blood picks up waste products as the body uses up the oxygen, nutrients and hormones.
- The coronary circuit: Coronary refers to your heart's arteries. This circuit provides the heart muscle with oxygenated blood. The coronary circuit then returns oxygen-poor blood to the heart's right upper chamber (atrium) to send to the lungs for oxygen.

What are the types of blood vessels?
There are three main types of blood vessels:

- Arteries: Arteries are thin, muscular tubes that carry oxygenated blood away from the heart and to every part of your body. The aorta is the body's largest artery. It starts at the heart and travels up the chest (ascending aorta) and then down into the stomach (descending aorta). The coronary arteries branch off the aorta, which then branch into smaller arteries (arterioles) as they get farther from your heart.
-
- Veins: These blood vessels return oxygen-depleted blood to the heart. Veins start small (venules) and get larger as they approach your heart. Two central veins deliver blood to your heart. The superior vena cava carries blood from the upper body (head and arms) to the heart. The inferior vena cava brings blood up from the lower body (stomach, pelvis and legs) to the heart. Veins in the legs have valves to keep blood from flowing backward.
- Capillaries: These blood vessels connect very small arteries (arterioles) and veins (venules). Capillaries have thin walls that allow oxygen, carbon dioxide, nutrients and waste products to pass into and out of cells.

What are the circulatory system organs?
Your heart is the only circulatory system organ. Blood goes from the heart to the lungs to get oxygen. The lungs are part of the respiratory system. Your heart then pumps oxygenated blood through arteries to the rest of the body.

Conditions and Disorders

What conditions affect the circulatory system?
Many conditions can affect the health of your circulatory system, including:

- Aneurysms: Aneurysms occur when an artery wall weakens and enlarges. The weak spot can bulge as blood moves through the artery. The weak spot may tear, causing a life-threatening rupture. Aneurysms can affect any artery, but aortic aneurysms, abdominal aortic aneurysms and brain aneurysms are the most common.
- High blood pressure: Your arteries work hard to circulate blood throughout the body. When the pressure (force of blood against the blood vessel walls) gets too high, you develop high blood pressure. When the arteries become less elastic (stretchy), less
- for cardiovascular disease, heart attacks and strokes. Plaque deposits: High cholesterol and diabetes can lead to fat and other substances collecting in the blood. These substances form deposits called plaques on artery walls. This condition is atherosclerosis, or narrowed or hardened arteries. Atherosclerosis increases the risk of blood clots and strokes, coronary artery disease, peripheral artery disease (and other artery diseases), heart attacks and kidney disease.
- Venous disease: Venous diseases tend to affect veins in the lower body. Problems like chronic venous insufficiency and varicose veins occur when blood can't flow back to the heart and pools in leg veins. Deep vein thrombosis (DVT), a blood clot in the legs, can lead to a life-threatening pulmonary embolism.

Care

How can I prevent circulatory system problems?
These steps can protect the health of your circulatory system:

- Aim for at least 150 minutes of physical activity every week.
- Eat a heart-healthy diet rich in vegetables and fiber and low in saturated fats and processed foods. Consider a Mediterranean-style diets or a plant-based diet, as they appear to be the most heart-healthy.

- Find healthy ways to ease stress.
- Maintain a healthy weight.
- Manage conditions like diabetes, high blood pressure and high cholesterol.
- Get help to quit smoking.

Reproductive system overview:
The reproductive system is a collection of organs and a network of hormone production that work together to create life.

The male reproductive system includes the testes (which produce sperm), penis, epididymis, vas deferens, ejaculatory ducts and urethra.

The female reproductive system consists of the ovaries (which produce eggs or oocytes), fallopian tubes, uterus, cervix, vagina and vulva.

Both the male and female reproductive systems must be functioning properly for a couple to conceive naturally. A problem with the structure or function of either reproductive system can cause infertility.

What does the reproductive system do?
The reproductive system is a collection of organs and a network of hormone production in men and women that enable a man to impregnate a woman who gives birth to a child. During conception, a sperm cell from the man fuses with an egg cell in the woman, creating a fertilized egg (embryo) that implants and grows in the uterus during pregnancy.

Abnormalities or damage to reproductive organs and malfunction of the hormone production and delivery system that governs reproduction are common causes of infertility in men and women.

How the brain works as part of the reproductive system?
Brain centers play a key role in the regulation and control of the reproductive hormones and system. Hormones are chemical messengers that affect the metabolism of other cells with receptors for the hormone. Hormones may be produced in one part of the body and travel in the blood to another part of the body to initiate an action.

The reproductive brain centers are made up of the hypothalamus, located in the central part of the brain, and the pituitary gland, located at the base of the brain just below the hypothalamus. Additional higher brain regions influence activity in the hypothalamus.

The hypothalamus produces gonadotropin-releasing hormone (GnRH) to regulate the production and release of FSH (follicle-stimulating hormone) and LH (luteinizing hormone) in the pituitary gland. FSH and LH are the two gonadotropic hormones involved in both male and female reproduction. The rate and magnitude of GnRH pulses from the hypothalamus regulate the release of FSH and LH from the pituitary gland.

Reproductive hormones in women
The menstrual cycle is regulated by the complex interactions of hormones produced in the hypothalamus, pituitary and ovary. FSH released from the pituitary stimulates the ovarian follicles to begin maturation and growth. Follicles are sac-like structures in the ovary containing eggs. As the follicle and egg develops, cells within the follicle produce estrogen. Follicle cells produce another hormone called inhibin that circulates back to the hypothalamus and pituitary to decrease the release of FSH.

The production of estrogen continues to rise under the influence of FSH as the follicle matures and increases in size. When the follicle is mature, maximum production of estrogen occurs and this signals a rapid rise in LH from the pituitary gland.

LH, along with the estrogen produced by the ovaries, helps in the maturation process of the egg. LH also triggers ovulation – the release of a mature egg from one of the follicles in the ovary. After ovulation, the follicle turns into a different structure, the corpus luteum, which produces progesterone.

Progesterone acts on the uterine lining (endometrium) causing it to thicken in preparation for implantation. Progesterone is essential for implantation and pregnancy. If implantation does not occur, the thickened endometrium will break down and be lost with menstrual bleeding.

The female reproductive organs include:

Ovaries — The ovaries are two small, oval-shaped glands located on either side of the uterus. They are home to the female sex cells, called eggs, and they also produce estrogen, the female sex hormone.

Fallopian tubes — The fallopian tubes are narrow tunnels for a fertilized egg to make its way down to the uterus. Damage or blockage to the fallopian tubes — called tubal disease — can sometimes cause fertility problems. Learn more about common fertility problems.

Uterus — The uterus is a hollow, pear-shaped organ located in a woman's lower abdomen, between the bladder and the rectum. It is also called the "womb" and holds the fetus during pregnancy. Each month, the uterus develops a lining (the endometrium) that is rich in nutrients. The reproductive purpose of this lining is to provide nourishment for a developing fetus. Uterine abnormalities, such as fibroids or endometriosis, may cause infertility by interfering with egg fertilization or embryo implantation and development.

Cervix — The cervix is the lower, narrow part of the uterus, located between the bladder and rectum. It forms a canal that opens to the vagina. Often called the neck or entrance to the womb, the cervix lets menstrual blood out and semen into the uterus. Growths in the cervix called polyps can sometimes affect the fertilization or embryo growth process.

Vagina — The vagina, also known as the birth canal, joins the cervix (the lower part of uterus) to the outside of the body.

Vulva — This is the external portion of the female genital organs.

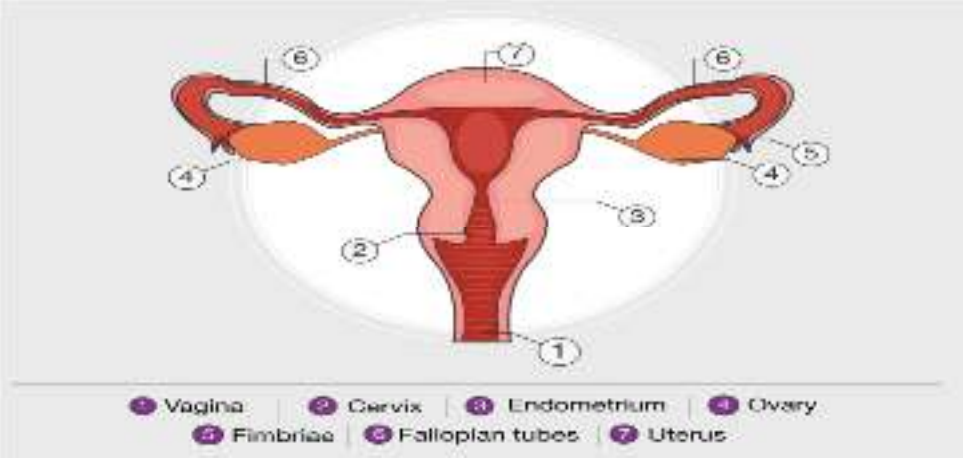


Figure: Female Reproductive system

What happens during the menstrual cycle?

Women or people of reproductive age (beginning anywhere from 11 to 16 years of age) experience cycles of hormonal activity that repeat at about one-month intervals. With every cycle, your body prepares for a potential pregnancy, whether or not that's your intention. The term menstruation refers to the periodic shedding of your uterine lining when pregnancy doesn't occur that cycle. Many people call the days that they notice vaginal bleeding their "period."

The average menstrual cycle takes about 28 days and occurs in phases. These phases include:

- The follicular phase (the egg develops).
- The ovulatory phase (release of the egg).
- The luteal phase (hormone levels decrease if the egg doesn't implant).

There are four major hormones (chemicals that stimulate or regulate the activity of cells or organs) involved in the menstrual cycle. These hormones include:

- Follicle-stimulating hormone.
- Luteinizing hormone.
- Estrogen.
- Progesterone.
- Follicular phase

This phase starts on the first day of your period. During the follicular phase of the menstrual cycle, the following events occur:

- Two hormones, follicle-stimulating hormone (FSH) and luteinizing hormone (LH) are released from your brain and travel in your blood to your ovaries.
- The hormones stimulate the growth of about 15 to 20 eggs in your ovaries, each in its own "shell," called a follicle.

These hormones (FSH and LH) also trigger an increase in the production of the hormone estrogen.

As estrogen levels rise, like a switch, it turns off the production of follicle-stimulating hormone. This careful balance of hormones allows the body to limit the number of follicles that will prepare eggs to be released.

As the follicular phase progresses, one follicle in one ovary becomes dominant and continues to mature. This dominant follicle suppresses all of the other follicles in the group. As a result, they stop growing and die. The dominant follicle continues to produce estrogen.

Ovulatory phase

- The ovulatory phase (ovulation) usually starts about 14 days after the follicular phase started (the exact timing varies). The ovulatory phase is the second phase of your menstrual cycle.
- Most people will have a menstrual period 10 to 16 days after ovulation. During this phase, the following events occur:
- The rise in estrogen from the dominant follicle triggers a surge in the amount of luteinizing hormone (LH) that your brain produces.
- This causes the dominant follicle to release its egg from the ovary.
- As the egg is released (a process called ovulation) it's captured by finger-like projections on the end of the fallopian tubes (fimbriae). The fimbriae sweep the egg into the fallopian tube.
- For one to five days prior to ovulation, many women or people AFAB will notice an increase in egg white cervical mucus. This mucus is the vaginal discharge that helps to capture and nourish a sperm on its way to meet the egg for fertilization.

Luteal phase

The luteal phase begins right after ovulation and involves the following processes:

- Once it releases its egg, the empty ovarian follicle develops into a new structure called the corpus luteum.
- The corpus luteum secretes the hormones estrogen and progesterone. Progesterone prepares your uterus for a fertilized egg to implant.
- If intercourse has taken place and sperm has fertilized the egg (conception), the fertilized egg (embryo) will travel through your fallopian tube to implant in your uterus. This is how pregnancy begins.
- If the egg isn't fertilized, it dissolves in your uterus. Not needed to support a pregnancy, the lining of your uterus breaks down and sheds. This is when your period begins.

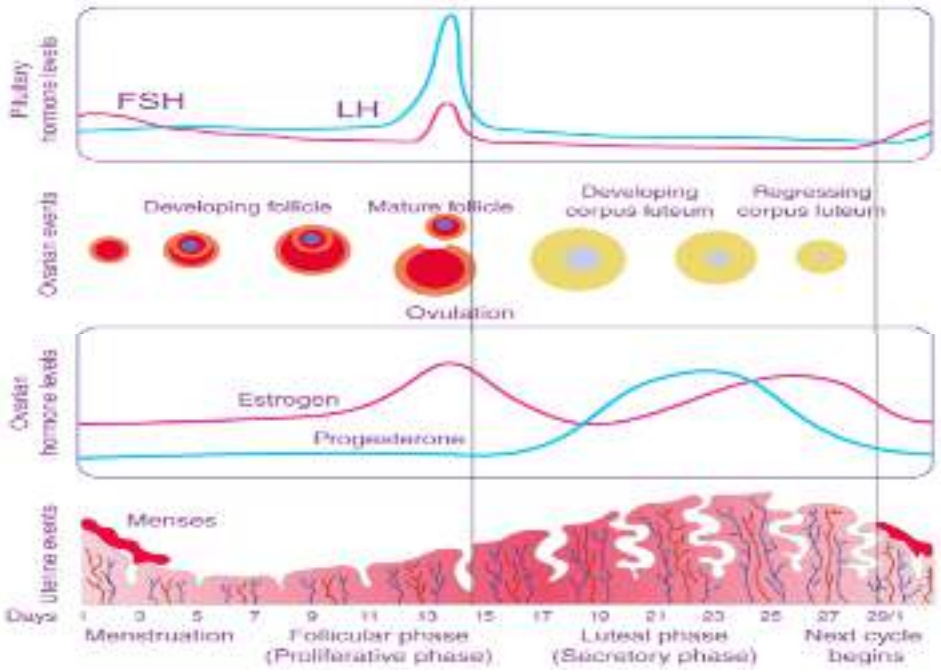


Figure: Menstrual Cycle

How many eggs does a woman have?
You're born with all the eggs you'll ever produce. During fetal development, you have about 6 million eggs. At birth, there are approximately 1 million eggs left. By the time you reach puberty, only about 300,000 remain. The number of eggs you have continues to decline as you age and menstruate each cycle. Fertility also declines with age due to the decreasing number and quality of your remaining eggs.

Reproductive hormones in men:
In men, FSH from the pituitary gland stimulates the testes to produce sperm by a process known as spermatogenesis. LH from the pituitary gland signals the testes to produce testosterone, which enhances sperm maturation. Testosterone is the primary male sex hormone.

The male reproductive system performs the following functions:

- Produces, maintains and transports sperm (the male reproductive cells) and protective fluid (semen).
- Discharges sperm within the female reproductive tract during sex.
- Produces and secretes male sex hormones responsible for maintaining the male reproductive system.

Unlike in the female reproductive system, most male reproductive organs are not located internally. They include:

- Penis — The penis is made up of two parts, the shaft and the head. The urethral opening at the tip of the penis delivers sperm into the vagina during sexual intercourse.
- Scrotum — The scrotum is the sac-like organ hanging behind and below the penis. It contains the testicles (also called testes), as well as many nerves and blood vessels.
- Testicles (testes) — The testes (oval organs that lie in the scrotum) are the primary male reproductive organ and are responsible for testosterone and sperm production.
- Epididymis — The epididymis is a C-shaped tube that rests on the backside of each testicle. It transports and stores sperm cells that are produced in the testes. The epididymis also brings the sperm to maturity, since the sperm emerging from the testes are immature and incapable of fertilization. During sexual arousal, contractions force the sperm into the vas deferens.

- Ductus (vas) deferens — The vas deferens is a long, muscular tube that travels from the epididymis into the pelvic cavity, to just behind the bladder. The vas deferens transports mature sperm to the urethra, the tube that carries urine or sperm outside of the body, in preparation for ejaculation.
- Ejaculatory ducts — These are formed by the fusion of the vas deferens and the seminal vesicles. The ejaculatory ducts empty into the urethra.
- Urethra — The urethra is the tube that carries urine from the bladder to outside of the body. In males, it has the additional function of ejaculating semen when the man reaches sexual climax. When the penis is erect during sex, the flow of urine is blocked from the urethra, allowing only semen to be ejaculated at climax.
- Other glands — Several glands produce semen or fluid in support of the reproductive process. The seminal vesicle produces fructose that provides energy to the sperm as they seek an egg. The prostate gland also produces a fluid that helps the sperm move more quickly through the female reproductive system. Another set of glands called bulbourethral, or sometimes Cowper's glands, makes a fluid for protecting the sperm on its way through the urethra.

Medical Specialties in India:

- When it comes to medical education, learning is a never-ending process. Professionals need to constantly upgrade, especially doctors. Doctors have to choose a specialization from plenty of medical specialties to have a successful and lucrative career.
- Additionally, specialists are in high demand around the world. The reason for this demand is the aging population. Specialists are needed to take care of the aged and the severely sick. The same report also shows us that the average salary is the highest, among doctors, for specialists.

Class - 26

For a medical graduate, your career does not start after you complete your MBBS. You have plenty of options to improve and upgrade your qualification before you begin to practice. You can also continue practice while doing so. It would help if you got a PG with a core specialization. Do you think your learning stop there? No, you have a long way to go and far more to learn. So, what can you do after completing your PG?

Below is a list of the top 13 medical specialties you can choose from in India after your postgraduate degree and stay upgraded.

There are around 60 medical specialties and 30 subspecialties that make it harder for doctors to choose their specialization. Based on interest, doctors can choose their medical specialties. However, there are aspects like demand, scope, salary, and availability of the PG medical seat.

In such a situation, decision-making would be a tougher job. However, your decision is crucial to can set up a rewarding or dismaying career. Thus, be careful while choosing your medical specialties. The medical courses listed below are in high demand and have a greater scope in India.

Medical tourism, the practice of travelling to another country for the sole purpose of seeking medical treatment, has witnessed exponential growth in recent years. As healthcare costs continue to rise in many developed nations, patients are increasingly looking beyond their borders for more affordable and accessible treatment options.

In this rapidly evolving landscape, India has emerged as a formidable player in the medical tourism industry, offering high-quality healthcare services at a fraction of the cost in other countries. With a combination of cutting-edge medical facilities, skilled healthcare professionals, specialized treatments, and a rich cultural experience, India has become a sought-after destination for patients from around the world.

Cost-effectiveness is one of the primary factors driving India's rise as a medical tourism hub. The country offers significantly lower prices for a wide range of medical procedures and treatments compared to the United States, Europe, and other developed countries. Even after considering travel and accommodation expenses, patients can still save between 65 to 90 per cent on medical costs by choosing India for their treatments. This affordability has been a compelling reason for patients, particularly those from countries with expensive healthcare systems, to seek medical care in India.

Furthermore, India's medical infrastructure has undergone remarkable advancements, boasting state-of-the-art technology and facilities on par with leading hospitals in developed nations. Many hospitals in India have achieved international accreditations, ensuring compliance with global standards of medical care and patient safety. This commitment to quality has garnered trust and confidence from international patients, making India an attractive destination for medical tourists seeking top-tier healthcare services.

Figure: India Medical Tourism

1. Orthopaedics:
Orthopaedic disorders have become the silent killers in India that affect around 15 million adults every year. Increasing incidence of osteoarthritis, osteoporosis, obesity, diabetes, and the aging population is worsening the number. Plus, it is expected to reach 60 million by 2025. This number shows that there will be a huge demand for orthopaedists in India.

Moreover, based on qualifications and experience, an orthopaedist can get up to ₹2,000,000 per year in India.

Since the demand, scope, and salary range for this medical specialty is high, orthopaedics tops the medical courses list. If you aspire to have a rewarding medical career, you can upgrade your PG medical degree with a specialty course in orthopaedics.

2. Internal Medicine:
When you are in great confusion in selecting the specialty, internal medicine is a good option. It has an 'n' number of subspecialties from which you can pick the most suitable one to fine-tune your medical career further.

As per PayScale data, the average salary a specialist in internal medicine in India is ₹1,192,770.

According to a recent report, India has a shortage of 6,000,000 doctors. So, India has a long way to fill this void. Most medical associations motivate students to take up their careers in internal medicine.

3. Obstetrics and Gynaecology:
"Obstetrics and gynaecology" are a popular specialization that can fetch you a lucrative and successful career in the medical sector. The demand for gynaecologists is high and consistent. If you get specialized in obstetrics and gynaecology with required educational qualification and proper experience, you will get better opportunities in India.

The average salary of an OB-GYN specialist in India is ₹1,500,000 per year.

However, the industry demands constant upgradation. Therefore, you need to upskill yourself and upgrade to the new technologies in the sector. It will enhance the effectiveness of your services in the sector.

4. Dermatology:
People who do not care for healthcare for their skill. Being the largest yet sensitive organ in the human body, the skin needs intense care to stay away from hundreds of thousands of allergies and diseases. People spend millions to make their skin hale and healthy.

The annual expenditure of the skin-care industry is estimated as $950 million and growing at the rate of 15%–20% annually. This annual growth rate evidences that dermatology is a lucrative career option. According to PayScale, the average salary of a dermatologist in India is ₹1,191,045.

Dermatology is one of the topmost medical specialties and the most satisfactory medical branch. Since this does not only involve core dermatology but also covers other sub-branches like cosmetology, dermatosurgery, dermatopathology, and so on, the demand for dermatologists is high. Unfortunately, the number of dermatologists is very low in India. However, the success rate depends solely on your qualification, experience, and talent to be successful as a dermatologist.

5. Paediatrics:
In the current medical scenario, paediatrics is the most prominent career option in India. The demand for qualified and proficient paediatricians is growing day by day. If you like treating children and can treat them with a high level of tolerance, then paediatrics would be the right choice where there is a wide scope too.

The salary of a paediatrician may solely depend on the qualification, experience, and organization. However, as per PayScale data, the average salary a paediatrician or child specialist in India is ₹1,183,670 per annum.

Moreover, you will have even better opportunities when you further go for neonatology. Opportunities are wide in the field of paediatrics. So, make a wise decision.

6. Radiology:
Primary diagnosis can save patients from severe health issues that may affect them and cost their lives. It saves millions of lives promptly. Thus, radiology plays a vital role in diagnosis, thereby becoming an important part of modern medicine.

Medical conditions such as cancer, brain tumor, appendicitis, stroke, lymphoma, and kidney and bladder stones can be identified with ease and even cured or treated without surgery.

The average salary of radiologists in India is estimated to be around ₹1,818,502.

7. General Surgery:
India is in high demand for surgeons. Primary health centers in India have only 16% of surgeons, where there is an 84% shortage. Therefore, approximately India is in need of 5,000 surgeons. This is a pressing issue and needs to be addressed immediately.

Becoming a surgeon is not easy and needs hard work, perseverance, and dedication. An MBBS degree is not enough to take up a surgeon role. A general surgeon should attain excellence with a PG medical course to get specialized as a surgeon with enhanced knowledge and application skills. A further upgradation is also advisable as the technology in the medical industry is growing at a faster pace.

In India, the average salary of a general surgeon is ₹1,145,156 per year.

8. Ophthalmology:
Again, ophthalmology is one of the medical specialties that have ample career prospects and has been considered as a highly remunerative option. Since the market is expected to reach $1.8 billion by 2022, India has an unmet need for ophthalmologists.

Moreover, an ophthalmologist in India can get an average salary of ₹1,211,243 per year in India.

When you may have to treat the paediatric to the geriatric population, you need better skills that range from medical to patient care to surgical. Besides, there is a much better scope for Indian ophthalmologists in first-world countries like the USA, the UK, and Gulf countries. Now, the choice is yours!

9. Family Medicine:
Family medicine is gaining prominence among the other medical specialties in India, as 90% of clinical conditions can be taken care of by these specialists. Family medicine specialists are considered as the backbone of the medical field as they cover all age groups, organs, and genders. Moreover, their roles in the community become crucial.

The average salary of a family medicine physician in India can earn around ₹1,662,002 per year.

If you equip yourself with the qualification and skills need to be a successful family physician, you have to stay upgraded. As the scope, demand, and salary of a family medicine doctor is high, it is worth considering to take up as a career path.

10. Chest Medicine:
Besides being a tricky medical branch, it has high demand and scope in the industry. Pollution has created a health emergency and has paved the way for plenty of chest-related diseases. This symbolizes the growing demand for these specialists.

The average salary of a specialist in chest medicine in India is ₹1,216,409 per year.

Like other medical specialties in India, the job outlook for chest medicine is very good. Such specialists are in great demand. When you are qualified with the necessary educational qualification and staying upgraded with additional courses, you can set up a rewarding career in this medical specialty.

11. Anaesthesia:
The World Health Organization recommends that there must be 1 anaesthesiologist for 5,000 people. Unfortunately, India has got 1 for 50,000 people. So, the demand is pressing. When it comes to salary, it is equally high.

According to PayScale, the average salary for an anaesthesiologist in India is ₹1,212,316.

Being the backbone of surgeries, the anaesthesiologist's role is key in the medical industry and has a greater demand across the country. Pursuing a specialty course in this medical specialty will do and help you set up a best-paying career.

12. Pathology:
As for other medical specialties, pathology is also an in-demand field. However, India is facing a huge shortage of this specialist. The diagnostic is a ₹75,000-crore market in India. Being new technologies implemented, the industry is growing at a faster pace and creating better space for specialists to thrive.

According to PayScale, the average salary for a pathologist in India is 1,019,045 per year in India. It is no wonder why pathology has been considered as one of the best medical specialties in India.

13. ENT:
Treatment for ear, nose, and throat (ENT) is gaining prominence along with the other medical specialties. And the industry needs a wide number of specialists to meet the health needs of the growing population. There are several vacancies unfilled in government hospitals due to a lack of qualified specialists. It is obvious that you can have a rewarding and lucrative career if you choose ENT in India.

As specified in Glassdoor, an ENT specialist can earn around ₹1,667,772 per year in India.

Besides demand, scope, and salary, the advancement in technology has revolutionized the ENT treatment. Pollution, unhealthy food habits, and other lifestyle-related issues increase the demand for ENT specialists. Thus, it is the best medical course that can be considered to get specialized.

There are thousands of diseases and conditions that can affect humans. Nearly everyone has suffered common illnesses like seasonal allergies or had an infectious disease like a stomach bug at some point in their lifetime. Chronic diseases like heart disease and diabetes affect millions of Americans.

Perhaps someone among your friends or family members has a relatively less common condition, such as inflammatory bowel disease (an autoimmune disease). A serious genetic condition like cystic fibrosis is far less common. Then, there are conditions like cancers with high morbidity and mortality rates.

Historically speaking, the United States and the world have been through many epidemics and pandemics. The HIV pandemic of the 1980s and the COVID pandemic first reported to the World Health Organization in 2019 come to mind.

Let's take a look at some of the most common diseases and conditions prevalent in the United States. Some of these conditions produce symptoms, while others are silent. Diagnosis, treatment, and interventions are available for most of these diseases, although, prevention is key.

Knowing the most common diseases in the US may help you recognize the symptoms early and seek timely medical care. Our goal in providing this information is also to encourage you to take preventive measures and work on modifiable risk factors to ensure healthy living and overall well-being.

Class – 27

What are the 10 most common diseases?

HEART DISEASE
According to the Centers for Disease Control and Prevention (CDC), cardiovascular diseases are the leading cause of death across all ethnic groups and genders in the United States. You may be surprised to learn that one person dies every 34 seconds in the US from cardiovascular diseases. More than 800,000 people suffer heart attacks in the US every year (that's one heart attack every 40 seconds). Heart disease is responsible for 1 in 5 of all deaths in the US, and it claims nearly 700,000 lives each year.

CANCER
At the beginning of 2019, it was estimated that almost 17 million Americans alive had a history of invasive cancer, with many diagnosed years ago and currently disease-free. However, an estimated 1.9 million new cases of cancer are diagnosed each year in the US. This figure excludes skin cancers (basal cell and squamous cell) and most non-invasive cancers. An estimated 600,000 Americans die of cancer each year. This is equal to more than 1600 cancer deaths every day. Cancer is only second to cardiovascular diseases as the most common cause of death among Americans.

CHRONIC RESPIRATORY DISEASES
The CDC estimates that 5% of American adults are living with a chronic disease of the lower respiratory tract, such as asthma, chronic bronchitis, COPD, or emphysema. These conditions are responsible for over 870,000 ER visits each year and approximately 152,000 deaths annually. Asthma and other diseases of the lower respiratory tract are the sixth leading cause of death in the US.

OBESITY
America is in the midst of an obesity epidemic. The CDC reports that over 42% of Americans are obese and approximately 9% have severe obesity. Being overweight or obese is more prevalent in men, but severe obesity is more common among women. Lifestyle changes like a healthy diet and regular exercise play a critical role in treating obesity, which is linked to many health complications. Some may also struggle with inflammatory bowel disease (IBD), which is characterized by chronic inflammation of the gastrointestinal (GI) tract.

ALZHEIMER'S DISEASE

As of 2022, approximately 6.5 million Americans are living with Alzheimer's disease. Around 1 in 9 Americans over the age of 65 have Alzheimer's. Nearly 3 out of 4 patients with this condition are aged 75 years or older. The disease is more prevalent among women than men, and almost two-thirds of Alzheimer's patients are women. Alzheimer's is also more common in Black and Hispanic people compared to Caucasians. Experts predict that by the year 2050, the number of Americans with Alzheimer's disease may be over 12.5 million. However, new treatments and medical breakthroughs may help to slow or cure this disease.

DIABETES

Diabetes is a chronic disease that can cause damage to tissues and organs like the kidneys, eyes, heart, and blood vessels. A sick person with diabetes often does not experience any symptoms until the disease is at an advanced stage. There are over 37 million Americans with diabetes (more than 11% of the total US population). About 1 in 4 people with diabetes are undiagnosed. Additionally, 96 million adults in the US have prediabetes. Nearly half of all adults aged 65 years or older have prediabetes.

SUBSTANCE ABUSE

Substance abuse can cause both physiological and emotional complications. It affects people of all ages, genders, ethnic groups, and socioeconomic status. The National Institute on Drug Abuse (NIDA) reports that 13% of Americans aged 12 years and over report illicit drug use within the past month. Over 25% of adults in the US report heavy alcohol use (five or more drinks per day for men and four or more drinks per day for women). Also, approximately 1.9% of Americans aged 12 years and older report nonmedical use of a therapeutic drug in the past month. According to the latest reports, almost 92,000 drug overdose deaths occur each year in the US, with 20% of these deaths attributed to opioid drugs.

INFECTIOUS DISEASES

Bacterial infections are treatable with antibiotics. Many illnesses caused by viruses are self-limited, such as the common cold. Antiviral medications are available to treat other viral illnesses. Some of the main types of bacterial and viral infectious diseases prevalent in the United States are listed below.

Influenza: In recent years, anywhere from 38 to 45 million Americans have had a symptomatic influenza illness every year.

Chlamydia: This is the most common sexually transmitted infection in the US, with over 1.5 million cases reported in 2020.

Staphylococcus: Approximately 119,000 bloodstream Staphylococcus aureus (staph) infections are reported in the US each year. These infections are responsible for nearly 20,000 deaths annually.

Escherichia coli: Bacteria called E. coli can cause diarrhea, urinary tract infections, pneumonia, and other illnesses. This large group of bacteria is responsible for 265,000 illnesses and around 100 deaths in the US every year.

HSV: Herpes simplex virus type 1 and type 2 causes cold sores (fever blisters) and genital herpes. Experts estimate that 50-80% of American adults have had oral herpes, and 90% of people have been exposed to the virus by age 50. Approximately 575,000 Americans are diagnosed with a new infection of genital herpes in the US each year.

CHRONIC KIDNEY DISEASE

Approximately 15% of the adult population in the US (37 million people or 1 in 7 adults) have chronic kidney disease (CKD). Interestingly, up to 90% of adults with CKD do not know they have the condition, including 40% of adults with severe CKD.

MENTAL ILLNESSES

More than 50% of Americans will be diagnosed with a mental disorder at some point in their life. Experts estimate that 1 in 5 Americans experiences a mental illness in any given year. Also, 1 in 25 Americans is living with a serious mental illness like bipolar disorder, schizophrenia, or major depression.

Conclusion:
These are just some of the most common diseases and conditions that afflict people in the United States. Most are covered by health insurance. You can reduce your risk of serious complications from these diseases by seeking timely diagnosis and treatment.

Researchers are working on finding cures and effective treatments for all forms of diseases that affect humans, like infectious disease and cardiovascular diseases. In the coming years, advances in research, the development of new drugs, and efforts to increase access to healthcare may make some of these diseases and conditions less common than they are at the present time.

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Multiple Choice Question

1. Life Science Industry refers to all the companies whose work is centered and focused on
a. Living objects

b. Non-living objects

c. Both Living and nonliving objects.

d.None of the above.

Ans:- a. Living objects

2.Top Indian Pharmaceuticals company is
a. Larsen & Tubro Limited

b. Sun Pharmaceuticals Industries Limited

c Tata Consultancy Services

d. Hindustan Unilever Limited.

Ans:-b. Sun Pharmaceuticals Industries Limited.

3.In pharmaceuticals Industry QC refers to as..
a. Quality Conscious.

b Quality Control.

c. Quality Complaint

d. Quality Complement.

Ans;- b. Quality Control.

4. Ideal Pharmaceuticals Distribution Channel comprises of the following:
a. Manufacturer, Whole sellers, Retailers. Consumers.

B. Distributors, Whole sellers, Retailers. Consumers

c. C&FA, Whole sellers, Retailers. Consumers

d. C&FA, Retailers. Consumers, customers.

Ans;- a. Manufacturer, Whole sellers, Retailers. Consumers.

5. A "sale" is an agreement between …… And ……. of the particular money, goods & services.
a. Medical representative and customer

b. Consumer and Customer

c. Seller and Buyer

d. Company and Customer.

Ans;- c. Seller and Buyer

6. Full form of FMCG is …
a. Future Moving Consumer Goods

b. Slow-moving Customer Goods

c. Future Motivated Consumer Goods.

d. Fast-moving consumer Goods.

Ans;- d. Fast Moving Consumer Goods.

7.In ethical Pharmaceutical Marketing practice, Product promotion is directed towards…..
a. Nurses

b. Retailers.

c. Doctors

d. Distributors.

Ans:-c. Doctors

8. Medical Representatives can get elevated/promoted to next higher level in sales function which is usually ……
a. National Sales Manager

b. Zonal Manager

c. Regional Manager.

d. Area Manager.

Ans:- d. Area Manager.

9. In Pharmaceutical Selling, Doctors act as…..
a. Customer

b. Consumer

c. Influencer

d. Liasoner.

Ans:-c. Influencer

10. Communication is the act of transferring of …… ideas, thoughts and feelings from one place, person or group to another.
a. Words.

b. Sign and Symbols.

c. Information.

d. Knowledge.

Ans:-c. Information.

11.Touch is an example of …….
a. Verbal Communication.

b. Non-Verbal Communication.

c. Written Communication.

d. Oral Communication.

Ans:-b. Non-Verbal Communication.

12. Proxemics refers to……
a. Residential space

b. Personal Space.

c. Inter Molecular space.

d. None of the above.

Ans:-b. Personal Space.

13. Communication through "TOUCH" is known as……
a. Haptics

b. Proxemics.

c. Para-Linguistics.

d. None of the above.

Ans:-a. Haptics

14. "DETAILING" can be defined as the presentation of … in the most logical sequence.
a. Collinear Points.

b. Selling Points.

c. Bogey Points.

d. Trailing Points.

Ans:-b. Selling Points.

15. "OTC" in Pharmaceutical Retail Marketing refers to as…
a. Online Terminal Change.

b. Over The Crypto.

c. Over The Counter.

d. Over The Current.

ANS: c. Over The Counter.

16. Who among the following is primarily responsible for product procurement in hospitals?
a. Chief Financial Officer

b. Chief Medical Officer

c. Procurement Manager

d. Nursing Head

Ans- c. Procurement Manager

17. In a pharmaceutical distribution network, who plays a critical role in ensuring timely delivery of products to pharmacies?
a. Pharmacist

b. Distributor

c. Patient Support Executive

d. Regulatory Authority

Ans: b. Distributor

18. Which government scheme provides free medicines to patients in public health facilities in India?
a. Ayushman Bharat

b. National Pharmaceutical Pricing Authority (NPPA)

c. Pradhan Mantri Jan Arogya Yojana (PMJAY)

d. Free Drugs Service Initiative

Ans: d. Free Drugs Service Initiative

19. What is the purpose of the National Health Mission (NHM)?
a. Encourage private healthcare

b. Improve access to affordable and quality healthcare services

c. Reduce healthcare exports

d. Regulate clinical research

Ans: b. Improve access to affordable and quality healthcare services

20. What is the role of the Central Drugs Standard Control Organization (CDSCO)?
a. Pricing of pharmaceutical products

b. Regulating clinical trials and approving new drugs

c. Ensuring patent protection for drugs

d. Handling environmental compliance for drug manufacturing

Ans: b. Regulating clinical trials and approving new drugs

21. The NPPA regulates pharmaceutical prices under which act?
a. MRTP Act

b. Drugs and Cosmetics Act

c. Essential Commodities Act

d. GST Act

Ans: c. Essential Commodities Act

22. The MRTP Act primarily aims to:
a. Prevent monopolistic and restrictive trade practices

b. Regulate medical research

c. Standardize pharmaceutical exports

d. Manage healthcare professional licensing

Ans. a. Prevent monopolistic and restrictive trade practices

23. The Drug Price Control Order (DPCO) is enforced by:
a. CDSCO

b. NPPA

c. Medical Council of India

d. FSSAI

Ans. b. NPPA

24. Which of the following entities directly supplies pharmaceutical products to retailers?
a. CFA

b. Stockist

c. Distributor

d. Manufacturer

Ans: c. Distributor

25. What is the role of a Carrying and Forwarding Agent (CFA) in pharmaceutical distribution?
a. Directly sells products to patients

b. Acts as a logistics intermediary between manufacturers and distributors

c. Manages the manufacturing process

d. Monitors retail pharmacy sales

Ans: b. Acts as a logistics intermediary between manufacturers and distributors

26. Which of these products is regulated differently compared to others in India?
a. Vaccines

b. Ayurvedic products

c. Generic medicines

d. Homeopathic products

Ans: b. Ayurvedic products

27. What is the purpose of liasioning agents in pharmaceutical distribution?
a. Manufacturing drug products

b. Facilitating communication between companies and regulatory bodies

c. Managing drug pricing

d. Handling clinical trials

Ans: b. Facilitating communication between companies and regulatory bodies

28. Which medical speciality deals with the treatment of heart-related conditions?
a. Nephrology

b. Cardiology

c. Pulmonology

d. Endocrinology

Ans: b. Cardiology

29. What is the primary function of the endocrine system?
a. Transport oxygen to tissues

b. Produce hormones that regulate bodily functions

c. Remove waste products from the blood

d. Protect against pathogens

Ans: b. Produce hormones that regulate bodily functions

30. Diabetes is most commonly treated by which type of specialist?
a. Oncologist

b. Endocrinologist

c. Neurologist

d. Orthopaedist

Ans: b. Endocrinologist

31. The central nervous system includes which of the following components?
a. Brain and spinal cord

b. Heart and blood vessels

c. Kidneys and ureters

d. Stomach and intestines

Ans: a. Brain and spinal cord

32. When presenting scientific data to healthcare professionals, what is most important?
a. Simplifying data into layman's terms

b. Using peer-reviewed, evidence-based information

c. Avoiding technical terms entirely

d. Emphasizing company achievements

Ans: b. Using peer-reviewed, evidence-based information

33. What is a common component of a pharmaceutical market briefing?
a. Financial performance of competitors

b. Technical details of a product's mechanism of action

c. List of all employees in the company

d. Historical prices of similar drugs

Ans: b. Technical details of a product's mechanism of action

34. How does knowledge of general anatomy and physiology help in product presentations?
a. Allows for a detailed explanation of drug pharmacokinetics

b. Helps avoid discussion of diseases

c. Simplifies the presentation for laypeople

d. Connects the product's benefits to specific human systems

Ans: d. Connects the product's benefits to specific human systems

35. Which of the following is a key challenge when presenting to healthcare professionals?
a. Lack of knowledge of medical terminologies

b. Ensuring regulatory compliance during discussions

c. Overloading with technical data

d. All of the above

Ans: d. All of the above

36. What are soft skills?
a) Specific technical abilities related to a particular job
b) Non-technical interpersonal and personal attributes
c) Computer programming skills
d) Academic qualifications and degrees
Answer: b) Non-technical interpersonal and personal attributes

37. Which of the following is an example of a soft skill?
a) Coding in Python
b) Problem-solving
c) Operating heavy machinery
d) Data analysis
Answer: b) Problem-solving

38. Why are soft skills important in the workplace?
a) They are not essential for career success.
b) They contribute to a positive work environment and enhance teamwork.
c) Soft skills are only relevant for leadership positions.
d) Soft skills are not transferable to different job roles.
Answer: b) They contribute to a positive work environment and enhance teamwork.

39. Which soft skill refers to the ability to convey information effectively and listen actively to others?
a) Creativity
b) Emotional intelligence
c) Communication
d) Time management
Answer: c) Communication

40. What is emotional intelligence?
a) The ability to understand and manage one's emotions and empathize with others
b) The capability to learn programming languages quickly
c) The skill of managing time effectively
d) The aptitude to work well in a team environment
Answer: a) The ability to understand and manage one's emotions and empathize with others

41. How do soft skills differ from hard skills?
a) Soft skills are specific and measurable abilities, while hard skills are transferable.
b) Soft skills are technical, while hard skills are interpersonal.
c) Soft skills are not essential in the workplace.
d) Soft skills and hard skills are synonymous terms.
Answer: a) Soft skills are specific and measurable abilities, while hard skills are transferable.

42. Which soft skill involves the capability to adjust to changing circumstances and embrace new challenges?
a) Emotional intelligence
b) Adaptability
c) Leadership
d) Conflict resolution
Answer: b) Adaptability

43. Why are employers seeking candidates with strong soft skills?
a) Soft skills are irrelevant in the workplace.
b) Soft skills contribute to a negative work environment.
c) Soft skills enhance teamwork and productivity.
d) Soft skills are only needed in creative fields.
Answer: c) Soft skills enhance teamwork and productivity.

44. What soft skill involves the capacity to influence and guide others toward shared goals?
a) Communication
b) Adaptability
c) Leadership
d) Decision making
Answer: c) Leadership

45. Which soft skill is crucial for effectively managing and resolving disagreements or disputes?
a) Time management
b) Creativity

c) Conflict resolution
d) Emotional intelligence
Answer: c) Conflict resolution

46. What is the significance of time management as a soft skill?
a) Time management leads to inefficiency and missed deadlines.
b) Time management has no impact on productivity.
c) Time management allows individuals to prioritize tasks and meet deadlines effectively.
d) Time management is irrelevant in the workplace.
Answer: c) Time management allows individuals to prioritize tasks and meet deadlines effectively.

47. How can soft skills contribute to personal relationships?
a) Soft skills limit effective communication and understanding.
b) Soft skills avoid empathy and emotional connection.
c) Soft skills foster effective communication, empathy, and mutual understanding.
d) Soft skills are not applicable in personal relationships.
Answer: c) Soft skills foster effective communication, empathy, and mutual understanding.

48. Why is adaptability important in today's fast-paced work environment?
a) Adaptability limits creativity and innovation.
b) Adaptability avoids change and challenges.
c) Adaptability allows individuals to adjust to evolving circumstances and remain effective.
d) Adaptability is only relevant for leadership positions.
Answer: c) Adaptability allows individuals to adjust to evolving circumstances and remain effective.

49. How can individuals develop their soft skills?
a) Soft skills cannot be developed or improved.
b) Soft skills are innate and cannot be refined.
c) Soft skills can be developed through training, practice, and real-life experiences.
d) Soft skills are irrelevant in personal development.
Answer: c) Soft skills can be developed through training, practice, and real-life experiences.

50. What soft skill involves the capability to think innovatively and generate original ideas and solutions?
a) Creativity
b) Decision making
c) Collaboration
d) Conflict resolution
Answer: a) Creativity.

51. How can soft skills benefit employees in customer-facing roles?
a) Soft skills are not relevant for customer interactions.
b) Soft skills enhance effective communication and build rapport with customers.
c) Soft skills lead to conflicts and challenges with customers.
d) Soft skills are not transferable to customer service roles.
Answer: b) Soft skills enhance effective communication and build rapport with customers.

52. What is the role of collaboration as a soft skill?
a) Collaboration limits effective teamwork and productivity.
b) Collaboration fosters the generation of multiple ideas and perspectives.
c) Collaboration avoids communication and interaction with others.
d) Collaboration has no impact on the work environment.
Answer: b) Collaboration fosters the generation of multiple ideas and perspectives.

53. How does emotional intelligence impact interpersonal relationships?
a) Emotional intelligence leads to a lack of understanding of one's emotions and others'.
b) Emotional intelligence fosters empathy, understanding, and effective communication with others.
c) Emotional intelligence limits the development of soft skills.
d) Emotional intelligence is irrelevant in interpersonal interactions.
Answer: b) Emotional intelligence fosters empathy, understanding, and effective communication with others.

54. What soft skill involves the skill of making informed and effective decisions based on available information?
a) Communication
b) Creativity
c) Decision making
d) Conflict resolution
Answer: c) Decision making

55. How can creative thinking benefit problem-solving?
a) Creative thinking leads to avoiding problem-solving and challenges.
b) Creative thinking has no impact on problem-solving.
c) Creative thinking fosters innovative and effective solutions to problems.
d) Creative thinking is irrelevant in problem-solving.
Answer: c) Creative thinking fosters innovative and effective solutions to problems.

56. Which soft skill involves the capability to manage and resolve disagreements or conflicts constructively?
a) Time management
b) Adaptability
c) Conflict resolution
d) Leadership
Answer: c) Conflict resolution

57. How can soft skills contribute to effective teamwork?
a) Soft skills hinder effective communication and collaboration in teams.
b) Soft skills lead to conflicts and challenges in team dynamics.
c) Soft skills foster mutual understanding, communication, and respect among team members.
d) Soft skills are irrelevant in team environments.
Answer: c) Soft skills foster mutual understanding, communication, and respect among team members.

58. What soft skill involves the capability to adjust to changing circumstances and embrace new challenges?

a) Emotional intelligence
b) Adaptability
c) Leadership
d) Conflict resolution
Answer: b) Adaptability

59. Why do employers value candidates with strong soft skills?
a) Soft skills are not essential for career success.
b) Soft skills contribute to a negative work environment.
c) Soft skills enhance teamwork and productivity.
d) Soft skills are only needed in creative fields.
Answer: c) Soft skills enhance teamwork and productivity.

60. What is the role of leadership as a soft skill?
a) Leadership involves following established rules and guidelines.
b) Leadership fosters effective communication and collaboration in teams.
c) Leadership has no impact on team dynamics.
d) Leadership involves influencing and guiding others toward shared goals.
Answer: d) Leadership involves influencing and guiding others toward shared goals.

61. How does conflict resolution contribute to effective team dynamics?
a) Conflict resolution encourages conflicts and disputes among team members.
b) Conflict resolution avoids effective communication and understanding.
c) Conflict resolution fosters constructive problem-solving and collaboration in teams.
d) Conflict resolution is irrelevant in team environments.
Answer: c) Conflict resolution fosters constructive problem-solving and collaboration in teams.

62. What is the role of time management as a soft skill?
a) Time management leads to inefficiency and missed deadlines.
b) Time management has no impact on productivity.
c) Time management allows individuals to prioritize tasks and meet deadlines effectively.
d) Time management is irrelevant in the workplace.
Answer: c) Time management allows individuals to prioritize tasks and meet deadlines effectively.

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a) Soft skills limit effective communication and understanding in personal relationships.
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c) Soft skills foster effective communication, empathy, and mutual understanding in personal relationships.
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d) Soft skills are irrelevant in personal development.
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