Regulatory Challenges of Indian Drugs

This editorial is based on **Safety first** which was published in The Hindu on 20/06/2023. It talks about safety issues related to Indian drugs and its consequences.

For Prelims: Central Drugs Standard Control Organization, Drugs and Cosmetics Act, 1940,

For Mains: Consequences of ineffective drug regulations

India is one of the largest producers and exporters of pharmaceutical products in the world, catering to **about 20% of the global demand for generic drugs.** India is **among the top 12 destinations for biotechnology worldwide** and **3rd largest destination for biotechnology in Asia Pacific.** In 2022, India's Biotechnology industry has **crossed USD 80.12 billion, growing 14% from the previous year.**

India's pharma industry has **contributed to improving the health outcomes and access** to affordable medicines for millions of people across the world, especially in developing countries. However, India's pharma industry has **also faced several allegations and incidents of producing substandard, contaminated or harmful drugs** that have caused adverse effects and deaths among patients in various countries such as in Sri Lanka, Gambia, Uzbekistan, United States etc.

These incidents have **raised serious concerns** about the **quality and safety** of Indian pharma products and the **role and effectiveness** of the Indian drug regulator in ensuring compliance with the standards and norms.

What are the Potential Causes of Inadequate Safety Standards of Drugs?

- **Lack of Adequate Regulation and Enforcement:**
  - India's drug regulation is **governed** by the **Drugs and Cosmetics Act, 1940**, which is **outdated and inadequate to deal** with the **complexities and challenges** of the modern pharma market.
  - The Act **does not cover many aspects such as clinical trials, bioequivalence studies, good manufacturing practices,** etc. that are essential for ensuring quality and safety of drugs.
  - Moreover, the **enforcement of the Act is weak and fragmented,** as it involves multiple authorities at the central and state levels, with overlapping jurisdictions and responsibilities.
- **Inadequate Resources:**
  - There is also a **shortage of manpower, infrastructure, funds and technology** to carry out **effective inspections, testing, monitoring and surveillance** of drug manufacturing units and products.
- **Lack of Transparency and Accountability:**

    - India's drug regulator, the **Central Drugs Standard Control Organization** (CDSCO), does not disclose much information about its activities, processes, outcomes, etc. to the public or the media.
    - There is no mechanism to evaluate its performance or impact on curbing substandard or spurious drugs.
        - There is also **no mechanism to ensure that the regulator is independent, impartial and free** from external influences or pressures from the government or the industry.
        - There have been **allegations of corruption, collusion and conflict of interest among some officials** of the CDSCO and some pharma companies.
- **Lack of Awareness and Compliance among Pharma Companies:**
    - Some pharma companies in India **do not adhere to the prescribed standards** and norms **for manufacturing, testing, labeling, packaging, storing** and distributing drugs.
        - Some pharma companies also resort to **unethical or illegal practices** such as using substandard or counterfeit raw materials, adulterating or **diluting drugs, falsifying or manipulating data** or documents, etc. to cut costs or increase profits.
        - They also **lack awareness or knowledge** about the regulatory requirements or guidelines for different markets or countries.
        - They may not have **adequate quality control systems or mechanisms** to detect or prevent errors or defects in their products.

What are the Consequences of Ineffective Regulations?

- **Harm to Public Health:**
    - Poor quality and safety of Indian pharma products can cause serious harm to public health by causing adverse effects such as **infections, allergies, organ damage, poisoning, etc.** among patients who consume them.
    - This can lead to treatment failure, drug resistance, complications or deaths among patients who suffer from **chronic or life-threatening diseases** such as HIV/AIDS, tuberculosis, malaria, cancer, etc.
- **Erosion of Public Trust:**
    - Ineffective regulation **undermines the trust and confidence of patients** and healthcare providers in Indian pharma products.
- **Harm to Economic Growth:**
    - Poor quality and safety of Indian pharma products **can cause harm to economic growth by affecting the reputation and competitiveness** of India's pharma industry in the global market.
    - This can lead to **loss of market share, revenue and profits for Indian pharma companies due to bans, recalls or rejections** of their products by foreign regulators or customers.
    - Consequently, lead to **loss of foreign exchange earnings, employment opportunities and investments** for India's pharma sector.
    - They can also expose India's pharma industry to legal liabilities or penalties for violating the laws or norms of other countries.
- **Harm to International Relations:**
    - Poor quality and safety of Indian pharma products can cause harm to international relations by affecting India's image and credibility as a responsible and reliable partner in global health initiatives.
    - This can **create diplomatic tensions or conflicts** between India and other countries that are affected by substandard or harmful drugs from India.
- **Harm to International Cooperation:**
    - They can hamper India's **cooperation or collaboration** with other countries or organizations in addressing common health challenges such as **pandemics, epidemics, etc.**

Major Bodies Regulating Drugs and Pharmaceutical in India

Ministry of Health and Family Welfare	Ministry of Chemicals and Fertilizers	Ministry of Commerce	Ministry of Science and Technology	Ministry of Environment
Directorate General of Health Services (DGHS) Indian Council of Medical Research (ICMR)	Department of Pharmaceuticals	Patent Office	Department of Biotechnology (DBT)	Environmental clearance for manufacturing
Central Drugs Standard Control Organization (CDSCO) headed by Drug Controller General of India, DCGI (I) + Statutory Committees + Advisory Committees	National Pharmaceutical Pricing Authority (NPPA); Drugs (Prices Control) Order (DPCO) 2013	Controller General of Patent	Council of Scientific and Industrial Research (CSIR) Laboratories	
Central Drugs Standard Control Organization (CDSCO) headed by Drug Controller General of India, DCGI (I) + Statutory Committees + Advisory Committees				

What Should be the Way Forward?

- **Amending the Drugs and Cosmetics Act, 1940:**
  - The government **should update the legal framework for drug regulation** to cover all aspects and challenges of the pharma sector and provide clear and uniform standards and norms for different categories of drugs and markets.
- **Streamlining and Rationalizing the Drug Regulatory Structure and Functions:**
  - The government **should create a single, central authority with adequate powers, resources, expertise and autonomy** to regulate the entire pharma sector and ensure effective enforcement and compliance of the drug laws and norms.
- **Fostering a Culture of Quality and Safety Among the Pharma Industry:**
  - The government should **provide incentives, recognition, support and guidance** to the industry for complying with the standards and norms and producing high-quality drugs and encourage them to adopt voluntary self-regulation and quality certification schemes.

Drishti Mains Question:

Analyse the causes and consequences of poor quality and safety of Indian pharma products in the global market. Suggest some measures to improve the quality and safety of Indian pharma products and enhance India’s reputation and competitiveness as the pharmacy of the global south.

UPSC Civil Services Examination Previous Year's Question (PYQs)

Prelims:

Q. Which of the following are the reasons for the occurrence of multi-drug resistance in microbial pathogens in India? (2019)

1. Genetic predisposition of some people
2. Taking incorrect doses of antibiotics to cure diseases
3. Using antibiotics in livestock farming
4. Multiple chronic diseases in some people

Select the correct answer using the code given below.

(a) 1 and 2
(b) 2 and 3 only
(c) 1, 3 and 4
(d) 2, 3 and 4

Ans: (b)

Exp:

- Antimicrobial Resistance (AMR) is the ability of a microorganism (like bacteria, viruses, and some parasites) to stop an antimicrobial (such as antibiotic, antiviral and antimalarial) from working against it. As a result, standard treatments become ineffective, infections persist and may spread to others.
- A genetic predisposition (sometimes also called genetic susceptibility) is an increased likelihood of developing a particular disease based on a person's genetic makeup. A genetic predisposition results from specific genetic variations that are often inherited from a parent. It has no direct relation with Antimicrobial Resistance. Hence, 1 is not correct.
- AMR occurs naturally over time. In many places, antibiotics are overused and misused in people and animals, and are often given without professional oversight. Examples of misuse include when they are taken by people with viral infections like cold and flu, and when they are given as growth promoters in animals or used to prevent diseases in healthy animals. Hence, 2 and 3 are correct.
- Multiple chronic diseases are two or more chronic diseases that affect a person at the same time. For example, either a person with arthritis and hypertension or a person with heart disease and depression, both have multiple chronic diseases. So it is not necessary that a person with Multiple chronic disease will have an antimicrobial resistance, because a chronic disease can be of type where administering antibiotics is not required. Hence, 4 is not correct.
- Therefore, option (b) is the correct answer