

Unsafe Cancer Drugs

Mains syllabus: GS II -Issues Relating to Development and Management of Social Sector/Services relating to Health, Education, Human Resources.

Why in News?

Recently a major investigation by the Bureau of Investigative Journalism has revealed that contaminated cancer drugs like methotrexate have been shipped to more than 100 countries around the world.

What are the challenges in maintaining drug quality?

- **Contamination Issues** - Staff working without proper disinfection processes can carry contaminants.
- Highly Sensitive Process - Even a technician moving too quickly in a clean room can create air movement that spreads bacteria.
- **Handling Issues** - Inadequate testing of raw ingredient, improperly cleaned equipment and unthoroughly filtered water, can make these lifesaving medicines become lethal.
- **Long Supply Chain** - The drugs travel through factories, storage facilities, transport systems, hospitals and pharmacies and at every stage of this process, the drug's quality must remain unharmed.
- **Inadequate Testing Infrastructure** - Unlike wealthy nations with robust tracking systems, low and middle-income countries often lack the infrastructure to monitor the journey.
- For example, only seven countries in sub-Saharan Africa, have laboratories that have been approved as meeting WHO standards.
- **Administrative Issues** - Corruption issues and porous borders, pave way for the potentially counterfeit drugs to enter healthcare systems.

What are the consequences of unsafe cancer Drugs?

- **Affects Treatment** - Substandard or ineffective drug will affect treatment of patients undergoing chemotherapy.
- **Endangers Life** - Drugs that have not been manufactured properly can be toxic or contaminated and put a patient in immediate danger.

Recent Incidents of Drug contaminations

- In 2019, five young patients from Saudi Arabia developed a high fever, and one died, after taking an Indian-made medicine given at the same time as chemotherapy drugs.
- Again in 2019, four children died and more than a 100 fell ill in Colombia when given the contaminated drug.
- In 2022, at least 10 children in Yemen died after receiving methotrexate, a critical chemotherapy drug used to treat leukaemia and other cancers, that had been contaminated with a deadly bacterium.
- In 2023, the Bureau uncovered a dozen poor-quality brands of a childhood cancer drug used in Brazil.

- **Affects the Credibility of India** - The revelation of reports about low quality drugs from India will affect India's image as "Pharmacy of the World".
- **Loss of Market** - The tainted pharma image will cause reduction in demand for drugs from India.
- **Impact on Pharma Economy** - The reduced demand for Indian drugs will result in production decline of pharma in India.

What is the role of WHO in ensuring drug safety?

- **Rapid Alert System** - WHO maintains a rapid alert system for dangerous drugs through which the drugs are assessed and an alert is then sent out to all member governments.
- **Global Benchmarking Tool** - It is a tool that assesses and rates national regulatory systems on a scale of 1 (least mature) to 4 (most mature).
- **Essential Medicines List** - A list of medications that are the safest and most effective for meeting the most important health system needs.
- Generic versions of drugs on this list could still be fake or substandard, But the existence of the list helps countries prioritise limited resources.
- **Prequalification Programs** - These are the lists that contain laboratories, specific drugs, and sources of active pharmaceutical ingredients that the WHO has inspected, evaluated, and confirmed to be acceptable for use.
- This helps governments and national regulators procure safe medicines.
- **Good Manufacturing Practices (GMP) Certification** - This ensures that pharmaceutical products are consistently produced and controlled to quality standards.
- Most countries will only accept the import and sale of medicines that have been manufactured by internationally recognised GMPs.
- It is used by pharmaceutical regulators and the pharmaceutical industry in over 100 countries.
- **WHO Certification Scheme** - A Certificate of Pharmaceutical Products (CoPP) can be requested by a country that wants to import a medicine, and it would be issued by the exporting country according to the WHO guidelines.
- It acts like a passport for medicines, proving the item is approved and safely made in the exporting country.

Pharmacovigilance

- World Health Organization (WHO) defines it as 'the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.
- It is the Worldwide Master Key for Drug Safety Monitoring

What lies ahead?

- There could be a clear drug safety regulatory mechanism in every country to ensure the substandard drugs are not consumed by the people.
- There must be a best oversight mechanism, like the U.K model to prevent the sale and supply of counterfeit drugs.

UK Drug Safety Mechanisms

- **Different Levels of Quality Testing** - Every batch undergoes two rounds of quality testing, at the manufacturing site, and then on entering the U.K.
- **Different Markers** - During each of these rounds of tests, 20 different markers of drug quality are checked.
- **Professional Experts** - Only specific experts, those registered with professional bodies like the Royal Society of Chemistry, are qualified to verify each batch.
- **Regular Inspections** - The Medicines and Healthcare products Regulatory agency regularly inspects manufacturing facilities, both in the U.K. and abroad.

Reference

[The Hindu| unsafe cancer drugs](#)