

## 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*.

- 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](#)