India-made Syrups and Deaths in Gambia

For Prelims: WHO, Diethylene glycol and Ethylene glycol, CDSCO, DGCI.

For Mains: Drug Regulatory Norms in India.

Why in News?

Recently, the **World Health Organisation (WHO)** issued an alert about four **Indian-manufactured cough syrups, which are** said to be linked to acute kidney injury in children and 66 deaths in the small West African nation of The Gambia.

- The WHO analysis of samples of each of these products had confirmed the presence of **"unacceptable amounts of diethylene glycol and ethylene glycol as contaminants".** These ingredients are not allowed in food or drugs, as they **can cause abdominal pain, vomiting, diarrhoea, headache,** severe renal injury and neurological toxicity.
- The company said these were not sold in India and are only for export markets already approved by the DGCI.

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Decoding the regulatory norms

Who can export drugs from India?
Any manufacturer with a certification from the Central Drugs Standard Control Organisation (CDSCO) – the apex regulatory body for cosmetics, pharmaceuticals and medical devices.

Do drugs manufactured in India for export need to be tested domestically?
At the time of issuing license, drugs inspectors assigned by the Indian regulator may lift samples in any phase of manufacturing for quality checks. It is, however, not mandatory; and rarely done

What safety norms need to be adhered to?
First point of testing is at a manufacturer's level, to ensure that the drug adheres to the safety norms prescribed by the Indian Pharmacopoeia, and the regulatory requirement of the country of export. However, generally speaking, destination countries expect nations of origin to strictly follow the norms prescibed by the pharmacopoeia under which the sale is governed.

What are the intn'l drug safety norms?
Drug regulatory norms are usually country-specific and are enforced at the level of individual countries. The US, Japanese, British, European and Chinese pharmacopeias act as reference points for uniform preparations for the most commonly used drugs — with tests to ensure their quality, potency and purity. The WHO's prequalification programme is another criterion wherein the UN body certifies sale of drugs/vaccines under the UN programmes.

Are destination nations responsible for safety?
Some countries do internal testing at the point of entry, but it is not mandatory and varies by the country.

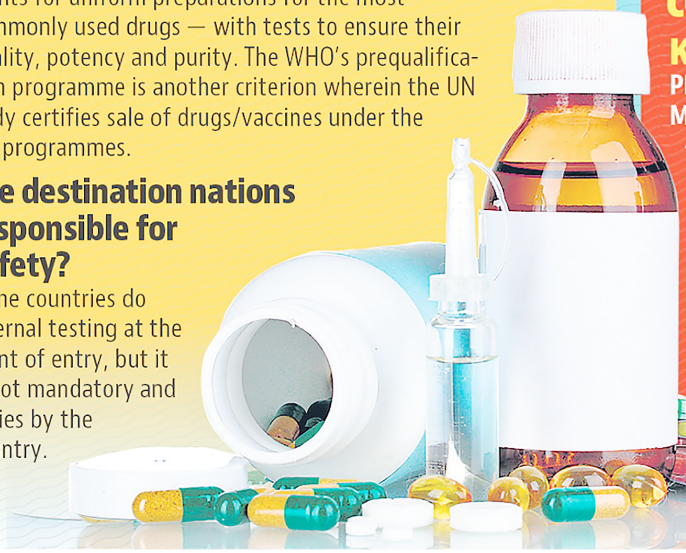
For sale domestically

What are the checks in place to ensure the safety of drugs in India?
The CDSCO and state drugs regulators are responsible for ensuring quality of drugs that are manufactured, sold or distributed in Indian markets.

Maiden Pharma controversies

KERALA: Maiden Pharmaceuticals' drugs – Metomin, Easiprin, and Maical-D – were lifted from the markets after they were found to be substandard

BIHAR: The state health department blacklisted the firm for 5 years in 2011 after six batches of two of its drugs were found "not of standard quality"



What are the Related Regulations in India?

- **The Drugs and Cosmetics Act:**
  - **The Drugs and Cosmetics Act**, 1940 and Rules 1945 have entrusted various responsibilities to central and state regulators for regulation of drugs and cosmetics.
  - It provides the regulatory **guidelines for issuing licenses to manufacture Ayurvedic, Siddha, Unani medicines.**
  - It is mandatory for the manufacturers to adhere to the prescribed requirements for licensing of manufacturing units & medicines including proof of safety & effectiveness, compliance with the **Good Manufacturing Practices (GMP).**
- **Central Drugs Standard Control Organisation(CDSCO):**
  - Prescribes standards and **measures for ensuring the safety, efficacy and quality of drugs,** cosmetics, diagnostics and devices in the country.
  - Regulates the **market authorization of new drugs and clinical trials standards.**
  - Supervises **drug imports and approves licences** to manufacture the above-mentioned

products.
    - **CDSCO regulates export** of drugs in India, any **manufacturer with the certification from CDSCO** can export drugs outside India.
- **Drugs Controller General of India:**
    - DCGI is the head of department of the CDSCO of the Government of India responsible for **approval of licences of specified categories of drugs** such as blood and blood products, IV fluids, vaccines and sera in India.
    - DCGI also sets **standards for manufacturing, sales, import**, and distribution of drugs in India.

Source: HT