Generic Cancer Drugs

> Mains Syllabus: GS II - Issues relating to development and management of Social Sector/Services relating to Health, Effect of policies and politics of developed and developing countries on India’s interests, Indian diaspora.

Why in the News?

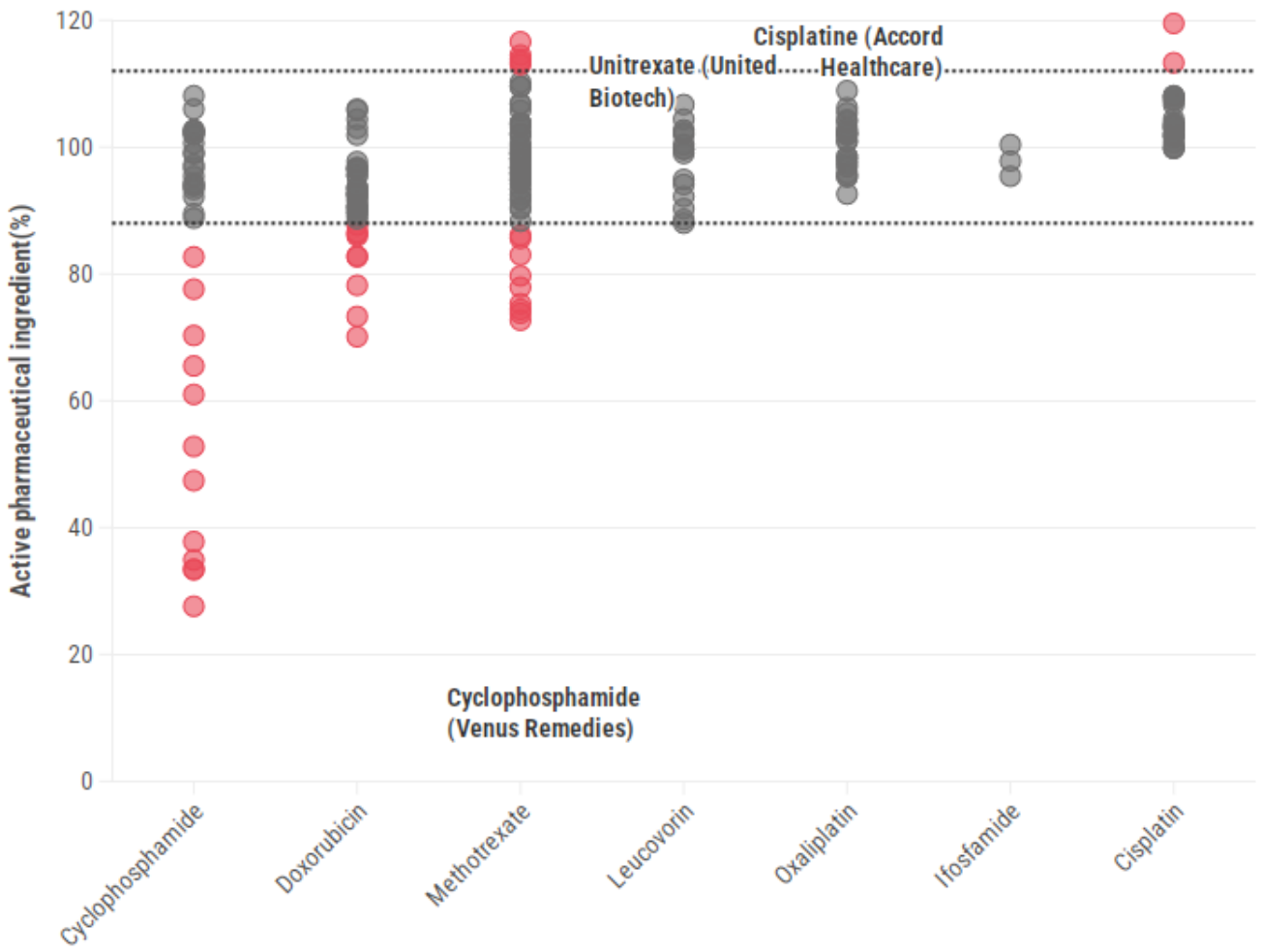
A landmark study published recently has reported that about a fifth of cancer drugs tested failed quality tests and 16 of the 17 implicated manufacturers are India-based.

What are the issues with cancer drugs ?

- **Low Quality Drugs** - Vital chemotherapy drugs used around the world have failed quality tests, leaving cancer patients in more than 100 countries at risk of ineffective treatments and potentially fatal side effects.

The results in full

(Dotted lines indicate standards of acceptable quality)



- **Essentiality of the Drugs** – They form the backbone of treatment plans for numerous common cancers – including breast, ovarian and leukaemia.
- **Toxic Nature of Ingredients** - In chemotherapy drugs, the active ingredient – which fights cancer cells – is also highly toxic.
- Patients need to receive enough of it to treat the cancer but not so much that they overdose and suffer damaging side effects.
- **Inadeqaute Key Ingredient** - Some drugs contained so little of their key ingredient that pharmacists said giving them to patients would be as good as doing nothing.
- **Over Dosage**- Other drugs, containing too much active ingredient, put patients at risk of severe organ damage or even death.
- **Ingredient Variance** - In some cases, pills from the same blister pack contained different amounts.
- **Limited Coverage under Essential Medicine** – Only 2 drugs, rituximab and trastuzumab, were included in the WHO's essential medicine list.
- **Fatal Impacts** – Low quality drugs leave patients suddenly unresponsive to treatment.
- Overdosed drugs make patients suffer side effects due to the toxicity of the ingredient and the patients become no longer tolerate the medicine.
- **Economic Deprivation** - In low income countries, the cost of 58% of essential cancer

medicines is paid by patients, compared with 1.8% in upper-middle-income countries.

What is the significance of generic drugs for cancer treatment?

- **Cancer** – It is one of the biggest killers worldwide, linked to around 10 million deaths every year – roughly one in six.
- **Increasing Burden** - The burden of cancer is growing, particularly in low- and middle-income regions.
- In sub-Saharan Africa, for example, instances of cancer have doubled in the last 30 years.
- **Generic Drugs in Cancer Treatment** - Much of the global demand for treatment is met by so-called generic drugs.

Generic drugs are versions of a drug that can be made once the original maker's exclusivity rights have expired, and are typically made far more cheaply.

- **Significance for Poor Countries** - Generics are widely used in all countries but are most crucial in those with fewer resources, where costlier treatments might be beyond reach.

What are the issues with generic drugs supply?

- **Profit Motive** – The pharmaceutical market, especially the generic drug , is often motivated by high profit.
- **Unfair Competition** – The drug market in which those operating under a less watchful eye find ways to undercut their competitors.
- **Monopoly** - The price-driven market creates a dangerous dynamic in which the number of companies making a particular drug shrinks and shrinks until global supply is precariously dependent on just a handful of manufacturers.
- **Impact on Quality** - This could mean scrimping on the amount or quality of the active ingredient – the most expensive component – or using cheap or outdated machinery.
- **Production Issues** - Research shows that the majority of substandard drugs occur due to problems with manufacturing, quality control, packaging or storage.

How have the safety nets failed?

- **Safety Nets -** Countries all over the world have systems in place to stop bad drugs reaching patients.
- **Ineffectiveness in Domestic Control** – Around 70% of countries cannot take care of their own medicine quality.
- **Inadequate Resources of Regulators** - Most governments have a national regulator – but their remit and resources vary hugely and even the better-funded regulators are far from foolproof.
- Event the US Food and Drug Administration (FDA), for instance, is struggling to keep up with inspections of manufacturing plants domestically and in India and China, and has admitted that its inspections have not been a reliable indicator of drug quality.
- **Inadequate Facilities** – Many countries that import cancer drugs, don't have the

facility to test those drugs.

- **Lack of Willingness** –There is lack of political will to take responsibility for ensuring proper treatment for cancer patients.

What lies ahead?

- Unannounced inspections especially at foreign manufacturing facilities, can be increased to expose those who falsify records or hide violations.
- World Health Organization can expand the list of essential medicine to include more cancer drugs.
- Global regulations and standards can be strengthened on testing of drugs and inspection of manufacturing plants.

Reference

The Hindu | Failure of Cancer Drugs

