6. Drug Ranitidine Found To Have Higher Levels Of Carcinogen

Prelims: Science & Technology- Medicine and Pharmaceuticals

Mains: GS-III- GS-II- Issues relating to development and management of Social Sector or Services relating to Health, Education, Human Resources.

Context:

- The Ranitidine drug has been found to have levels of a carcinogen above the US FDA prescription.

Background

- Ranitidine Hydrochloride capsules in the US has confirmed contamination with **N-Nitrosodimethylamine (NDMA)** above levels established by the Food and Drug Administration (FDA) in batches of Sandoz Ranitidine Hydrochloride capsules.
- Sandoz has withdrawn 14 batches of the drug which it manufactured in 2017 and 2018 and which were set to expire in 2020 and 2021.

N-Nitrosodimethylamine (NDMA)

- According to the FDA, NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests.
- NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables.

Ranitidine

- Ranitidine is a prescription drug but is also sold over the counter (OTC).
- As an OTC drug, it is used to decrease the volume of acid produced in the stomach.
- It is also used to prevent and relieve heartburn associated with acid ingestion and sour stomach.
- As a prescription drug, it has multiple uses, including treatment and prevention of ulcers of the stomach and intestines and treatment of gastroesophageal reflux disease or GERD.

Outside America:

- Besides the FDA, the European Medicine Agency has also launched a similar enquiry, the results of which are awaited. The Singapore drug regulator banned the supply of the drug in the country early this month. Meanwhile, **in India**, Central Drugs Standard Control Organisation (CDSCO) has also asked state drug controllers to ensure that the drug is safe.
- Indian doctors have advised patients here to avoid over-the-counter (OTC) use of popular antacid ranitidine.

US FDA:

- The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.