GS-II: Ranitidine

News

- India’s drug regulator this week began looking into concerns of potential cancer-causing substances contaminating popular acidity drug ranitidine.
- The move came over a week after the US flagged the issue to American patients, some companies have suspended sales of the product worldwide, and some have ordered recalls of the product.

Ranitidine:

- Ranitidine is an over-the-counter prescription antacid used in the treatment of acid reflux and peptic ulcer diseases.
- It is popularly known through brand names like Aciloc, Zinetac, Rantac and Rantac-OD, R-Loc and Ranitin.
- It is commonly used to relieve acid-related indigestion and heartburn by decreasing stomach acid production.
- While other medicines like pantoprazole and omeprazole (omez) too treat these symptoms and are more commonly prescribed today, ranitidine is still widely used in India.

Why in news?

- Ranitidine is a much older medication, but it was always thought to be a very safe drug because it has less side effects than the other drugs that patients use nowadays to treat these symptoms.
- The US FDA stated in a release that it had learned that some ranitidine medicines contained “low levels” of a substance called N-nitrosodimethylamine (NDMA).
- An environmental contaminant found in water and foods, NDMA has been classified as probably carcinogenic to humans, which means it has the potential to cause cancer.

How has India responded?

- The Drugs Controller General of India (DCGI) wrote to state regulators asking them to direct ranitidine active pharmaceutical ingredient (API) manufacturers to verify their products and take appropriate measures to ensure patient safety.
- DCGI asked states to inform him of action taken in this matter “at the earliest”.
- So far, the DCGI has not called for any halting of supplies, which means the ranitidine brands marketed in the country can continue to be sold until further notice.
- APIs are the ingredients that give a medicine its therapeutaeutic effect.

How have other countries responded?

- While India and the US are still looking into the issue, regulators of around 15 countries are learnt to have called for recalls of ranitidine sold in their markets.
- These include Singapore, Canada, Italy, Denmark, Finland, Norway, Switzerland and Pakistan.