Barcoding of Medicine

The government plans to make barcoding mandatory on all medicines sold locally in a bid to offset India's growing reputation as a source of counterfeit medicines.

Why it is done?

- The office of the **United States Trade Representative (USTR)** recently highlighted that India has a growing problem of counterfeit medicines, in its annual **'Special 301 Report' on intellectual property protection** and review of 'notorious markets' for piracy and counterfeiting released in April.
- According to the USTR report, almost 20% ($4.3 billion in 2013-14) of all pharmaceutical goods sold in the Indian market are counterfeit.

Pharmaceutical Sector in India

- India is one of the leading global producers of low-cost generic medicines due to its high domestic demand and inexpensive manufacturing costs. The country's pharmaceutical market is the world's third largest in terms of volume, but the thirteenth largest in value.
    - While counterfeiting is a global issue, it is much more prevalent in low and middle-income countries with an estimated 10 to 30% of medicines in these countries being counterfeit, compared to just 1% of medicines in high-income countries.

Reasons for counterfeit medicines market in India

- limited access to medical care, especially in rural areas
- fragmented supply chain
- lack of consumer awareness
- prevalent practice of self-medication
- high cost of genuine medicines
- weak enforcement of legislation and corruption
- prevalence of online pharmacies
- technology advancements in counterfeiting

Classification of Spurious and Substandard drugs in India

- As per Drug and Cosmetic (D and C) Act, 1940, poor quality drug comprises of misbranded, spurious and adulterated drugs, respectively.
- Central Drugs Standard Control Organisation (CDSCO) under Directorate General of Health Services,Ministry of Health & Family Welfare has categorised not of standard quality (NSQ) products in three categories A, B and C that is helpful in categorising the products during quality evaluation.

Category A	Category B	Category C
▪ It incorporates **spurious and adulterated drug**	▪ It includes **grossly substandard drugs** in	▪ It involves **products with minor defects** like

products; which conceal the real identity of the product or formulation and be similar to some well-known brand. ▪ These products may or may not contain active ingredients and generally manufactured by unlicensed antisocial people or sometimes by licensed manufacturers.	which product fails the disintegration or dissolution test and where active ingredient assay get below 70% and 5% of permitted limit.	emulsion cracking, change in formulation colour, small variation in net content, and sedimentation in clear liquid preparation, failing of weight variation test, spot or discolouration on product, uneven coating, and presence of foreign matter and labelling errors.

How barcoding will change it?

- Barcoding for domestic sales of drugs **will ascertain the authenticity of medicines,** ability to monitor their ready availability, expiration, track and trace their recalls when needed.

What else can be done?

- **Raising public awareness:** approximately 78% of India's 650 million mobile phone users have access to the internet, and online education about counterfeit and spurious medicine may be an effective way to tackle the issue quickly and efficiently.
- **Implementing innovative anti-counterfeiting measures:** New generation anti-counterfeiting technologies, such as the use of forensic markers (chemical, biological and DNA taggants), cloud-based supply chain data repositories, and blockchain technology in supply chains can be used to fight the menace of counterfeit drugs.