Syllabus subtopic: Issues relating to development and management of Social Sector/Services relating to Health, Education, Human Resources.

Prelims and Mains focus: about the threat of antimicrobial resistance; Challenges and efforts made by the world community; About DGCI

News: The Drug Controller General of India (DCGI) has asked authorities of all states and Union territories (UTs) to stop pharmacies from selling antibiotic drugs without a doctor's prescription in a step aimed at tackling drug resistant bacteria.

- The regulator also asked All India Organization of Chemists & Druggists (AIOCD) to “educate their members” on licensing conditions regarding antibiotic sales, and told drug makers to discourage pharmacists from selling drugs without prescriptions.

Background

- The ministry of health and family welfare had issued a National Action Plan on anti-microbial resistance (AMR) in 2017, seeking a coordinated move with the help of various other ministries such as animal husbandry and environment.
- The advisory by the DCGI comes two months after the department of pharmaceuticals wrote to drug manufacturers, warning against antibiotic residues in the effluents of their plants.

Current scenario of Antibiotics market in India

- Antibiotics fall under schedules H and H1 of the Drugs and Cosmetics Rules, which means they can be sold only under prescription.
- However, regulations for pharmacies are lax and violations are rampant. A number of such medicines are sold widely over the counter without prescriptions.

What does this move signify?
The move by the regulator indicates increased awareness about anti-microbial resistance, where bacteria and other microbials become immune to medicines on overuse, thereby making them ineffective against the infection.

**Challenge of anti-microbial resistance**

- Anti-microbial resistance is globally seen as a major problem in the pharmaceutical sector with the United Nations’ Interagency Coordination Group on Antimicrobial Resistance estimating drug-resistant infections to cause at least 700,000 deaths every year, including 230,000 from multidrug-resistant tuberculosis alone.
- A worst-case scenario developed by the World Bank has suggested that this figure could rise to 10 million deaths every year by 2050 if no action is taken.
- Around 10 million lives a year and a cumulative $100 trillion of economic output will be at risk because of the rise of drug-resistant infections by 2050, according to estimates from another study supported by the UK government and Wellcome Trust in 2016.

**Situation in India**

- India, home to an estimated 130,000 multidrug resistant TB patients in 2019 according to the World Health Organization, is crucial to the success of this global fight.
- However, the sale of medicines without prescriptions is not the only reason for the rise in anti-microbial resistance, according to experts. Effluents discharged by drug manufacturing units also add to the problem.
- The Central Pollution Control Board (CPCB) is working on effluent treatment norms for pharmaceutical companies. CPCB had set up an expert committee to draft standards for antibiotic residue in industrial effluents. The draft is now close to finalization.

**About Drug Controller General of India (DCGI)**

- DCGI under gamut of Central Drugs Standard Control Organization (CDSCO) is responsible for approval of licenses of specified categories of
drugs such as blood and blood products, vaccines, IV fluids and sera in India.

- **DCGI lays down** standards and quality of manufacturing, selling, import and distribution of drugs in India.
- It acts as **appellate authority** in case of any dispute regarding quality of drugs.