Regulatory Issues in Indian Pharmaceutical Sector

This editorial is based on the article "Indian pharma at the crossroads as US cracks the whip" which appeared in "Livemint" on 17th May, 2019. The article talks about implications of poor regulation of Pharmaceutical industry.

Why in News?

Recently 44 states of USA initiated lawsuits against Indian Pharmaceutical companies over cartelization of generic drug prices. This calls for understanding the regulatory structure and the issues associated with it.

Why we need Regulation?

Regulatory scenario in this sector is extremely crucial not only due to the rapid and ongoing changes at the global level, largely with reference to **good manufacturing practices (GMP)**, good **clinical practices (GCP) and good laboratory practices (GLP)** but also due to the onus on the regulatory bodies to **ensure a healthy supply of quality drugs at affordable prices** to the Indian masses.

Major Bodies Regulating Drugs and Pharmaceutical in India

<table>
<tr><th>Ministry of Health and Family Welfare</th><th>Ministry of Chemicals and Fertilizers</th><th>Ministry of Commerce</th><th>Ministry of Science and Technology</th><th>Ministry of Environment</th></tr>
<tr><td>Directorate General of Health Services (DGHS) Indian Council of Medical Research (ICMR)</td><td>Department of Pharmaceuticals</td><td>Patent Office</td><td>Department of Biotechnology (DBT)</td><td rowspan="4">Environmental clearance for manufacturing</td></tr>
<tr><td>Central Drugs Standard Control Organization (CDSCO) headed by Drug Controller General of India, DCGI (I) + Statutory Committees + Advisory Committees</td><td rowspan="3">National Pharmaceutical Pricing Authority (NPPA); Drugs (Prices Control) Order (DPCO) 2013</td><td rowspan="3">Controller General of Patent</td><td rowspan="3">Council of Scientific and Industrial Research (CSIR) Laboratories</td></tr>
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<tr><td>State Licensing Authories</td></tr>
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- **Role of CDSCO**
  - **Prescribes standards and measures** for ensuring the safety, efficacy and quality of drugs, cosmetics, diagnostics and devices in the country.

    - **Regulates the market authorization** of new drugs and clinical trials standards.
    - **Supervises drug imports** and approves licences to manufacture the above-mentioned products.
- **Role of National Pharmaceutical Pricing Authority (NPPA)**
    - **Fixes or revises the prices** of decontrolled bulk drugs and formulations at judicious intervals.
    - Periodically **updates the list under price control** through inclusion and exclusion of drugs in accordance with established guidelines.
    - **Maintains data on production, exports and imports** and market share of pharmaceutical firms.
    - **Enforces and monitors the availability** of medicines in addition to imparting inputs to Parliament in issues pertaining to drug pricing.

Issues at the Regulatory Level

- **NPPA**
    - NPPA chairman is officer of secretary level from **Indian administrative services** .There is no fixed tenure of chairman. Further there is no permanent staff at NPPA . For implementing its orders, NPPA has to depend upon state authorities.
- **CDSCO**
    - **Lack of access to resources** (both physical infrastructure and human resources).
- **The Drugs Controller General of India (DCGI)**
    - MDs in pharmacology and/or microbiology is given preference for appointment to the job of the Drugs Controller General of India (DCGI): but this can generate conflict of interest sometimes.
- **State Drug Regulatory Authority (SDRA)**
    - Most of the regulators at SDRA are pharmacist: this creates a conflict as, most of the regulators at central level are Doctors.
    - Lack of access to resources (both physical infrastructure and human resources).

Challenges in Pharma Regulation Sector

- **Autonomy**
    - Both the CDSCO and the SDRAs are umbilically tied to their parent ministries and departments of health respectively.
    - This impedes flexibility in decision-making and autonomy in a host of areas beginning with finance, recruitment and other areas of institutional policy.
    - Regulators are effectively accountable to bureaucrats in their respective parent ministries.
    - Any decision passes through various ministerial channels, weakening the autonomy of CDSCO.
- **Power**
    - Section 33P15 which empowers the CDSCO to issue directions to SDRAs, to ensure that provisions of DCA are implemented uniformly in all states, has been rarely used and, even if it is used, the CDSCO has no power to enforce compliance by states.
    - Drug inspectors have no assurance of their safety and do not have the power of arrest.
- **Capacity**
    - At the **administrative level**, lack of access to resources (both physical infrastructure and human resources).
    - At the **financial level**, both organisations completely depend upon budgetary allocation, and minimal user fee is charged from the industry.
    - **Lack of planning and execution** of training programmes for drug inspectors/ad hoc in approach.
    - **Institutional channels of interaction** between the CDSCO and the SDRAs are lacking.

Challenges in Pharma Regulation Sector

- **Fragmented nature of drug regulator:**
    - Indian pharmaceutical sector is **highly fragmented** with multiple regulatory units, which

impede regulatory effectiveness of a country.
    - For example, division of regulatory responsibilities between the centre and the states (lack of uniformity in legal interpretation and harmonisation of the enforcement function), resource deficits owing to the absence of substantial investments in public infrastructure (specifically laboratories) and personnel, and low levels of transparency owing to lack of digitisation, and processing timelines are some of the issues.
- **Industrial lobbying:**
    - The 59th report of Parliamentary standing committee on Health and Family Welfare found that, due to lobbying, medical opinions sought from experts appeared to have become a farcical exercise. Opinions were given in a subjective fashion without citation of any hard scientific evidence. Also the letters of many of the experts read almost verbatim.
- **Unethical practices in clinical trials:**
    - Corruption, the low cost of conducting trials, poor compliance and collusion between drug companies and doctors have led to a rise in unethical drug trials in India. The Indian parliamentary committee on health and family welfare, in its report to **CDSCO , noted: 'There is sufficient evidence on record to conclude that there is collusive nexus between drug manufacturers, some functionaries of CDSCO and some medical experts'.** The committee also pointed out that the CDSCO had approved 33 drugs, out of a randomly selected sample of 42, without clinical trials on Indian patients.
- **Proliferation 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. CDSCO 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 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.	It include grossly substandard drugs in which product fails the disintegration or dissolution test and where active ingredient assay get below 70% and 5% of permitted limit.	Category C involved products with minor defects like 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.

According to a report, International Policy Network, globally 0.70 million deaths were reported for malaria and tuberculosis because of counterfeit drugs. This data reveals the loopholes in the regulatory system.

Enforcement of quality in India takes place at marketplace where regulator takes the drug off the shelf and does testing .Due to health as a state subject, CDSCO can’t control it, unlike in the developed countries where quality control intervention is done at process level.

Way Forward

- Provision like Cadre restructuring in State Drugs Controls, strengthening of NPPA and National Pharmaceutical Policy 2017 should be implemented at the earliest.
- Provisions of National Health Policy, 2017, like strengthening and rationalizing the drug regulatory system, promotion of research and development in the pharmaceutical sector and building synergy and evolving a convergent approach with related sectors, should be implemented.
- Various committee/commissions have called for making CDSCO like body withs its own independent staffing and finance. **(Mashelkar Committee Report, DCA bill 2015, Professor Ranjit Roy Chaudhary Committee report)**

It is high time to radically clean the anarchy in drug regulation in India in the interests of public health. The “Pharmacy of the World” deserves a better regulatory body so that Scylla of exorbitant pricing and Charybdis of spurious drugs do not raise its ugly head.

Regulatory conflict in Indian pharmaceutical sector has to be solved, for realization of Ayushmaan Bharat. Discuss.