

Regulation of Food and Drugs, Public Health and Practice in Medicine

Strengthening the Drugs Regulatory System

Major challenges with present system:

- Inadequate manpower at the State and Central level
- Inadequate or weak drug control infrastructure at the State and Central level
- Inadequate testing facilities
- Non-uniformity of enforcement
- Lack of Training to enforcement officials
- Lack of data base
- Inadequate IT services

Recommendations on Strengthening of CDSCO:

- Creation of additional posts to comply with the recommendations of Dr. Mashelkar Committee Report (One drugs Inspector for 50 manufacturing units and One Drugs Inspector for 200 sale premises)
- Setting up of new CDSCO offices
- Creation of new drugs testing labs. and upgradation of existing labs.
- Establishing CDSCO Training Academy
- Mobile Drugs Testing Labs. to check spurious drugs
- Creation of State of Art Pharma Research Laboratory
- Setting up of CDSCO offices abroad
- Establishing an e-Governance system with IT Enabled Services for Networking, Registration and Archiving
- Strengthening the Pharmacovigilance Programme of India to capture Adverse Drugs Reactions
- Clinical Trials ---- compensation, ethics committee, informed consent form, registration of CROs.

Strengthening of Drugs Regulatory System in States:

Background

- States grant/renew drugs manufacturing licenses
- They have a major role in enforcement
- States have inadequate infrastructure, both physical and human resource
- States have inadequate resources for augmenting and strengthening the Regulatory System

Recommendation

- Start a Centrally Sponsored Scheme (CSS) to strengthen the infrastructure both Physical And Human Resource in the States, subject to MOU with clear deliverables

Strengthening the Food Regulatory System

Background

- The Food Safety and Standards Act, 2006 came into force from 5.08.2011.
- It replaced multiple food laws, standard setting bodies and enforcement agencies with one integrated food law.
- The Acts and Orders repealed are:
 - The Prevention of Food Adulteration Act, 1954,
 - The Fruit Products Order, 1955
 - The Meat Food Products Order, 1973
 - The Vegetable Oil Products (Control) Order, 1947
 - The Edible Oils Packaging (Regulation) Order, 1998
 - The Solvent Extracted Oil, De oiled Meal and Edible Flour (Control) Order, 1967
 - The Milk and Milk Products Order, 1992

Challenges FSS Act seeks to address

- Shift from multilevel and multi-department control to a single line of command
- Shift to a unified licensing system
- Effective enforcement and encouraging self compliance
- Provision of graded penalties based on severity of offence
- Mechanism of speedy disposal of cases
- Focus on food safety
- Harmonization between domestic and international food policy issues without compromising on public health and national interest.

Recommendations

- Proper surveillance system needs to be set up which should be directed to build public information on current and new food threats.
- Food surveys must be carried out regularly and results made public.
- Develop food safety policies which promote good health in consultation with the concerned Ministries like MH&FW, MWCD etc.
- A mid-term appraisal of FSSAI may be carried out in the 3rd year of the 12th Plan for any course correction that may be required.
- Strengthening of food regulatory infrastructure in the States

Recommendations

Strengthening of Food Safety departments in States-
Creation of a dedicated structure of food safety, D.O's ;
A.O's. On an average 10 FSO per district ,Tribunal to be
created.

- (a) Food Safety Office in each district
- (b) E-governance for transparency, creation of database
- (c) Emergency Response Centre in each State
- (d) Strengthening of food laboratory infrastructure
- (e) District Food Laboratories @ 1 in every 5 Districts
- (f) Awareness, Training, Capacity Building and Educational Programmes

Planning Commission Comments

Comments

- No measures to address loop holes in implementation
- No view CDA
- No focus on innovative measures (checking work to be outsourced to QCI)
- Integration with other labs and outsourcing to private labs
- No priority on ADR, re-evaluation of products
- Setting up of intelligence and legal cells
- Weeding out of FDCs

Response

- Measures have been recommended to strengthen infrastructure and manpower
- CDA is under examination of the ministry. Consultations with states have been held who are opposed to CDA
- It would be better, in the long run, to strengthen our own systems
- Not in favour of outsourcing regulatory work to private labs
- The Pharmacovigilance Programme of India has been launched which will collect ADR data. Initiation of prescription audit, weeding out of irrational FDCs
- Manpower strengthening will involve this
- DTAB will set up such a mechanism

Planning Commission Comments (contd)

Comments

- High Intermediary premium and high OTC prices issues have not been dealt with
- Should factor AYUSH drugs procurement and distribution
- Less expenses on R&D and high on sales promotion

Response

- Brought out NLEM 2011. DoPharma requested to include the entire list under DPCO. Free medicine scheme will benefit the poor
- Working group did not have the mandate to consider AYUSH drugs procurement and distribution
- R&D expenses of the Indian drug companies is rising. DoPharma has come out with voluntary code of conduct for Pharma companies. This will curb sales expenses

Planning Commission Comments (contd)

Comments

- Strategy for securing vaccine and drugs security by promoting PSUs
- TKDL to be used as a source of new drug discovery
- NICE like institution for inclusion of new drugs and vaccine in Public health system

Response

- Three vaccine PSUs revived. IVC being set up.
- Relates to Do AYUSH
- Will be considered

Planning Commission Comments (contd)

Comments

- Safeguarding 3(d) of the Patent Act from dilution.
- Data exclusivity clause to be removed from trade agreements
- Accountability framework lacking

Response

- Ministry's position on these issues have been unambiguous and have been conveyed to DoIPP, DoC
- Provision of midterm review of the work of FSSAI/ e-Governance

Public Health

- Need for a Public Health Workforce/ Cadre
- Public Health Board at the State level and also at the district level to address issues of public health and to coordinate among various agencies
- Water, Sanitation and Hygiene : need of a Monitoring Mechanism
- Need to set standards of potable water

Practice in Medicine

- Clinical Establishments (Registration and Regulation) Act, 2010
- Setting Minimum Standards and Categorization of Clinical Establishments
- Standard Treatment Guidelines
- Patient Protection Guidelines

Thanks