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- The Acts and Orders repealed are: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	Response
➢ High Intermediary premium and high OTC prices issues have not been dealt with	➢ Brought out NLEM 2011. DoPharma requested to include the entire list under DPCO. Free medicine scheme will benefit the poor
➢ Should factor AYUSH dugs procurement and distribution	➢ Working group did not have the mandate to consider AYUSH drugs procurement and distribution
➢ Less expenses on R&D and high on sales promotion	➢ 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	Response
• Strategy for securing vaccine and drugs security by promoting PSUs	➢ Three vaccine PSUs revived. IVC being set up.
• TKDL to be used as a source of new drug discovery	➢ Relates to Do AYUSH
• NICE like institution for inclusion of new drugs and vaccine in Public health system	➢ Will be considered

Planning Commission Comments (contd)

Comments	Response
➢ Safeguarding 3(d) of the Patent Act from dilution.	➢ Ministry's position on these issues have been unambiguous and have been conveyed to DoIPP, DoC
➢ Data exclusivity clause to be removed from trade agreements	
➢ Accountability framework lacking	➢ 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