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• The Acts and Orders repealed are:
  o The Prevention of Food Adulteration Act, 1954,
  o The Fruit Products Order, 1955
  o The Meat Food Products Order, 1973
  o The Vegetable Oil Products (Control) Order, 1947
  o The Edible Oils Packaging (Regulation) Order, 1998
  o The Solvent Extracted Oil, De oiled Meal and Edible Flour (Control) Order, 1967
  o 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)

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<td>• Strategy for securing vaccine and drugs security by promoting PSUs</td>
<td>➢ Three vaccine PSUs revived. IVC being set up.</td>
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<td>• TKDL to be used as a source of new drug discovery</td>
<td>➢ Relates to Do AYUSH</td>
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<td>• NICE like institution for inclusion of new drugs and vaccine in Public health system</td>
<td>➢ Will be considered</td>
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## Planning Commission Comments (contd)

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<td>➢ Safeguarding 3(d) of the Patent Act from dilution.</td>
<td>➢ Ministry’s position on these issues have been unambiguous and have been conveyed to DoIPP, DoC</td>
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<td>➢ Data exclusivity clause to be removed from trade agreements</td>
<td>➢ Provision of midterm review of the work of FSSAI/ e-Governance</td>
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<td>➢ Accountability framework lacking</td>
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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