Final Dissemination Seminar on
Drug Regulatory Reforms in India
Year 1

Administrative Structure and Functions of Drug Regulatory Authorities in India

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Outline

- Effective Drug Regulation – meaning
- Study Objectives
- Research Methodology
- Key Regulatory Challenges
- Major Policy Recommendations

Effective Drug Regulation

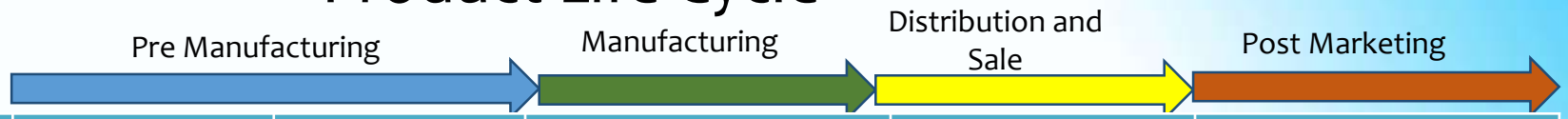
- Objectives of Drug Regulation
  - Ensure patients access to safe, good quality and efficacious drugs
- How do we design a drug regulatory administration that would facilitate the achievement of this objective?
  - 'Smart or Responsive Regulation': Design of regulatory system – sensitive to regulatory space – characteristics of a range of stakeholders

Objectives of the Study

- Map the functioning of Central Drugs Standard Control Organization (CDSCO) and State Drug Regulatory Authorities (SDRAs)
- Examine the nature and scale of challenges confronting the regulatory authorities
- Explore lessons drawn from experiences in other foreign jurisdictions
- Document information, opinion and perception through stakeholder interviews and RTI applications
- Evolve a set of actionable policy recommendations

SCOPE - Substantive policy areas such as clinical trials, pricing and post-marketing surveillance are not covered in this study.

Distribution of Regulatory Functions along the Drug Product Life Cycle



STAGE	CLINICAL TRIALS	NEW DRUG APPROVALS	MANUFACTURING	DISTRIBUTION AND SALE	POST MARKETING SURVEILLANCE
Regulatory Functions	• Applications online in the Clinical Trials Registry - India (CTRI) • Approval of applications • Good Clinical Practices • Inspections • Registration of Ethics Committee • Serious Adverse Events (SAE)	• 12 Subject Expert Committees (SECs) for deliberation on new drug applications for grant of marketing licence • Import of new drugs (Registration of foreign manufacturers and grant of licence to import)	• Application for Licence to manufacture (Generics and those with marketing licence) • Inspection of Good Manufacturing Practices (WHO-GMP/Schedule M) • Grant of Licence to Manufacture • Collection of Samples, testing and prosecution for Non-Compliance	• Application for Licence to distribute and sell • Inspection of Good Distribution Practices (GDP) and sale premises • Grant of Licence to distribute and sell • Prosecution for Non-Compliance	• Periodic Safety Update Reports (PSURs) required to be submitted (Schedule Y of the Drugs and Cosmetics Rules) for new drugs granted marketing licence • Banning of Drugs considered harmful or sub-therapeutic under Sec. 26A of the DCA • Pharmacovigilance Programme of India (PvPI) is the national co-ordinating centre for collecting Adverse Drug Reaction Reports from Adverse Drug Monitoring Centre(AMCs)
Authority Responsible	CDSCO (appointed by the MOHFW, Central Government.) has the sole responsibility – relies on expert committees.	CDSCO has the sole responsibility	SDRA (appointed by the Department of Health, State Government) has primary responsibility Exceptions (CDSCO competence) • CDSCO acts as SDRA in Union Territories (e.g. Delhi) • WHO-GMP Inspections • High Risk Products (IV Fluids, Large volume parenterals, Vaccine and Sera, Blood and Blood Products, r-DNA products (CDSCO may include new products in this list via notification)	SDRA has the sole responsibility	CDSCO has sole responsibility for PSURs and Indian Pharmacopoeia Commission (IPC) is in charge of co-ordinating Adverse Drug Reports (ADRs)

Source: Authors' own compilation

Recent reform efforts

- Mashelkar Committee Report 2003 – quite comprehensive
  - Recommendations on spurious drugs adopted
  - Ratio of personnel to operations – yet to be implemented

- Ranjit Roy Chaudhary Committee Report 2013
  - Recommendations on Clinical trials and new drug approvals adopted

- Drugs and Cosmetics Amendment Bill 2015
  - Centralization - Central Licensing for 17 categories of drugs
  - Drugs, Cosmetics and Medical Device Committee (replace DCC) – limited change in rules of functioning

Piecemeal implementation of reforms – regulatory 'systems' approach to reform is missing! (usually the focus is confined to CDSCO and not SDRAs)

Research Methodology

- Law and Policy analysis of Drugs and Cosmetic Act, 1940, Parliamentary Committee Reports, and Annual Reports of Ministry of Health and Family Welfare

- Field research involved semi-structured qualitative interviews
  - 4 states – Gujarat, Himachal Pradesh, Bihar and Kerala (pharmaceutical manufacturing capacity, population proxy scale of manufacturing/regulatory enforcement)

  - 4 jurisdictions - European Union, USA, Indonesia, China (regulatory leadership + comparative case study)

Key Issues

- Uniformity (interpretation and enforcement) and absence of an autonomous regulatory body
- Central coordination agency – no singular body responsible for effectiveness
- Financial dependence – complicated system of procurement and lag in recruitment
- Upgrade infrastructure - especially SDRAs– laboratories, digitalization, transportation
- Inspections – disparate inspection protocols especially in SDRAs
- Human resources – match drug inspectors to scale of operations (remuneration, training, work conditions)
- Public access to information and international networking

Key observations from the RTI applications

- Only Orissa and Tamil Nadu have submitted an Institutional Development Plan (IDP) for disbursement of budgetary allocation as per the 12th Five-year Plan. Interestingly, Orissa has submitted a proposal indicating a requirement of 90 drug inspectors (as per Mashelkar Committee Report formula) whereas the current sanctioned strength is only 44.

- In West Bengal, out of 50 sanctioned positions of senior drug inspectors' positions, 56 per cent are vacant. And of the 90 sanctioned positions of drug inspectors, 66 per cent are vacant. A similar state of affairs was observed in Tamil Nadu with more 50 per cent vacant positions for drug inspectors.

- No separate funds have been allocated in the budget for training in West Bengal, Tamil Nadu, and Kerala and no training programme, such as refresher courses and orientation camps, were held in West Bengal and Tamil Nadu. In Kerala, training sessions are conducted by the Institute of Management in Government.

Source: As per the RTI (partial) responses received from the Drugs Control offices of West Bengal (No. DCWB/2015/RTI/195), Tamil Nadu (Ref. No. 12504/E5/2015), Kerala (No.P – 6502/2015/DC), Gujarat (No.RTI/ID-67/2015/517) and Orissa (No. 6516/DC-RTI-18/2015)

Major Policy Recommendations