



Final Dissemination Seminar on
Drug Regulatory Reforms in India
Year 1

Drug Quality and Safety Issues in India

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Outline

- Preamble
- Scope of work presented
- Approach
- Outcomes



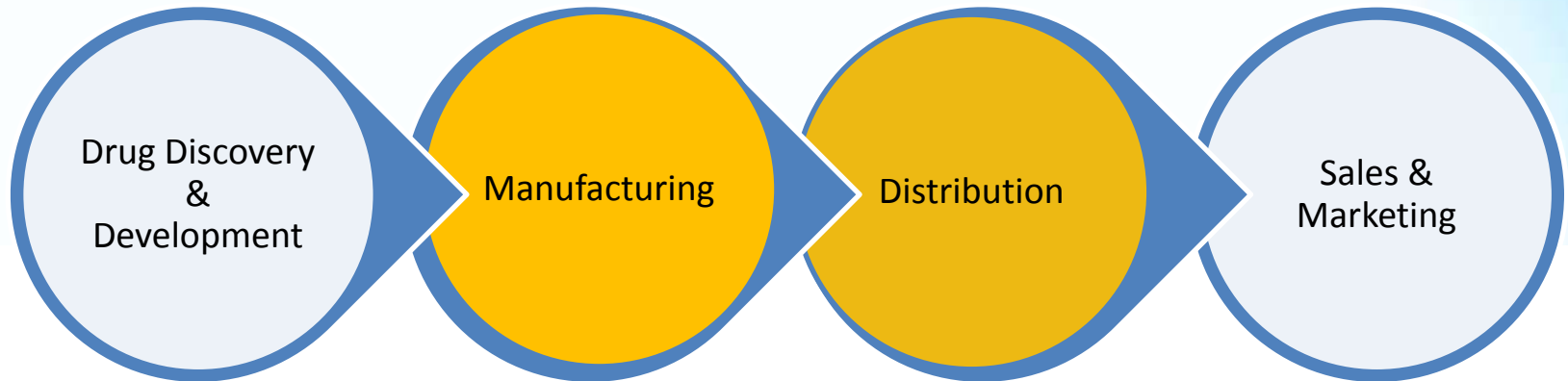
Preamble

- Quality of medicine is an outcome of processes followed through entire value chain
- Poor Quality of medicine may be an intentional or non intentional outcome
- Eventually affects consumer, health systems, and industry
- Issues raised on quality of medicines produced in India

Scope of work

- Within manufacturing and distribution processes of value chain, understanding what results into poor quality of medicines-India specific
- And if there are challenges at these two levels-what are the national and international experiences to address them

Value Chain



Approach

- Mixed approach-use of snow balling
- Key informant interviews (n=104) - 5 states and 4 countries
- Five broad themes were identified
- Preliminary findings dissemination



Outcomes

Theme 1

Issues with Defining Quality of Medicine

Issue with Defining Quality of Medicine



Recommendation 1:

Include clear description of SSFFC terms in any ongoing or future studies instituted to quantify the extent of poor quality medicine in India and abroad

- Currently spurious, sub-standard, falsified, false labelled and counterfeit definitions are used interchangeably
- Exception: Regulatory Sphere

Interpretation of SSFFC framework in India

Packaging & Labelling*	Wilful Trademark Infringement	Right Active Pharmaceutical Ingredient (API)	Right Dose of Active Pharmaceutical Ingredient (API)	WHO definition of Counterfeit ²⁵	Type of Drug (as defined in India)
Fake	✓	✓	✓	Counterfeit	Counterfeit/Spurious*
Fake	✓	x	✓	Counterfeit	Counterfeit/Spurious [#]
Fake	✓	✓	x	Counterfeit	Counterfeit/Spurious [#]
Fake	✓	x	x	Counterfeit	Counterfeit/Spurious [#]
Fake	x	✓	✓	Counterfeit	Falsified/Falsely-labelled/Spurious [~]
Fake	x	x	✓	Counterfeit	Falsified/Falsely-labelled/Spurious [^]
Fake	x	✓	x	Counterfeit	Falsified/Falsely-labelled/Spurious [^]
Fake	x	x	x	Counterfeit	Falsified/Falsely-labelled/Spurious [^]
Genuine	-	x	✓	Counterfeit	Falsified/Spurious ⁺
Genuine	-	x	x	Counterfeit	Falsified/Spurious ⁺
Genuine	-	✓	x	Counterfeit	Substandard/Spurious [§]

Source: Author's compilation

Issue with Defining Quality of Medicine



Recommendation 2:

Training directed at a clear understanding of these definitions should be imparted to stakeholders across the country and especially to regulatory officials.

- Variations amongst state
- Individual based interpretation

Recommendation 3:

Any ongoing or future study instituted to quantify the extent of poor quality medicine in India should focus equally on sampling from both urban and rural settings.



Theme 2
Good Manufacturing
Practices (GMP)
Compliance



Good Manufacturing Practices (GMP) Compliance

Recommendation 1:

In order to ensure uniform understanding and interpretation by all stakeholders, there is a definite need for a guidance/reference document for Schedule M on the lines of those for WHO-GMP guidelines

- Current guidelines based on WHO GMP 1982-renewed in 2001
- Uniform standards for domestic and export market
- Problems with record keeping interpreted as breach of protocols
- ICH though cost effective will take time



Good Manufacturing Practices (GMP) Compliance

- Recommendation 2:

We recommend that the state drug regulatory authorities impart more specialized skills to their inspectors and government analysts, either product-based or process-based. This can be achieved by ensuring that each inspector is trained in a niche segment and develops specialty in it through continuous experience

- Product based capacity building
- Clear division of labor

Good Manufacturing Practices (GMP) Compliance

- Recommendation 3:

Stringency with regard to GMP non-compliance should be increased, with a fixed time frame for submission of response to a CAPA report should be made mandatory and failure to do so should trigger strict punitive action such as financial penalty on the defaulter

- Found to be in use in USA and China
- Alternative to the existing system of suspending a single production license.
- Voluntary compliance works the best



Good Manufacturing Practices (GMP) Compliance

- Recommendation 4:

Use of 'reputation effects' as a deterrence mechanism can be carried out by regularly updating non-compliance data and making it available in the public domain.

- Used by EMA and EUDRA
- Has domino effect

- Recommendation 5:

Setting up of a permanent office of the CDSCO in countries that are high volume sources of API and an alert warning Indian manufacturers

- Tracing all final products a challenge so focus on API
- Currently imported from China, Taiwan, S Korea



Good Manufacturing Practices (GMP) Compliance

- Recommendation 6:

The consolidation and building of a national registry of pharmaceutical manufacturers

- Recommendation 7:

Refined guidelines for labelling requirements and liability in the case of both loan licensing and third party manufacturing.

- Legal liability under contract manufacturing is not clearly understood
- Currently assumed to be on manufacturer
- No direct connection found between the size of enterprise and quality of products
- Labelling is of marketer and many a times manufacturer is not identifiable



Theme 3

National Medicine Testing capacity

Testing capacity

- Recommendation 1:

Partner with private NABL till public testing facilities are strengthened

- Huge backload of testing samples
- Entire market cannot be tested-65000 in India
- More random sampling
- Need to decrease time lag for testing



Theme 4

Drug alerts and product recall

Drug alerts and product recall

- Recommendation 1:

Introduce an online monitoring system for product recalls that requires a manufacturer to provide real-time information about the progress of the recall process

- Voluntary recall is tricky due to costs
- Can result into market shortage
- In India no mechanism to identify if process initiated in India

- Recommendation 2:

A system that integrates the drug alerts generated by the states and the center should be developed

- Recommendation 3:

Integrate with Pharmacovigilance program of India (PvPI)



Theme 5

Role of Technology

Role of Technology

- Recommendation 1:

Bar coding at all packaging levels (with phased implementation).

- Various cost estimates for implementation
- Public health perspective an important step
- Currently implemented at tertiary level for export market
- Systemic issues should be addressed by regulator

- Recommendation 2:

Integrate it with Pharmaceutical Database Management System acting as PMIS

- Recommendation 3:

Full implementation of XLN software across states

Key Take-Aways

- The identified issues are complex and interlinked
- Needs enhanced number of trained people and infrastructure
- The role of Information technology is decisive
- Private sector contribution



Thank you