



Special Round Table on

IMPORTANCE OF STRONG DRUG REGULATORY SYSTEM

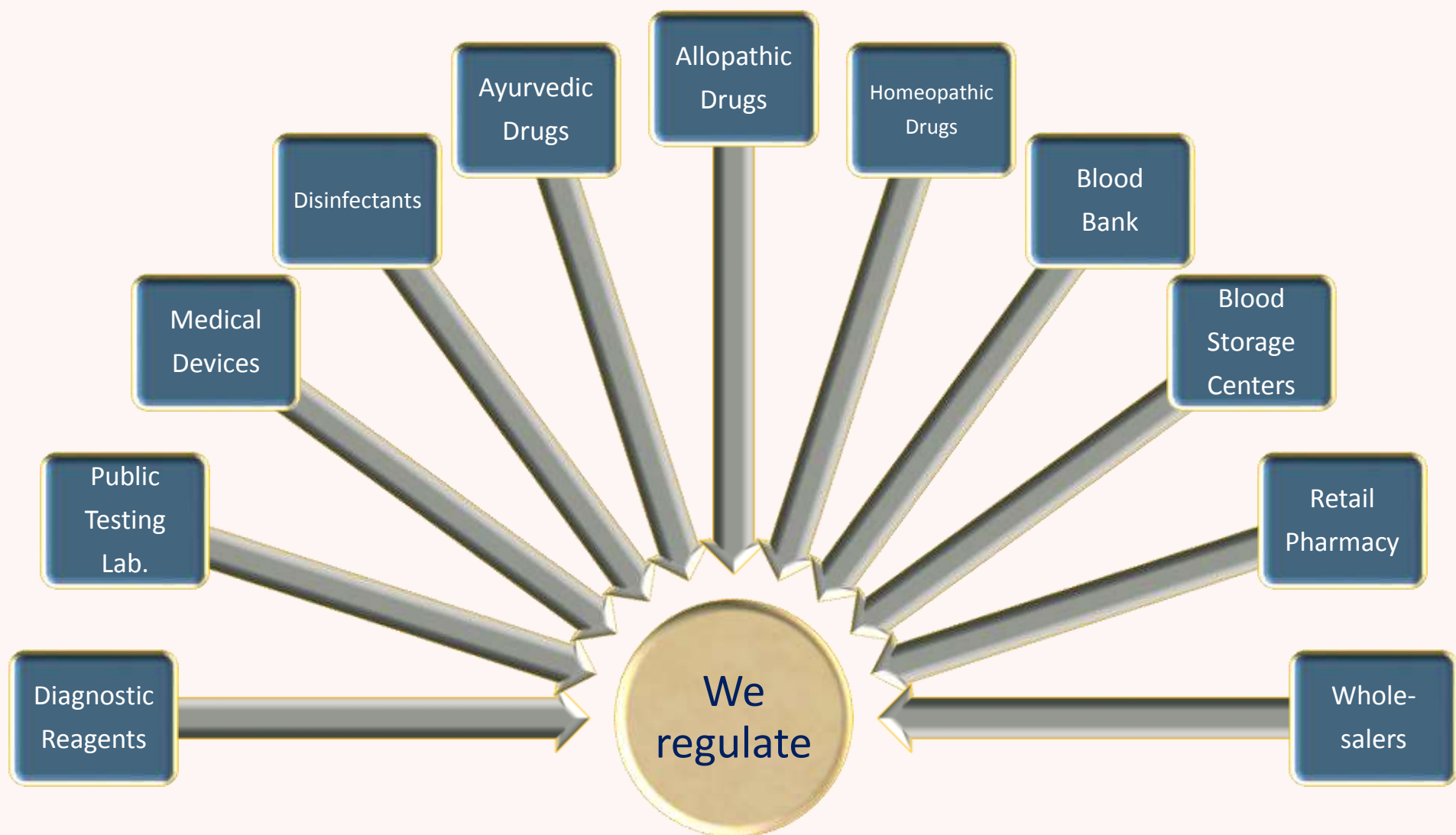


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Central Acts & Rules implemented in India

- ☐ **Drugs & Cosmetics Act 1940**
- ☐ **Drugs & Cosmetics Rules 1945**
- ☐ **Drugs (Price Control) Order 2013**
- ☐ **Drugs & Magic Remedies (Objectionable Advertisement) Act 1954**
- ☐ **Drugs & Magic Remedies (Objectionable Advt.) Rules 1955**







Punitive actions

Suspension of
Licenses

Cancellation of
Licenses

Launch
Prosecution in
the court of Law



Lacuna in Harmonization – CDSCO & SLAs

- QMS approach not adopted
- No predefined SOPs for various tasks
- Variation in decision making process among officers at Head Quarter, Zonal Offices and District Office level.
- Lack of coordination and communication through IT enabled services
- Lack of transparency



Lacuna in Harmonization – SLA to SLA

- Variation in policies, procedures and perception from State to State e.g. Approval of plan before commencement of construction. Approval of Product Licenses in contravention of the Rules, a major concern for DCGI and other SLAs.
- Variation in administrative and / or legal action in case of NSQ or spurious drugs e.g. In case of NSQ drugs some SLAs suspend product License only and others suspend mfg. Licensees Form no. 25 / 28. Decision for launching of prosecution vary from SLA to SLA.
- Cooperation in intra state investigation varies from State to State.



Harmonization – A step towards Strong Drug Regulatory System

- Good Regulatory Practices (GRP) for CDSCO and all SLAs. GOI need to take initiative.
- Optimum use of IT solutions. A high level committee of CDSCO and SLAs officers to implement a common IT solution for CDSCO and all SLAs covering all activities. Stand alone IT solutions should be discouraged.
- Minimum discretionary powers to CDSCO and SLAs.



Drug Manufacturing License (Allergies) - GSK A

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e-Governance – XLN & DMLA

FDCA, Gujarat's small initiatives towards Strong Drug Regulatory System



- ✓ Bulk SMS Alerts to all DEALERS, FDCA officers & other State Drugs Controllers regarding “Not of Standard Quality” drug for prompt & effective recall.
- ✓ Details of Drugs declared as NSQ can be accessed on public domain.

Mass SMS Alerts = Effective recall



FDCA, Gujarat's small initiatives towards Strong Drug Regulatory System



**Mobile Drug
Testing Van
launched
First
in India**



RAMAN SPECTROMETER

**Handheld
instruments
for
on site testing**



XRF METAL ANALYZER



NIR MATERIAL ANALYZER

Thanks