Legal & Regulatory Myths-Challenges in Improving Regulatory Frame Work to go Beyond Domestic Market

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Pakistan's First Pharma & Healthcare Law Firm


Every two minutes, the energy reaching
the earth from the sun ……
Equivalent to the whole
annual energy use of humanity

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Advocates & Legal Consultants

Agenda

1. History of Evolution of Healthcare Legislations
2. Global Regulatory Framework for Pharma & Healthcare Business
3. Best Regulatory Framework & Indicators
4. Challenges in Improving Regulatory Framework
5. Way Forward


MYTH

Myths

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authenticity of ex-CJ's affidavit | physical remand | corps level exercise

Punjab labs 'fail to authenticate' alternative medicines

By Asif Chaudhry

LAHORE: Unnecessary drug sampling and poor techniques of testing/analysis in the government laboratories in Punjab to check the components of alternative medicines have raised doubts about the authenticity of the reporting mechanism.

Numerous complaints are emerging that the results of most test reports generated by Punjab government's five labs are being negated by the National Institute of Health (NIH), Islamabad when they were challenged in re-testing complaints.

An official associated with the Provincial Quality Control Board (PCQB) unveiled inside picture saying the quality of the drug testing has been compromised owing to two major reasons and the complaints are going unreported. He said the percentage of the drug testing reports of Punjab's labs challenged in NIH had increased to 70 per cent after the provincial labs failed to check the components of alternative medicines.

He said the drug sampling was being done unnecessarily and the government labs were being headed by inexperienced officials instead of qualified pharmacists. He said the DTLs of Punjab were largely using British and United States pharmacopeias to test /analyse herbal, homeopathic and nutraceutical products ingredients in which they often fail to check alternative medicines.

The official said the alternative medicines could only be checked by methods developed by alternative medicine manufacturers called "Manufacturer's Specifications".

"Instead of demanding these methods from alternative medicine manufacturers, our DTLs test these products using British or US pharmacopeias and declare the drugs 'unregistered' while reporting that they contain allopathic ingredient," the official said.

He said unnecessarily increasing the number of sampling for drug testing in Punjab was also damaging resources besides making courts overburdened.

While quoting a recent international report, he claimed, in the USA, the Food and Drug Authority was collecting around 28,000 samples for drug testing annually. On the other hand, a DTL of Lahore collected approximately 40,000 samples annually, he said, adding that the unnecessary litigation had put the alternative medicine industry in severe distress.

He recalled a drug scam at Lahore's Punjab Institute of Cardiology where several patients had died after using contaminated medicine. He said natural herbs contained allopathic drug ingredients in traces like ephedrine in ephedra vulgaris but a hapless alternative medicine manufacturer is prosecuted for the "innocent" offence.

"It is high time that Research and Development Sections be set up in every drugs testing laboratory comprising formulation scientists who can give expert opinion," the official said. He said the Quality Control Boards should be manned by experts of relevant field.

He said 30 PhD pharmacists in the health department of Punjab had been posted at irrelevant positions in rural health facilities and government hospitals. The Punjab government should review the policy and utilise the knowledge of these highly qualified and experienced pharmacists by making postings in the DTLs, he suggested.

Myths

- Criminal System under CrPC–Drug Courts Lack Of Transparency
- Appellate Board Meeting- Conflict of Interest
- Field Force (FID/PID) Training System
- Government Laboratories Testing & Procedures
- Central Research Fund
- The concept of contract/outsourcing has steadily evolved and quickly adapted.

Myths

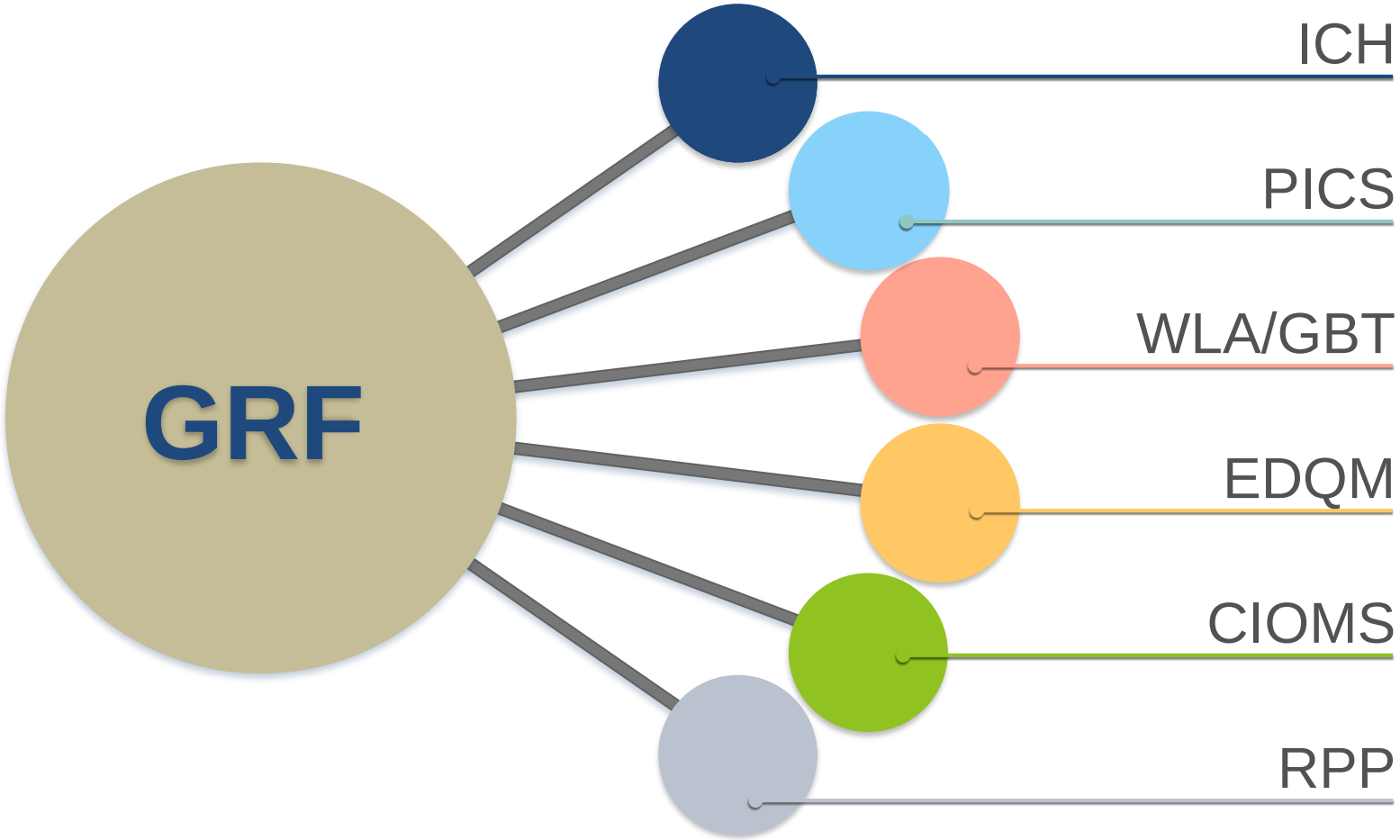
- GMP Audit System of DRAP and Provincial Govts
- Separate Section/Manufacturing Facility Requirements
- Price Fix and Refixation Delays
- Emergency Use & Priority Approval Authorization Delays
- H & OTC Rules, 2014- Creation of New World
- Deferred- Pending- Rejected

Myths

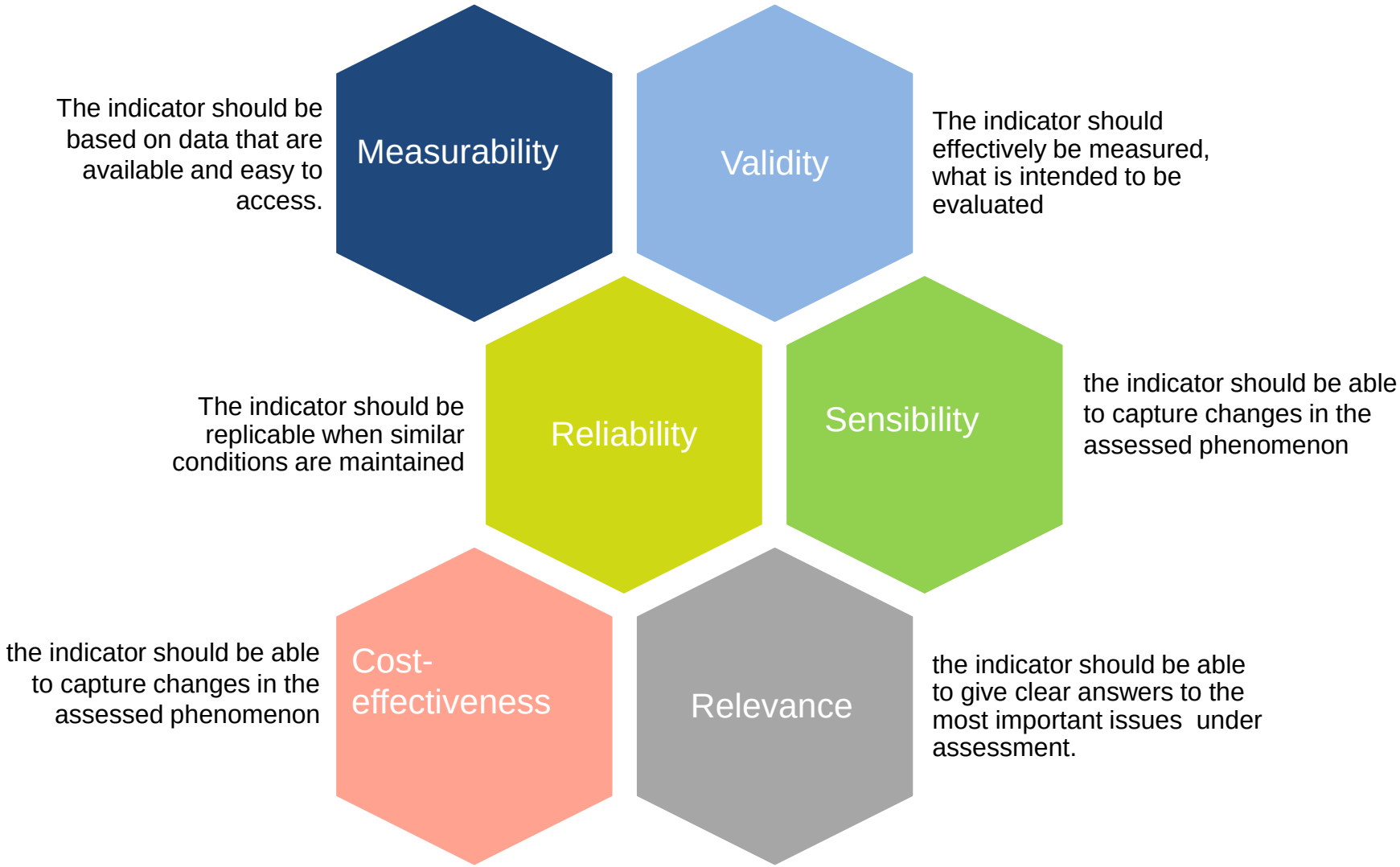
- Barcode and serialization of pharmaceutical drugs
- Layout approval and Regularization Process
- Biotech/Biosimilar registration process
- Advertisement of therapeutic goods

Global Regulatory Framework

Global Regulatory Framework



Indicators for Good Regulatory Framework



Best Regulatory Framework

Regulation should have a sound legal basis and should be consistent with existing legislation, including international

Regulation and regulatory decisions should be impartial in order to be fair and to avoid conflicts of interest, unfounded bias or improper influence

Regulations should be clear and predictable; both the regulator and the regulated party should understand the behavior and the conduct that are expected and the consequences of noncompliance

Regulations should not be prescriptive; they should allow flexibility in responding to a changing regulated environment and different or unforeseen circumstances

Regulations and regulatory decisions should be proportional to the risk and should not exceed what is necessary to achieve the objectives

Regulations should produce the intended result

Regulatory systems should be transparent; requirements and decisions should be made known to affected parties and, where appropriate, to the public in general.

Regulations should be accessible to, and understood by, the users

Challenges in Improving Regulatory Framework

will

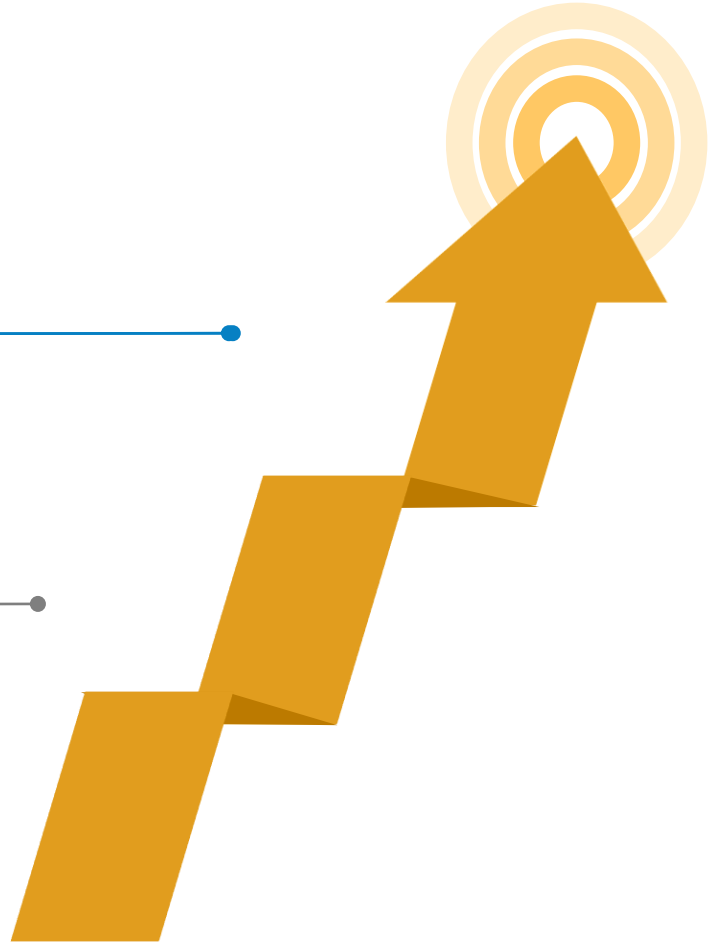
Will to make change and improvement in system

Transparent System and consistent Regulations

Regulations should be clear and predictable; both the regulator and the regulated party should understand

Best Minds

Relevant Qualification and experience



Cooperation and Collaboration needs Best Minds

Which one of these empty chairs can collaborate more efficiently?

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