Overview of WHO and other global initiatives

Dr. Petra Doerr
Director
Petra Doerr Consulting GmbH

Disclaimer

The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to DIA, its directors, officers, employees, volunteers, members, chapters, councils, communities or affiliates, or any organization with which the presenter is employed or affiliated.

Disclosure Statement

X **I have no real or apparent relevant financial relationships to disclose**
□ **I am employed by a regulatory agency, and have nothing to disclose**

Please note that DIA is not requesting a numerical amount to be entered for any disclosure, please indicate by marking the check box, and then providing the company name only for those disclosures you may have.

Type of Financial Interest within last 12 months		Name of Commercial Interest
□	Grants/Research Funding	
□	Stock Shareholder	
□	Consulting Fees	
□	Employee	
□	Other (Receipt of Intellectual Property Rights/Patent Holder, Speaker's Bureau)	

Will any of the relationships reported in the chart above impact your ability to present an unbiased presentation? □ Yes □ No

In accordance with the ACPE requirements, if the disclosure statement is not completed or returned, participation in this activity will be refused.

Outline

Introduction

Overview

WHO initiatives

Summary & Conclusion

Introduction

Introduction

Definition of regulatory convergence

A voluntary process whereby regulatory requirements across countries or regions **become more similar or "aligned" over time** as a result of the gradual adoption of internationally recognized technical guideline documents, standards and scientific principles, common or similar practices and procedures, or putting into place appropriate domestic regulatory mechanisms that align with shared principles to achieve a common public health goal.

Definition of regulatory harmonisation

The process by which technical guidelines **are developed to be uniform** across participating authorities.

WHO draft GRP: http://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodRegulatory_PracticesPublicConsult.pdf

Introduction

Definition of reliance and work-sharing

Reliance: the act whereby the regulatory authority in one jurisdiction may take into account / give significant weight to work taken by another regulator in reaching its own decision. (WHO GRP)

Work-sharing: work-sharing entails exchange of confidential information consistent with the provisions of existing agreements and compliant with each agency's legislative framework for sharing such information with other regulatory authorities. Some opportunities for work sharing include: assessing therapeutic product manufacturing sites; post-market surveillance of therapeutic product safety; assessment reports for medicinal products; development of technical guidelines and regulatory standards and collaboration on information technology. (WHO GRP)

Introduction

Characteristics of reliance and work-sharing

- Based on equivalence of requirements and/or application of internationally harmonised standards and
- Established confidence and trust in the regulatory system(s) (achieved through activities such as information sharing or staff exchange)
- Independent decision-making
- Benefit: reduced workload for individual agency

Introduction

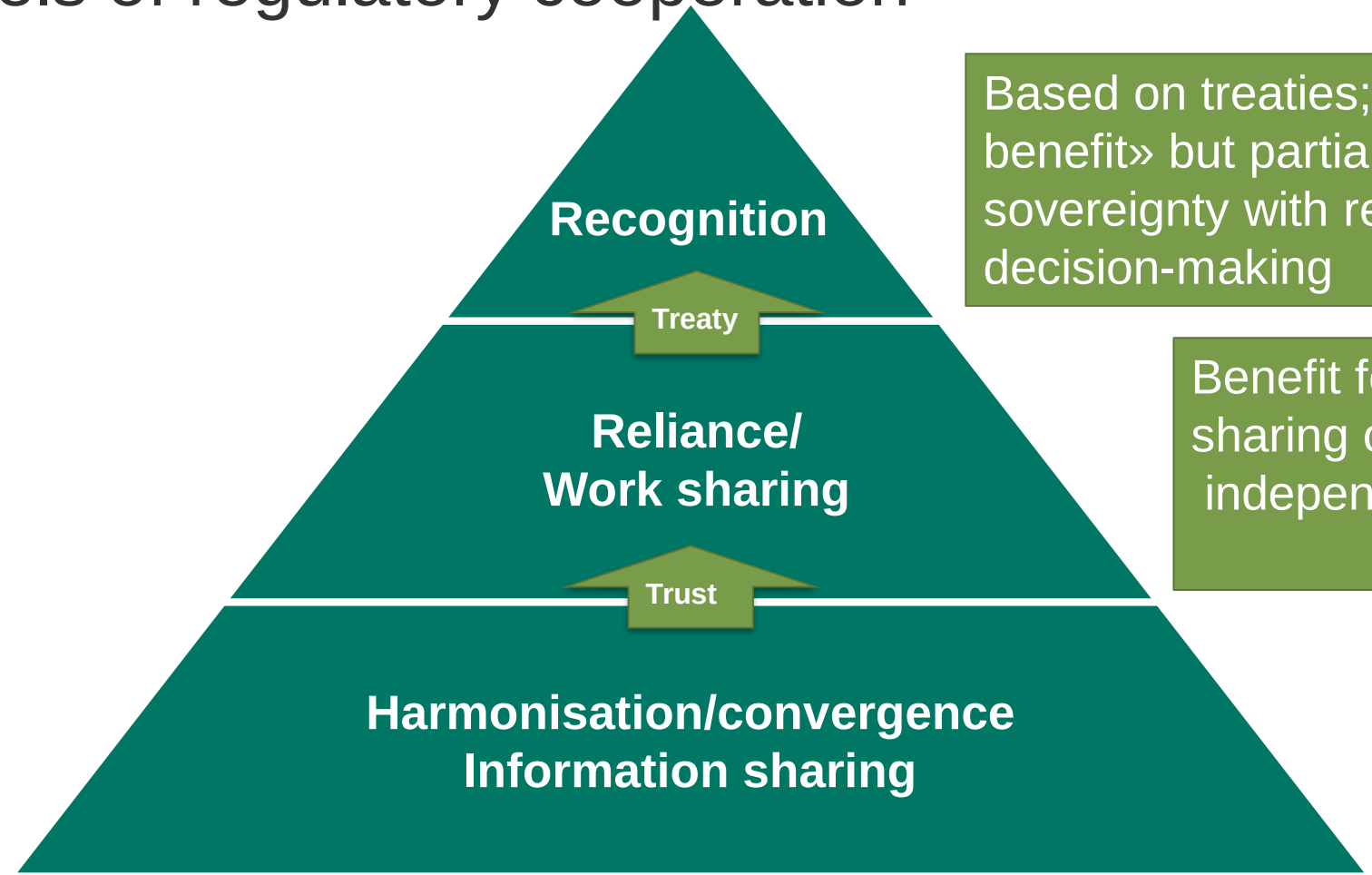
Characteristics of (mutual) recognition

- Based on treaties between countries (e.g. Mutual Recognition Agreements)
- Legally binding
- (Partial) loss of autonomy for decision-making
- Benefit for industry and regulators: avoiding duplication of efforts, e.g. GMP inspections

Overview

Overview

Levels of regulatory cooperation



Based on treaties; «maximal benefit» but partial loss of sovereignty with regard to decision-making

Benefit for regulators; sharing of workload, but independent decisions

Equivalence of requirements; Building confidence/establishing trust

Overview

- Examples of initiatives: harmonisation and convergence

Initiative	Scope	Main objective(s)/areas of work
ICH www.ich.org	Human medicinal products	Harmonisation of requirements for registration for human medicinal products
VICH www.vichsec.org	Veterinary medicinal products	Harmonisation of requirements for registration for veterinary medicinal products
IPRP www.iprp.global	Medicinal products	The IPRP promotes regulatory convergence by means of practical and operational information exchange; it is committed to promoting information sharing and collaboration

Overview

- Examples of initiatives: harmonisation and convergence

Initiative	Scope	Main objective(s)/areas of work
IMDRF www.imdrf.org	Medical Devices	Accelerate international medical device regulatory harmonisation and convergence
WHO www.who.int	Health Products	Development of international standards for the manufacturing and regulation of health products
PIC/S www.picscheme.org	GMP inspections	Developing and promoting harmonised GMP standards and guidance documents
ICMRA http://icmra.info/drupal/en/home	Medicines	Promote convergence of regulatory frameworks, where appropriate; promote the leveraging of regulatory authorities' collective resources, including the sharing of knowledge, work products, expertise, experience and best practices

Overview

Examples of initiatives: reliance and work-sharing

Initiative	Scope	Main objective(s)/areas of work
WHO Prequalification http://www.who.int/topics/prequalification/en/	Drugs, vaccines, devices	The prequalification process consists of a transparent, scientifically sound assessment, which includes dossier review, consistency testing or performance evaluation and site visits to manufacturers.
EAC MRH, ZAZIBONA, other RECs http://mrh.eac.int/; http://www.mcaz.co.zw/index.php	Medicines	Joint assessment; work-sharing in the marketing authorisation of medicinal products, supported by WHO and stringent regulatory authorities
ACSS Consortium	Medicines/ medical devices	Various collaborative projects ranging from marketing authorisation, post-market surveillance to IT. Work-sharing in the review of generic medicines and NCE's.

Overview

- Examples of initiatives: reliance and work-sharing

Initiative	Scope	Main objective(s)/areas of work
WHO Prequalification http://www.who.int/topics/prequalification/en/	Drugs, vaccines, devices	The prequalification process consists of a transparent, scientifically sound assessment, which includes dossier review, consistency testing or performance evaluation and site visits to manufacturers.
PIC/S www.picscheme.org	GMP inspections	Developing mechanisms for reliance on GMP inspection results

Overview

- Examples of initiatives: unilateral and mutual recognition

Initiative	Scope	Main objective(s)/areas of work
Mutual Recognition Agreements between the EU and partner states http://ec.europa.eu/growth/single-market/goods/international-aspects/mutual-recognition-agreements_en	Medicinal products/ medical devices (and others)	"Reduction of barriers to trade"; mutual recognition of conformity assessments in areas such as medical devices, GMP and GLP inspections
EU Mutual Recognition Procedure/Decentralised Procedure http://www.hma.eu/medicinesapprovalsystem.html	Medicinal products	Based on common EU-legislation; avoids multiple reviews of marketing authorisations in EU countries.

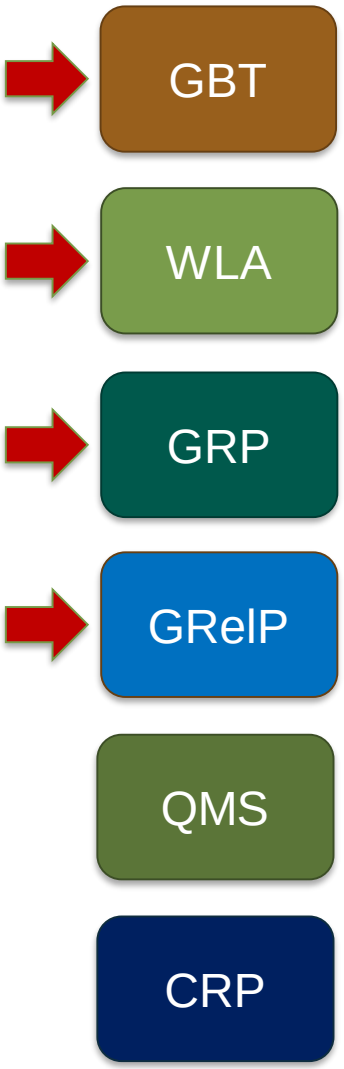
Overview

- Examples of initiatives: unilateral and mutual recognition

Initiative	Scope	Main objective(s)/areas of work
Unilateral recognition of marketing authorisations by COFEPRIS, Mexico http://www.cofepris.gob.mx/MJ/Paginas/Acuerdos/AcuerdosSecretario.aspx	Innovative medicinal products	COFEPRIS unilaterally recognises marketing authorisations for innovative medicines issued by the US-FDA, Health Canada, the EMA, Swissmedic, the TGA. These agreements have been signed off on 22 November 2012.

WHO Initiatives

WHO Initiatives



- Global Benchmarking Tool (GBT) to assess National Regulatory Authority capacity and identify gaps
- “WHO Listed Authorities (WLA)” based on the benchmarking using the GBT and performance evaluation
- Good Regulatory Practices (GRP)
- Good Reliance Practices (GRelP)
- Quality Managements Systems Guidelines (QMS)
- Promoting reliance and facilitated market authorization through the Collaborative Registration Procedure (CRP)

WHO Initiatives

GBT

Global Benchmarking Tool (GBT)

Evaluation of regulatory systems to:

- Identify strengths and areas for improvement;
- Facilitate the formulation of an institutional development plan (IDP) to build upon strengths and address the gaps;
- Prioritize IDP interventions; and
- Monitor progress and achievements.

https://www.who.int/medicines/regulation/benchmarking_tool/en/

WHO Initiatives

GBT

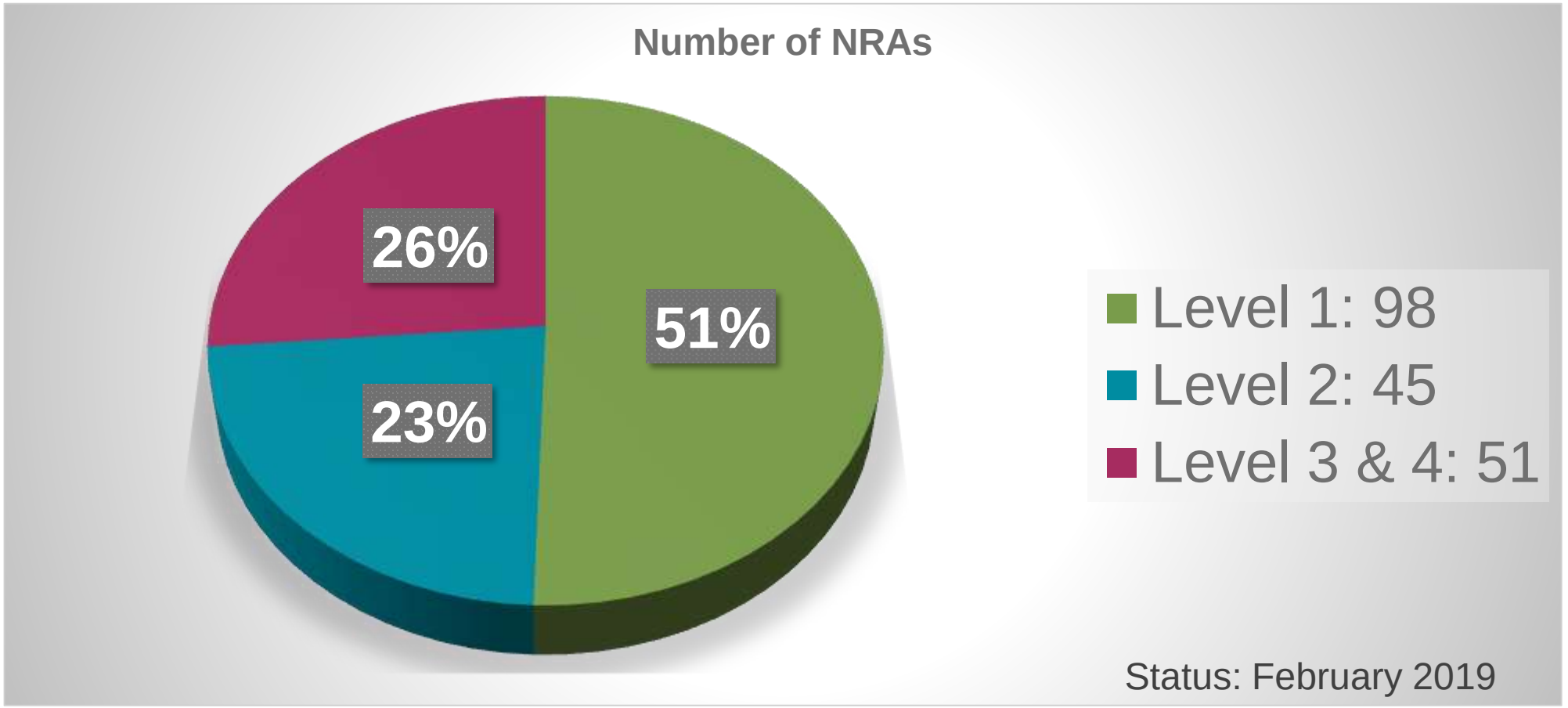
Global Benchmarking Tool (GBT)

	ISO	GBT	
Level 1	No formal approach	Some elements of regulatory system exist	→ Can ensure the quality of products if relies on ML3 / ML4 regulatory systems
Level 2	Reactive approach	Evolving national regulatory system that partially performs essential regulatory functions	
Level 3	Stable formal approach	Stable, well-functioning and integrated regulatory system	→ Target of WHA Resolution 67.2
Level 4	Continual improvement emphasized	Regulatory system operating at advanced level of performance and continuous improvement	→ Advanced/reference Regulatory Authorities

WHO Initiatives

GBT

Global Benchmarking Tool (GBT)



WHO Initiatives

WLA

“WHO Listed Authorities (WLA)” based on benchmarking using the GBT and performance evaluation

- To replace term ‘Stringent Regulatory Authority (SRA)’, defined as original ICH member or observer
- Growing concerns with term SRA with the fact that ICH doesn’t have remit or competence to assess regulatory capacity; coupled with expanding membership
- WHO expert committee asked WHO to develop new proposal in October 2017 – based on Global Benchmarking Tool assessments
- Extensive discussions and consultations, concept note published May 2019, stakeholder meeting 23 September 2019

https://www.who.int/medicines/areas/quality_safety/quality_assurance/qas19_808_WHO_listed_authorities.pdf?ua=1

WHO Initiatives

GRP

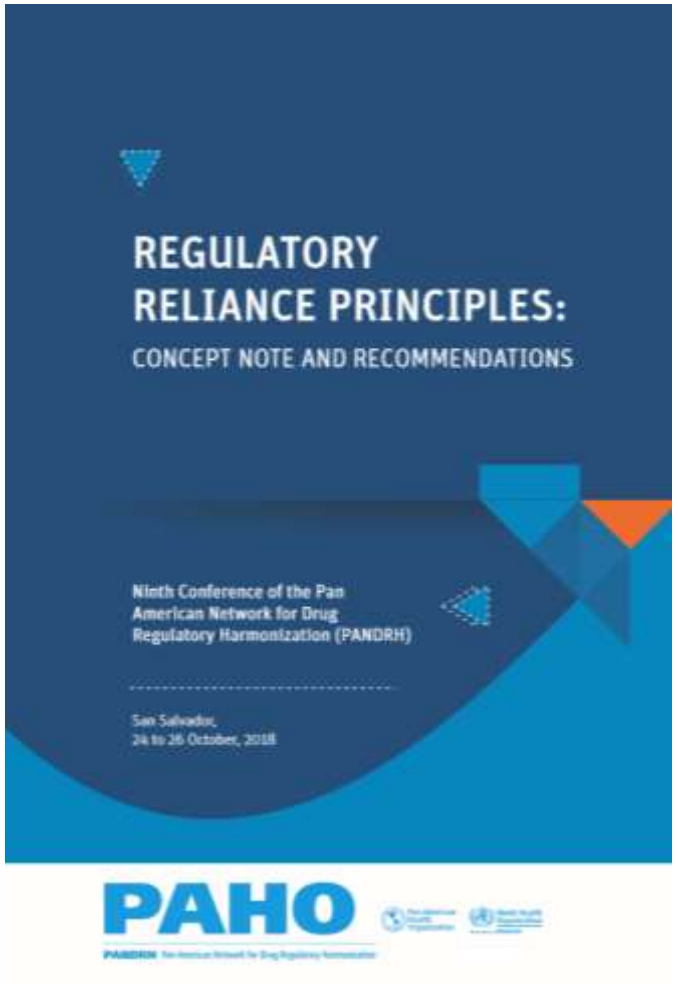
GRelP

Good Regulatory Practices: draft available

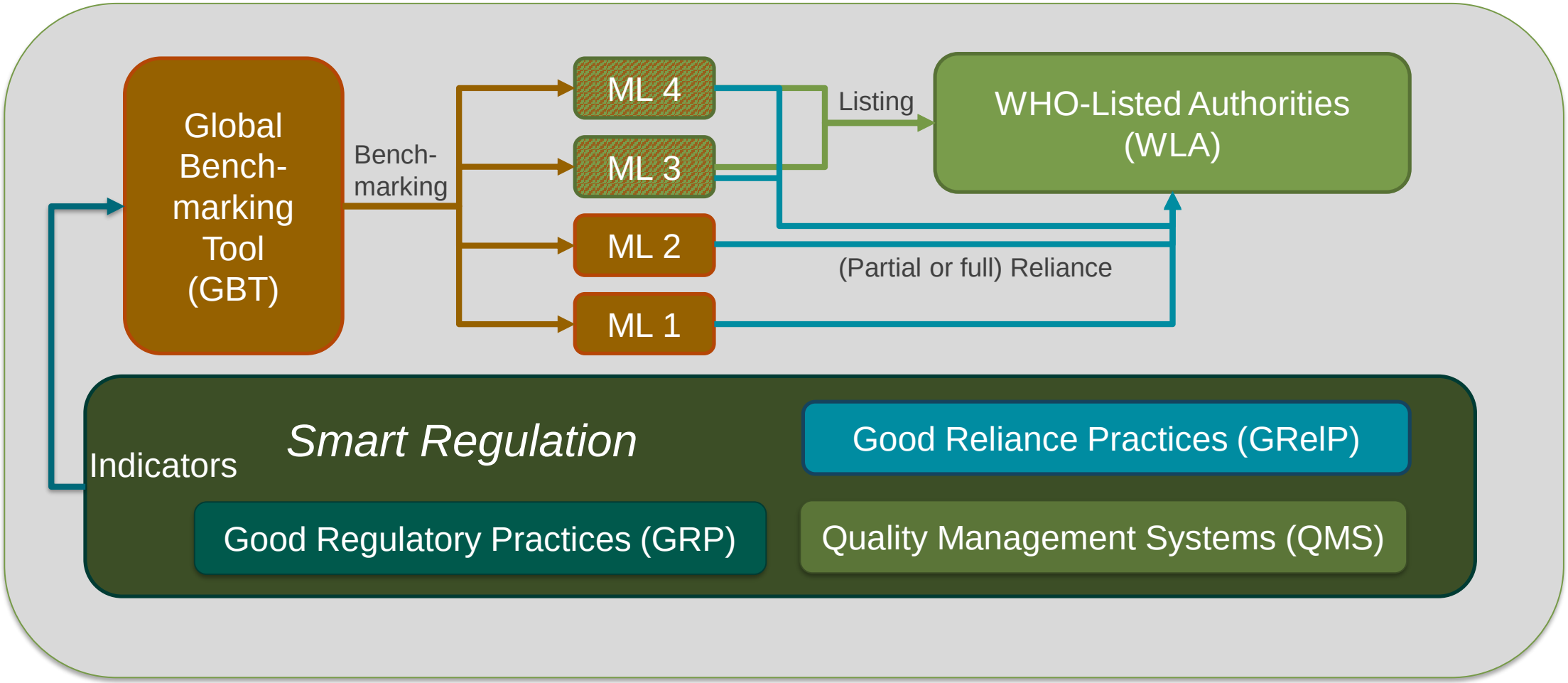
https://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodRegulatory_PracticesPublicConsult.pdf

Good Reliance Practices: work initiated

PANDRH/PAHO has recently published “Regulatory Reliance Principles”



WHO Initiatives



Summary and Conclusions

Summary and Conclusions

Harmonisation & Convergence

- Initiatives with the focus on harmonisation/convergence are well under way
- Increasing participation from regulators in multilateral/ global initiatives
- Avoidance of overlap and duplication is important
- Convergence/harmonisation: benefit for industry – basis for real benefit for regulators (equivalence of requirements enables trust, interoperability)

Summary and Conclusions

Reliance and work-sharing

- Increasing number of initiatives focussing on reliance and work-sharing
- Increased awareness and acceptance of reliance and work-sharing concepts among regulators (“even the largest ones cannot do everything themselves”)
- Reliance also applied by large/“listed regulatory authorities” (e.g. GMP inspections, sharing of assessment reports)
- WHO increasingly and successfully promotes reliance and work-sharing models in developing countries

Summary & Conclusions

WHO Initiatives

- The WHO is supporting strengthening of regulatory systems based on WHA resolution 67.20 to bring NRAs to a functional stage (maturity level 3).
- The WHO is promoting smart regulation including the use of reliance approaches underpinned by guidelines on QMS, GRP and GRelP.
- Reliance will be facilitated by introducing a framework on WHO-listed Authorities (WLA), replacing the existing approach of “Stringent Regulatory Authorities”.
- Through the Collaborative Registration Procedure and other collaborative mechanisms, WHO is helping to accelerate marketing authorisations in target countries based on previous SRA approval or WHO Pre-Qualification.


Thank you for your attention!
Questions?

List of abbreviations (in alphabetical order)

ACSS	Australia-Canada-Singapore-Switzerland Consortium
COFEPRIS	Federal Commission for the Protection against Sanitary Risk, Mexico
CRP	WHO Collaborative Registration Procedure
EAC MRH	East African Community Medicines Regulatory Harmonisation
EU	European Union
GBT	Global Benchmarking Tool, WHO
GMP	Good Manufacturing Practices
GRelP	Good Reliance Practices
GRP	Good Regulatory Practices
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMRA	International Coalition of Medicines Regulatory Authorities
IDP	Institutional Development Plan
IMDRF	International Medical Device Regulatory Forum
IPRP	International Pharmaceutical Regulators Programme
ISO	International Organization for Standardization
JFDA	Jordan Food and Drug Administration
JPMA	Japan Pharmaceutical Manufacturers Association
ML	Maturity Level
NCE	New Chemical Entity
NRA	National Regulatory Authority
PANDRH	Pan-American Network for Regulatory Harmonisation
PAHO	Pan-American Health Organization
PIC/S	Pharmaceutical Inspection Cooperation Scheme
QMS	Quality Management System
SRA	Stringent Regulatory Authority
TGA	Therapeutic Goods Administration, Australia
US-FDA	United States Food and Drug Administration
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
WHA	World Health Assembly
WHO	World Health Organisation
WLA	WHO-Listed Authority
ZAZIBONA	Zambia-Zimbabwe-Botswana-Namibia Joint Registration

List of abbreviations (in alphabetical order)

PhRMA	Pharmaceutical Research and Manufacturers of America
PIC/S	Pharmaceutical Inspections Cooperation Scheme
PMDA	Pharmaceuticals and Medical Devices Agency, Japan
RHI	Regional Harmonisation Initiative
Roszdravnadzor	Federal Service on Surveillance in Healthcare, Russia
RSS	Regulatory Systems Strengthening
RWD/RWE	Real-world data/real-world evidence
SADC	Southern African Development Community
SAHPRA	South African Health Products Regulatory Authority
SCDMTE	Scientific Center of Drug and Medical Technologies Expertise, Armenia
SFDA	Saud Food and Drug Authority, Saudi Arabia
TFDA	Taiwan Food and Drug Administration
TGA	Therapeutic Goods Administration, Australia
TİTCK	Turkish Medicines and Medical Devices Agency
US-FDA	United States Food and Drug Administration
USP	United States Pharmacopeia
WG	Working Group
WHO	World Health Organisation
WLA	WHO Listed Authority
WSMI	World Self-Medication Industry