World Health Organization

Regulatory Co-operation: A nicety or a necessity?

PMDA 10th Anniversary

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Content

- World Health Organization and its role in medicines
- Regulatory co-operation, experiences, challenges and opportunities
- Key elements for success
- Concluding remarks

Long standing collaboration WHO – Japan in medicines / medical products

- Pharmacovigilance
- Biologicals
- Narcotics
- Medical devices
- Founding member of ICH

The World Health Organization (WHO) is the directing and coordinating authority on international health within the United Nations' system. WHO experts produce health guidelines and standards, and help countries to address public health issues. WHO also supports and promotes health research. Through WHO, governments can jointly tackle global health problems and improve people's well-being.

193 countries and two associate members are WHO's membership. They meet every year at the World Health Assembly in Geneva to set policy for the Organization, approve the Organization's budget, and every five years, to appoint the Director-General. Their work is supported by the 34-member Executive Board, which is elected by the Health Assembly. Six regional committees focus on health matters of a regional nature.

WHO ARE OUR PARTNERS IN HEALTH?

WHO and its Member States work with many partners, including UN agencies, donors, nongovernmental organizations, WHO collaborating centres and the private sector. Only through new ways of working and innovative partnerships can we make a difference and achieve our goals.

The World Health Assembly. WHO's 193 member countries meet to decide policy for improving health.

More about WHO
www.who.int/about/en/

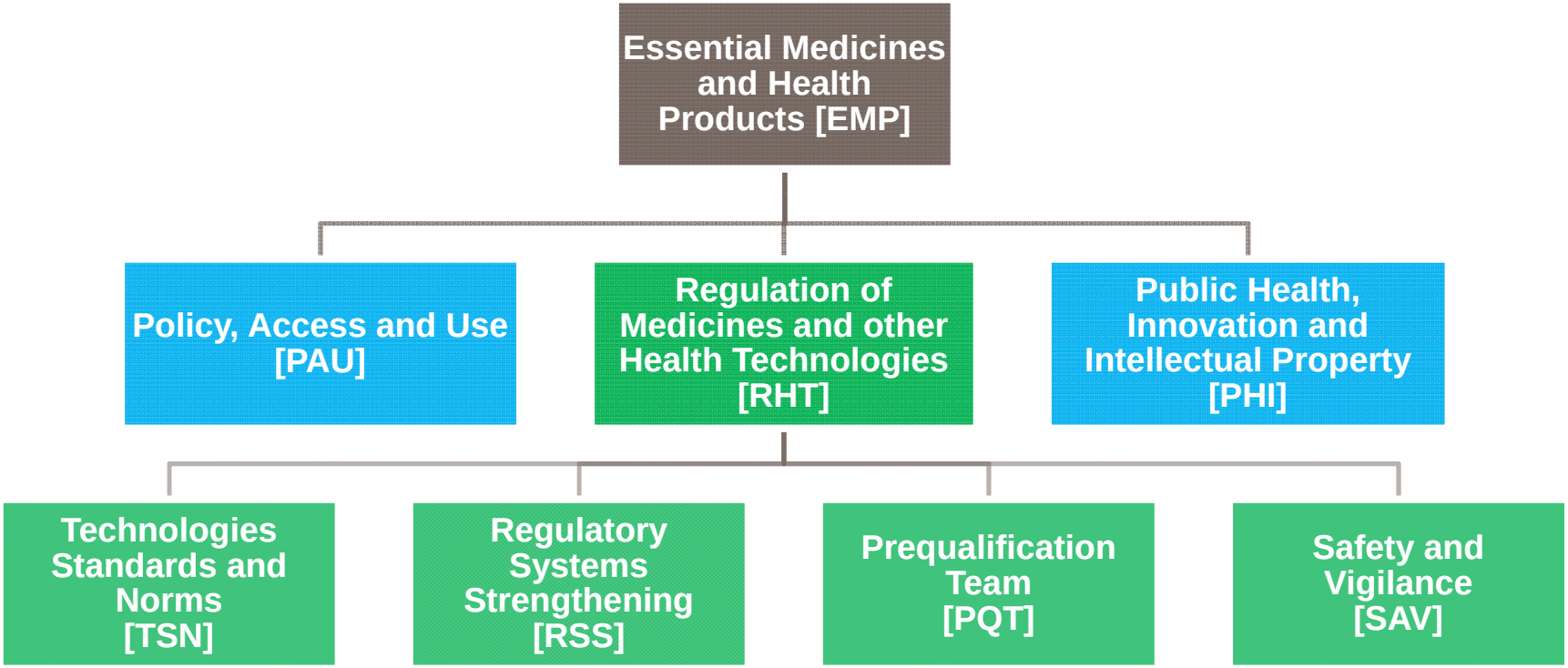
WHAT IS THE WORLD

PEOPLE

Last but not least, WHO is people. Over 8000 public health experts including doctors, epidemiologists, scientists, managers, administrators and other professionals from all over the world work for WHO in 147 country offices, six regional offices and at the headquarters in Geneva, Switzerland.

HEALTH ORGANIZATION?

New structure of Department of Essential Medicines & Health Products



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Standards and WHO

- WHO is **mandated** to "*develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products*" *(Article 2, WHO Constitution)*; *the work is at large focusing on specific topics not address by other parties and complimentary to other standard setting initiatives*

- WHO Expert Committee on Specifications for Pharmaceutical Preparations
  - WHO International Working Group on International Nonproprietary Names
- WHO Expert Committee on Biological Standardization

  …

- Joint FAO/WHO Expert Committee on Food Additives

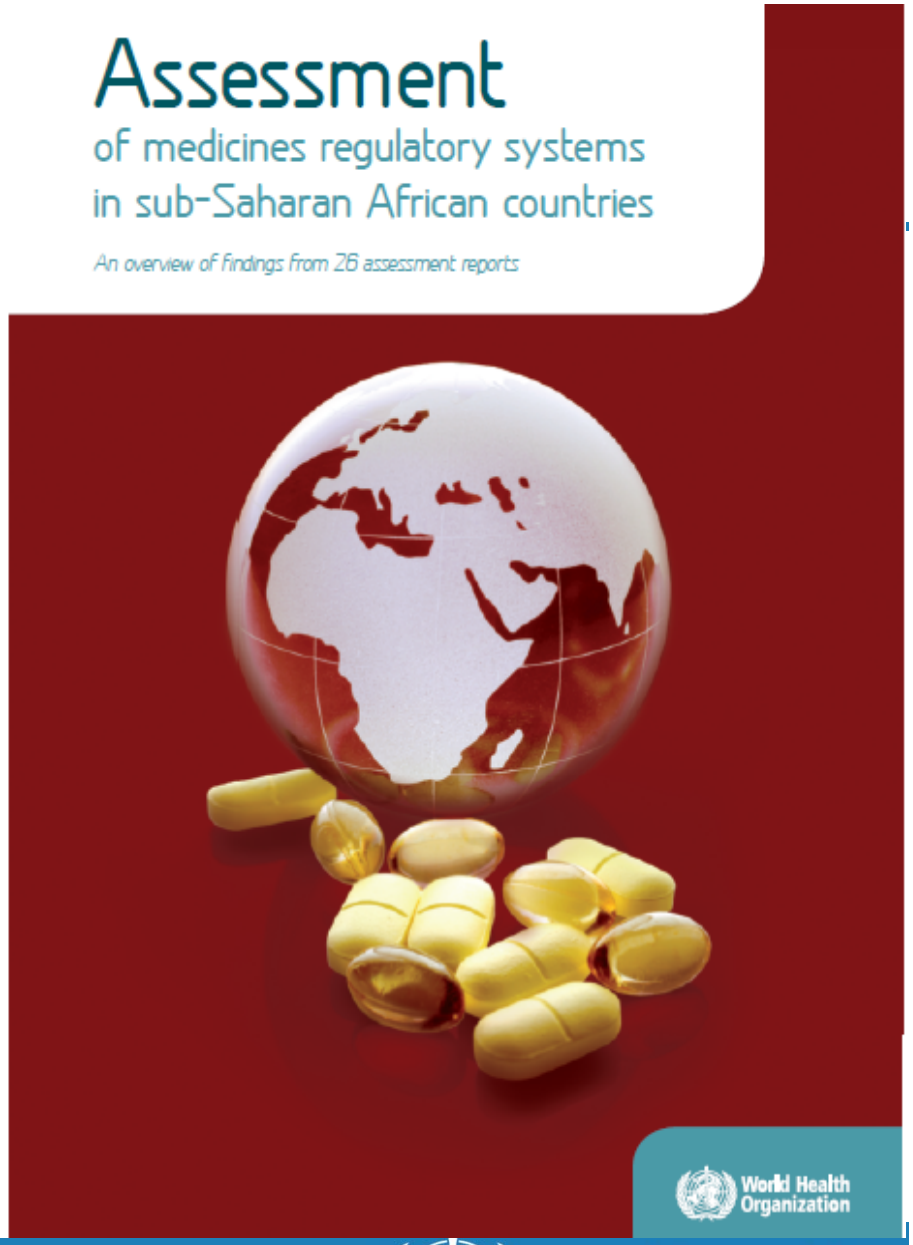
Where we are with medicines regulatory systems today?

WHO has developed a comprehensive Assessment Tool for National Regulatory Authorities with objectives:

1. To identify gaps and help to develop institutional development plans
2. In conjunction with vaccines prequalification: as a pre-condition of prequalification

The attached publication from 2010 is a good example of this work and available also on web site.

- *Note. Each study published is out of date in certain details and progress has been made since assessments in several countries*



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New: Harmonization of pharmacopoeias

- Pharmacopoeial Discussion Group (PDG)
  - ICH parties - US, Japanese and European Pharmacopoeia
  - WHO observer

- Harmonization beyond PDG – WHO has taken lead for convening all functioning pharmacopoeias for *further convergence and harmonization:*

- The 1st International Meeting of World Pharmacopoeias, 29 February – 2 March, 2012, Geneva; Switzerland

- The 2nd International Meeting of World Pharmacopoeias, 18-19 April 2013, New Delhi, India

Harmonization and convergence of regulatory requirements: creating basis for regulatory cooperation

- Objective of drug regulation: TO IMPROVE AND PROMOTE PUBLIC HEALTH
- Harmonization/convergence is aimed to diminish duplicative efforts, creates "common language", can facilitate cooperation and access to medicines
- In case of harmonization/convergence of regulations the main objective should be:
  - Measurable public health gains
  - Efficiency savings

Harmonization and convergence initiatives

- Inter-regional, regional and sub-regional – ICH, APEC, Pan American Network for Drug Regulatory Harmonization (PANDRH), ASEAN, SADC, EAC (part of AMRHI), Gulf Cooperation Council etc.

- Not harmonized! – *Good Harmonization Practice (GHP) needed?*
  - Different organization – with or without strong secretariat
  - Different involvement of industries and other parties
  - Different in terms of implementation – some focused on implementation, others rather focused on convergence of regulatory thinking and eduction
  - Different focus technical areas/products

…

Key elements of success (1)

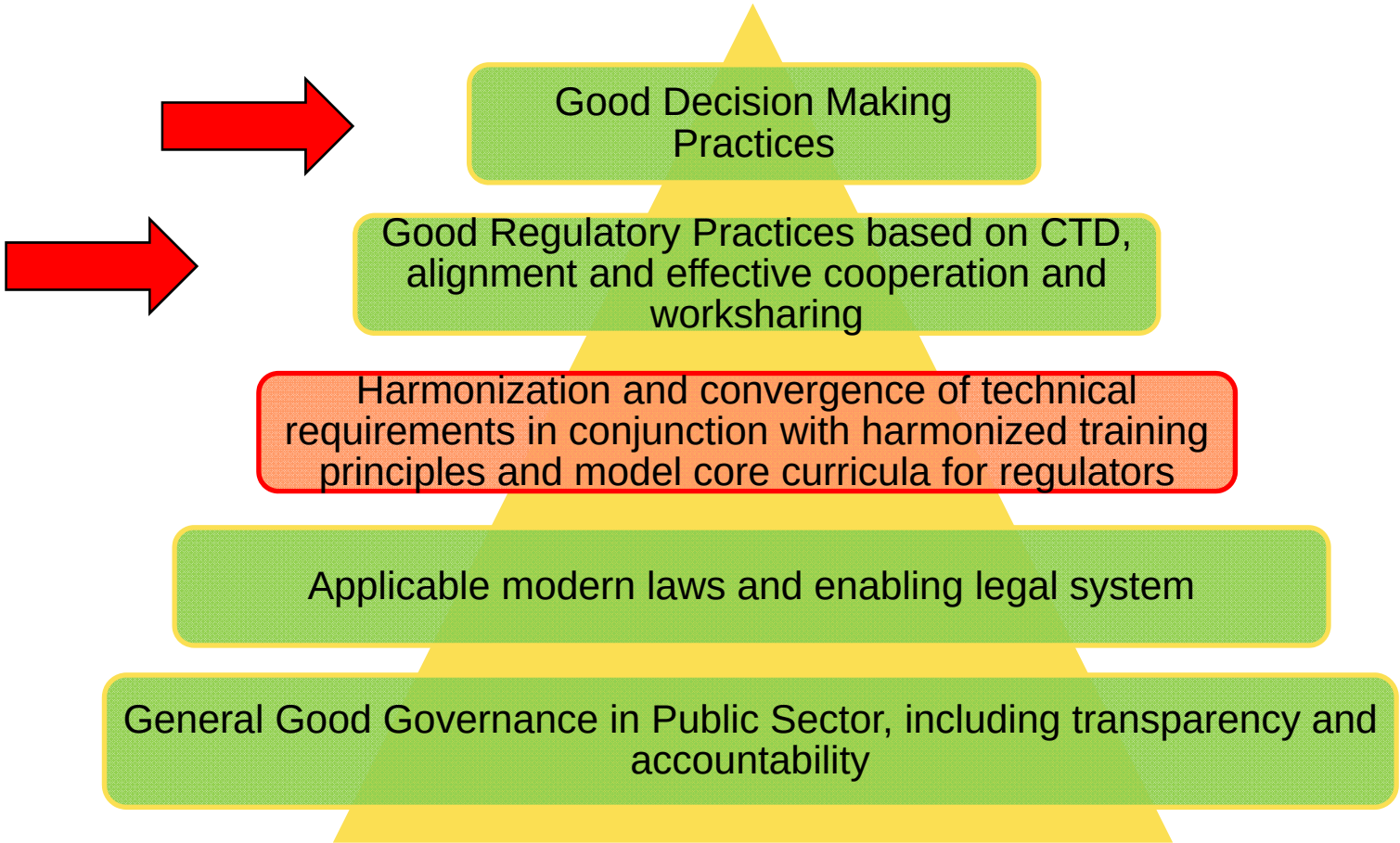
- Enabling environment and foundation
  - Good Governance principles implemented
  - Modern legal systems allowing certain flexibilities
- Political will and shared common vision
- Similar socioeconomic development of participating countries
- Participants functional regulatory authorities with necessary capacity and resources available

Key elements of success (2)

- Willingness to invest into harmonization and convergence
- Effective governance and secretariat
- Willingness to cooperate and compromise
- Commitment for implementation and updating/revision
- Commitment for applying Good Regulatory Practice principles when implementing
- …

Timely access to better (hopefully) **medicines ladder.**

Where the cooperation and reliance on work done by other regulators fits in?



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Regulatory co-operation

- In nowadays complex and interlinked world with rapidly advancing science not a single regulator can operate in isolation, or cope with all the work to be done
  - *Regulators have ONE common thing across small and big – all complain about lack of resources*
- Cooperation can be passive/receiving and active/contributing
- Cooperation can be institutionalized and legally mandated or voluntary
- Whatever the option/s cooperation enables saving resources and making more QUALITY DECISIONS

Experiences of success

- EU experiences – few regulators from 28 MS take the active lead but **all benefit** (harmonization and legal framework major enabling factor)
- Joint reviews of clinical trial applications/products across borders
  - AVAREF
  - Medicines Prequalification Programme jointly with EAC regulators
- Promoting international harmonized standards and good review by staff exchange
  - Medicines prequalification has a 3 months rotational fellow position for quality assessors has lead to local subregional activities of cooperation

Concluding remarks (1)

- WHO has promoted regulatory collaboration, harmonization and convergence long time and will continue to do so being open to new ideas
- Making medicines is not any more a "local" business and the era of only locally operating regulators starts to end
- The future of medicines regulation is more in effective collaboration and networking; regulators starting to function more as a functional network rather than individual players, and individual players focusing on what they can give the best *added value to public health*

Concluding remarks (2)

ICDRA recommendations in 2010/2012 for Medicines Regulatory Authorities in Singapore and Tallin:

- Take account of one another's work with a view to improving the efficiency of the global regulatory system.
- Commit resources to form cooperative networks based on uniformity of standards and inspection systems.
- Engage with regional and international initiatives promoting harmonization, information sharing and use of data generated by other regulators as a tool for improving timely access to medicines and medical products.

Concluding remarks (3)

- Harmonization and convergence alone cannot help, but can form a solid basis for the new regulatory paradigm to evolve in the future –
  - *Doing locally what nobody is doing/can do for you, (added value) and decide in which area you invest to specialize to be a "world class player" in the Regional/Global Network*

- Cooperation (in majority of cases) will not replace national sovereignty of regulatory decision making. However, the results of effective cooperation are increasingly important part of integrated national regulatory decision making

Collaboration is a necessity.

Next ICDRA hosted by ANVISA Brazil

World Health Organization

Thank you

Happy anniversary !