WHO Activities: focus on reliance

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Infectious (preventable) diseases remain a leading cause of death among children under age 5

Global distribution of deaths among children under age 5 by cause, 2018

One child under age 15 died every five seconds in 2018

UN Inter-agency Group for Child Mortality Estimation
Access to medical products – global challenge

— Good health is impossible without access to medical products;
— Universal Health Coverage depends on the availability of quality-assured affordable health technologies in sufficient quantities;
— An estimated two billion people have no access to essential medicines, effectively shutting them off from the benefits of advances in modern science and medicine.
— Reasons for limited/insufficient access are numerous – including inadequate regulatory capacity and lack of collaboration and work sharing in medicines regulatory area between countries.
Globalization in medical products regulation (1)

― All medical products should be used in the countries only after approval by the national or regional regulatory authority - in line with current international standards (WHA Resolutions: WHA 67.20 (2014); WHA 67.21 (2014); WHA 63.12 (2010));

― There is no clear vision or policy about HOW to set up regulatory systems in times when it is unrealistic to manage all functions in one national setting for most regulators – due to globalization of regulatory science;

― New products are likely more complex and sophisticated – demanding advanced health systems and "quality use".
Globalization in medical products regulation (2)

- Ability/need to assess and inspect all products coming to the markets:
  - Does repetitive assessments and inspections give any added value?
- How to build confidence in scientific assessments/ inspections carried out by other regulators?
- Are new products equally fit for all types of health systems and health providers available?
- Benefit/risk assessment taking into consideration health systems in which product is to be launched?
- What exact competencies are needed for regulators – to perform key regulatory functions?
The Sixty-seventh World Health Assembly resolution 67.20 recognized that:

— Effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes;

— Regulators are an essential part of the health workforce, and

— Inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products.
— ≈30% of NRAs globally have limited capacity to perform core regulatory functions
— Regulatory capacity gap between different countries (low- and high-income) in terms of:
  — Human and financial resources;
  — Regulatory functions effectively performed;
  — Expertise available for fulfilling regulatory functions;
  — Availability of proper systematic training for regulators;
  — Applying quality management principles.
Facilitation of good quality national decisions – WHO efforts

— Promoting good governance and transparency in medical products sector – Good Regulatory Practices process;
— Promoting and facilitating building up strong national regulatory systems as:
  — part of overall health systems strengthening – Global Benchmarking process;
  — important contributor to achieving Universal Health Coverage and able to address public health priorities;
— Supporting regulatory workforce development – Global Regulatory Curriculum;
— Promoting regulatory cooperation, convergence and harmonization;
— Promoting work sharing – based on reliance on the work of trusted authorities to inform national regulatory decision-making.
Options to facilitate good quality regulatory decisions – reliance in the focus

Regulatory cooperation based on convergence/harmonization to improve the quality of decision making process

- **Unilateral or mutual recognition**: mutual recognition is based on treaties or equivalent, providing maximal benefits but partial loss of sovereignty with regard to decision-making

- **Reliance on regulatory decisions**: performed by other competent and trusted agencies and/or cooperation/collaboration with other regulators to reduce the workload, with independent final decision-making

- **NRA makes independent decisions based on its own reviews or inspections**

Adopted by ECSPP, 15 October 2020
Concept of facilitated registration (based on reliance)

Regulators worldwide can benefit from already conducted scientific assessments and inspections to support the national registrations, if:

- Have access to regulatory expertise from trusted party (complete assessment and inspection reports);
- Have the same product;
- Have the same essential technical data;
- Understand validity of B/R for local environment;
- National legislation and sovereignty are not affected;
- Confidentiality of commercially sensitive information is respected;
- Regulatory follow-ups are properly managed.
If the information is shared (assessments, inspections, testing) for WHO PQ-ed or “SRA”-approved products

THEN...

NRAs can rely on the shared information to facilitate national decisions

- avoid duplications
- reduce regulatory burden
- assess B/R in local context

Reliance / Recognition

Timely access to quality-assured products with positive B/R

Normal pathway

Re-allocate resources

Enhanced NRA’s oversight on other products & sites
Regulatory information & knowledge could be transferred through facilitated pathways

MAIN PRINCIPLES:

- **Sharing information / expertise** (assessment, inspection and testing results or expertise) that serve as basis for authentic national decisions – avoiding duplication.
- **Voluntary participation** – reference authorities, participating entities and manufacturers/sponsors

WHO PQ collaborative registration procedure
- Vaccines: 2004
- Medicines: Started in 2012
- Diagnostics: Pilot 2019
- Vector control: Pilot 2020

“SRA” collaborative registration procedure
- Initiated in 2015
- European Medicines Agency (EMA)
- UK Medicines and Healthcare Products Regulatory Agency (MHRA)
- 20 African NRAs

Regional networks
- African Medicines Regulatory Harmonization Project (AMRH)
- ASEAN SIAHR Project

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Building Trust & Partnership to Deliver UHC in Asia
WHO Collaborative Registration Procedure

*Including regulatory time and applicant time

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Timely access to medical products – never-ending challenge

— All patients/consumers deserve access to quality assured medical products with positive benefit-risk characteristics – Universal Health Coverage;

— Today’s reality and demand:
  — To generate quality national decisions regulators globally MUST collaborate and MUST take into consideration the information available from other regulatory authorities;
  — Not using the outputs and outcomes from other (better resourced) regulatory authorities would only mean lost opportunity, duplication of efforts, increased regulatory burden and waste of scarce resources.
Summary/conclusions

— Not a single regulator anymore can fulfil all regulatory work alone and independently;

— The future of medical products regulation is in convergence/harmonization, collaboration and networking based on reliance and trust;

— More and more regulators are starting to operate as a functional network rather than individual players, and individual players focusing on where they can give the best added value.
Thank you!

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