Global context of harmonization and innovative models

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Key Themes of WHO’s 13th General Programme of Work 2019-2023

Mission
Promote Health - Keep the World Safe - Serve the Vulnerable

Strategic Priorities
Health Coverage: 1 billion more people with health coverage
Health Emergencies: 1 billion more people made safer
Health Priorities: 1 billion lives improved

at EB/WHA 2019
Roadmap on access to medicines and vaccines
http://www.who.int/medicines/access_use/road-map-medicines-vaccines/en/
SDG 3 – Target 3.8

Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.
Objectives of the WHO regulatory system strengthening programme

1. Build regulatory capacity in Member States consistent with good regulatory practices

2. Promote regulatory cooperation, convergence and transparency through networking, work-sharing and reliance

- WHA Resolution 67.20 in 2014
  ✓ Recognized the importance of strong regulatory systems to a well-functioning healthcare system and the attainment of health-related SDGs and UHC.
To continue to support Member States upon their request in the area of regulatory system strengthening, including, as appropriate, by continuing to:

- **Evaluate**: Evaluate national regulatory systems
- **Tools**: Apply WHO evaluation tools
- **Performance**: Generate and analyze evidence of regulatory system performance
- **IDPs**: Facilitate the formulation and implementation of institutional development plans
- **Technical support**: Provide technical support to national regulatory authorities and governments

WHA Resolution 67.20

*What WHO should do*
<table>
<thead>
<tr>
<th>WHO GBT Performance Maturity Levels</th>
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<tr>
<td><strong>ISO 9004</strong></td>
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<tr>
<td><strong>1</strong> No formal approach</td>
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<tr>
<td><strong>2</strong> Reactive approach</td>
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<td><strong>3</strong> Stable formal system approach</td>
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<td><strong>4</strong> Continual improvement emphasized</td>
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<td>WHO GBT</td>
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<tr>
<td>99 Countries</td>
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<td>45 Countries</td>
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<td>50 Countries</td>
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- **No formal approach**
  - Some elements of regulatory system exist
  - Can ensure the quality of products if rely on ML 3/ML 4 regulatory systems
  - 99 Countries

- **Reactive approach**
  - Evolving national regulatory system that partially performs essential regulatory functions
  - 45 Countries

- **Stable formal system approach**
  - Stable, well-functioning and integrated regulatory system
  - Target of WHA Resolution 67.20
  - 50 Countries

- **Continual improvement emphasized**
  - Regulatory system operating at advanced level of performance and continuous improvement
  - Advanced and well resourced regulatory systems
Status of National Regulatory Systems by Maturity Levels (ML)

194 WHO Member States

**Facts**
- 51% have limited capacity to perform core regulatory functions
- Applicants face a landscape of disparate regulations, frequent delays and limited transparency

**Implications**
- Access to quality assured and safe medicines and vaccines in countries at ML 1 & 2
  - high risk of SF medical products
- Cost of inefficient regulatory systems drives up prices
- Regulators less prepared for public health emergencies
Reliance gaining ‘recognition’

- No longer a question of ‘if’, but when and how
- About smart regulation and investment
- Occurring amongst even most resourced regulatory agencies
- Benefits don’t accrue by magic – requires framework and planning
- One element of a larger international strategy and toolkit
Views on Regulatory Cooperation

Convergence & harmonization

- Recognition
- Reliance
- Work-sharing
- Information-sharing

Reliance

- Recognition

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

Benefit for regulators; sharing of workload, but independent decisions

«Foundation», Equivalence of requirements

Information-sharing

1. Confidence building
2. Harmonisation/convergence
3. Trust
Reliance and Recognition

- Both reflect ‘taking account of’ the output of other regulatory authorities;
- Increasing prevalence/necessity, even with most mature/resourced authorities;
- Prerequisite: regulatory system and functions that can be the object of reliance or recognition;
- Both may be unilateral or mutual;
- NB: sovereignty maintained in both cases.

Reduction: streamline/reduce internal work

Replacement: operationally, rely on decisions
Access to Safe, Effective, Quality and Affordable Medical Products

Legal framework mandate and enforcement power
Norms and standards
Leadership, coordination & Strategic Planning
Quality Management/Risk Management System
Resources HR, FR, IMS, Infrastructure

Inspection and Audit
Vigilance and Surveillance

Quality control/testing
Scientific evaluation and oversight

Assuring quality of products

Good Regulatory Practices (GRP)
CONCEPT NOTE: A FRAMEWORK FOR EVALUATING AND PUBLICLY DESIGNATING REGULATORY AUTHORITIES AS WHO-LISTED AUTHORITIES

(May 2019)

DRAFT FOR COMMENTS
Convergence and harmonization

Regulatory convergence:
- a voluntary process
- regulatory requirements become more similar or “aligned” over time
- gradual adoption of internationally recognized technical guidelines, standards and scientific principles
- common or similar practices and procedures.

Regulatory harmonization:
- process by which technical guidelines are developed in order to be uniform across participating authorities in multiple countries.
True harmonization is NOT just development of common documentation

- Appropriate legislative and regulatory requirements:
  - **Legal framework** to define the basis and conditions for collaboration and work sharing/acceptance of information and decisions;
  - **Regulatory framework** defining the practical arrangements;
  - **Technical framework**: applicable guidelines

- Application of these provisions:
  - Operational procedures for implementation;

- Appropriate interpretation of the requirements:
  - Competence of the personnel;
  - Capacity development, training, etc.
Success factors for convergence and harmonization initiatives (1)

- Well elaborated and clearly understood vision, mission, roles and responsibilities;
- Political will and continuous support;
- Effective management and administration;
- Active participation of all potential stakeholders (NRAs, industry, development partners);
- Ownership by the NRAs.
Success factors for convergence and harmonization initiatives (2)

- Science and consensus driven
- Engagement by all parties to implement
- Adequate human and financial resources
- Transparency, effective communication and Accountability
Conclusion

- Regulatory capacity building, promotion of collaboration, convergence and harmonization will continue to be one of the priorities for WHO.
- Making medicines is no longer a "local" business.
- Future of medicines regulation is in convergence/harmonization, collaboration and networking.
- Regulators functioning more as a functional network rather than individual players, and individual players focusing on where they can give the best added value.
- All about smart regulation in contributing to access and public health.