Regulatory Agility

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Disclaimer

The views in this presentation are those of individual contributors and do not represent formal consensus positions of Roche Diagnostics.

Acknowledgement

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1. Define Regulatory Agility

- Agility/nimbleness in regulatory processes & decision-making
- Utilize information and resources available to anticipate and mitigate risk and to effectively navigate
- Regulators work together to minimise redundancy and time loss

What it is about

- Does not mean cutting corners
- Does not mean compromising safety, quality or efficacy/performance
- Does not mean relying on factors other than robust science (e.g. political pressure)

What it is not about

Source: Murray M. Lumpkin, Lead for Global Regulatory Systems Initiatives, Bill and Melinda Gates Foundation, APACMed MedTech Forum 2020；
Panel discussion with regulators and experts on Regulatory Agility during the APACMed MedTech Forum 2022.

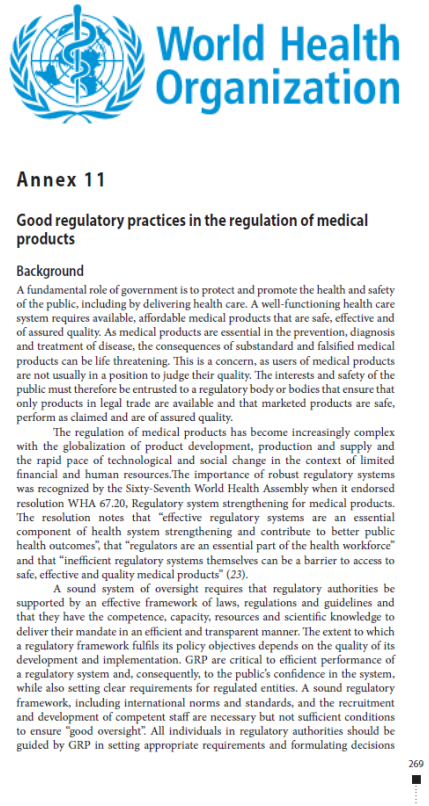
Regulatory agility refers to adoption of *risk-based, context-driven approaches* and *regulatory cooperation* based on *sound scientific evidence* and *information*.

Source: Whither-asean-regulatory-agility-and-convergence-in-the-ongoing-covid-19-pandemic. Duke-NUS CoRE. 2021.
https://www.duke-nus.edu.sg/core/core-regulatory-perspective/whither-asean-regulatory-agility-and-convergence-in-the-ongoing-covid-19-pandemic

2. WHO Principles of Good Regulatory Practices (GRP)

Regulatory agility concept is not brand new!

- Legality
- Consistency
- Independence
- Impartiality
- Proportionality
- Flexibility
- Clarity
- Efficiency
- Transparency



World Health Organization

Annex 11

Good regulatory practices in the regulation of medical products

Background

A fundamental role of government is to protect and promote the health and safety of the public, including by delivering health care. A well-functioning health care system requires available, affordable medical products that are safe, effective and of assured quality. As medical products are essential in the prevention, diagnosis and treatment of disease, the consequences of substandard and falsified medical products can be life threatening. This is a concern, as users of medical products are not usually in a position to judge their quality. The interests and safety of the public must therefore be entrusted to a regulatory body or bodies that ensure that only products in legal trade are available and that marketed products are safe, perform as claimed and are of assured quality.

The regulation of medical products has become increasingly complex with the globalization of product development, production and supply and the rapid pace of technological and social change in the context of limited financial and human resources.The importance of robust regulatory systems was recognized by the Sixty-Seventh World Health Assembly when it endorsed resolution WHA 67.20, Regulatory system strengthening for medical products. The resolution notes that "effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes", that "regulators are an essential part of the health workforce" and that "inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products" (23).

A sound system of oversight requires that regulatory authorities be supported by an effective framework of laws, regulations and guidelines and that they have the competence, capacity, resources and scientific knowledge to deliver their mandate in an efficient and transparent manner. The extent to which a regulatory framework fulfils its policy objectives depends on the quality of its development and implementation. GRP are critical to efficient performance of a regulatory system and, consequently, to the public's confidence in the system, while also setting clear requirements for regulated entities. A sound regulatory framework, including international norms and standards, and the recruitment and development of competent staff are necessary but not sufficient conditions to ensure "good oversight". All individuals in regulatory authorities should be guided by GRP in setting appropriate requirements and formulating decisions

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Source: WHO *Guidance on Good Regulatory Practices (GRP),* WHO_TRS_1033 Annex 11. 2021

Proportionality

Regulatory oversight and regulatory decisions should be proportional to the risk and to the regulator's capacity to implement and enforce the decisions

Key elements

- Be adequate to achieve the objectives without being excessive
- Be proportionate to the risk of the product or activity or service
- Should not exceed the national capacity to implement and enforce them
- Based on a benefit–risk evaluation and continuous monitoring of the benefit–risk profile

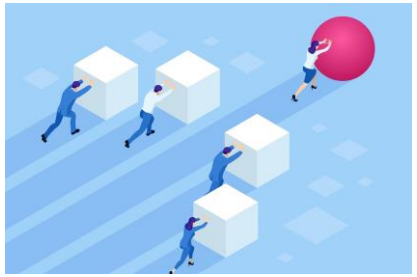
Flexibility

Flexibility is essential to ensure that regulatory frameworks and regulatory systems remain "fit for purpose"

Key elements

- Provide sufficient flexibility to reflect or respond to changes in the regulated environment (e.g. new technologies)
- Be prepared to provide timely responses to urgent situations
- The language of regulation should allow for alternative approaches to achieve the same result
- Should provide the flexibility for applying good judgement
- Should be risk-based and should not compromise the quality, safety, efficacy or performance

Efficiency



Policy-makers should seek the most efficient, least burdensome means of achieving their regulatory purposes and confirm effectiveness after implementation

Key elements:

- Achieve the intended public health goals
- Competent staff and effective use of resources and information from other authorities
- Continually explore ways of improving efficiency
- Alignment of regulatory requirements with those of other countries and international platforms
- The efficiency of regulatory operations should be assessed with performance-based indicators

To sum up, many regulatory agility elements appeared BEFORE the pandemic; many will stay or evolve to continuously enable a more efficient & resilient health system BEYOND the pandemic.

Regulatory agility should become part of **regulatory "new normal"** to support innovation and future public health challenges

The COVID-19 Crisis as an Opportunity to Strengthen Global Regulatory Coordination for Sustained Enhanced Access to Diagnostics and Therapeutics. Clinical and Translational Science. 13 Dec 2020. DOI: 10.1111/cts.12954

3. Examples of Regulatory Agility

Singapore Health Sciences Authority

- ✓ Enhance **international regulatory cooperation** and participate in single review project, **work sharing, reliance** and other related initiatives
- ✓ To adopt regulatory principles from alternative pathways in full fledged registration of COVID-19 diagnostics
  - ✓ To accept **real world clinical data**, where available during pre-market evaluation
  - ✓ To leverage **post-approval monitoring and reporting**, where feasible
- ✓ To embrace the key innovative approaches implemented during the pandemic to **improve agility** in MD regulatory processes even **beyond the pandemic**
  - ✓ **Alternate scientific methods** to validate safety and efficacy of MDs
  - ✓ **"Fit for purpose" risk management** approaches

Source: Dr Rama Sethuraman. Regulatory Agility – Facilitating access to essential medical devices. DIA Singapore Annual Conference July 2021.

WHO/ICMRA report on implemented agilities during the pandemic

Remote inspection & virtual approaches

Accelerated approvals (e.g. EUA) based on limited data with ongoing post-authorization monitoring

Risk-based postponement of certain post authorization changes & validations with justifications

Increased adoption of abridged pathways via reliance and recognition; reduction of local requirements

Early engagement (pre-submission consultation) with observed increased communication and transparency

Allow for “rolling submissions”

Source: https://www.icmra.info/drupal/sites/default/files/2021-12/Regulatory_Flexibilities_during_COVID-19_Report.pdf

4. Regulatory Agility Tools & Pathways

Tools

- International collaboration/ information sharing/confidentiality
- Digitalization/remote inspection
- Pre-submission consultation
- Capacity/Capability building
- Cross-ministry policy synergy/ Prioritization
- Pro-active communication/ transparency/clarity in regulation/guidance

4. Regulatory Agility Tools & Pathways

Pathways

- Regulatory reliance, information sharing & work sharing
- Regulatory convergence (IMDRF, GHWP, etc.)
- Alternative pathways (EUA, fast track)
- Accelerated access (rolling submission)
- Alternative evidence (RWE/RWD)
- Fit-for-purpose & trust-based authorization for innovation
- Regulatory sandbox/pilot with the ecosystem

Source: Panel discussion with regulators and experts on Regulatory Agility during the APACMed MedTech Forum. September 2022.
Panel discussion with WHO, GHWP and experts on Regulatory Agility during the DIA-CoRE Singapore annual conference. July 2022.

In a Nutshell: how to achieve regulatory agility

Tools, Pathways & Foundation

Tools

- International collaboration/ information sharing/confidentiality
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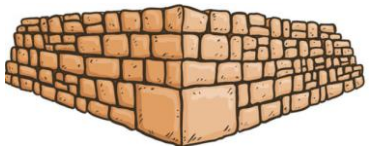
Foundation



- Patient centric
- Science & evidence
- Legal framework
- Risk/Context -based
- Agility/open-ness mindset
- Trust & Confidence

5. Benefits of regulatory agility

- Improved patient access & accelerated innovation locally & globally
- More efficient regulatory systems and better public health outcomes
- Higher-quality regulation, better regulatory decision-making and compliance
- Ensure that regulatory systems remain up-to-date as the medical technologies and systems continue to evolve
- Promote trust among regulatory authorities and other stakeholders (e.g. industry, academia, and health care professionals) and thereby facilitate international cooperation and better adoption of international standards & guidelines

Your kind feedback and suggestions will be highly appreciated!!!

For any further questions or comments, please contact me via yasha.huang@roche.com

Doing now what patients need next