IMDRF International Medical Device Regulators Forum | 26th Session

Enabling conditions for effective regulation of medical devices

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Introduction

Objective

Overview of essential conditions for effective regulation of medical devices, including IVDs

Importance

Ensuring the safety, effectiveness, and quality of medical devices

5. Enabling conditions for effective regulation of medical devices including IVDs

Public confidence in medical devices including IVDs requires effective and efficient regulation built upon a sound legal and policy foundation, as well as GRP. The general principles provided in WHO Good regulatory practices in the regulation of medical products (*4*) should be applied when establishing a new – or revising an existing – system for regulating medical devices including IVDs. These principles include:

- legality
- consistency
- independence
- impartiality
- proportionality
- flexibility
- clarity
- efficiency
- transparency
- science based.

World Health Organization

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WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices, Annex 3

WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices, Annex 3

22 March 2023 | Technical document

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Overview

Adopted by the seventy-sixth meeting of the World Health Organization Expert Committee on Biological Standardization, 24–28 October 2022. A definitive version of this document, which will differ from this version in editorial but not scientific details, will be published in the WHO Technical Report Series.

This revised GMRF recommends guiding principles and harmonized definitions, and specifies the attributes of effective and efficient regulations to be embodied within binding and enforceable national laws. Its main elements are derived from international regulatory harmonization guidance documents developed by the Global Harmonization Task Force (GHTF) and its successor, the International Medical Device Regulators Forum (IMDRF), along with regional harmonization initiatives.

WHO TEAM

Health Product Policy and Standards (HPS), Norms and Standards for Biological Products (NSB), Technical Standards and Specifications (TSS)

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Legal requirements

Clear legal framework for regulating medical devices

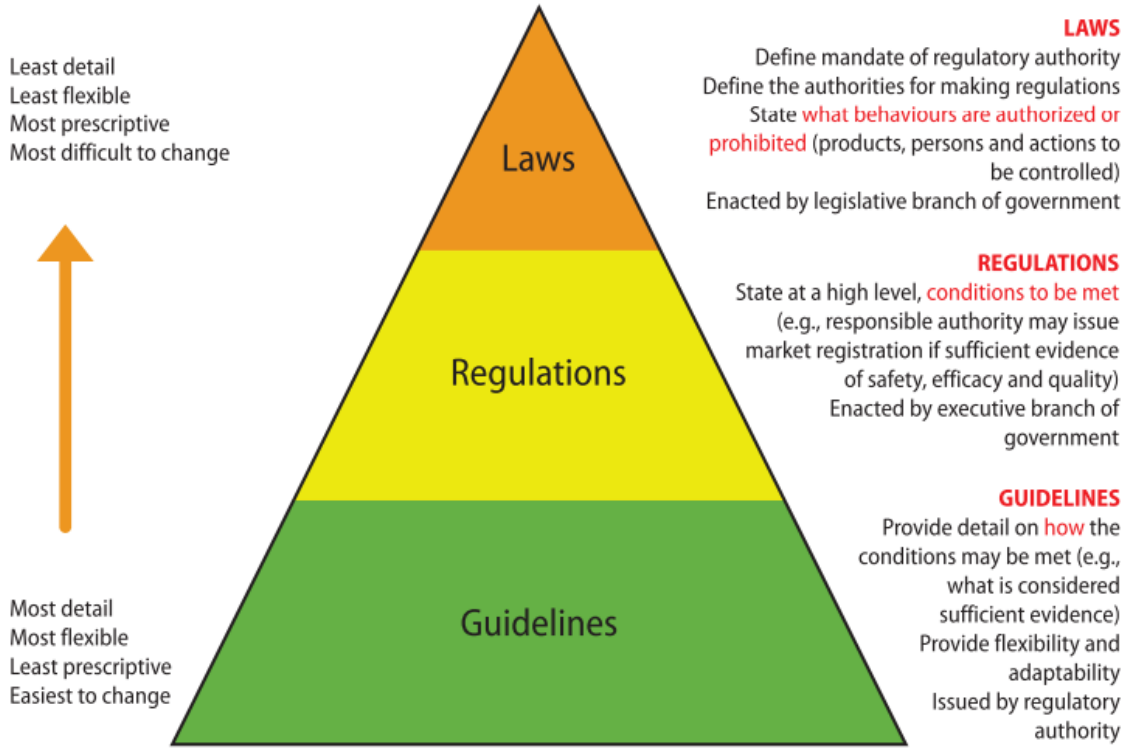
Components

Specific laws, regulations, and guidelines defining standards

Key points

Transparency, continuous updates, alignment with international standards

Fig. 5.1
Architecture of a regulatory framework (4)



Gap analysis of existing controls

Evaluation of gaps in current existing controls to identify deficiencies

Steps in gap analysis

1. Identify existing regulatory controls
2. Compare with WHO and other international benchmarks
3. Engage stakeholders including healthcare professionals and industry representatives
4. Identify gaps and areas for improvement

Box 5.1

Non-exhaustive list of elements to be considered in a gap analysis of medical device regulation

Are medical devices including IVDs regulated at all?

Are they currently regulated as medicines or some other product category?

Is there a specific and sound legal foundation for the regulation of medical devices including IVDs?

Does the NRA observe GRP when drafting regulations?

Has a regulatory impact analysis been performed?

Is there a clear definition of the term "medical device" and does it match the definition recommended by this GMRF?[56]

What are the public health risks that exist in the country, and can those risks be mitigated by the use of medical devices including IVDs?

Is there a system of market authorization?

Does the NRA use international standards and harmonization or benchmarks in its regulatory process?

Does the NRA use reliance or recognition mechanisms in its regulatory process?

Is there an NRA with clear powers and oversight for health products?

Does the regulator have the proper competencies required for effective implementation and enforcement?

Where there is a legal framework, is it enforced, and does the NRA have sufficient resources, expertise and funding to perform its duties?

Does the NRA adopt codes of conduct to be observed by all its staff members?

What proportion of medical devices including IVDs are imported and from where?

Are there local manufacturers of medical devices including IVDs? If so, are their activities regulated, and how?

Are all relevant stakeholders adequately represented in consultations?

Are distributors and importers subject to appropriate controls?

Is there evidence that substandard and falsified (SF) medical devices including IVDs have been placed on the market?

Are there processes and procedures in place to prevent, detect and respond to SF medical devices including IVDs?

Do existing laws and regulations comply with international good practices and treaty obligations?

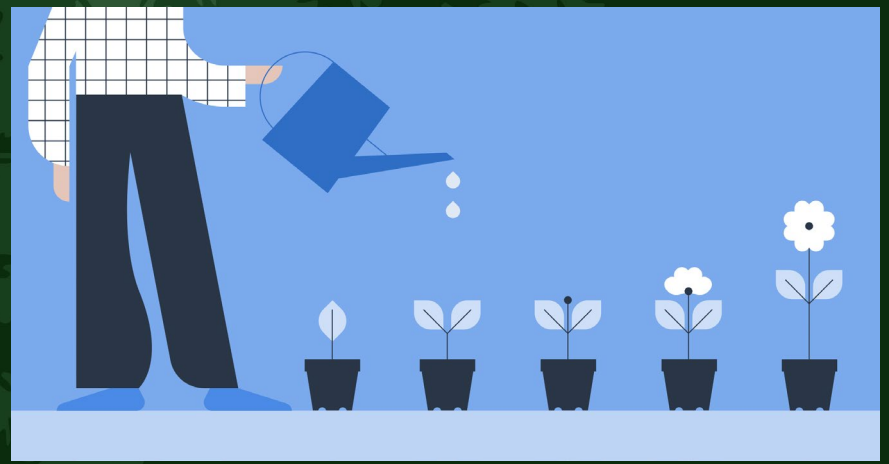
Implementation plan

Detailed plan for implementing regulatory improvements

Steps to implementation

1. **Prioritization:** focus on high-risk areas and public health priorities
2. **Stakeholder engagement:** continuous involvement of relevant parties
3. **Resource allocation:** ensure adequate funding, staffing, and training
4. **Transition periods:** allow time for adaptation to new regulations

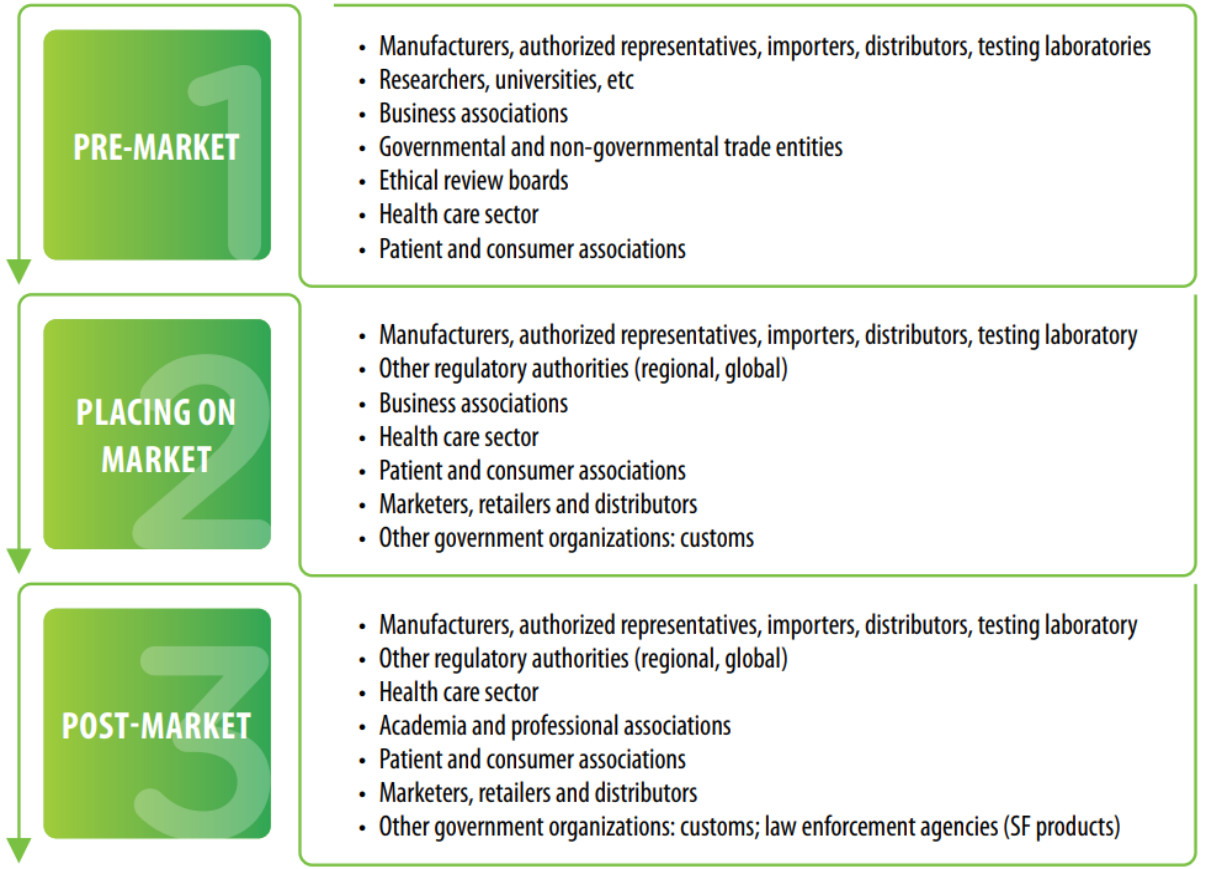
	very low consequences	low consequences	medium consequences	high consequences	very high consequences
very low probability	low risk	low risk	low risk	low risk	medium risk
low probability	low risk	low risk	low risk	medium risk	medium risk
medium probability	low risk	low risk	medium risk	medium risk	critical risk
high probability	low risk	medium risk	medium risk	critical risk	critical risk
very high probability	low risk	medium risk	critical risk	critical risk	critical risk



Stakeholder involvement

Considerations

- ✓ Who would be impacted by the regulatory controls, implementation process and policy, and in what way
- ✓ Who has or may have influence over the regulatory controls, implementation process and policy
- ✓ Who has or may have an interest in whether regulatory control implementation is successful or unsuccessful



Monitoring implementation

Ongoing monitoring

- ✓ Establish clear metrics for success
- ✓ Regular audits and inspections
- ✓ Continuous stakeholder feedback
- ✓ Adaptation and improvement based on monitoring results

Competencies

- ✓ Recruit and train regulatory staff
- ✓ Ensure staff has mandatory and core competencies
- ✓ Use advisory committees for specialized expertise

Regulatory Authority

Organization responsible for regulating medical devices

Functions

- ✓ Licensing
- ✓ Oversight
- ✓ Compliance enforcement

Governance structure

- ✓ Checks and balances
- ✓ Periodic public reports on performance

Funding the Regulatory System

Challenge

Ensuring adequate financial resources for regulation

Funding sources

- ✓ Regulatory fees
- ✓ Government budget

Considerations

- ✓ Financial sustainability
- ✓ Transparency in resource use

Fees

- ✓ Predictable
- ✓ Transparent
- ✓ Reasonable in relation to the services

Ways to increase efficiency and reduce costs

Consider outputs of other NRAs

Reliance or recognition

Conflict of interest and impartiality

Importance

Maintaining the integrity of the regulatory system

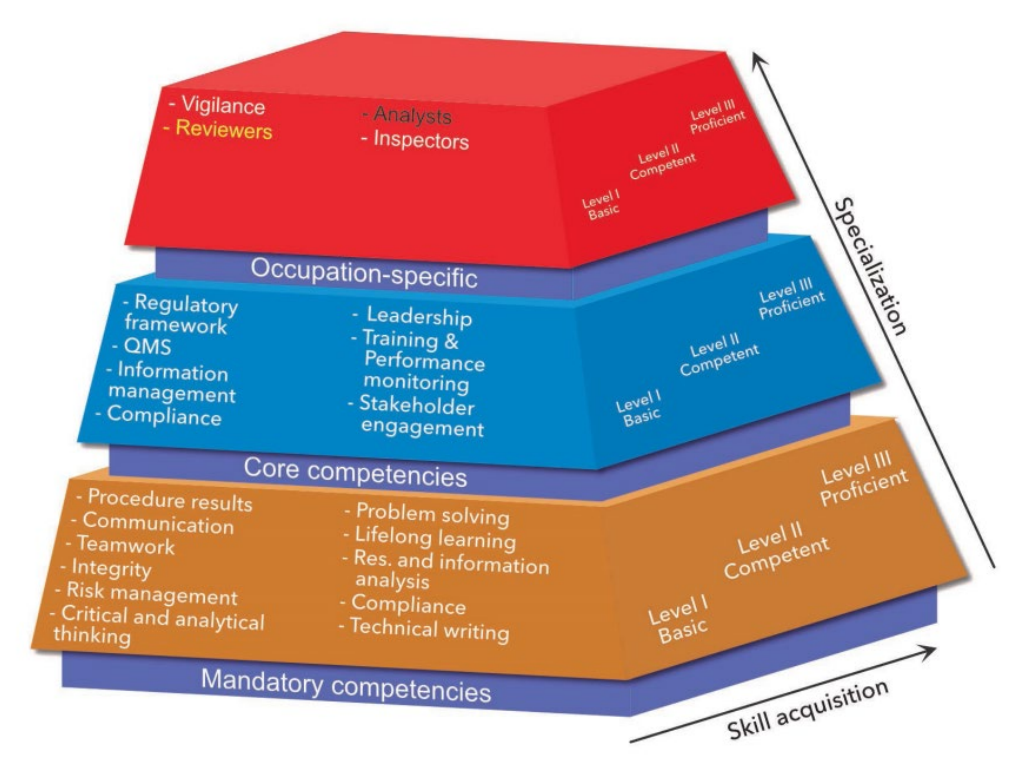
Strategies

- ✓ Conflict of interest policies
- ✓ Staff training

Benefit

Public and industry trust in the regulatory system

Regulatory competencies and resources



Capacitating human and material resources for effective regulation

Components

- ✓ Continuous training
- ✓ Adequate infrastructure
- ✓ Technology

Objective

Develop specific competencies to meet regulatory demands

Conclusion

- ✓ Effective regulatory controls are crucial for ensuring the safety and efficacy of medical devices
- ✓ A systematic approach from gap analysis to roadmap development is essential
- ✓ Continuous engagement, monitoring, and adaptation are key to successful implementation

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