

# *International Regulatory Convergence*

## *Challenges of the Global Health System*

*IMDRF – 3*  
*Open Stakeholders Forum*

**Brazilian Health Surveillance Agency - ANVISA**  
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**ANVISA**  
Agência Nacional de Vigilância Sanitária

Ministério da  
**Saúde**



## INTERNATIONAL COMMON TASKS

**PROTECT PUBLIC  
HEALTH**

Minimize the risks that may be originated from the production and consumption of goods and services

**PROMOTE PUBLIC  
HEALTH**

Enlarge the access to goods and services to improve health and the population life quality

Achievement of the proper balance between regulation / health control and access

## INTERNATIONAL ENVIRONMENT

- ✓ Change in demographic basis
- ✓ Competitive environment around innovation
- ✓ Increased complexity and volatility of technology
- ✓ Increasing pressure for health protection
- ✓ Need for answers on adequate and shorter timeframes

## INTERNATIONAL ENVIRONMENT

- ✓ Requirement of rigor with the public expenditure and efficiency management
- ✓ Entry of new producers and new players in the health market
- ✓ Globalization of supply chain
- ✓ Improve the prevention of falsified products
- ✓ Growing need of expanded human and financial resources

- As regulators, the responsibilities on Health Protection go beyond our borders
- Need to look at global trends and to seek global solutions
- Open discussion and information sharing among Regulatory Authorities
- Strengthen regulatory capacity globally
- Identify synergies and avoid duplication of efforts
- Improve communication and exchange of information among regulators and stakeholders
- Explore new and effective arrangements of cooperation
- Promote global quality of products

# THINKING FORWARD

## CHALLENGES

Potential health risks posed by the complexity of the health product supply chain

Multiplication of efforts

Harmonization / Standardization

## PRINCIPLES FOR THE FUTURE

Improve the regulation and surveillance global capacity

Identify synergies, reunite all efforts and build coalition mechanisms

Convergence and achievement of adequate level of protection

- ✓ It is possible to build a different pathway: we support new global arrangements that could provide an efficient platform for collaboration
- ✓ We are watching a global movement, based on the regulatory capacities, which benefits from existing national competences
- ✓ The safety of the products available for the population and the health systems is a shared responsibility among regulators, healthcare services and the supply chain

Initiatives such as the IMDRF have the role of put forward new global models and paths that enhance results based on effective actions, focusing on the protection of health with efficiency, quality and safety



# Thank you! Merci! Obrigado!

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