

# WHO initiatives on access to medicines in the European region

multipronged approaches for complex problems

Facing the Challenges: Equity, Sustainability and Access to Medicines

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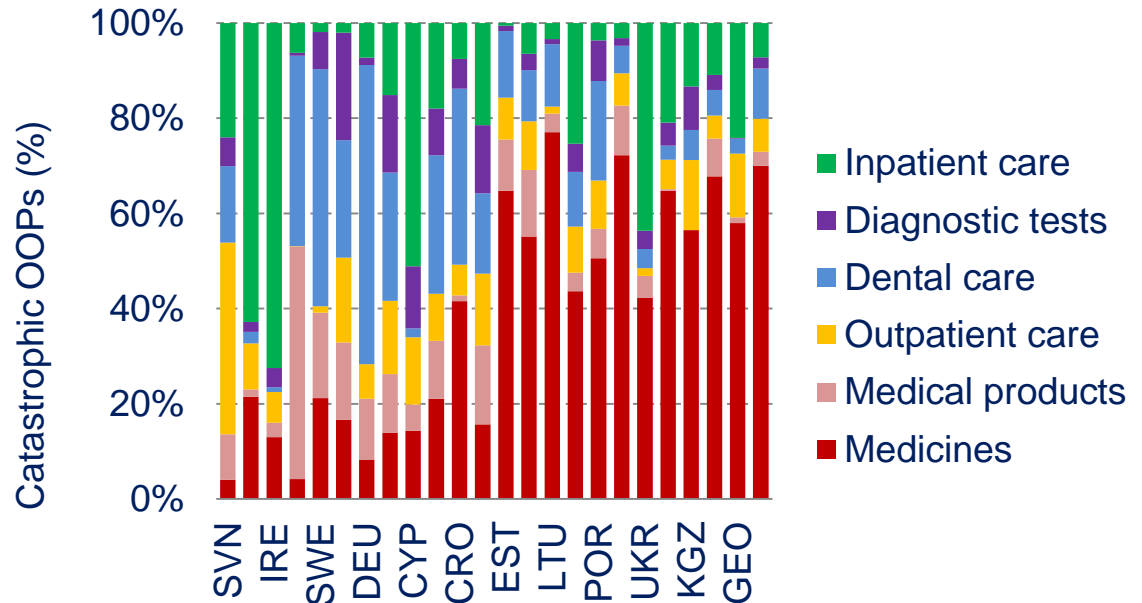
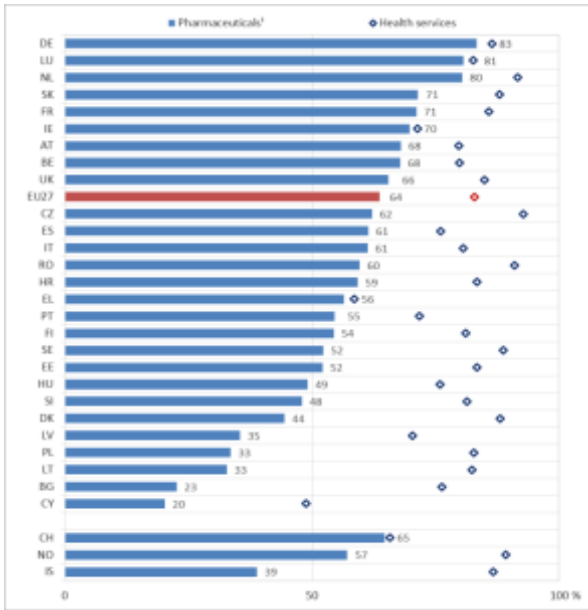


# WHO Regional European Office (EURO)



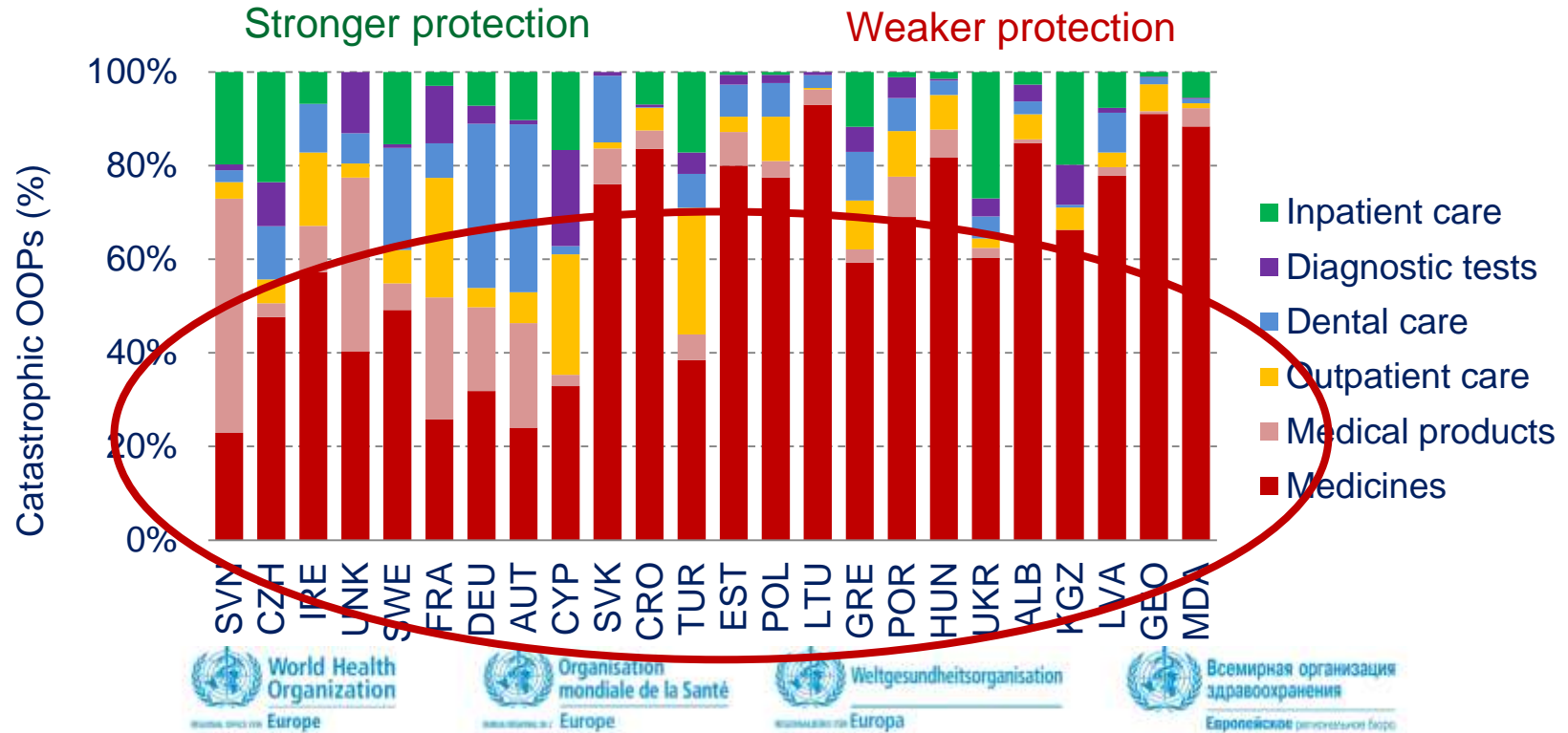
- 53 Member States
- 900 million inhabitants
- 4 official languages
- Headquarters in Copenhagen
- 29 country offices
- 5 geographically dispersed offices

# Public share of spending on pharmaceuticals is lower when compared with health services

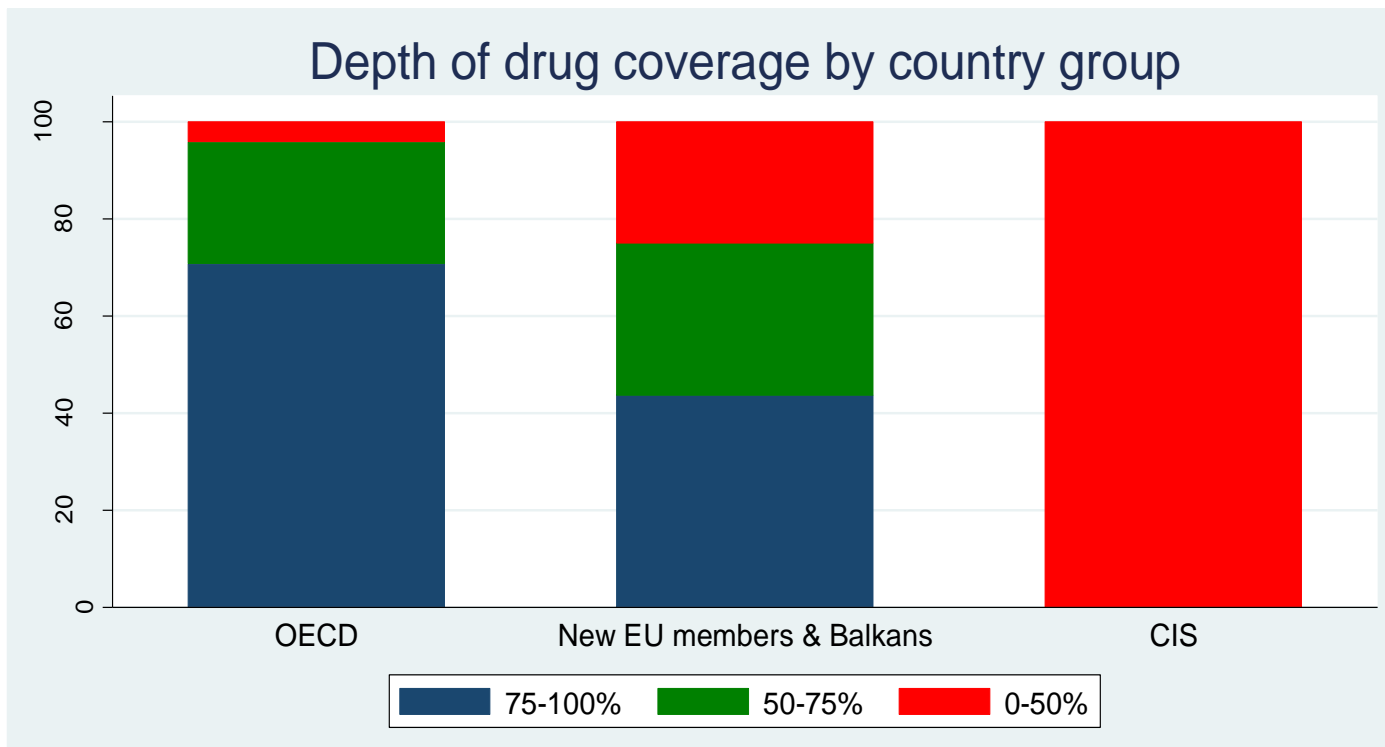


Source: OECD/EU (2016),  
Health at a Glance: Europe  
2016 and WHO HFI 2018

# Medicines are the main driver of catastrophic spending among poor households



# Gaps in cost coverage of medicines in many countries



## 1. Efficient regulation and rational selection

Efficient regulation of quality and safety. Reimbursement lists elaborated using transparent and accountable procedures, up-to-date treatment guidelines elaborated using the best evidence, etc.



## 2. Quality assured medical product at affordable prices

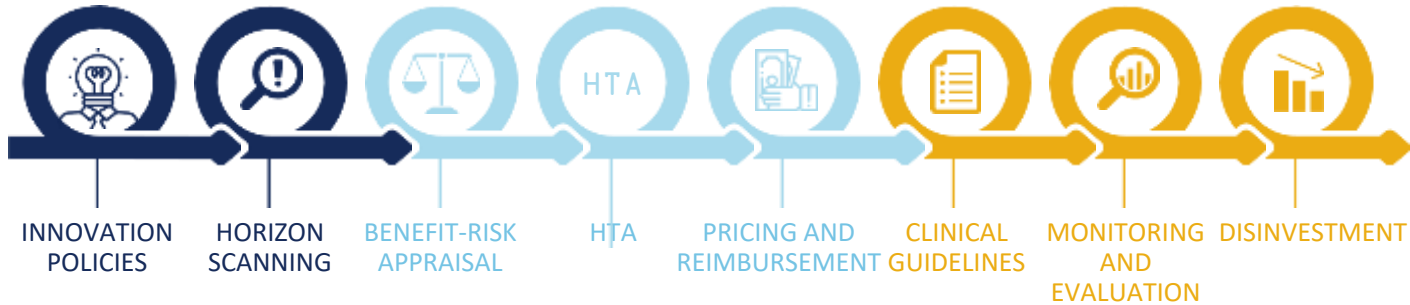
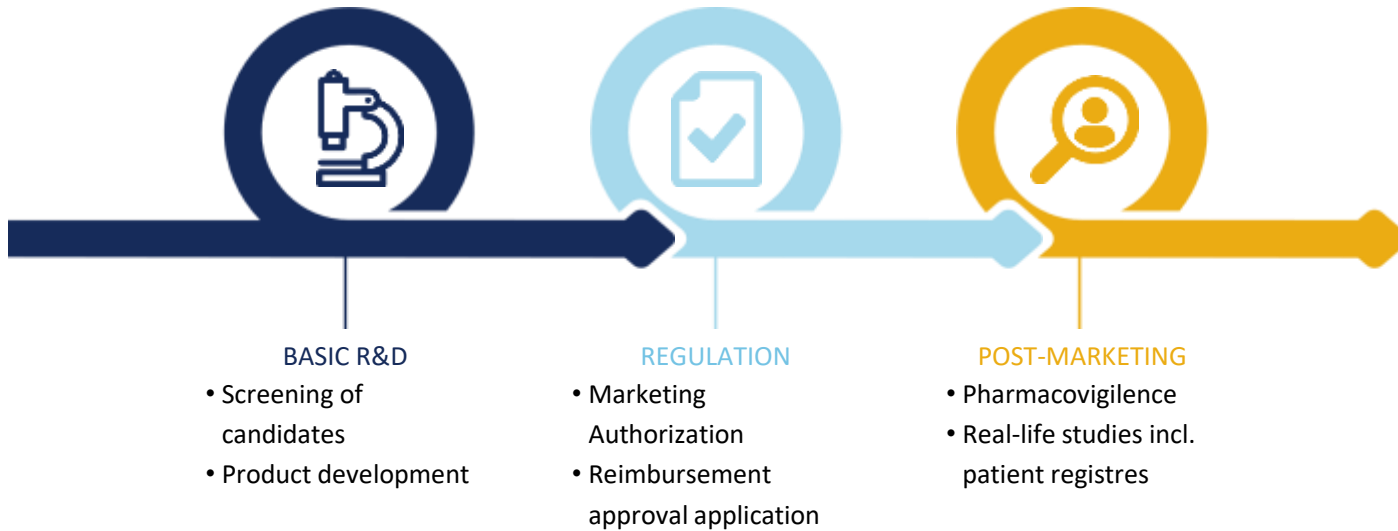
Price negotiation, sound generic policies, etc.

## 4. Reliable health and supply systems

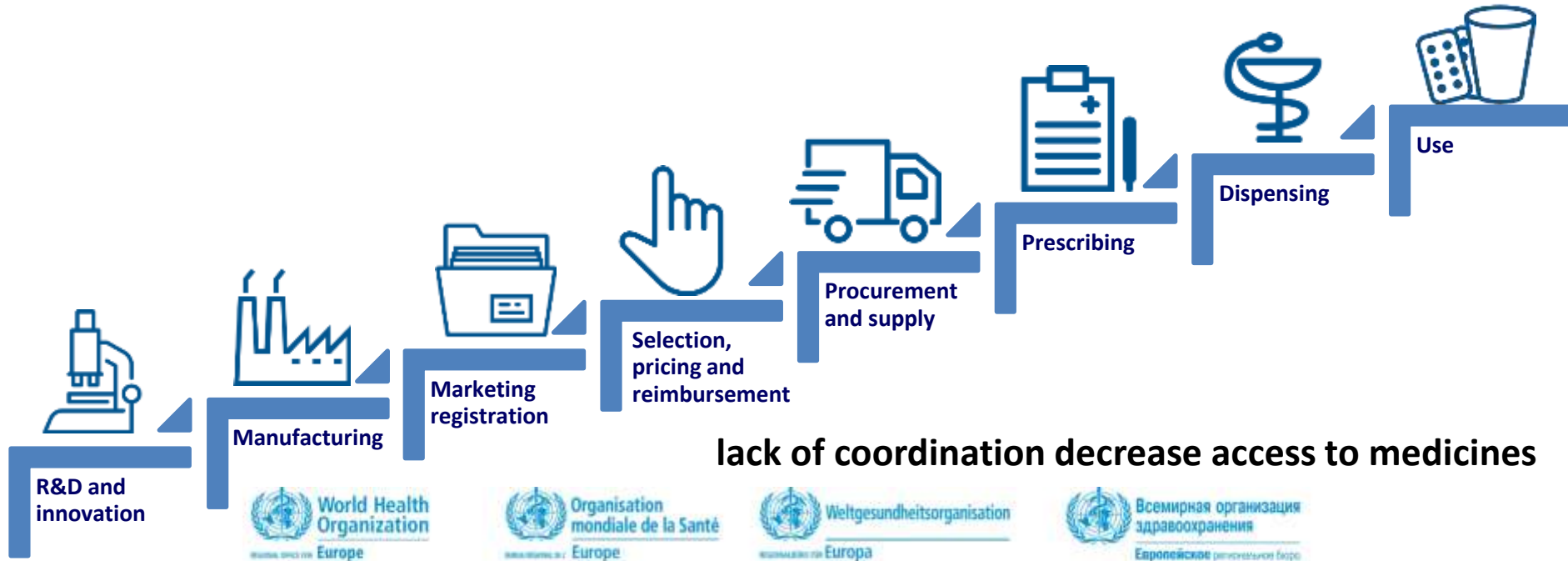
Development of pharmaceutical national policies, quality assurance reinforcement, etc.

## 3. Sustainable financing

Increase and prioritization of public funding for medicines, identification of efficiency gains, etc.



# Ensuring access to medicines and health products **requires efficient regulation, policies and regulation in all steps of the value chain**





# Let us look at some of the individual steps in the value chain



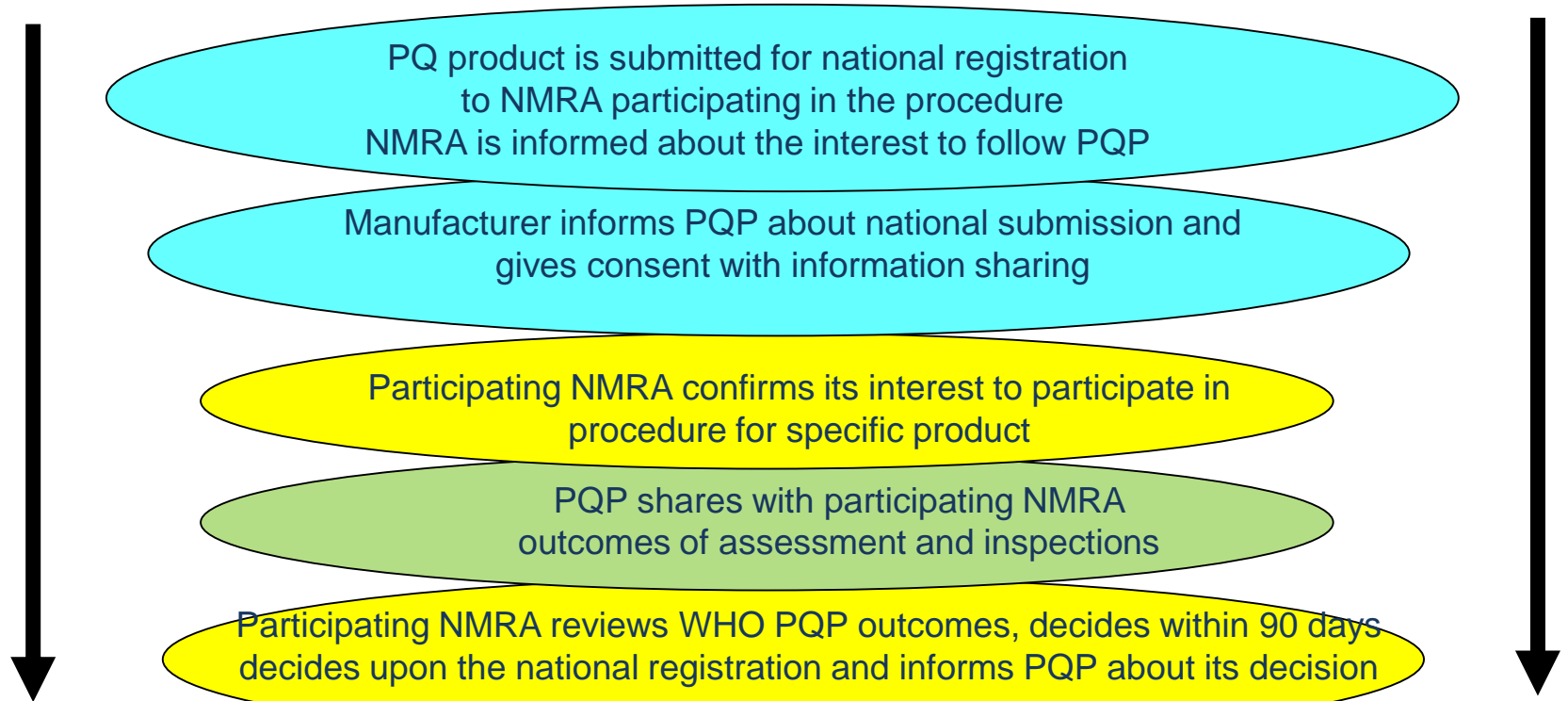
## Collaboration and convergence in regulation of quality and safety

- Efficiency in regulation as the basis for access - WHO prequalification
- WHO Collaborative Registration Procedure (CRP)

# Principles of WHO Collaborative Procedure

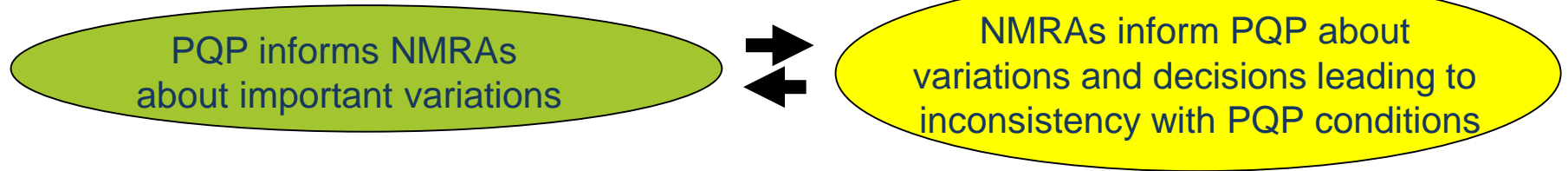
- Voluntary for manufacturers and NMRAs and does not interfere with national decision making process and regulatory fees
- WHO-PQT shares with interested regulators detailed outcomes of its assessment and inspections to support their decision making in exchange for accelerated registration process
- Product and registration dossier in countries are 'the same' as approved by PQP. Co-operation among PQ holder (manufacturer), NMRA in interested country and PQP overcomes confidentiality issues, ensures information flow and product identity
- 'Harmonized product status' is monitored and maintained

# Steps of the procedure: registration

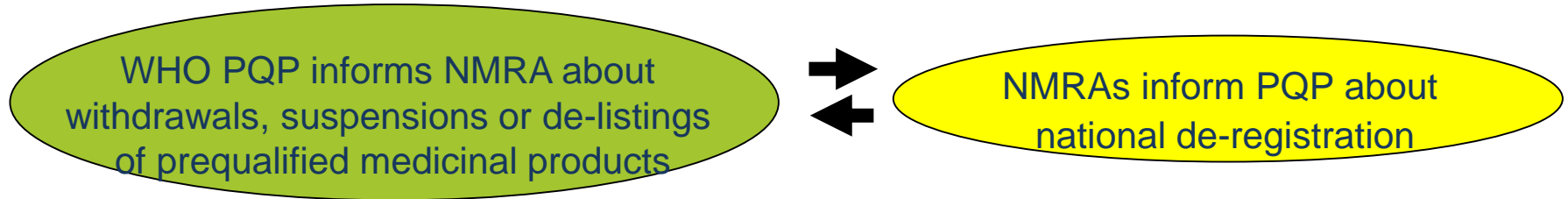


# Steps of the procedure: post-registration

## Variations



## Post-PQ and post-registration actions



# Pilot initiated in June 2012, now operational process

## Participating NMRAs from 35 countries

### Africa

- Botswana
- Burkina Faso
- Burundi
- Caribbean Community (CARICOM)
- Cameroon
- Côte d'Ivoire
- Democratic Republic of the Congo
- Eritrea
- Ethiopia
- Ghana
- Kenya

- Madagascar
- Malawi
- Mali
- Mozambique
- Namibia
- Nigeria
- Senegal
- Sierra Leone
- South Africa
- Tanzania
- Uganda
- Zambia
- Zanzibar
- Zimbabwe

### Europe/Asia

- **Armenia**
- **Belarus**
- **Georgia**
- **Kazakhstan**
- **Kyrgyzstan**
- **Ukraine**
- Lao People's Democratic Republic
- Philippines

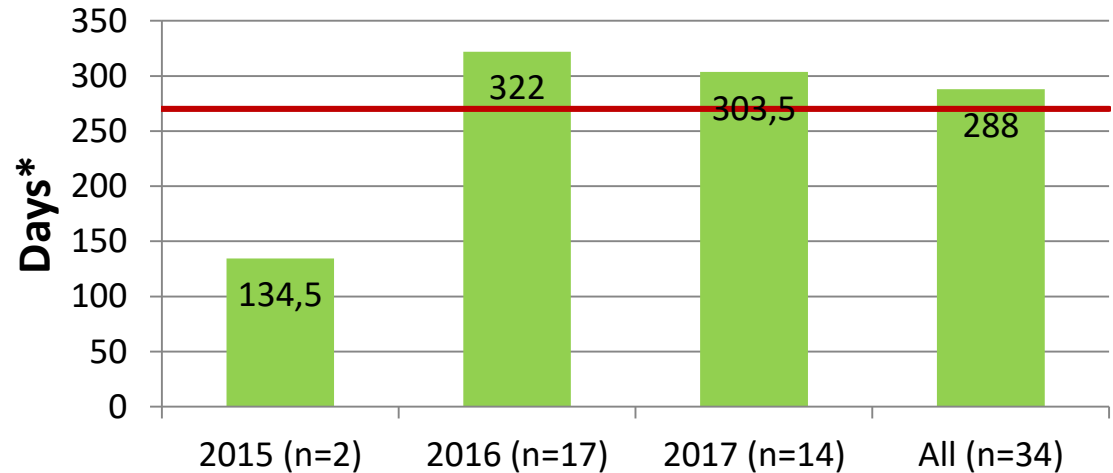
# Median time to registration



Days



Median Time (days) to Registration



# Win-win outcomes for all stakeholders

- Manufacturers
  - Harmonized data for PQ and national registration
  - Facilitated interaction with NRAs in assessment, inspections & testing
  - Accelerated and more predictable registration
  - Easier post-registration maintenance
- Procurers
  - Time, assurance, availability
- Patients
  - Fast access to new medicines and medical devices





# Selection, pricing and reimbursement

- WHO model list on essential medicines
- WHO list of essential diagnostics
- WHO list of priority medical devices
- WHO priority assistive product list



# Selection, pricing and reimbursement

WHO Model List in combination with WHO PQ has increased equity in access for some key products and moved toward UHC - for certain diseases like HIV, HCV where WHO prequalified medicines and medical devices have become available at affordable prices. So prioritization and efficient regulation is the basis - an important step ....

**Looking beyond the WHO PQ there are other fast track regulatory systems - the questions is who stands to benefit the most from these other schemes?**



# Procurement and supply management

We all know that effective procurement can deliver real benefits

- Procurement is viewed, by many, as a strategic function working to improve the organization's cost base and WHO Europe has targeted their country collaboration around this key step in the value chain
- It can be seen as helping to streamline processes, reduce input costs, and identify better sources of supply
- In essence, helping to reduce the 'bottom line'
- Several WHO consultations has been held in 2017-18 to foster knowledge sharing and collaboration



# Procurement and supply management

WHO Europe's focus has been on strategic procurement and poor practice costs money. Some critical reasons why procurement exercises fail

- Not being clear about what you are prepared to pay, poor assessment of true cost & poor management of information asymmetry
- Poor analysis of the market and poor planning - timing of procurement leading to lost opportunities, delays and additional costs
- Buying the wrong product - Clarity of purpose and stakeholder engagement
- Poor bid assessment processes
- Procurement team does not access the right skills and support.



# Procurement and supply management

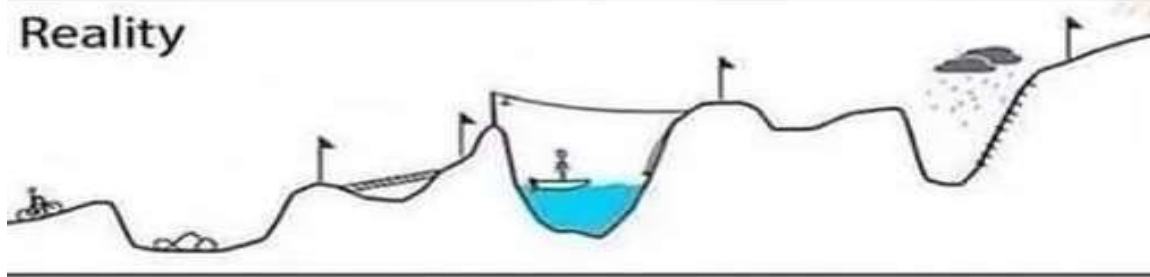


Managing the risk of failure...  
Planning is key!

Your plan



Reality



**Procurement is hard! You must plan for and expect the unexpected!**

# Procurement and supply management

- Cross-border dialogue and collaboration on procurement an important element is shaping procurement scenarios for new high priced medicines as well as for addressing shortages

# Challenges and problems along the value chain: lack of coordination of regulation, policies and strategies that increase access to medicines



Pharmaceutical budget do not cover the 'need' for all medicines



Prioritisation, monitoring, reassessment and redistribution of pharmaceutical spend



Prioritization of the public pharmaceutical expenditure 'out of tune'



OOPP on essential medicines too high in some countries

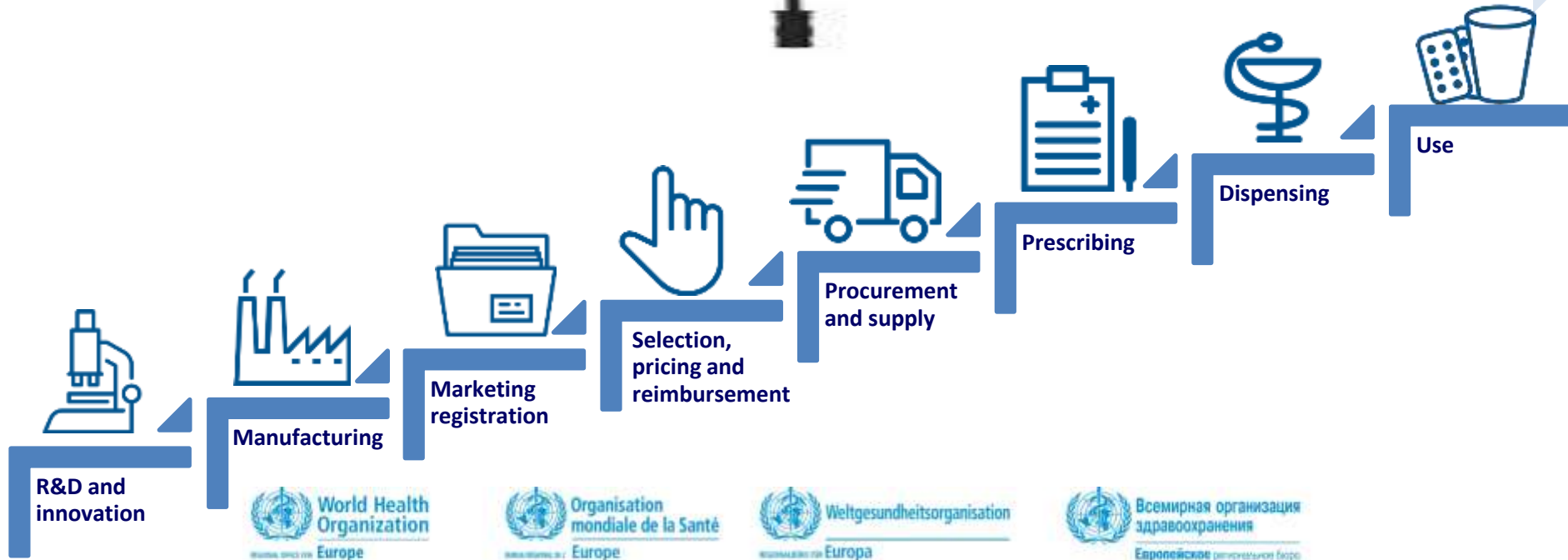


Achieving UHC requires coordination and balancing competing objectives



# Ensuring access to medicines and health products requires

Legislation, regulation, governance, monitoring, follow up throughout the product life cycle



# THANK YOU