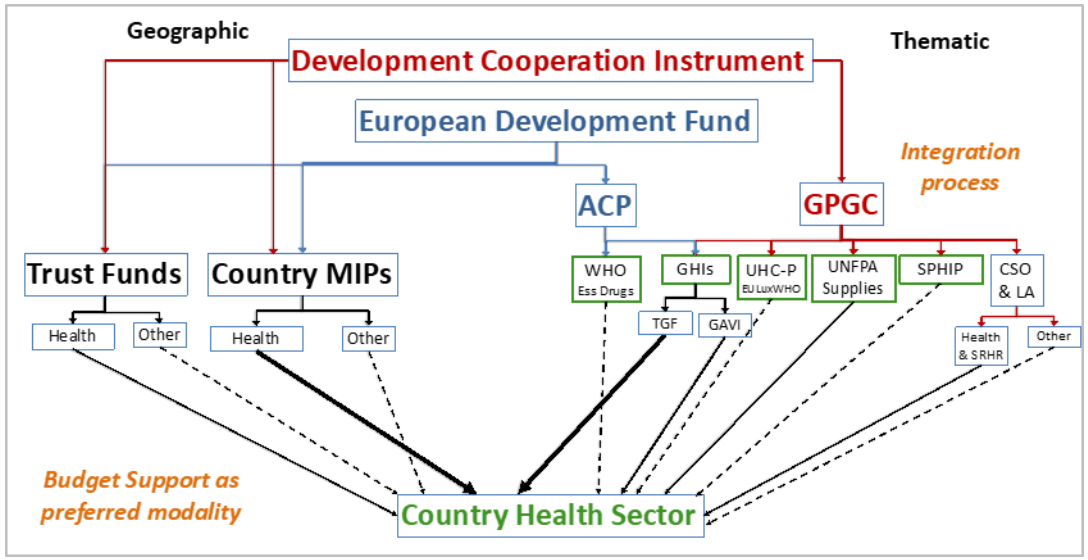
The role of donors in assuring quality of medicines:

(how) can we harmonize the audits' practices and the purchase policies?

DEVCO/B4, 20 Nov 2018, Brussels

Access to quality medicines: DEVCO approach

- 2030 Agenda for Sustainable Development / EDC/aid effectiveness principles
- 2017 European Consensus on Development / 2010 Communication on the EU role in global health: **comprehensive HSS**



- Adherence to WHO standards: prequalification, MQAS
- QA delegated to GHIs (GFATM, GAVI, UNFPA supplies); reliance on procurement agents – predominantly international ones- to adhere to best practices
- No distinct QA policy/guidelines for pharmaceutical products

(European Medicine Agency's assessments for markets outside EU, ECHO/QUAMED, EDCTP/R&D of medicines needed in LMICs)

One dedicated multi-country program:

The Renewed Partnership on strengthening pharmaceutical systems

- **EU/ACP/WHO**
- **2012-2017, 10 M EUR**
- **Objective:** strengthen pharmaceutical systems and improve availability, affordability and use of quality essential medicines for priority communicable and NCDs in 15 African countries
- 5 results areas, including **quality** (35% of budget): *'improved quality of medicines and reduced occurrence of falsified medicines and of medicines that do not meet safety standards, through the enforcement of medicines regulations and quality assurance systems'*

⇒ Support to National Medicines Regulatory Agencies (NMRAs)

✓ *At country level:* TA for strengthening NMRAs, developing tools & guidelines, strengthen pharmacovigilance systems; specific training for regulation/QA of bloodproducts

✓ *At REC level:* TA for medicines regulatory harmonisation

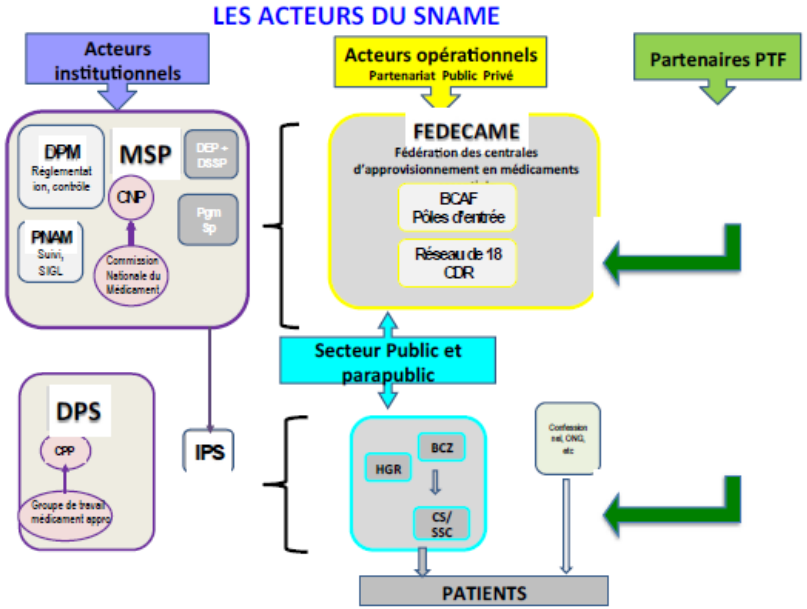
Burundi, Cameroun, Congo Brazza, Congo DRC, Ethiopia, Ghana, Guinea Conakry, Kenya, Mali, Mozambique, Senegal, Tanzania, Togo, Zambia, Zimbabwe

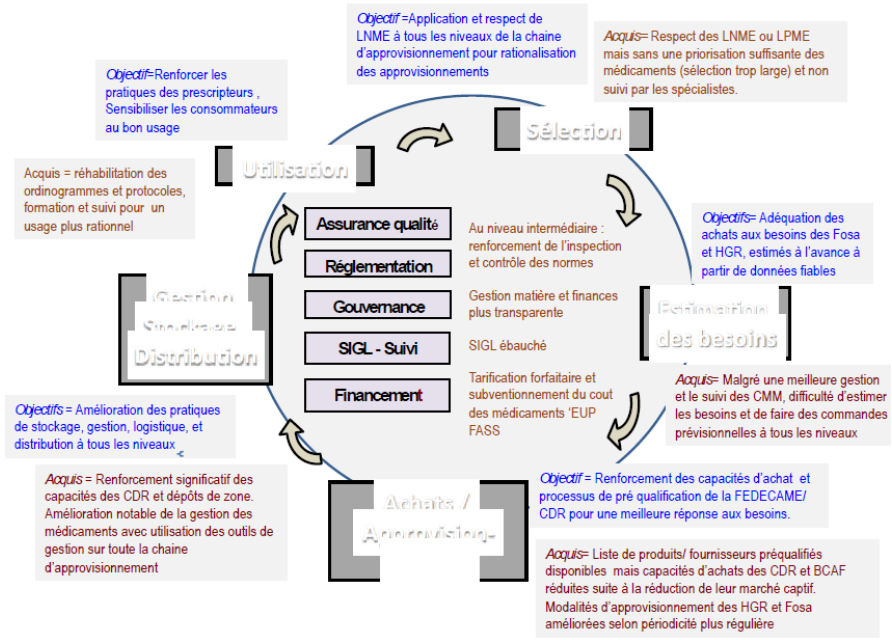
European Commission

In bilateral health programs:

Strengthening national procurement and supply chain systems

Example of DRC:





Source: Evaluation 10th EDF, Ecorys

Challenges

- Stringent donor-driven quality requirements for ARVs, anti-TB and anti-malarial, but for a wide range of essential medicines: no internationally accepted certification process
- Many LMICs have either weak or absent regulatory systems

=> As QA is delegated to implementers & international procurement agencies due to weakness of regulatory framework, NMRAs are sidelined , which weakens national regulatory capacity further

- Same with procurement: reliance on international agents results in fragmented procurement channels in countries; national procurement entities often sidelined
- Multiplicity of standards and difficulty to apply them
- Lack of cooperation
- Affordability vs quality
- Globalisation of the market
- Growing issue of substandard medicines
- Quality control and QA: blurred concept for many actors

DEVCO's standpoint going forward

Contribute to the development of a more conducive environment for access to quality essential medicines in low income countries. This requires:

- Addressing availability, affordability, acceptability & use, safety and quality
- Increasing cooperation, information sharing, common approaches
  (recommendations from 2011 WHO-GF Joint stakeholder meeting on QA of essential medicines)
- Harmonizing donor policies, standards, approaches to QA and assessment tools for essential medicines
- Strengthening NMRAs and country-based (national) procurement centres
- Supporting regional cooperation: in RECs + African Medicines Agency
- Important coordination and technical role of WHO

Pragmatic approach: optimize use of existing mechanisms while building country ownership and regulatory capacity

Thank you