



ROYAUME DE BELGIQUE

Service public fédéral

Affaires étrangères,

Commerce extérieur et

Coopération au Développement

The Belgian commitment to pharmaceutical quality:
a “best practice” to assure the quality of medicines available
through humanitarian and development programs



KONINKRIJK BELGIË

Federale Overheidsdienst

Buitenlandse Zaken,

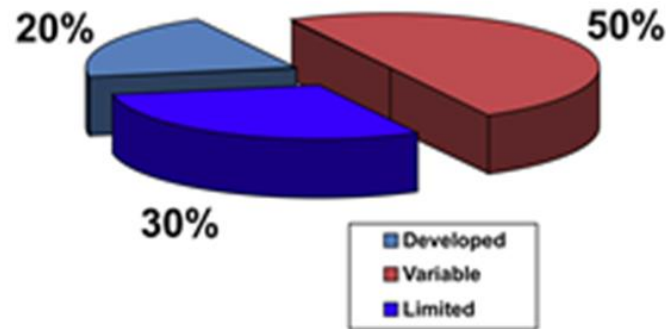
Buitenlandse Handel en

Ontwikkelingssamenwerking

Be-cause Health Conference 2018

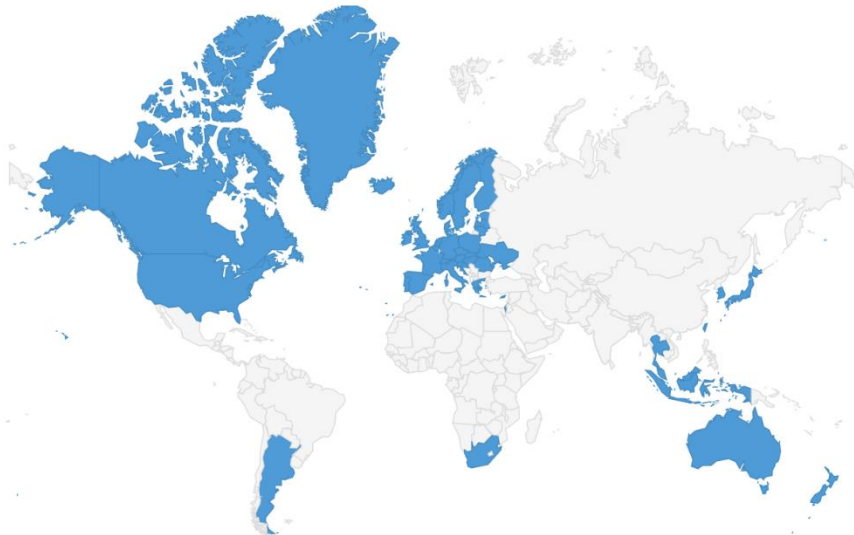
Brussels, 20 November 2018

Responsibility & regulation



WHO estimates that only 20% of countries have adequate medicines regulation.

LIST OF PIC/S PARTICIPATING AUTHORITIES



"The reality is that many regulatory authorities don't have the full capacity to perform all regulatory functions, due to chronic shortages of human, technical, financial and other resources" WHO 2010

Belgian DG Development Cooperation and Humanitarian Aid (DGD)

Objectives: Sustainable human development & Eradication of poverty and inequalities

Values & approach: Rights based approach, aid effectiveness, context adapted

Budget (2018):

- Development Cooperation: 1.8 billion € (0.41% of GNI)
- DGD: 1 billion €

Accountability: Report to the federal Parliament

Implementation:

- 3 cooperation channels
 - Governmental cooperation: 14 partner countries
 - Non-governmental cooperation: 113 partner Belgian non-governmental actors
 - Multilateral cooperation: 15 partner international organizations, European Union, OECD
- Other instruments: Humanitarian aid, etc.



Health is a priority in governmental cooperation (Health system strengthening)



Sources: Belgium's Law on Development Cooperation 2013, Infocycle 2016, www.dg-d.be (ODA.be 2018)

Belgium: Key facts

22% of Belgian ODA for health sector to purchase medical products

Incidents by Belgian actors (responsibilities & tenders)

Moral responsibility to avoid double standard in quality assurance when we operate overseas

To avoid incidents and/or mitigate risks: "Commitment" of all Belgian stakeholders to quality assurance of medical products available through development and humanitarian programs (ODA)



Belgium: « Commitment » to QA, 2017

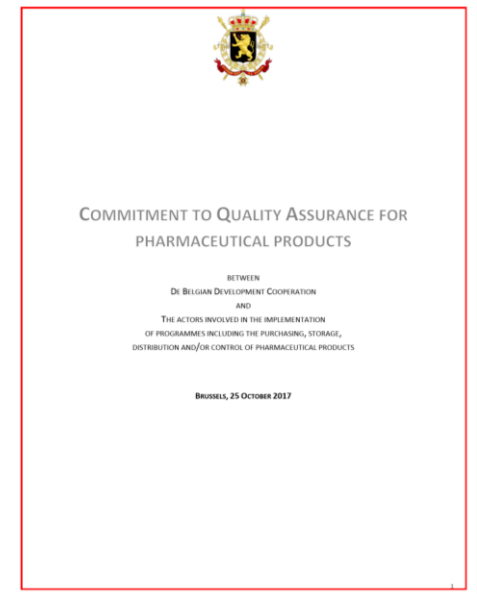
Commitment of all stakeholders (Oct. 2017)

- **Deputy Prime Minister** and Minister for Dev. Cooperation
- **19 Belgian implementers of development and humanitarian programs** (NGOs, etc.)
- Financial controllers of the Administration

Implementing actors are final responsible

Objectives

- Ensure quality of essential medicines and medical products in Belgian-funded development and humanitarian programs (**no double standard**)
- **Build local capacity**
- Provide quality-assured medical products to recipients



Sources: (1) https://diplomatie.belgium.be/sites/default/files/downloads/commitment_to_quality_assurance_for_pharmaceutical_products.pdf ; (2) [Ravinetto R, Roosen T, Dujardin C. The Belgian commitment to pharmaceutical quality: a model policy to improve quality assurance of medicines available through humanitarian and development programs. JPPP 2018; 11:12: 1-5](#)

Belgium: « Commitment » to QA, 2017

2 main components:

- Quality assurance system
- Local capacity building

Pragmatic financial and administrative rules:

- Budgeting in programmes
- Networking (pooling financial, technical, human resources)
- Stepwise approach



Harmonisation of policies and practices?

Inspiring approach...

If more donors and international actors join forces in requiring quality-assured products, they would create a “**market incentive**” to quality that could in the long-term lead to broader availability and lower prices of such products.

Ongoing...



Thank you!

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