

# Pharmaceutical supply chains in low and middle-income countries

Raffaella Ravinetto

*QUAMED Research & Networking*

*Institute of Tropical Medicine Antwerp, Belgium*

10th July 2017



# Context

30 years of globalization of the pharmaceutical market

Production  
Distribution  
YES



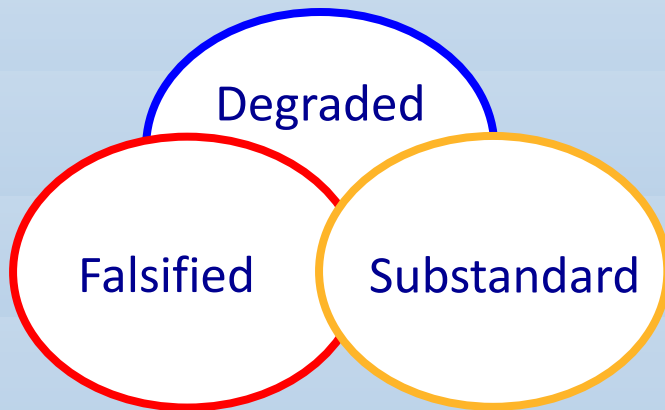
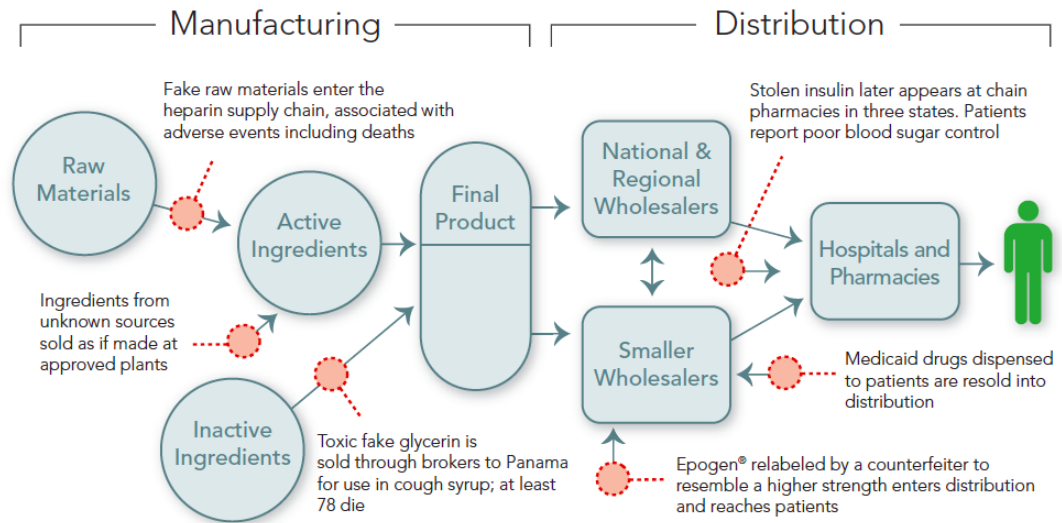
Regulation  
NO



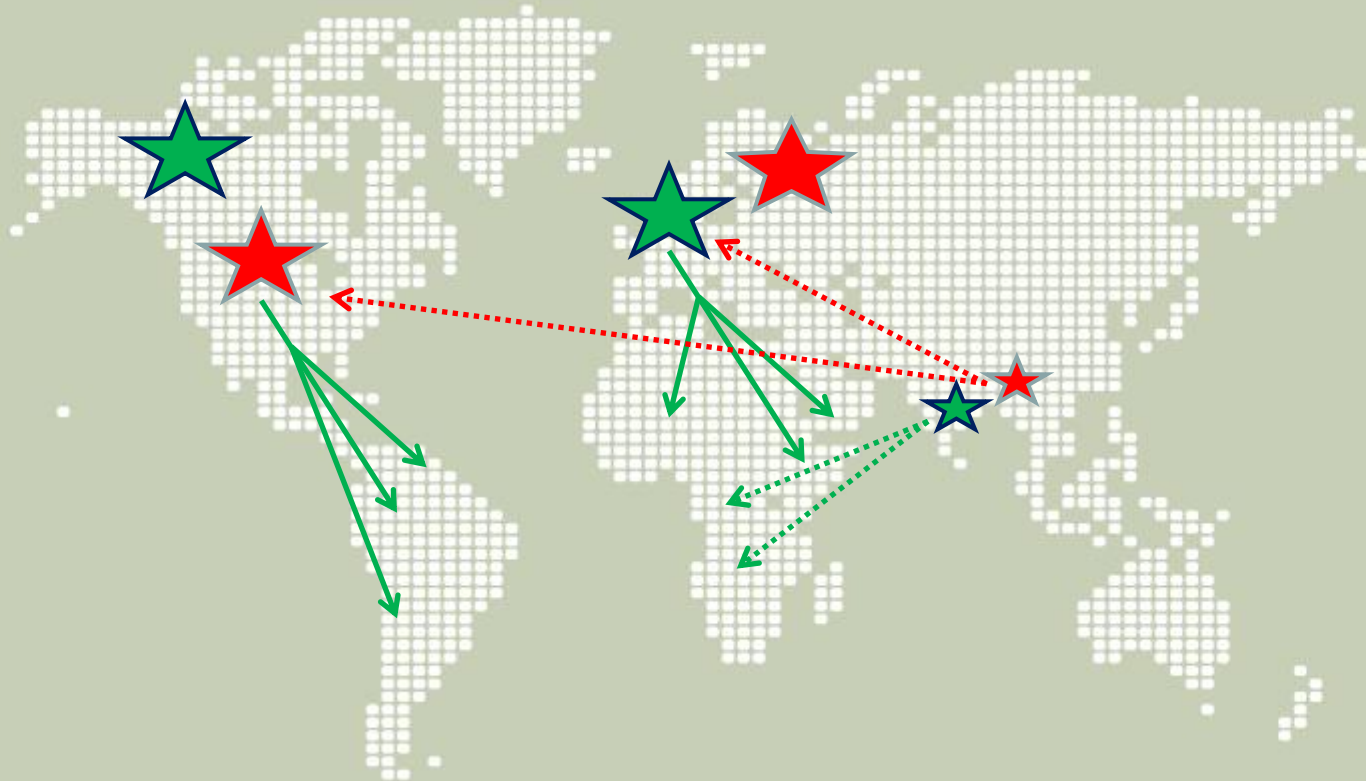
# Context


« As production goes global, drug supply faces greater risks to safety and quality »


## The pharmaceutical supply chain with examples of vulnerabilities




# International pharmaceutical market: before 2000



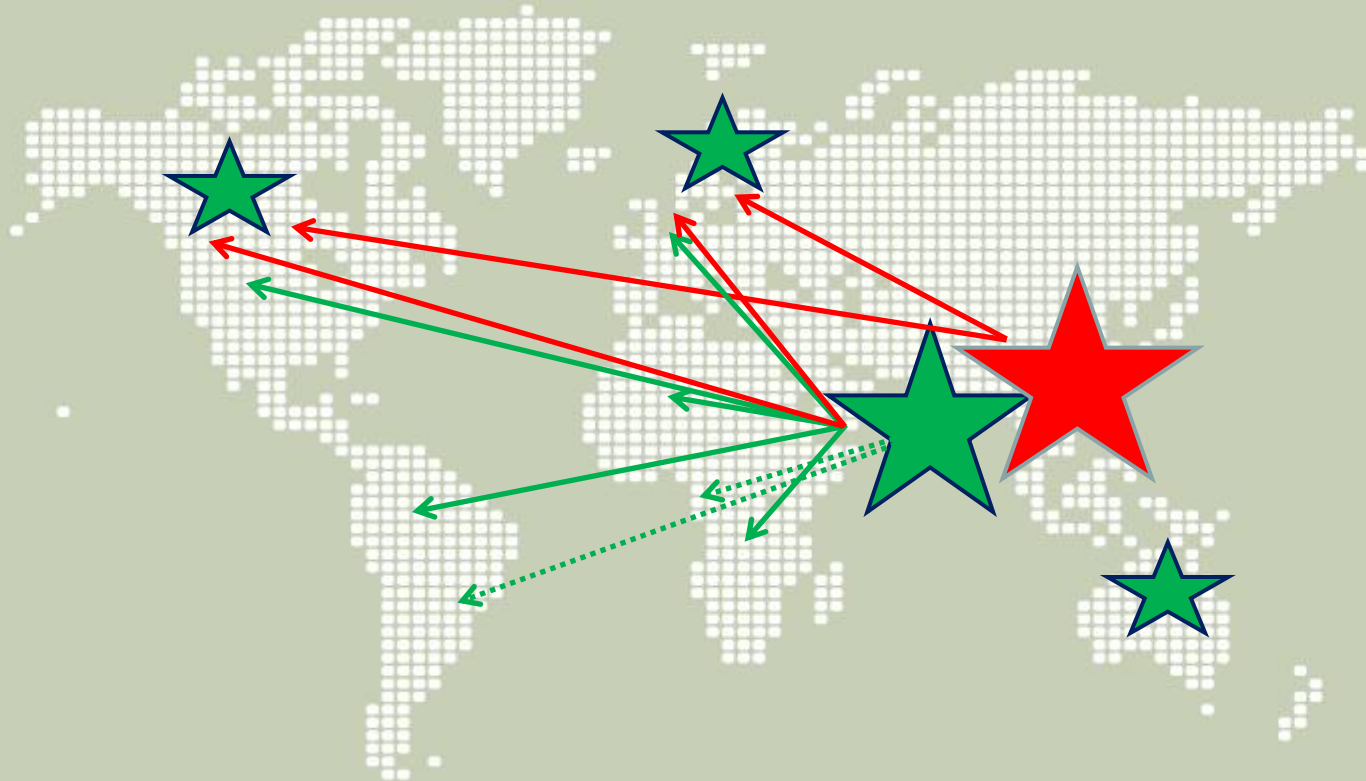
 **Active ingredients:**  
Europe and USA = 90 à 95% autonomy



 **Finished products:**  
Europe and USA = main exporters towards LMICs

 Less than 5% of circulating products are generics



# International pharmaceutical market: after 2000



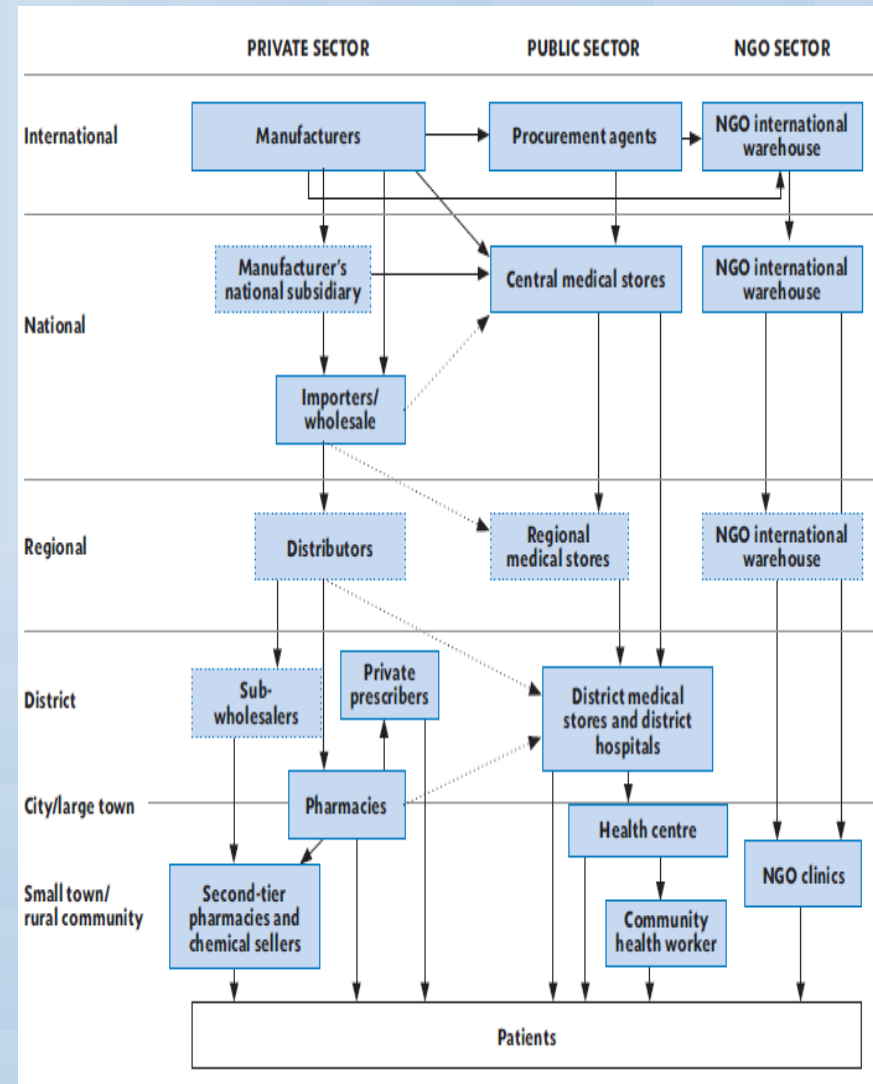
-  **Active ingredients:**  
>80% API manufactured in Asia
-  **Finished products:**  
India is the first exporter of generics toward LMICs

 More than 50% of circulating products are generics



# The global market today ....

- **Heterogeneous competences, mandates and objectives**
- **Weak regulatory supervision in many LMICs + no transnational regulation**
- **Supply chain diversification**
  - Commercial intermediates
  - Subcontracting
  - Long-distance shipments
  - *Lack of traceability*
- **Quality: not a market incentive**
  - Profit-driven vs patient-driven
  - Pressure on low prices

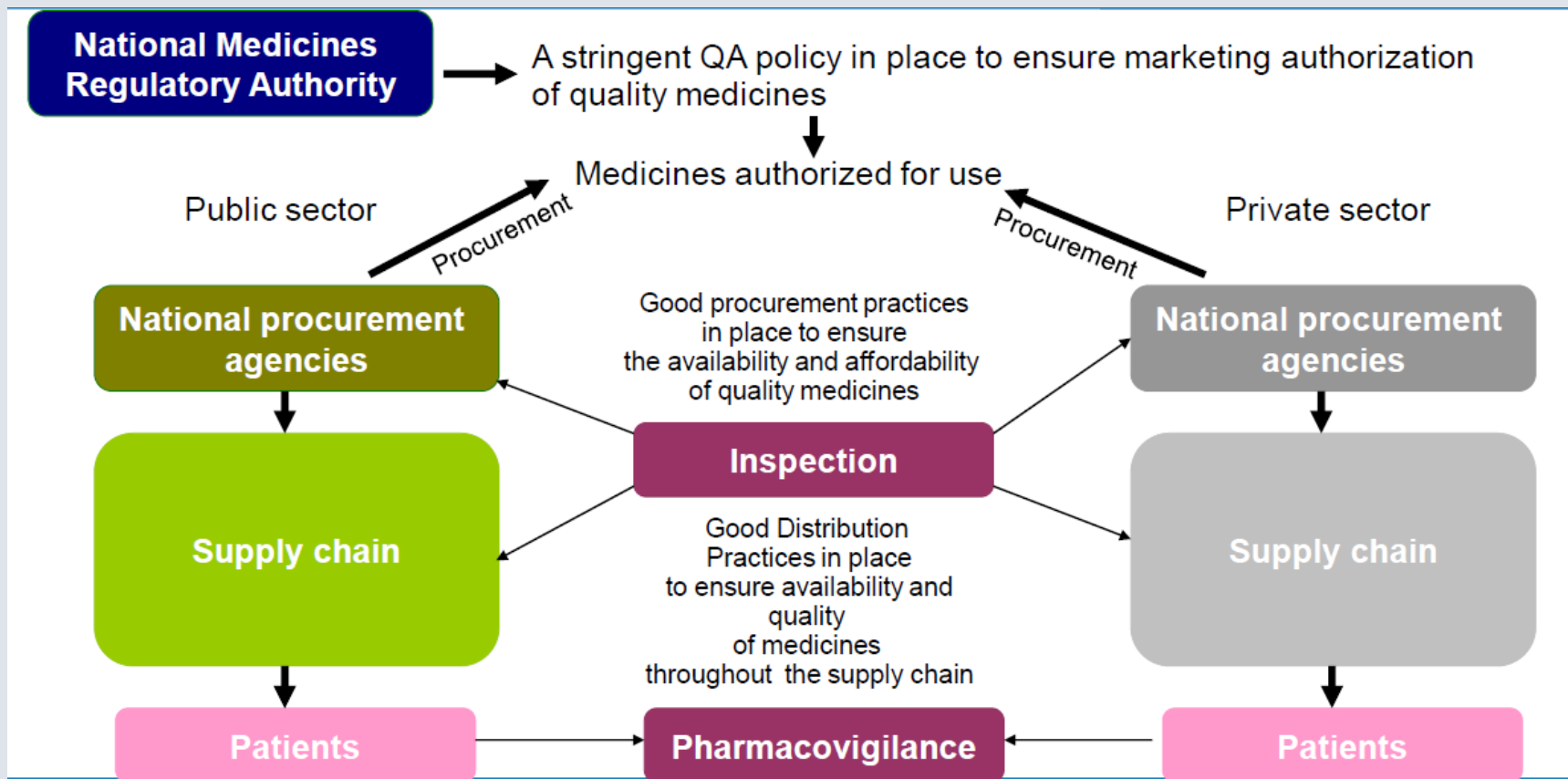


# Mapping of medicines procurement and supply management (PSM) systems in 16 African countries

(A study of Magali Babaley, WHO)



## What do we want to achieve?



# Mapping of medicines procurement and supply management (PSM) systems in 16 African countries

(A study of Magali Babaley, WHO)



## ● Objectives:

- map out all partners/actors involved in medicines PSM systems: "Who does what, how (procurement, quality assurance, distribution and financial policies, strategies and methods of intervention....) and with which funds"
- compare systems identified with i) pharmaceutical norms and standards, ii) national, regional and international policies, legislation and regulation for pharmaceuticals iii) good pharmacy practices, iv) guidelines for drug donation, v) The Paris declaration, vi) The Dakar declaration (ACAME) ...
- use evidence as basis of advocating strategies to strengthen coordination, capacity building and alignment of partners involved in PSM systems.

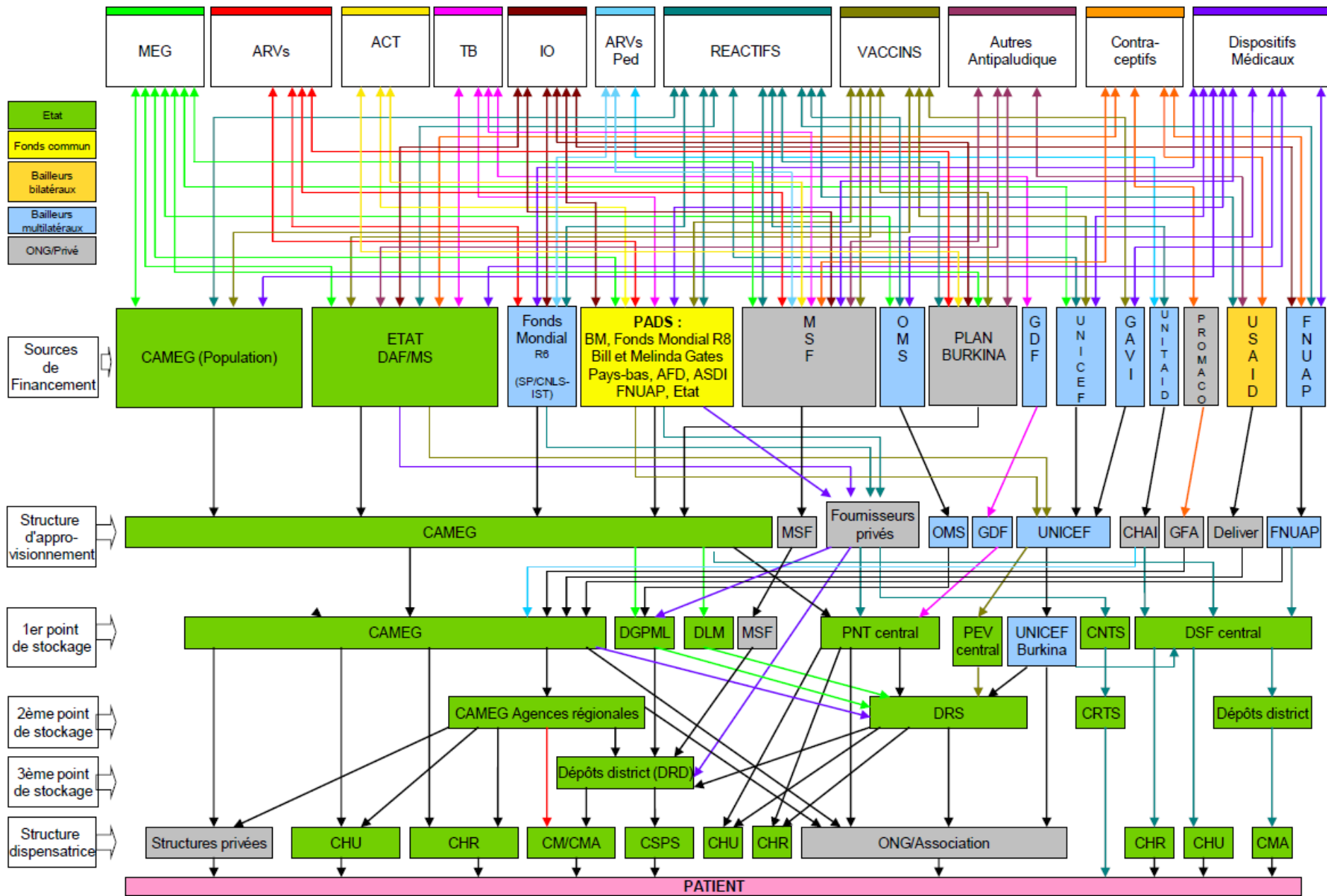


# Mapping of medicines procurement and supply management (PSM) systems in 16 African countries (A study of Magali Babaley, WHO)

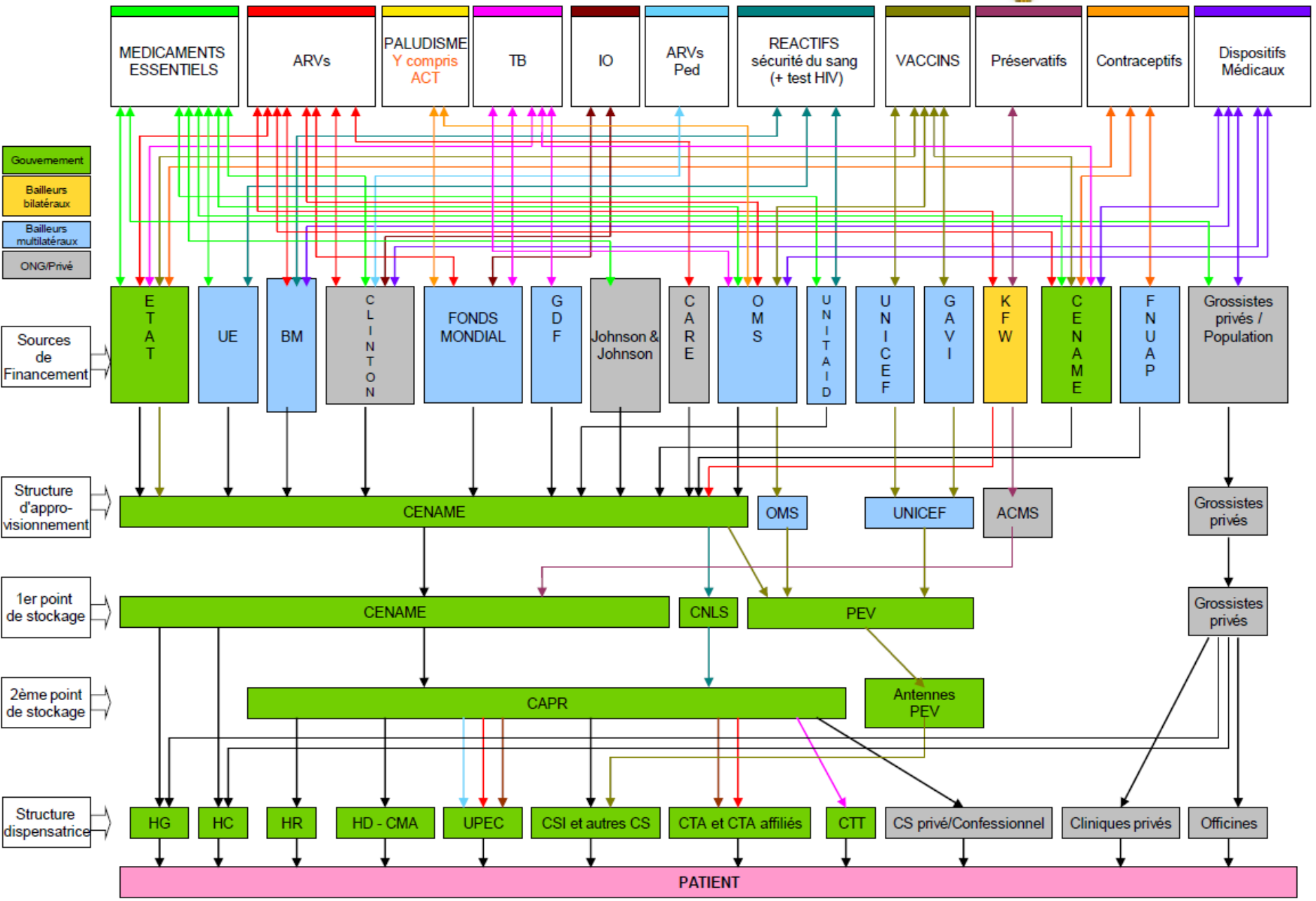


## ● Objectives:

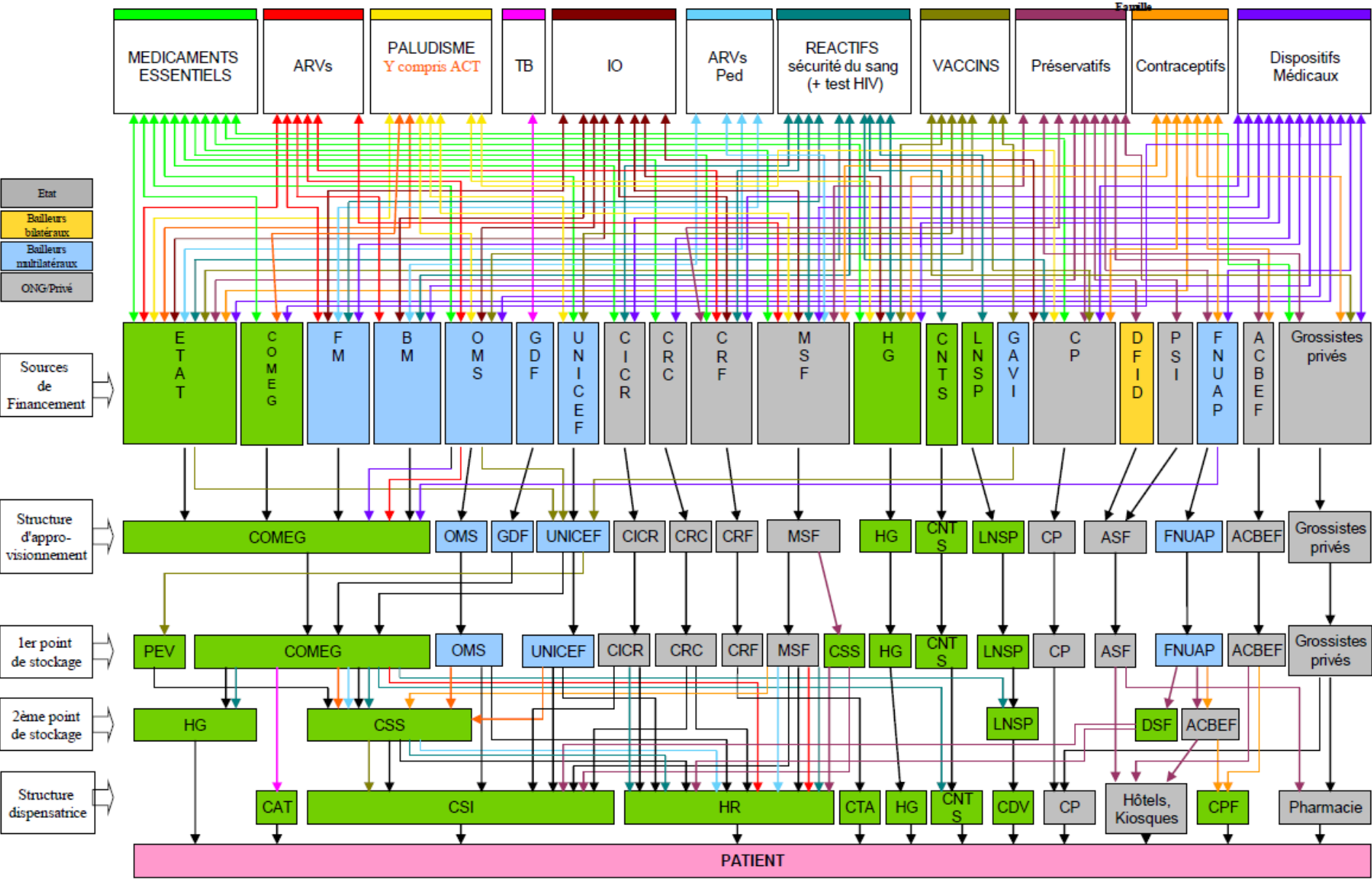
- support the MoH to carry out the in-depth assessment of medicines PSM system of the various public structures involved in the medicines supply chain (MoH, health programmes, Central Medical Store (CMS), regional stores/district stores, health facilities from central, regional and peripheral level)
- calculate indicators for each of the components of the medicines supply management cycle and for each level of the supply chain in order to measure strengths and weaknesses of each level (central, regional, peripheral),
- Identify gaps and proposed strategies and recommendations to fill in the gaps.

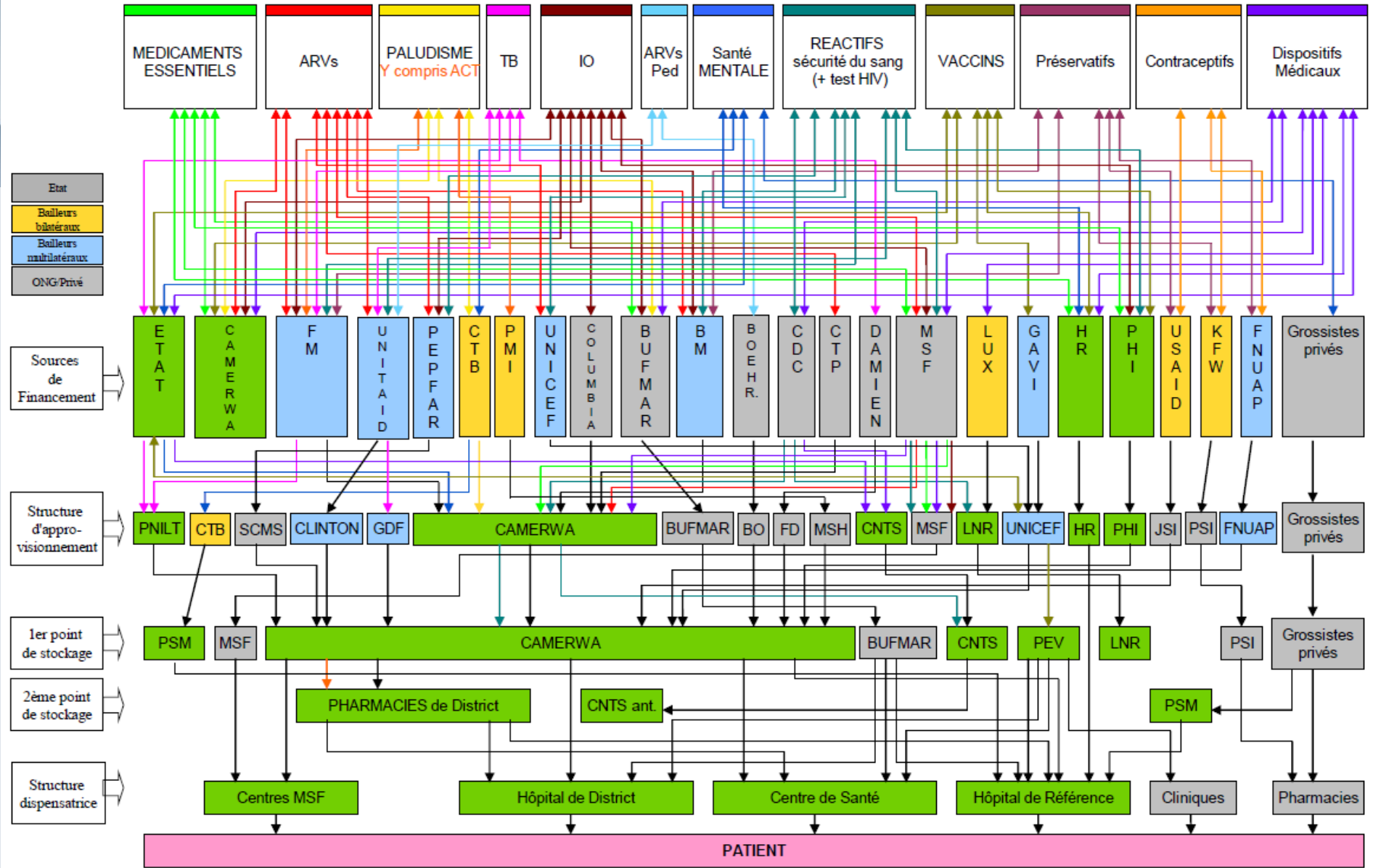


# Systèmes d'approvisionnement des produits pharmaceutiques au CAMEROUN, Sept 2007



# Systèmes d'approvisionnement des produits pharmaceutiques Rép. du CONGO Sept 2007





# Main results: Strengths



- National procurement and supply systems (public and private) exist in all countries studied
- Increased funding for procurement of specific essential medicines, e.g.: GF, UNITAID, PEPFAR, Clinton Initiative, WB etc.
- Several partners offer technical support, *though not coordinated*, to strengthen national capacities in procurement and supply
- Some categories of products receive logistic support from donors to improve distribution and physical availability
- Support in human resource

# Main results: Challenges (1)

## **Organization of the PSM system:**

- Complex and magnitude not known to the actors
- Responsibilities and tasks of each actor not clearly defined

## **Selection:**

- Supply outside the EML/Standard Treatment Guidelines

## **Quantification:**

- Lack of coordination MoH/CMS and partners for forecasting
- No adequate logistic information system (system complexity?)

## Main results: Challenges (2)

### Financing:

- Donors target disease-specific programs, eg HIV, TB, malaria and EPI
- Lack of coordination between MoH and donor(s) for estimating budgets for procurement of medicines
- Transparency not always assured by donor(s) on available funds
- Logistics is underfunded → some CMS, regional stores or health facilities are obliged to fund management and distribution of medicines for specific health programs
- Difficult to manage the various financial procedures specific to each donor (average of 17/country)



# Main results: Challenges (3)

## Who manages procurement?

### *Medicines funded by donors*

- International procurement agencies (IPA), used by an average of 82,3% of donors
- Central Medical Stores, private wholesalers, Health Programs, MoH: used by an average of 17,7% of donors

### *Medicines funded by State or cost recovery*

- Central Medical Stores
- Private wholesalers
- Health Programs, MoH, NMRA and UNICEF (vaccines)

# Main results: Challenges (4)

## **Which QA policy is used by donor and international procurement agencies (IPAs) to ensure quality of medicines?**

- For ATM medicines : prequalified by WHO, authorized by a stringent national medicines regulatory authority, eligible by the expert review panel (ERP-GF)
- For non ATM medicines: No QA policy available at country level, except for the GF

*For medicines imported and not registered in country, NMRAs are forced to issue exceptional marketing authorization only based on bills and delivery notes. This practice does not favor the strengthening of NMRAs*

# Main results: Challenges (5)

## - **Stock management:**

- Often, separate by partner → increasing the burden of work and adding to the complexity of stock management.
- Storage capacity exceeded at all levels, due to a lack of coordination

## - **Monitoring-Evaluation:**

- Each unit/project has its stand alone M&E project for its products (e.g. condoms, ARVs, PMTCT, ITN, Kits etc).
- Not easy to manage due to the number of different reporting tools

## Need to:

- Develop transparency
- Create with partners a mechanism for a coordinated, harmonized, coherent and efficient national medicines supply system, *including QA policy*
- Mobilize resources for under-served program areas
- Organize and plan capacity building at each level
- Monitor the performance of the system

# Relevance of findings to partners

## Need to:

- Prioritize investments in medicines procurement
- Target support to address gaps identified in the procurement and supply management system
- Provide information to monitor progress and plan for future support
- Have a platform to share information and coordinate procurement and distribution of medicines among partners

# The global market and its unwanted consequences



# Supply chains: open challenges

- Coordination among supply systems: public, GHI, NGOs, confessional, private for-profit .....
- Coordination and resources-sharing for QA, storage facilities, HR training, management systems
- Pooling of consumption data for needs calculation
- Strengthen the bottom level, as it impacts on all the chain
- Increase all products' availability, also to reduce the informal flow



# Supply chains: to be planned upfront!

Why?

- *“the nice thing about not planning is that failure comes as a complete surprise rather than being preceded by a period of worry and depression.”  
(unknown source)*

