

# ***A VIEW ON DRUG SHORTAGES FROM EIPG***

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# What is EIPG?

*E.I.P.G. is a European association representing the national, professional organizations of **pharmacists** employed in the pharmaceutical or allied industries of the Member States of the European Union, the European Economic Area, or European countries having a mutual recognition agreement with the European Union on compliance control of regulated medicines.*



# Chronology of drug shortages

November 2012

- + EMA issues Reflection paper on medicinal product supply shortages caused by manufacturing/Good Manufacturing Practice Compliance problems.

May 2013

- + European pharmacist organisations (PGEU, EAHP, EIPG) make joint call for action on medicines shortages, followed by EAHP survey results.

July 2013

- + European Association of Euro-Pharmaceutical Companies releases birgli<sup>®</sup> ag report.



# ***Chronology of drug shortages***

- + Heightened awareness by Governments and national regulators of the critical impacts medicines shortages have in relation to patient welfare, and the accompanying need for urgent action
- + Greater investigation of the impact that national strategies on medicines pricing and reimbursement are having on the operation of the supply chain
- + Better sharing an implementation of best practices between countries in responding to medicines shortage, including the operation of information portals and early warning systems



# Chronology of drug shortages

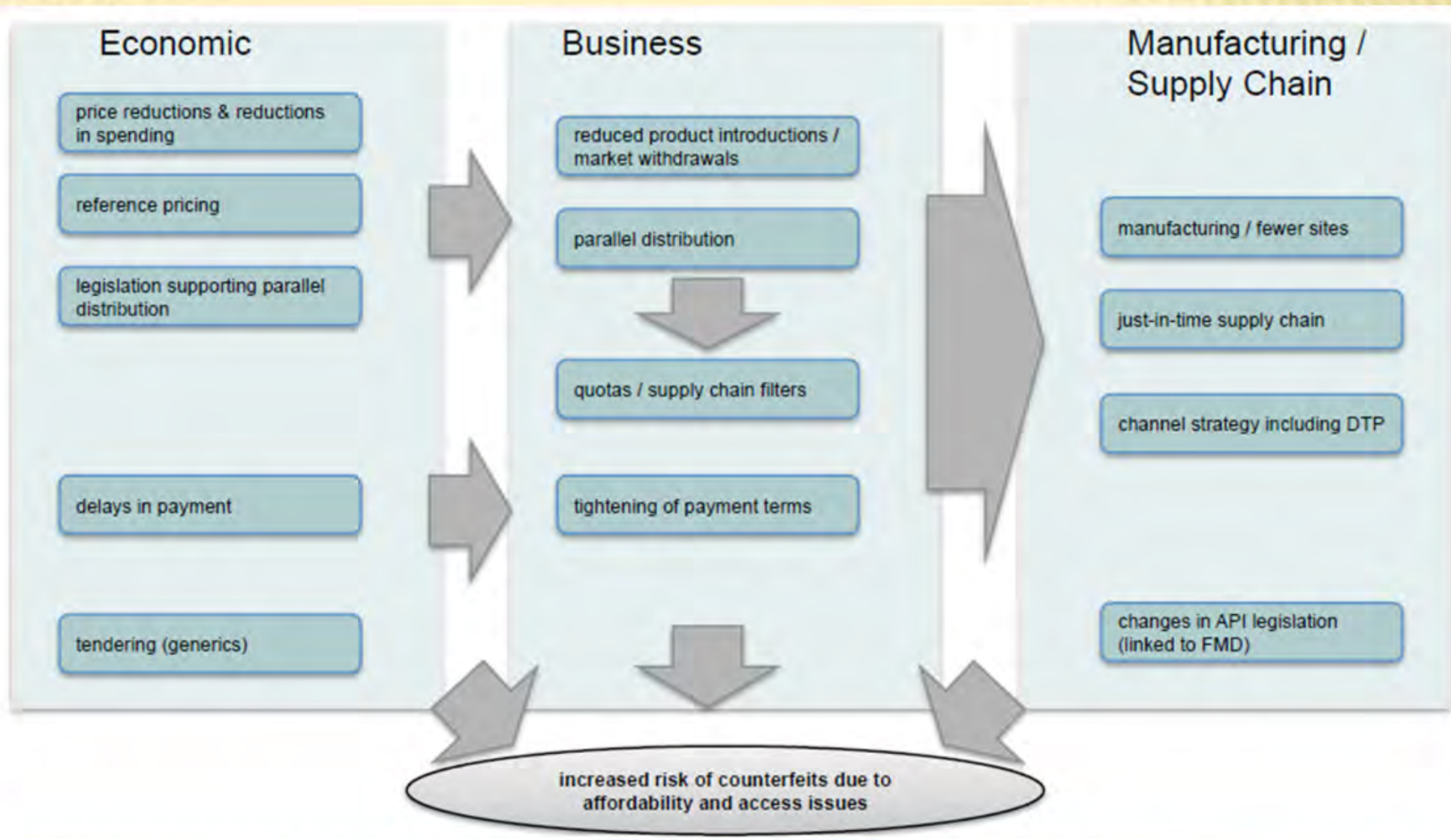
*“Each field of the pharmacy profession brings an important perspective to the issue of medicines shortages. From the industrial pharmacist perspective we have strong concerns that some of the requirements that the otherwise welcome 2011 Directive on falsified medicines may unintentionally increase the experience of medicines shortages.....All supply chain partners need to work together in sharing their experiences, identifying the problems, and advancing solutions.”*

*(Prof. Luig Martini, EIPG Past-President)*





# Factors effecting drug shortages



# ***Chronology of drug shortages***

January 2014

- + EIPG draft position paper circulated within EIPG.

October 2014

- + EAHP publishes survey of medicines shortages amongst hospital pharmacists in Europe.
- + International Society for Pharmaceutical Engineering (ISPE) releases Drug Shortages Prevention Plan, based on June 2013 survey. Focus on manufacturing and quality issues.

December 2014

- + AESGP-EFPIA-EGA-PPTA communication document.



# ***Chronology of drug shortages***

- + Ability to maintain adequate levels of supply subject to a balanced product-by-product risk analysis based on "available alternative therapies and the type of disease" so that security stocks for "sensitive and essential medicines" can be made available.
- + API manufacturers inspected and approved by PIC/S including the FDA should be automatically recognized within the European Union.
- + Essential early discussions with local health authorities as soon as a potential risk of shortages identified, followed by smooth method of fast communication between all players concerned in the provision of healthcare.



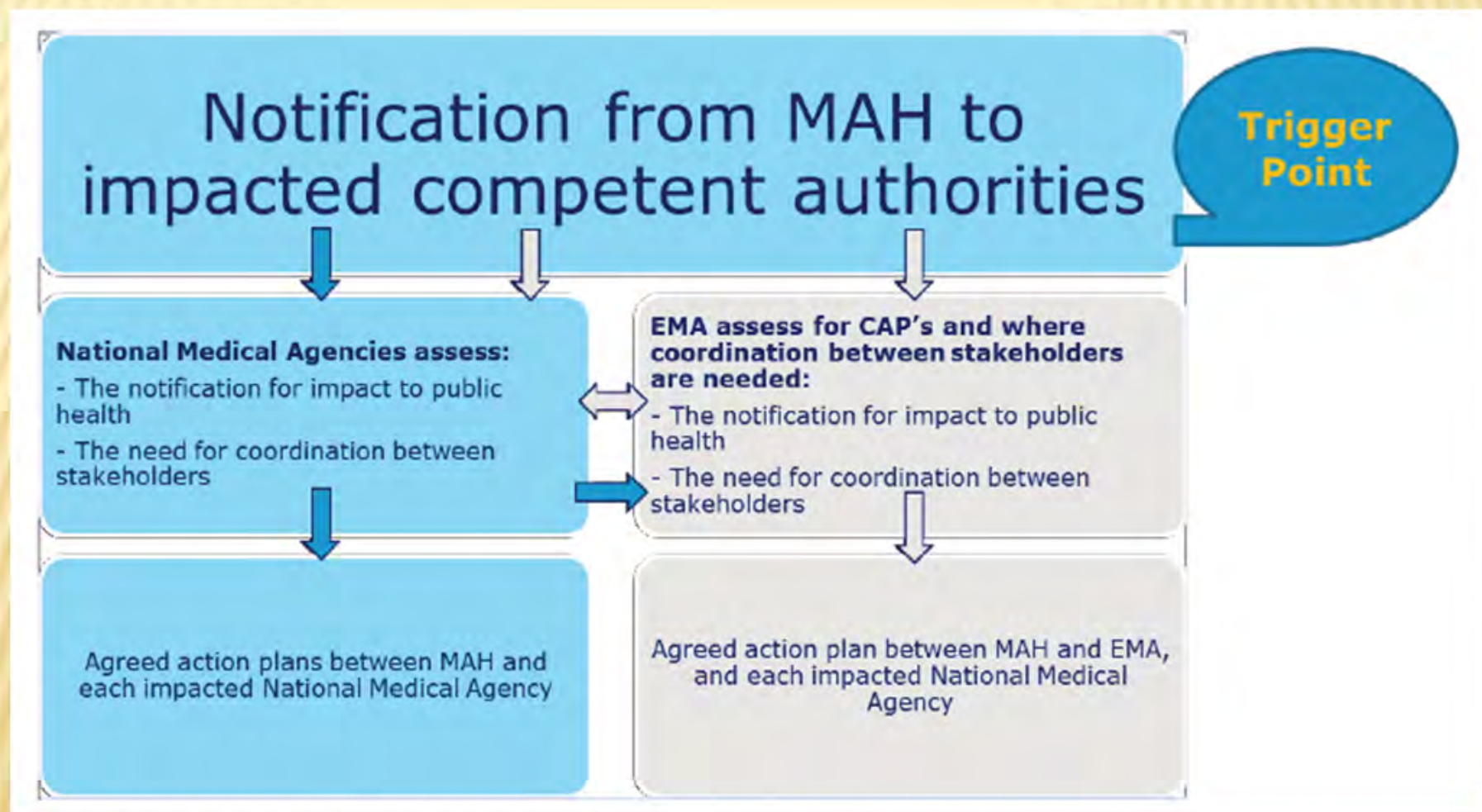
# Chronology of drug shortages



- Greater legal clarity on the responsibility of manufacturers
- A comprehensive database, run by the European Medicines Agency, of all medicines reported to be in current shortage in at least 5 EU Member States
- A high level investigation, led by the European Commission, of the holistic causes of medicine shortages in Europe
- Annual reporting of the extent of the medicines shortage problem by the European Medicines Agency



# Chronology of drug shortages





# Chronology of drug shortages





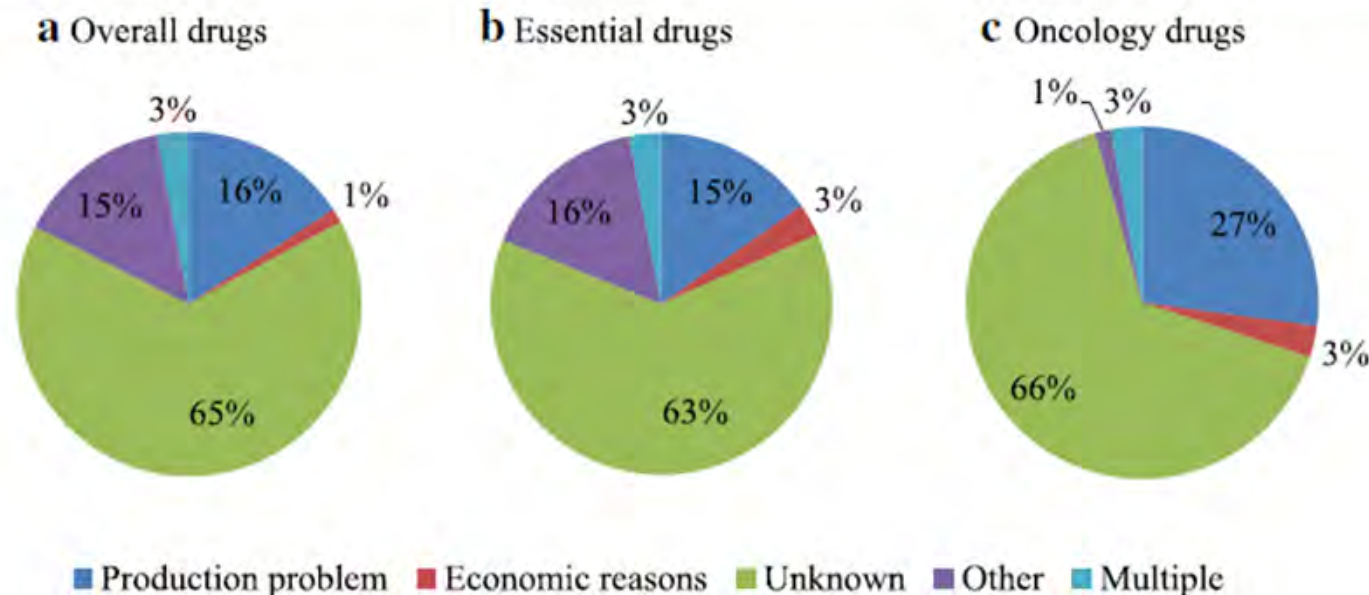
# ***EIPG view of events***

- ✘ EMA's focus is on shortage due to manufacturing/GMP compliance issues, while «Interested Parties» seem more willing to include other causes and involve supply chain actors.
- ✘ **Marketing authorisation holder** is always reported as the key responsible of performing the risk assessment, taking the decision and communicating with the competent authority.
- ✘ It is evident that all technical activities and risk evaluation are part of the duties of industrial professionals, in most cases pharmacists, who occupy a key position in manufacture/GMP/quality compliance management.



# EIPG view of events

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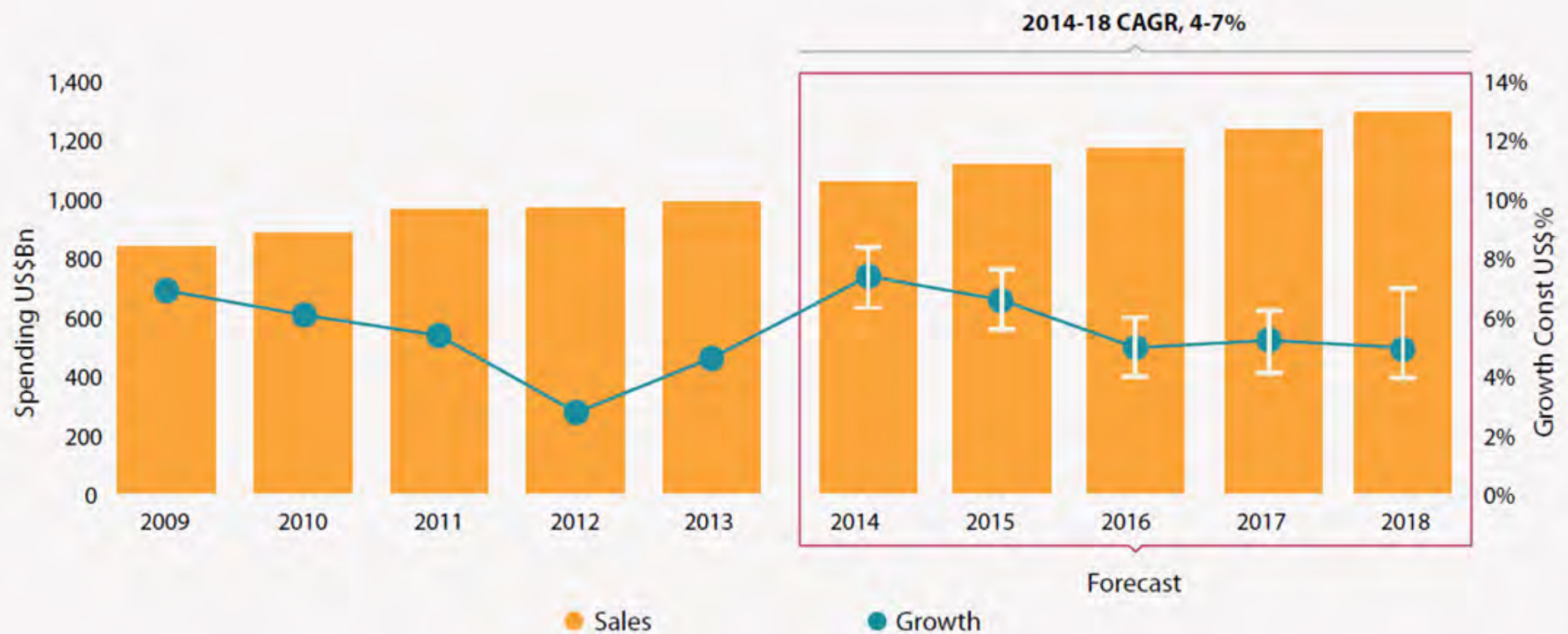


**Figure 4** Proportion of the reported drugs per cause for drug shortages. The proportion of drugs per cause is shown for a) overall drugs (n = 171), b) essential drugs (n = 200) and c) oncology drugs (n = 71).



# Addressing the problem

## Global spending and growth, 2009-2018

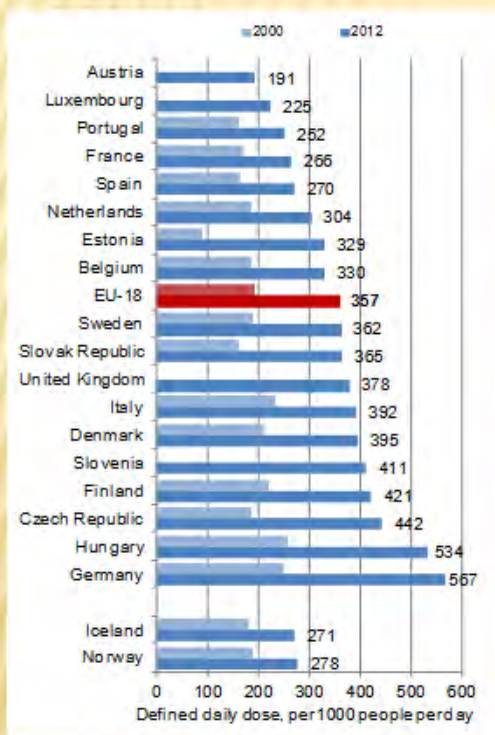


Source: IMS Market Prognosis, September 2014

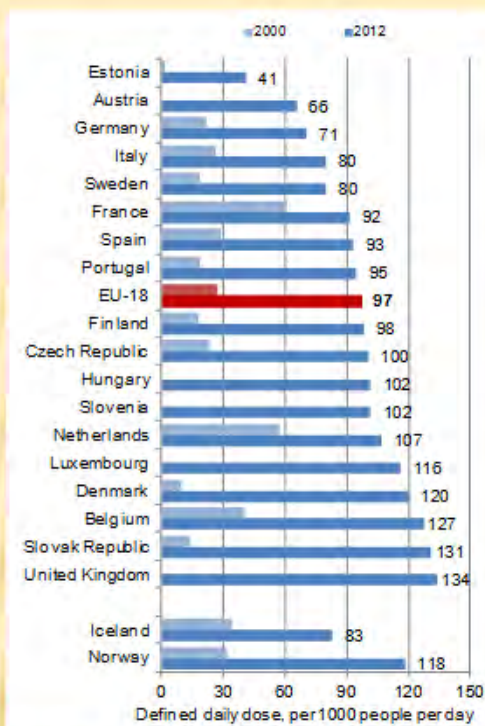


# Addressing the problem

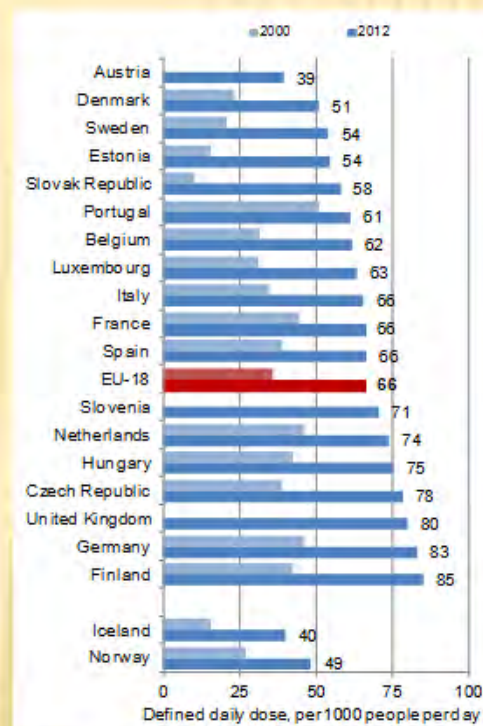
## Consumption of medicinal products in Europe, 2000 and 2012 (or nearest year)



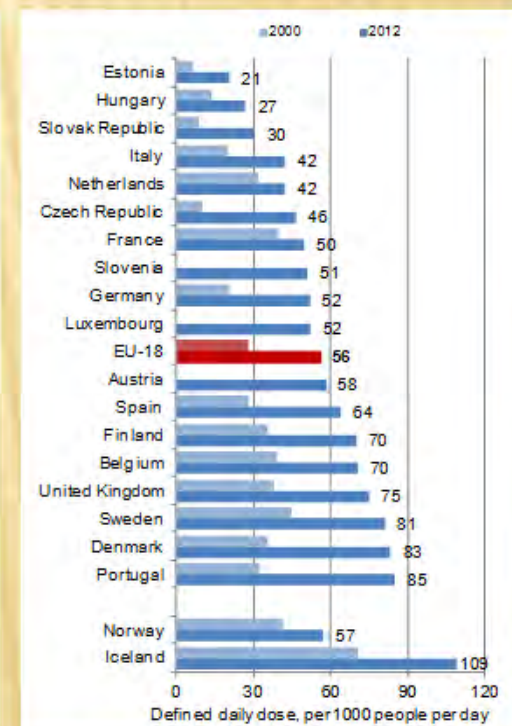
**Antihypertensives**



**Cholesterol-lowering agents**



**Antidiabetics**

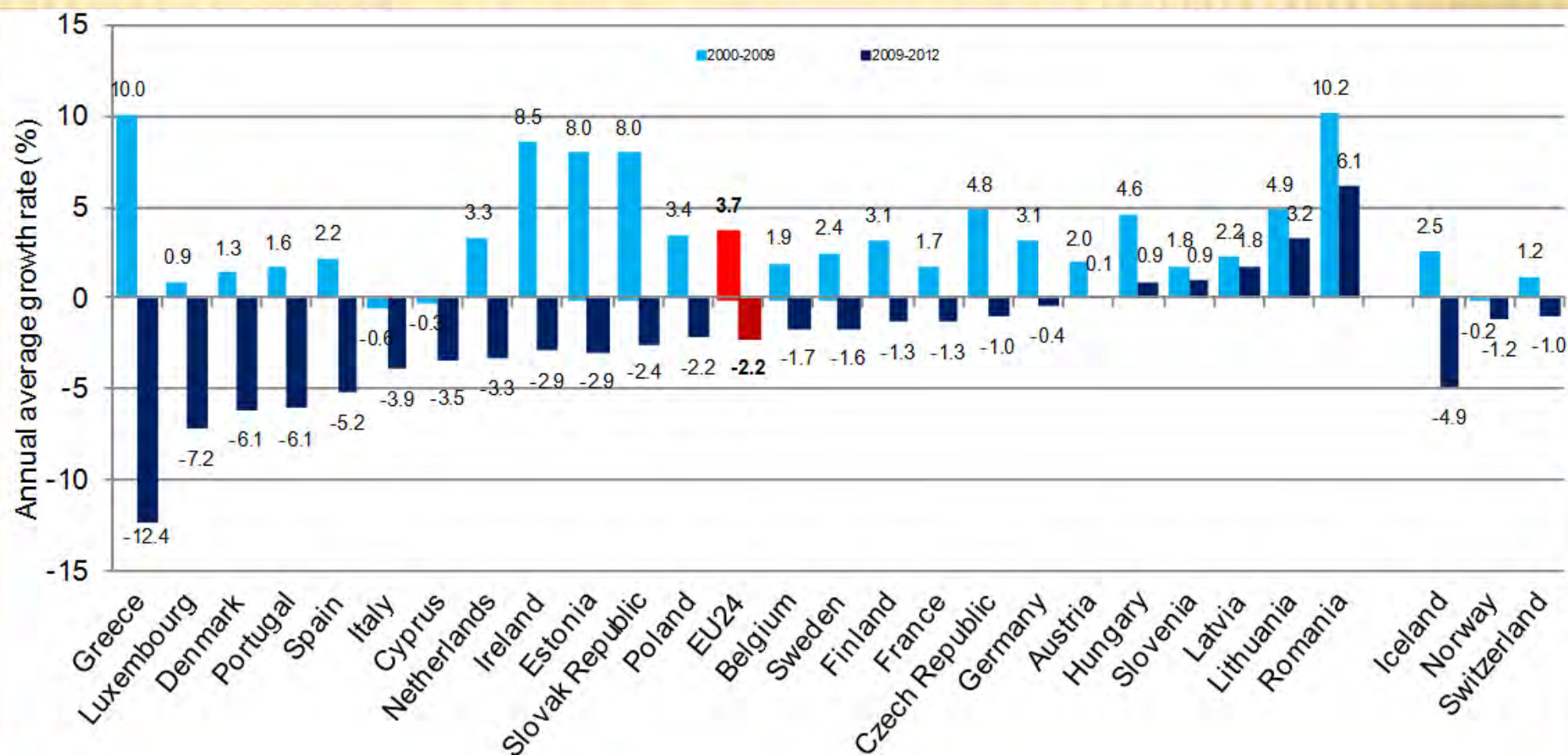


**Antidepressants**



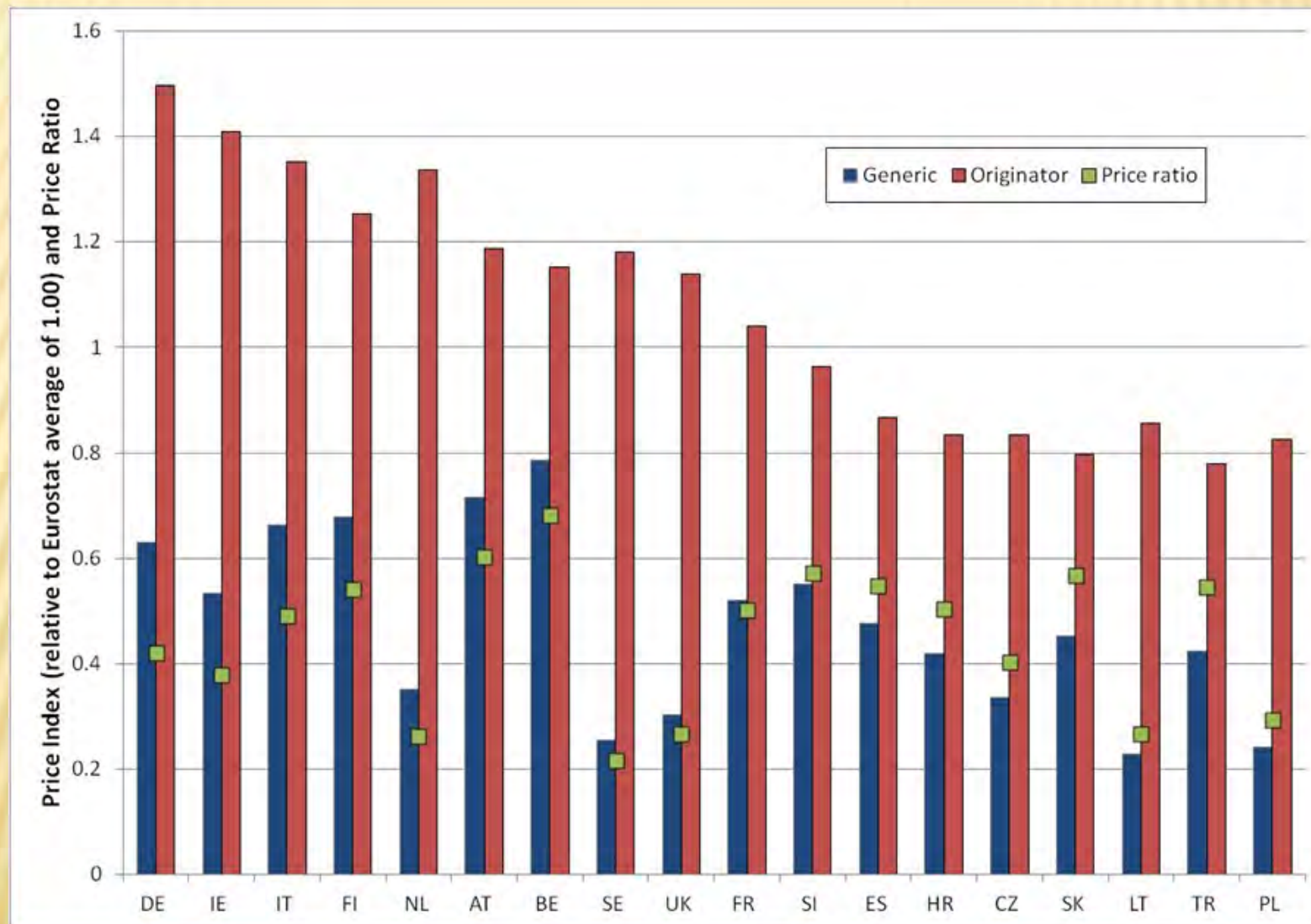
# Addressing the problem

Average annual growth in pharmaceutical expenditure (including medical non-durables) per capita, in real terms, 2000 to 2012 (or nearest year)





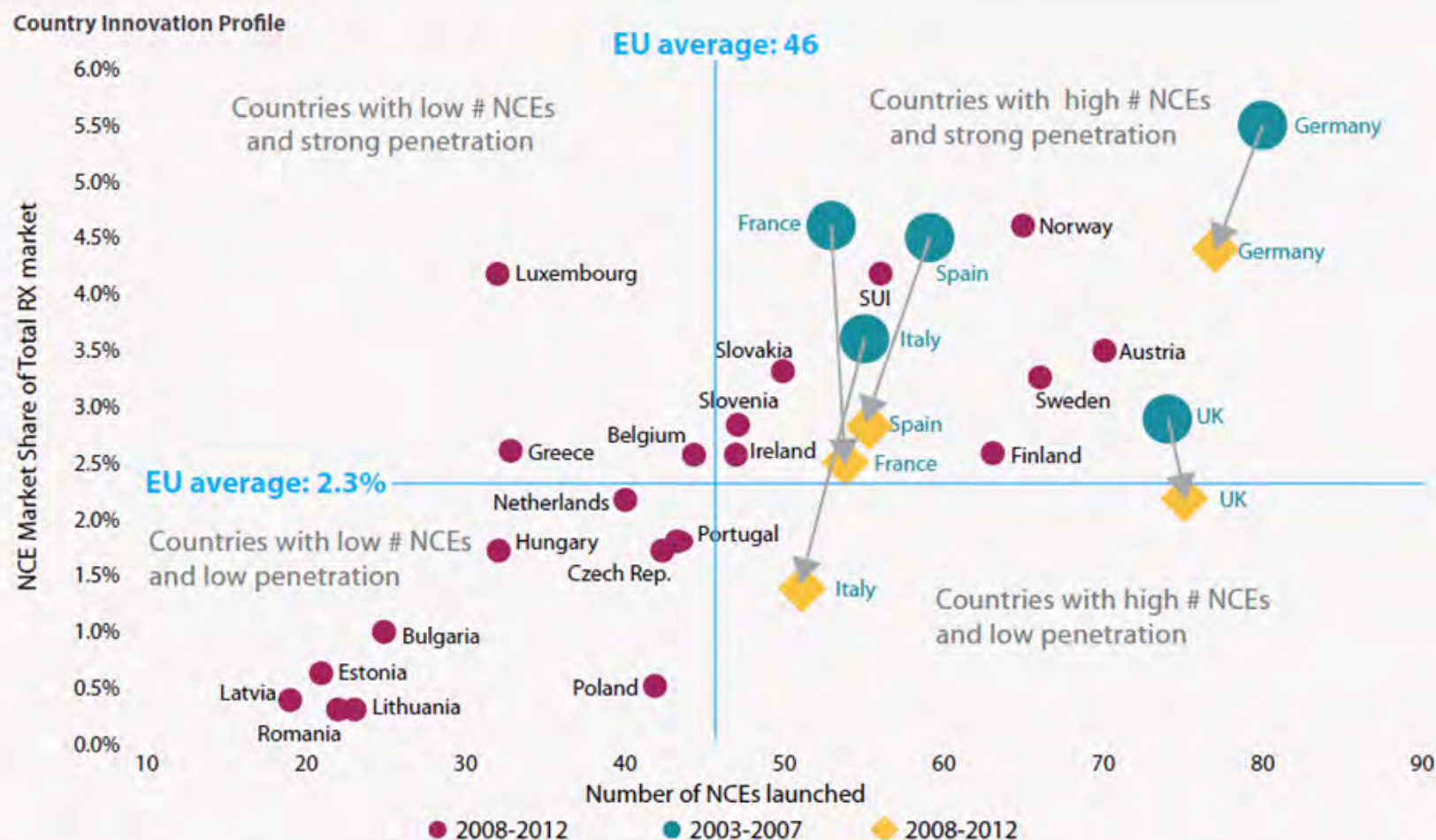
# Addressing the problem





# Addressing the problem

## NCEs launched vs. Market Share achieved

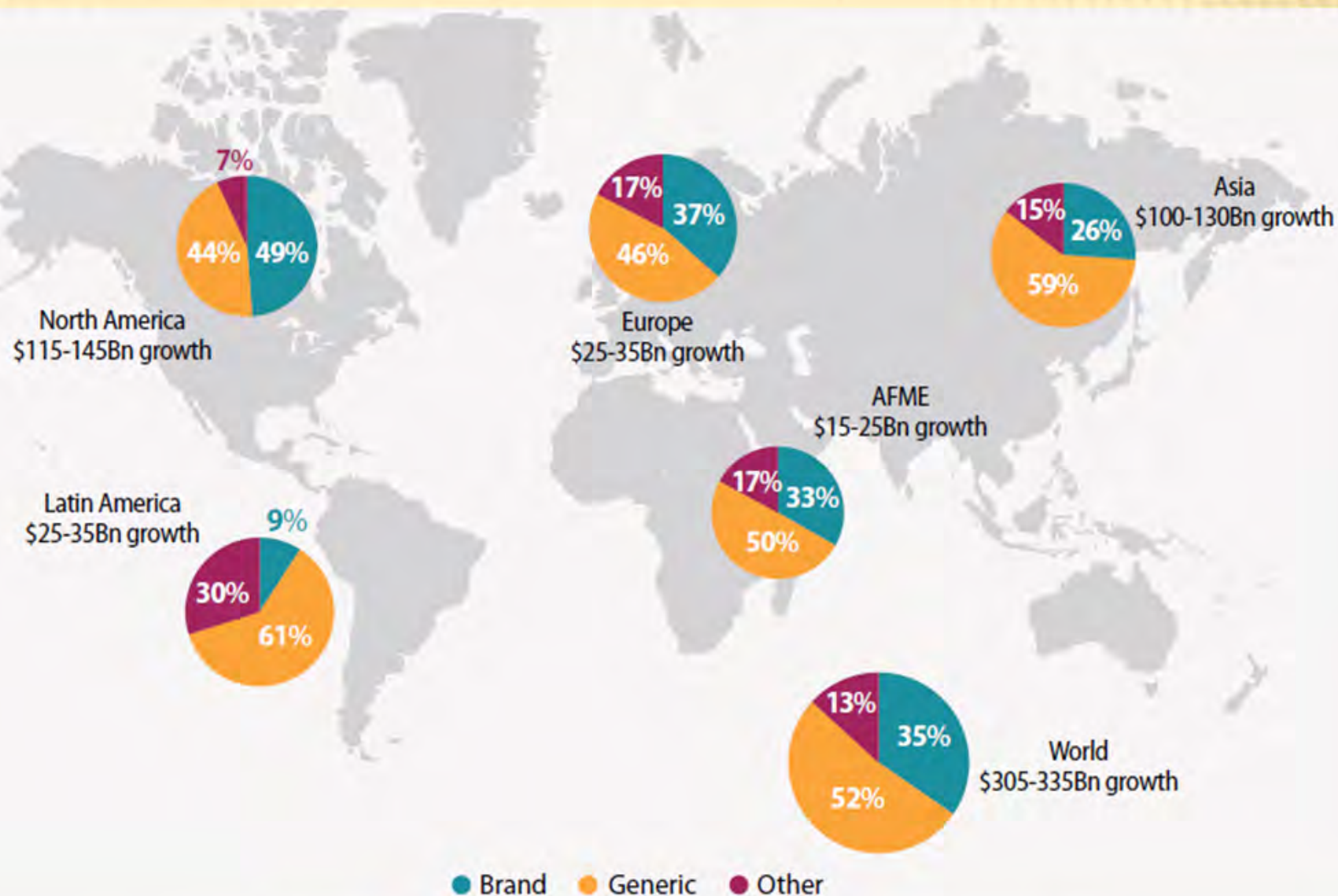


Between the time periods 2003/7 and 2008/12, NCE # and uptake decreased for all countries except Norway and Bulgaria. Movements of the top 5 European markets shown for illustration.

Source: IMS Health MIDAS, September 2013



# Addressing the problem

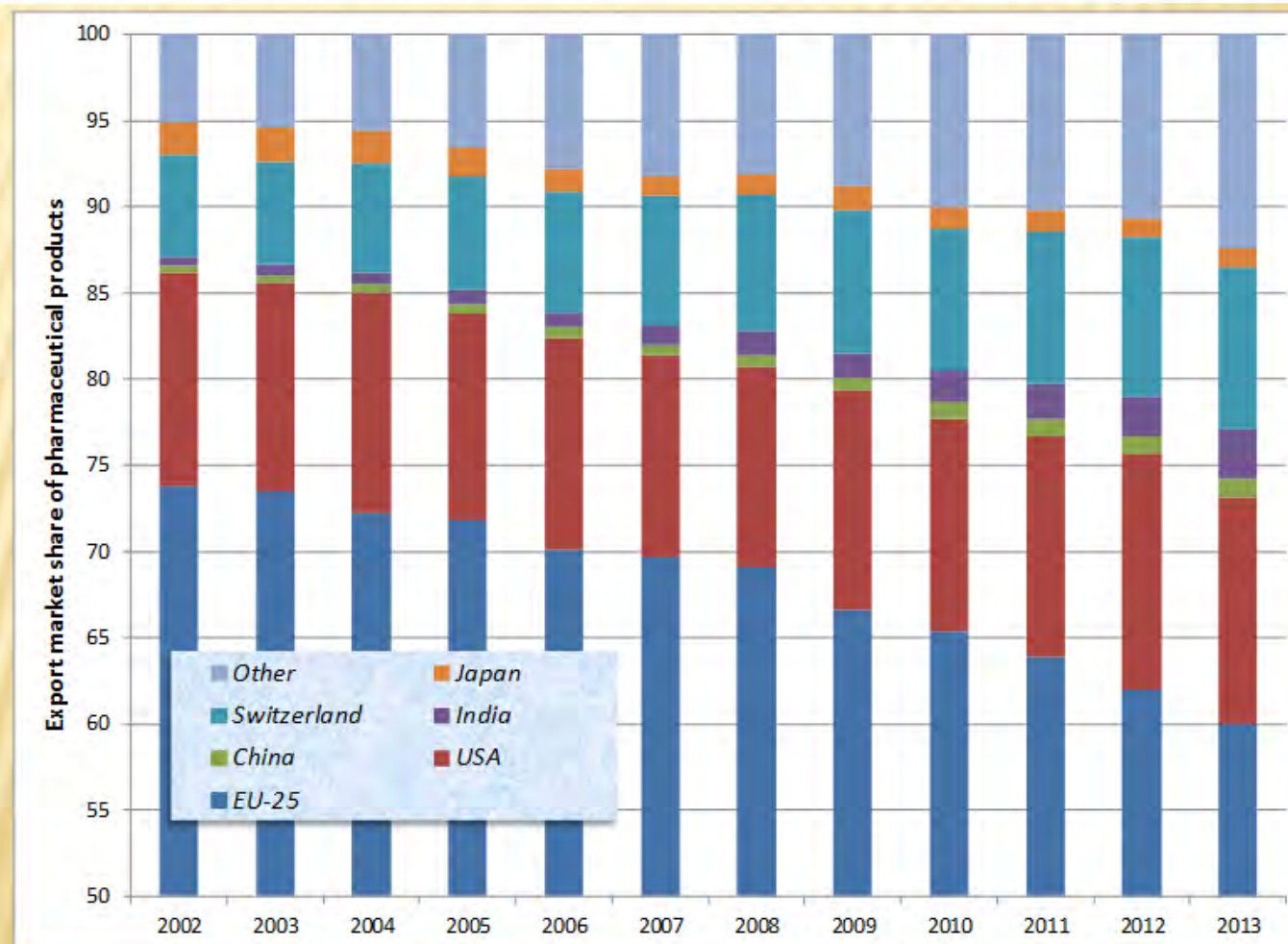


Source: IMS Market Prognosis, September 2014; IMS Institute for Healthcare Informatics, October 2014



# Pharmerging markets are players

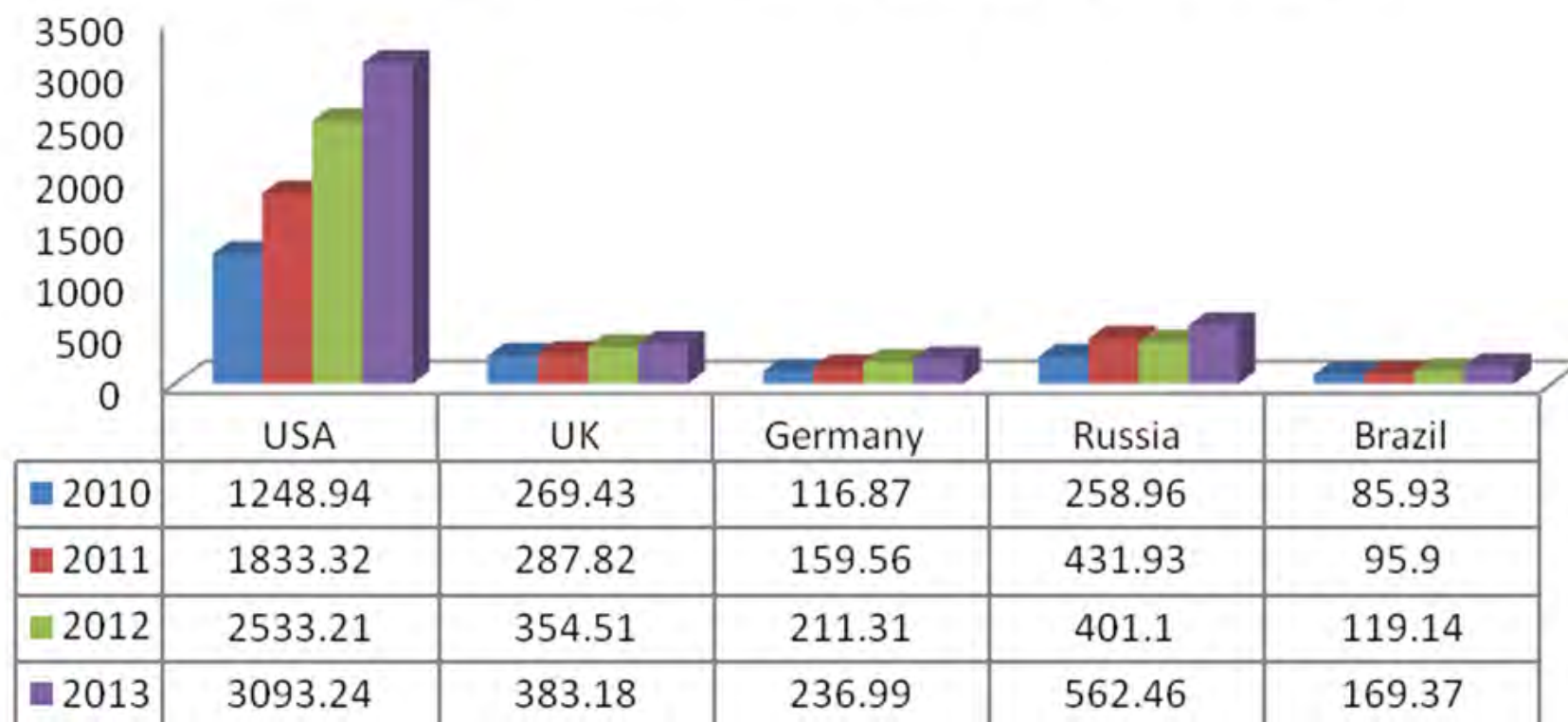
## Global share of pharma exports





# Pharmerging markets are players

*Pharma exports from India (US \$ Million)*





# Pharmerging markets are players

## Pharma exports from India (US \$ Million)

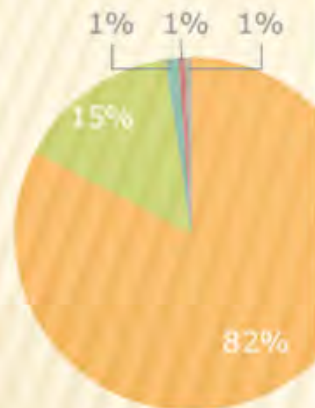
USFDA import alert on Indian manufacturing facilities





# Lessons from the United States

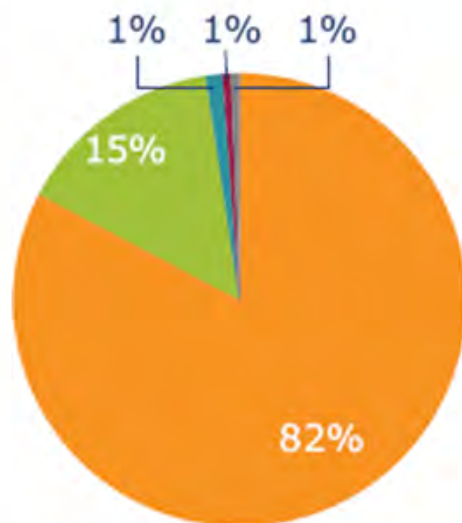
Form Type



- Injectables
- Orals
- Inserts/Implants
- Rectals, Topical
- Dermatologicals

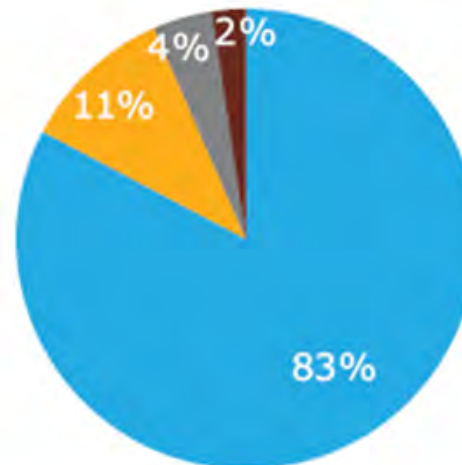
Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011

Form Type



- Injectables
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Brand-Generic Type



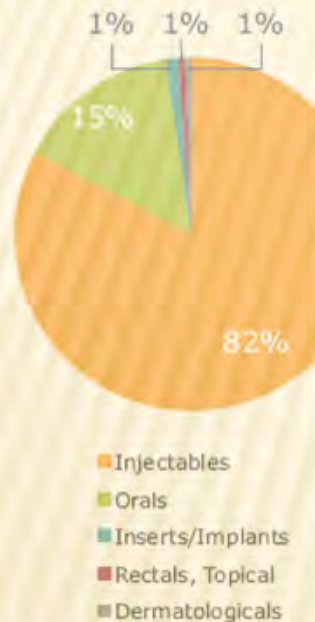
- Generic
- Brand
- Branded Generic
- Other-Branded Generic

Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011



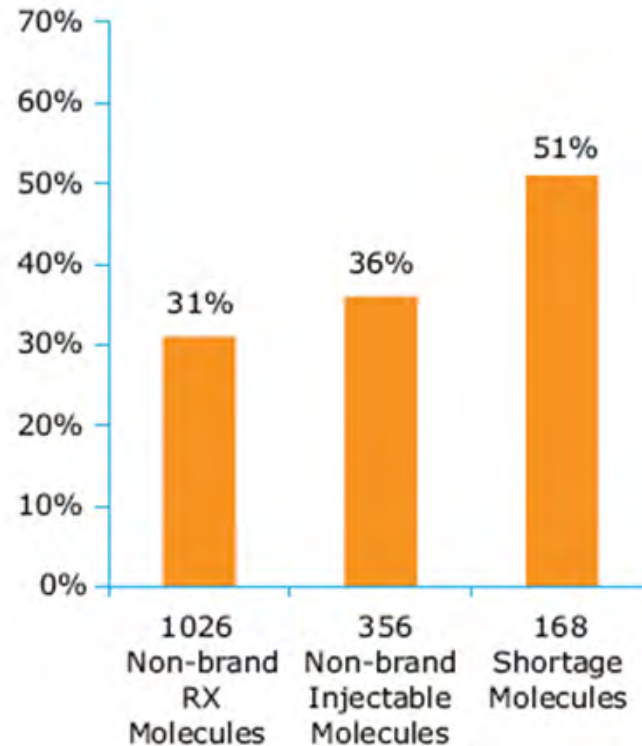
# Lessons from the United States

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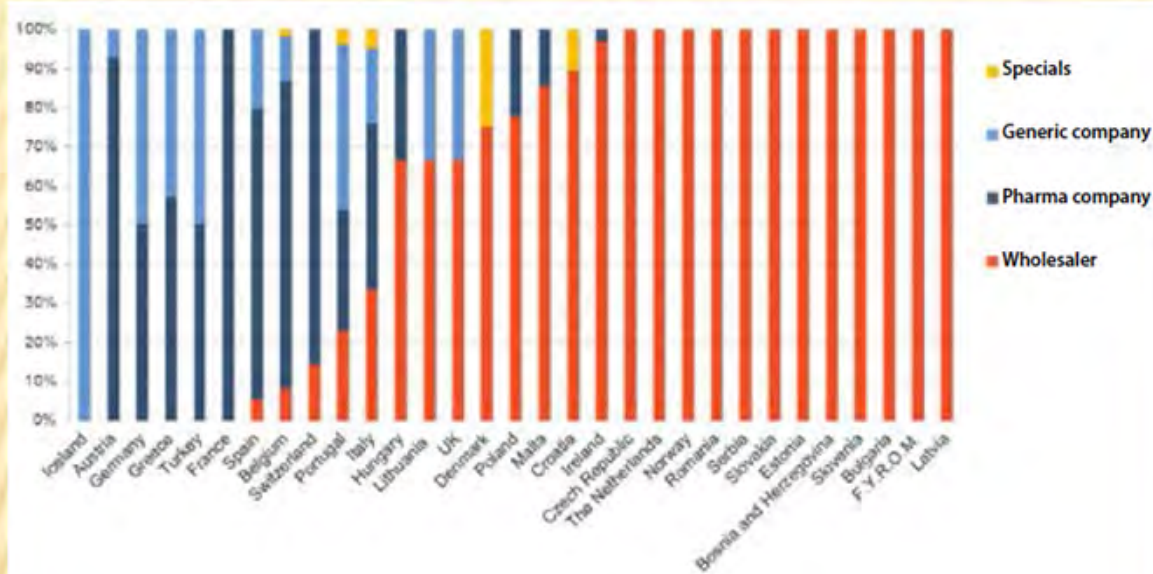
Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011

Molecules with Limited Suppliers

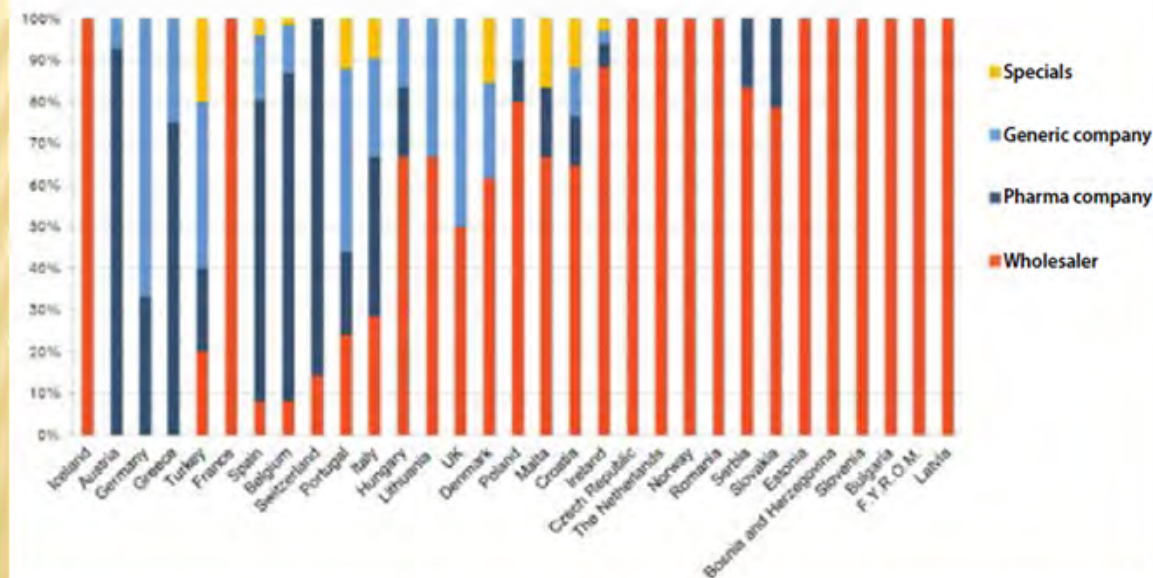


Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011

# Addressing the problem



*Source of main purchasing*



*Source with which supply shortage is most commonly associated*



# Addressing the problem

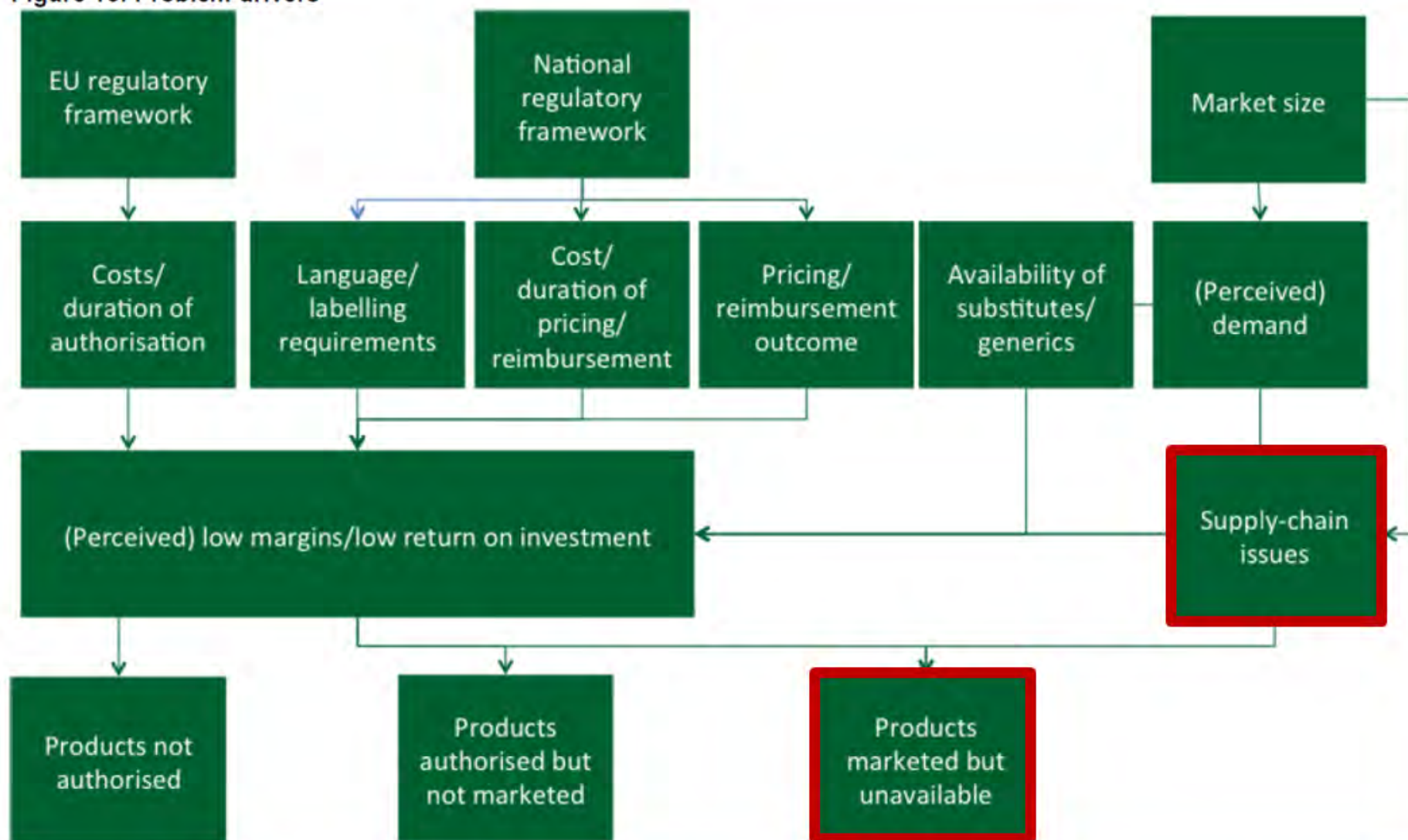
*There seems to be a consistent reluctance to ascribe movement of medicinal products within the Union as contributing in a significant manner to drug shortages.*

**HOWEVER**

*A number of countries (Bulgaria, Hungary, Greece, Czech Republic, Spain) have implemented legislation empowering the competent authority to prohibit the export of a particular medicine if there is a risk to patient supply.*

# Addressing the problem

Figure 16: Problem drivers





# Addressing the problem

*“The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.”*

*Art. 81, Directive 2001/83/EC*



# ***EIPG view of events***

- ✧ EMA's focus is on shortage due to manufacturing/GMP compliance issues, while «Interested Parties» seem more willing to include other causes and involve supply chain actors.

## ***Addressing the problem***

- ✧ Marketing authorisation holder is always reported as the key responsible of performing the risk assessment, taking the decision and communicating with the competent authorities.

## ***Communication is the key***

- ✧ It is evident that all technical activities and risk evaluation are part of the duties of industrial professionals, in most cases pharmacists, who occupy a key position in manufacture/GMP/quality compliance management.



## The DP Portal for information of supply disruptions



# Regulatory context

**Decree n° 2012-1096 of 28 septembre 2012** relating to the supply of medicinal products for human use establishes rules for the management of supply interruption as follows:

- **Article R.5124-49-1**

I. — **La rupture d'approvisionnement** se définit comme **l'incapacité** pour une pharmacie d'officine ou une pharmacie à usage intérieur définie à l'article L. 5126-1 **de dispenser un médicament à un patient dans un délai de 72 heures**. [...]

II. — Lorsque **l'exploitant anticipe** une situation de rupture potentielle d'approvisionnement, il en **informe l'Agence nationale de sécurité du médicament et des produits de santé** [...].

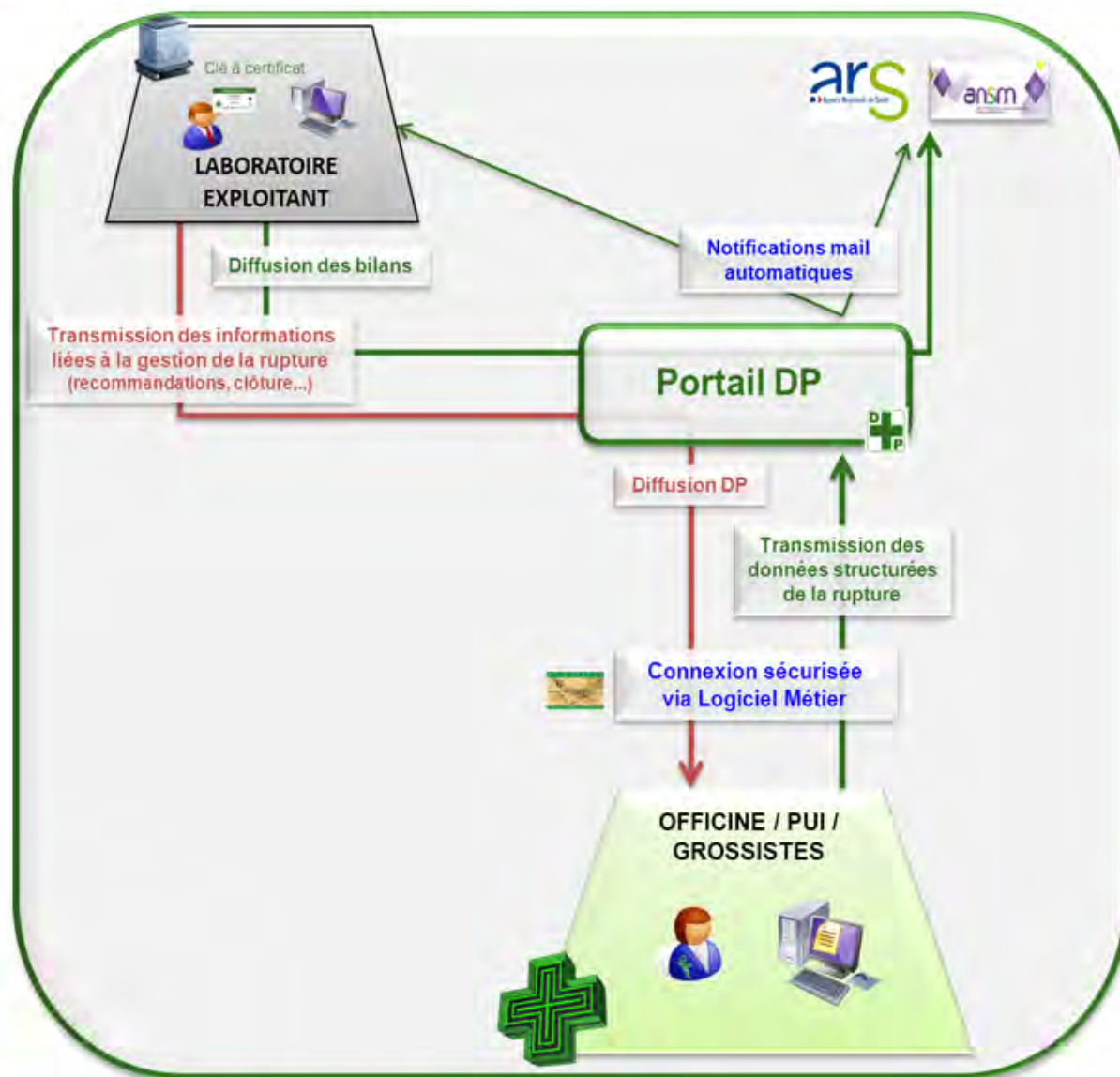
III. — [...]. **En cas de recours aux centres d'appel d'urgence**, le pharmacien en informe **l'agence régionale de santé**. [...]

[...] **Un bilan trimestriel** de ces **approvisionnements d'urgence et des déclarations** est réalisé **par l'exploitant** et **adressé à l'agence (ANSM)**, chronologiquement pour chaque médicament avec mention, le cas échéant, des quantités fournies et de leurs destinataires.





# Target solution device generalisation phase



## Objectives

Provision of a system to manage information flow of supply disruptions to **Logiciels Métier**

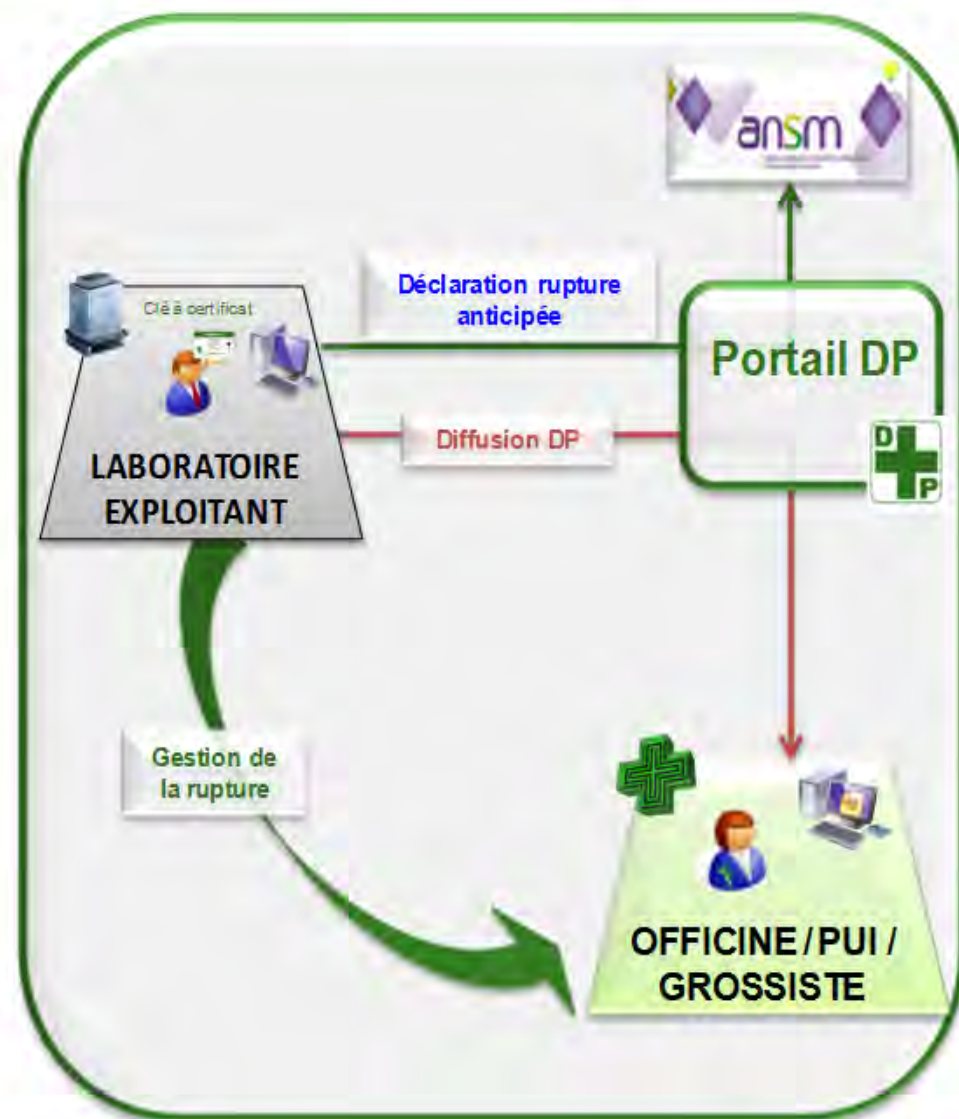
## Perimeter

- **All the operators** in the **supply chain** (pharmacists, wholesalers and laboratory operators)
- **L'ANSM et les ARS**

# The DP Portal and the expected disruption

Through the dedicated interface the Responsible Pharmacist of the operator can:

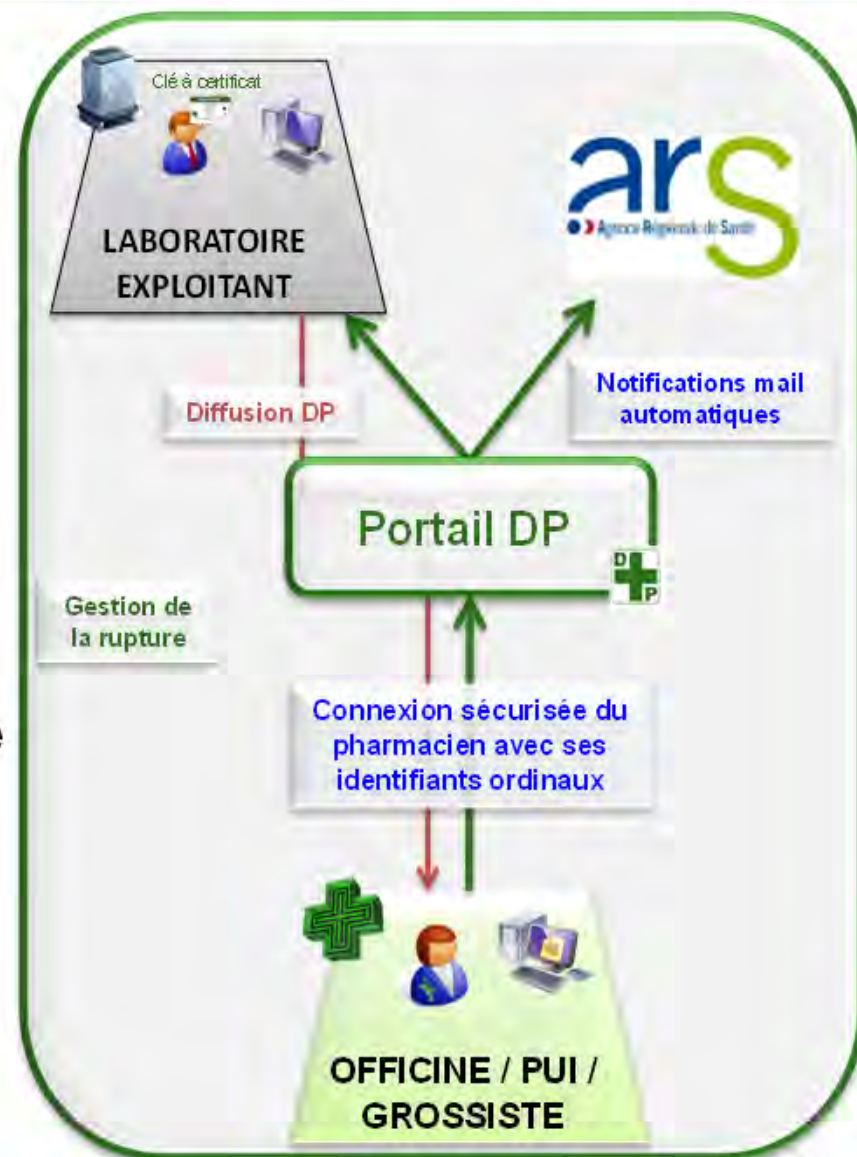
- **Inform** ANSM of the risk of an early disruption event
- **Communicate** the stock recovery time
- **Transmit** information to pharmacists via the DP platform
- **Generate and disseminate quarterly balance sheets** of statements and actions taken to manage the disruption



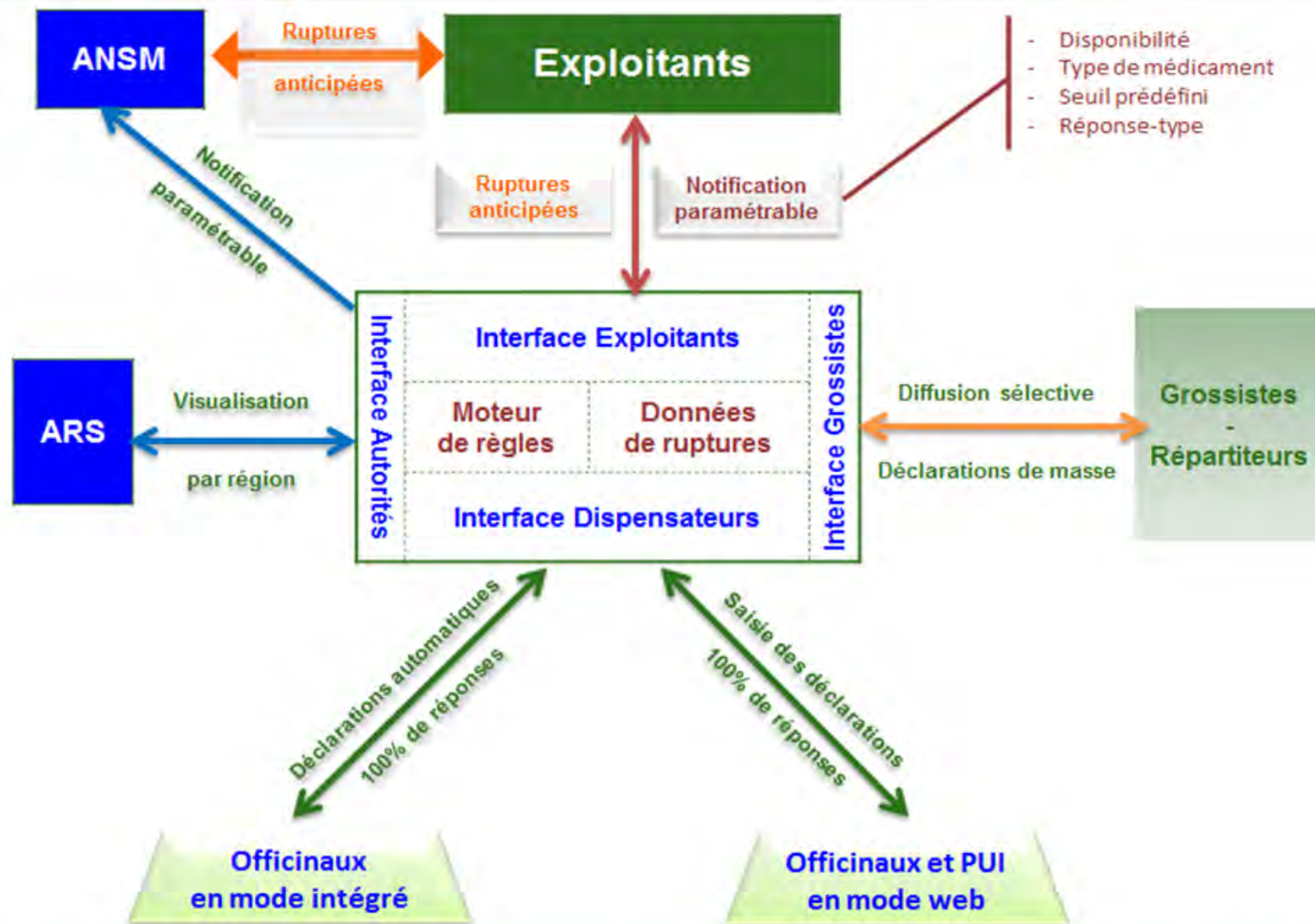


# The DP Portal and the existing disruption

- Through the **alert interface** of the DP Portal, pharmacists can :
  - **Declare** a disruption
  - **Know** product availability
  - **Be informed** of recovery times, if these are known
- The **operator** is **notified** of each new **declaration that concerns him and can**, via the DP platform:
  - **Inform ARS** of the actions taken to handle the disruption directly through the portal
  - **Transmit** information to pharmacists
  - **Generate and disseminate quarterly balance sheets** of statements and actions taken to manage the disruption



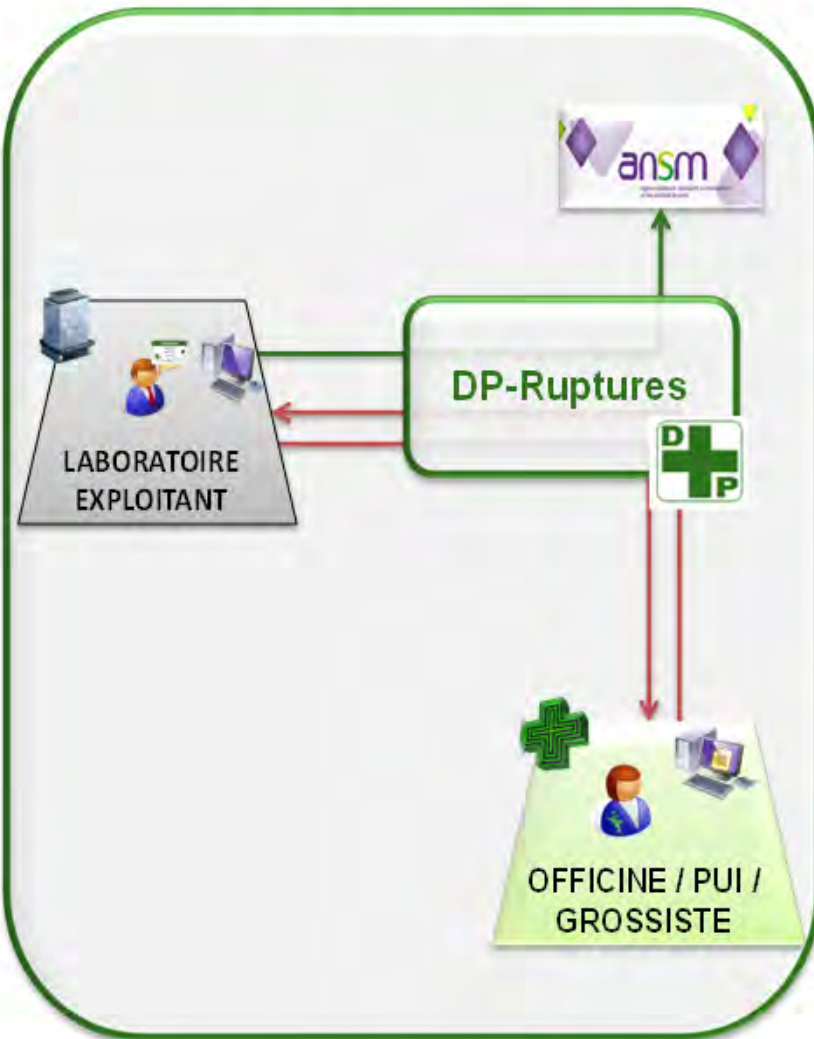
# The portal DP-Ruptures overview





# Information flow managed by the portal

## DP-Ruptures allows:



- **Communication with ANSM**

- Implement the declaration of supply disruption or risk of anticipated disruption online (replacing the current paper-based procedure)
- Discuss with ANSM actions to manage the disruption with traceability of actions taken

- **Communication with clients**

- **Downstream information** related to management of anticipated disruptions
- **Upstream information**: central reporting of established disruptions
- Reactive information in response to a declaration of an established disruption

- **Generate quarterly statements** with one action, balances are transmitted:

- **Globally**, to **ANSM**
- **Selectively**, to **ARS** affected by the disruption



# Addressing the problem

## *The pharmacist is the key*



**THANK YOU**