

# **The needs of health systems**

## **From efficacy to effectivity**

### **The search of efficiency of pharmaceuticals in the European Union**

# Summary

2

- Similar challenges in all EU Member states
- Different solutions to tackle the pharmaceutical expenses
- Attempts to cooperate accross Europe

# All the countries face similar challenges

3

- The number of persons over 80 years will double until 2050
- Budget constraints are inscreasing (health expenses account already for 8,9% of GNP)
- Innovation is increasing at an unprecedented speed = opportunities and costs

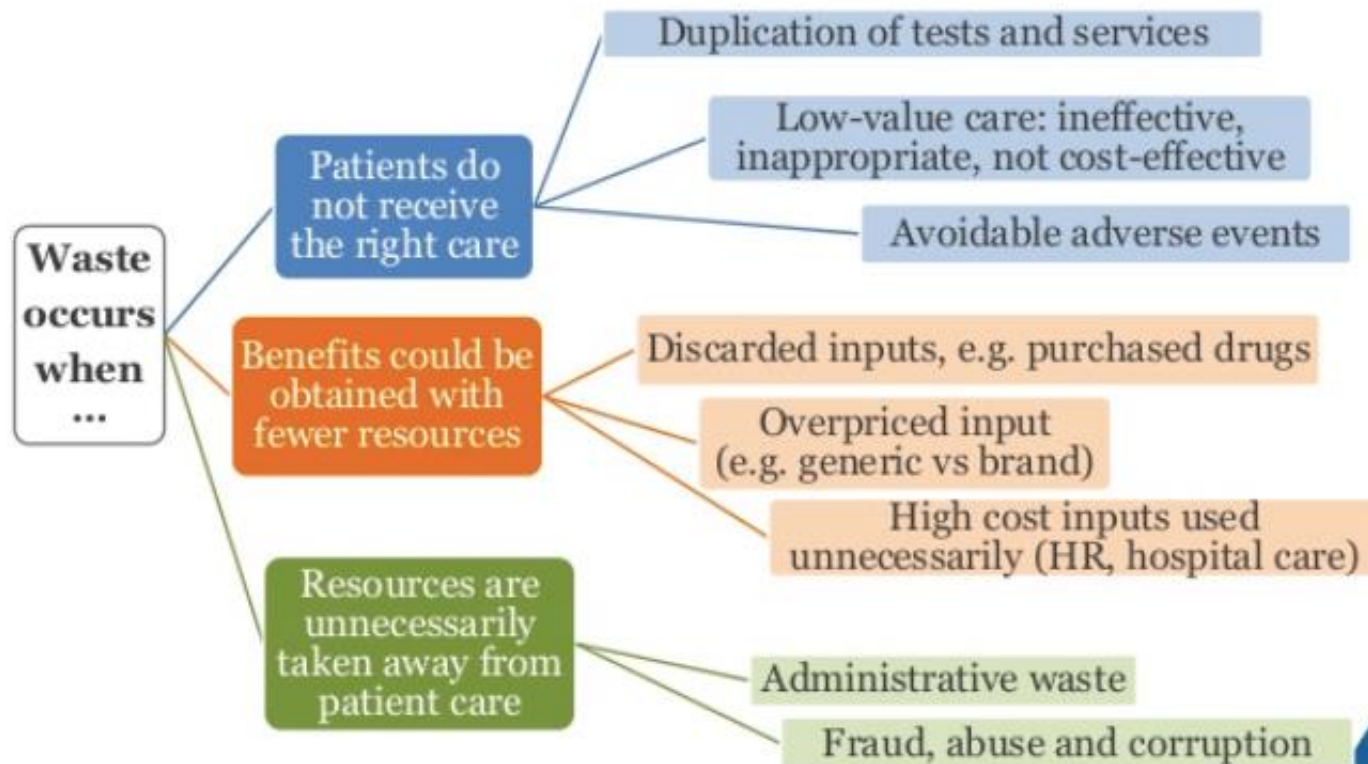
(OECD data)

# Tackling wasteful spending on health

## learning from OECD countries' experience-OECD 2017

4

« A significant share of health spending in OECD countries is at best ineffective and at worst, wasteful » « Up to a fifth of health spending could be channeled to better use »



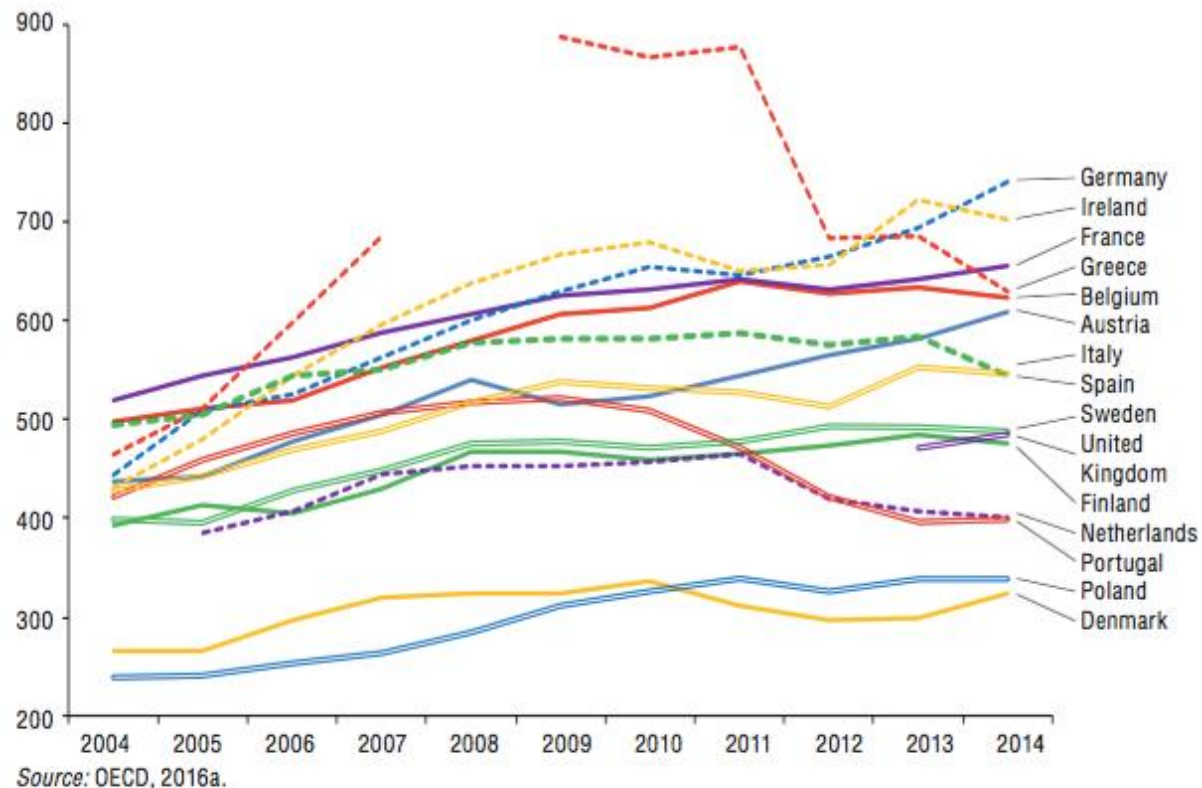
# In the pharmaceutical field

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- The level and the structure of pharmaceutical expenses vary importantly from one country to an other
- Some comparative figures (retail pharamcies)

# Per capita expenditure range from 324.6 (Denmark) to 741.1 US\$ PPP (Germany) in 2014

Per capita expenditure on "retail" pharmaceuticals and other medical non-durables (in US\$ PPP), 2004–2014



# Retail pharmaceuticals as share of GDP

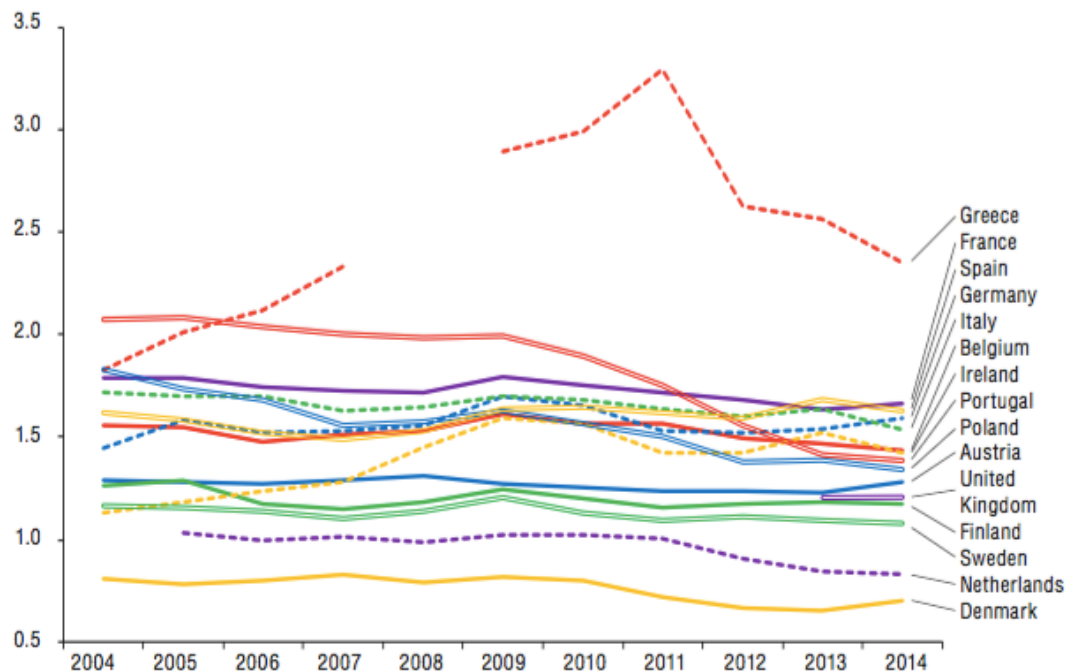
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Greece : 2.3%,

The highest cluster :  
France, Spain and  
Germany between 1.60%  
and 1.67%

At the lowest end of the  
spectrum : Denmark  
(0.71%) and the  
Netherlands (0.83%)

Expenditure on "retail" pharmaceuticals and other medical non-durables as a share of GDP, 2004–2014



Source: OECD, 2016a.

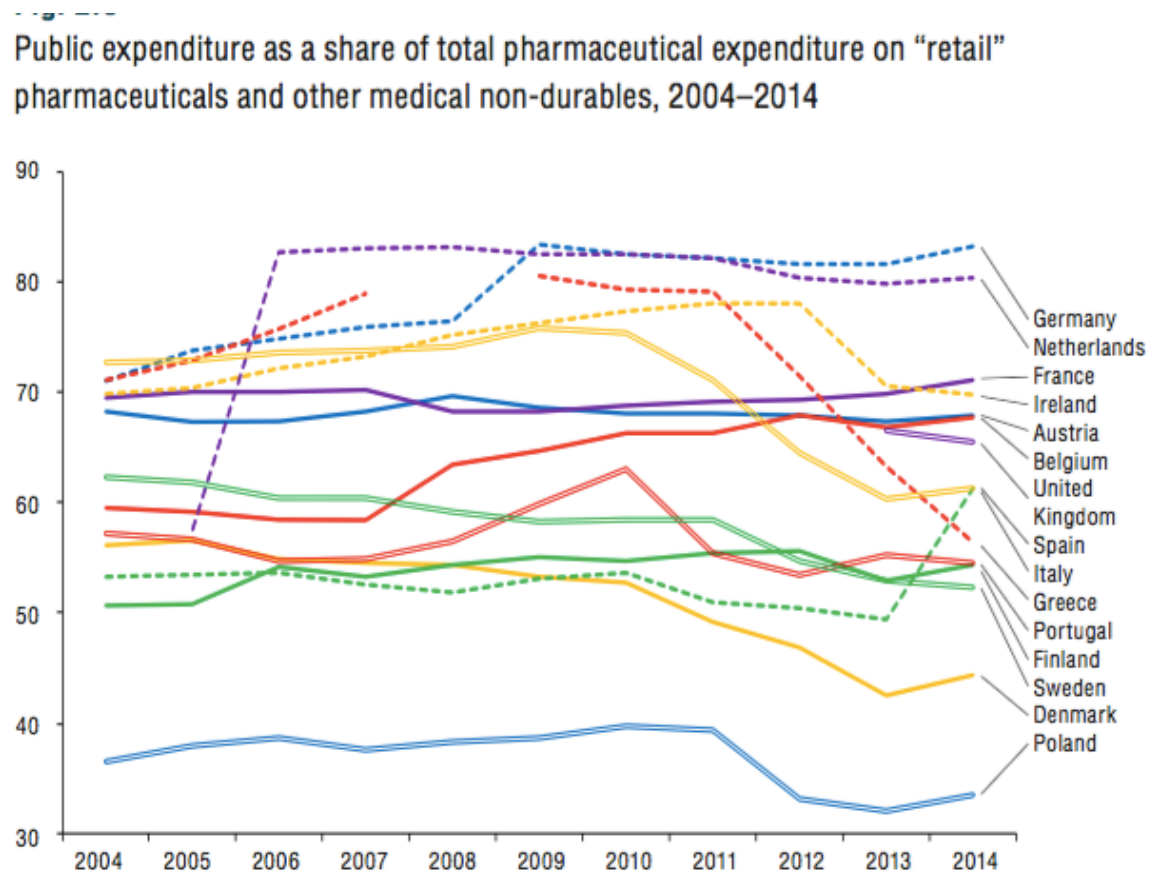
# Public expenditure as share of total pharmaceutical expenses (2004-2014)

8

A low of 33.5% in Poland and a high of 83.3% in Germany.

The Netherlands and France also showed values above 70%.

At the other end of the spectrum, Denmark remained below 50%



Source: OECD, 2016a.



# Common trends

9

- The expenses are more and more concentrated on a limited number of very costly medicines
- High prices at market launch, not always linked to an additional efficacy (rare diseases, cancer)
- Very effective medicines with a good price/efficacy ration in the long run, but addressing large population ( anti HCV)
- Still major unmet medical need ( antibiotics, Alzheimer disease)
- The sustainability of pharmaceutical expenses is a problem for every country

Source : New Health Technologies : Managing Access, Value and Sustainability ( OCDE janvier 2017)

Marie-Paule SERRE

16 février 2018

# Regulation tools differ from one MS to an other

10

- Harmonization applies to marketing authorisations
- **Pricing and reimbursement decisions**, as part of the organisation and delivery of **healthcare systems** are under the responsibility of each individual **Member State**
- – Criteria and procedures are defined at the national level
- MS watch carefully its neighbours' best practice

# Each country applies a range of regulation tools

11

- ~~marketing authorization;~~
- Limited reimbursement lists ( positive or negative)
- pricing and price updates;
- post-marketing evaluations guiding coverage decisions (health technology assessment);
- Prescription guidelines;
- Financial incentives for prescribers ( pay for performance)
- Managed entry agreements
- patient cost-sharing;
- specific cost and quality control measures targeting individual stakeholder groups (manufacturers, wholesalers/pharmacists, prescribers);
- generic substitution;
- .....

# Collaboration between Member States in the UE

12

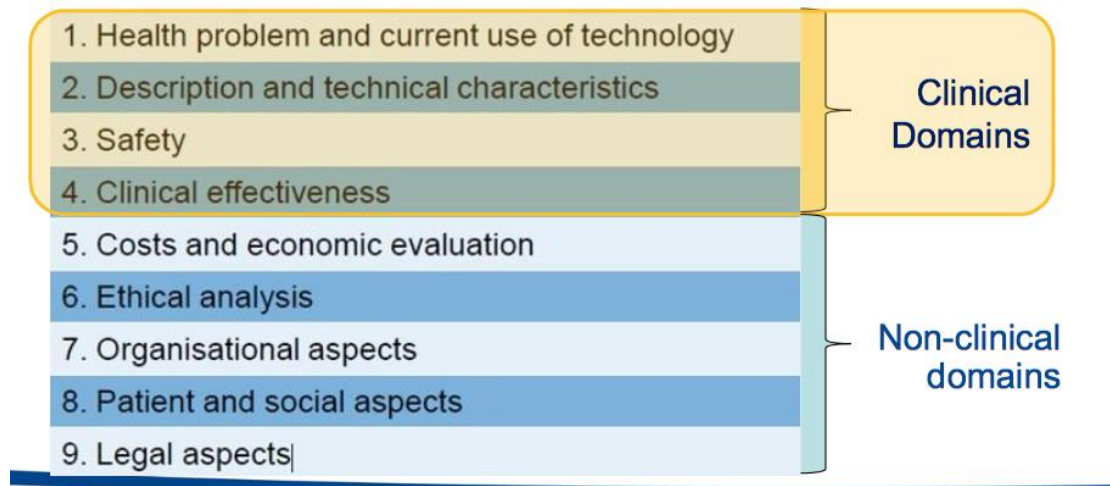
- Health technology assessment
- Attempts of cooperation regarding prices and procurement of pharmaceuticals

# HTA : a comprehensive, multidisciplinary process

13

- that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner.
- Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. [EUnetHTA]

## The HTA domains (EUnetHTA Core Model ®)



# Why developing HTA at the European level ?

14

- In the EU: more than 50 national and regional HTA bodies, all embedded in different institutional settings.
- National procedures and the nature of the reports differ (e.g. recommendations vs. legally binding reports).
- Even advanced HTA bodies do not have expertise in all areas or are confronted with resource constraints,
- Not all health technologies can be assessed or that no reassessment is possible after launch.

# Main steps

15

- 20 years of voluntary cooperation between Member on HTA
- Voluntary cooperation between HTA bodies
  - Joint action 1 ( 2010-2012), JA 2( 2012-2015), JA3 ( 2016-2020)
- Adoption of the Cross-border Healthcare Directive (2011/24/EU), legal basis for a voluntary EU-wide network on HTA composed of national HTA bodies or agencies established in 2013

Objectives : to provide strategic and political guidance to the scientific and technical cooperation at EU level on HTA. complemented by three consecutive Joint Actions on HTA

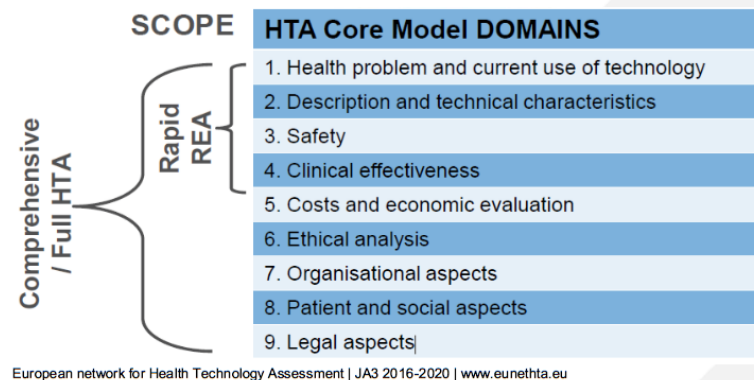
# Output

16

- EunetHTA **guidelines**, to help the assessors of evidence to process, analyse and interpret the data.
- **Tools** to support the conduction of Joint Assessments, and to facilitate the collection of evidence from the companies.
- **Joint assessments** : joint production in which 2 or more countries work together to prepare shared products or agreed outcomes ( 20JA medicines and MD)

2 types of JA

- ✓ Relative Effectiveness Assessments (REA)
- ✓ Full assessment including non-clinical domains





# Strengthening EU cooperation on HTA

## A legislative proposal adopted by the European Commission on 31 January 2018

17

- ❑ Final objective: set up practical conditions for a permanent (post-2020) collaboration on evidence generation all along the life-cycle of a technology to ensure HTA initiative sustainability beyond 2020
  
- ❑ Member States will be able to use common HTA tools, methodologies and procedures across the EU, working together in four main areas:
  - ❑ **joint clinical assessments** focusing on the most innovative health technologies with the most potential impact for patients;
  - ❑ **joint scientific consultations** whereby developers can seek advice from HTA authorities;
  - ❑ **identification of emerging health technologies** to identify promising technologies early; and
  - ❑ continuing **voluntary cooperation** in other areas.
  
- ❑ Individual EU countries will continue to be responsible for assessing non-clinical (e.g. economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

# Attempts to coordinate pricing decisions and procurement between Member States

18

- ❑ « Transparency Directive » ( 1989) : the first and only community framework on pricing and reimbursement
  
- ❑ Objective of recent initiatives : increase the bargaining power of Member states regarding pharma industry

# Attempts to coordinate pricing decisions and procurement between Member States

19

- ❑ June, 2014 : Joint Procurement Agreement, published by the European Commission and signed by 23 member-states
  - ❑ Enables all EU countries to procure pandemic vaccines and other medical countermeasures as a group, rather than individually, on a voluntary basis
  - ❑ Ensures that pandemic vaccines and medicines are available in sufficient quantities and at a correct price should a cross border health threat emerge.
- ❑ A complex mechanism, with restricted conditions and limited impact

# Attempts to coordinate pricing decisions and procurement between Member States (ctnd)

20

- Health Ministry Council , June 2016- Member states
  - Express concerns about the high prices of some products, that could limit patient access
  - Require the Commission to carry on inquiries on anti-competitive behaviours
  - Are encouraged to carry joint negotiations on prices with pharma companies
  
- « La Valette coalition » ( May 2017) : initiative of some MS to gather in order to explore ways of common negotiation with pharma companies
  - Malta, Cyprus, Greece, Italy, Spain, Portugal
  - + Ireland, Romania, Croatia and Slovénia ( January 2018)

# Attempts to coordinate pricing decisions and procurement between Member States (ctnd)

21

- ❑ A similar agreement has been signed previously between Austria, the Netherlands, Belgium and Luxemburg :  
« Collaboration BeNeLuxA », 2016.
- ❑ Objectif : place in commun their strenghs regarding reimbursement decisions, particularly :
  - ❑ Horizon scanning : a watch on new drugs that will be marketed in the short terme and may have un important impact on the healthcare system.
  - ❑ HTA
  - ❑ Share information on pricing and reimbursement decisions

## In conclusion

22

- ❑ Up to now, only sharing information between EU MS on economic decisions or about the methodology of assessment is effective;
- ❑ Cooperation on HTA, pricing and procurement policies is limited by the strong will of MS to remain independent regarding their social security system.
- ❑ It will be interesting to watch the fate of the EC proposal on HTA to assess how far MS are ready to go on harmonization

# Main sources of information

23

- OECD
  - New Health Technologies : *Managing Access, Value and Sustainability* ( 01/2017)
  - Panorama de la santé
  - Les prix des médicaments sur un marché global
  - Tackling Wasteful Spending on Health (2017)
- WHO Europe :
  - Pharmaceutical Regulation in 15 European countries  
(Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czech Republic, Germany Denmark, Estonia ,Spain, Finland, France, Greece, Croatia, Hungary, Ireland, Iceland, Italy, Liechtenstein, Lithuania, Luxembourg, Latvia ,Malta, Netherlands, Norway, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia, United Kingdom) ( 2016)
- <http://www.eunethta.eu>

**Thank you for your attention**