# PATIENTS, NOT PAYTIENTS!

## What role can the EU play to make access to make access to innovative medicines more sustainable?

The European & National Medicines Regulatory Systems: the challenges for an equitable, timely and suitable access to innovation

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# Scientific progress, public investment in research: 1995


Credits: Serge Braun, AFM-Telethon

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# The EU should propose a more comprehensive approach for negotiating prices, considering:

- The revenues the developer is expecting to generate to continue to exist (Discounted Cash Flow method, Nuitjen et al. 2017)
  - Development and placing on the market of medicines delegated to the private sector
  - Consider a company with its first authorised product, and 6 other in R&D
- The product utility (efficacy, safety, quality, relative efficacy, effect size) → EUnetHTA
- The respective contribution of public and developer spending in R&D
- The healthcare system financial constrains (Budget Impact Analysis) and organisation (who pays, when, who gets the benefit)
- The duration of the patent (Intellectual Property Rights) and the possible price decrease with the introduction of generics
- When price abnormally high (fair pricing), consider compulsory licensing

# Compulsory licensing – legal background, France

- **Article L613-16, m**odified by Law n°2004-1338 8/12/2004 - art. 10
- In the interest of public health
  - And only if the products cannot be supplied in large enough quantities or good enough quality
  - Or at an abnormally high price (after negotiations)
- Then the license can be passed to another manufacturer
  - At a lower price
  - Some royalties paid to the originator company

**Prof. Dominique Maraninchi: Why not use it for cancer products in our countries?**
http://www.assemblee-nationale.fr/14/cr-soc/15-16/c1516059.asp
Assemblée Nationale, Commission des Affaires Sociales, 15 June 2016

# The role of regulators


## Improve Compassionate use programmes

- France: 73% of orphan medicinal products that receive marketing authorisation (MA) are available in average 36 months before the MA (see position here)

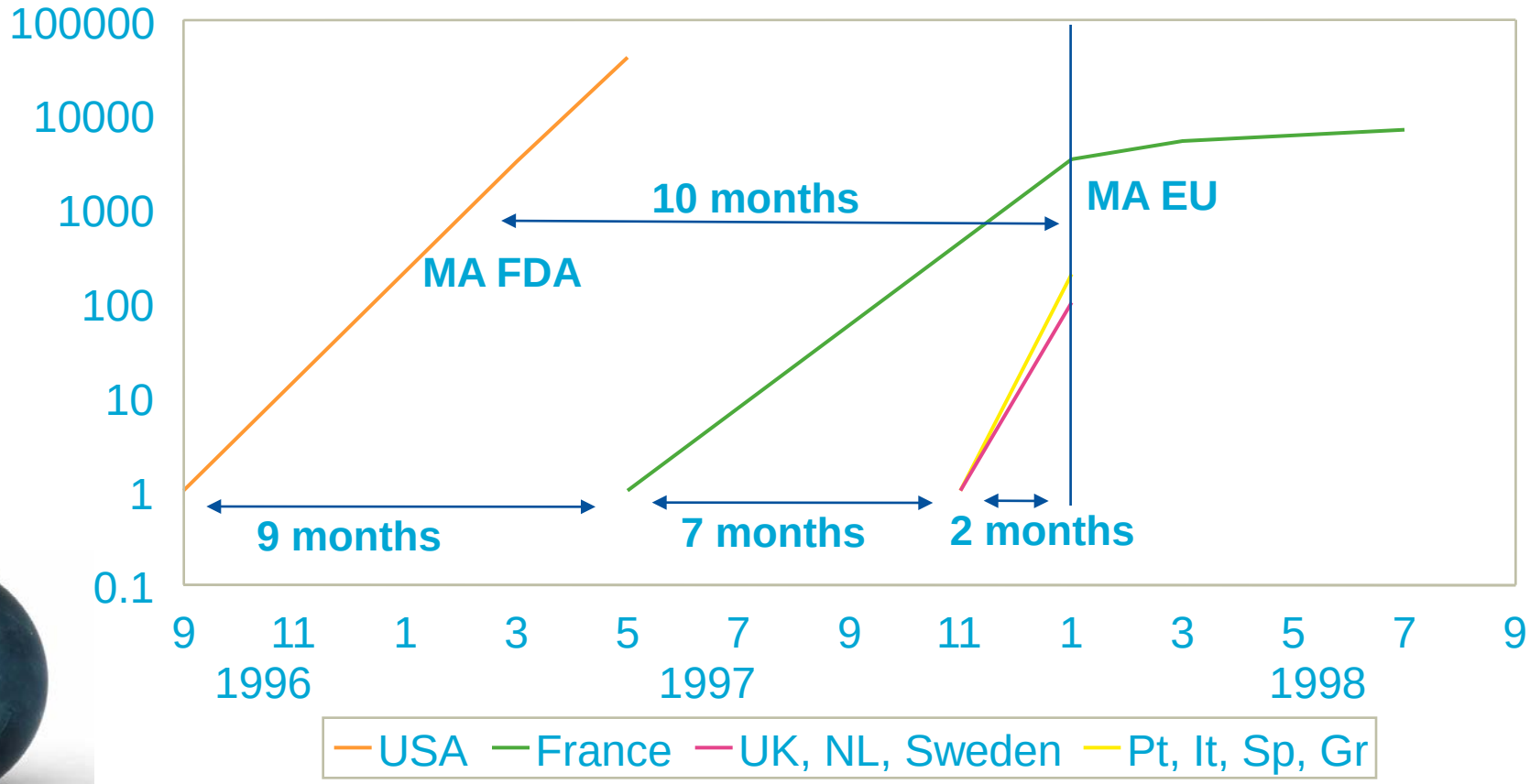
## Organise Synergies between HTA and payers

- Parallel scientific advice, Priority Medicines (PRIME), Adaptive pathways, alignment of regulatory/HTA timelines and sharing of information, HTA @ CHMP

## Develop Post-marketing authorisation monitoring / real word data

- monitoring the effects of medical drugs after they have been authorised, under the usual circumstances of health care practice, compared to one or more alternative interventions
- Pay for performance: the pinnacle of "individualised pharmaco-vigilance" (Hans Georg Eichler, EMA)

# ATU provides access earlier than in any other EU MS (e.g. nelfinavir 1997)




# The role of the EU institutions

## Protect the solidarity principle / Charter of Fundamental Rights

- Article 35 "A high level of human health protection"

## Encourage Transparency

- Pursue the revision of the Transparency Directive 89/105/EEC (adopted by EC 1/03/2012, by EESC on 12/07/2012, and voted by EP on 5/02/2013 with 559 in favour, 54 against, 72 abstentions)

## Encourage/organise European Cooperation on HTA

- EUnetHTA to become EU permanent scientific secretariat for HTA. Consensus on cost and economic methods

## Generalise the Mechanism for Coordinated Access to Orphan Medicines

- Discussions cover all aspects of the product and the disease, including reimbursement and financing scheme
- Process on Corporate Responsibility in the Field of Pharmaceuticals, Belgian Presidency, 2010

## Encourage joint procurement of medicines

- Price and volume agreement: powerful tool to reduce prices. Multi-Member States joint procurement+++

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# Thank you for your attention.

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