



Darrin, Multiple Sclerosis



Michelle, Gaucher disease



Antoine, Flu immunization



Darcus and Vernee, High cholesterol level



James, Prostate Cancer



Mizutani, Pain



Gustavo, Pompe disease



Irène, Diabetes



In Brazil, Dengue immunization



# The role of HTA in patient access to innovative medicines

Lars Wormhoudt, Head Market Access Sanofi Netherlands

# Who is presenting

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# What about Sanofi



## Vaccines Sanofi Pasteur

- Influenza
- Pediatric Combinations
- Meningitis
- Adult Boosters
- Travelers



## Consumer Healthcare

- Cough & Cold, Allergy
- Pain Care
- Digestive Health
- Nutritional Health



## Primary Care in Mature Markets

- Diabetes and Cardiovascular
- Established Products



## Specialty Care Sanofi Genzyme in Mature Markets

- Immunology
- Multiple Sclerosis
- Rare Diseases
- Oncology
- Rare Blood Disorders



## China & Emerging Markets

- Established Products
- Diabetes and Cardiovascular
- Specialty Care

# Patient access & market access

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## Patient Access

- reimbursed
- self-paid
- humanitarian



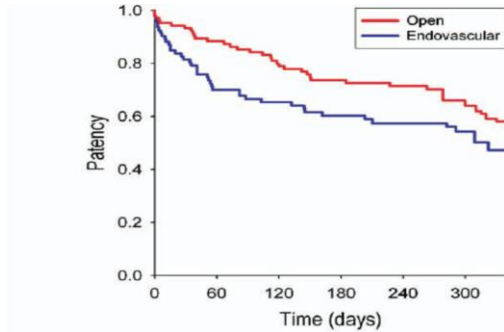
## Market Access

- to ensure patient access to treatment through **sustainable reimbursement**



# Health Technology Assessment (HTA)

## Relative effectiveness



## Cost effectiveness



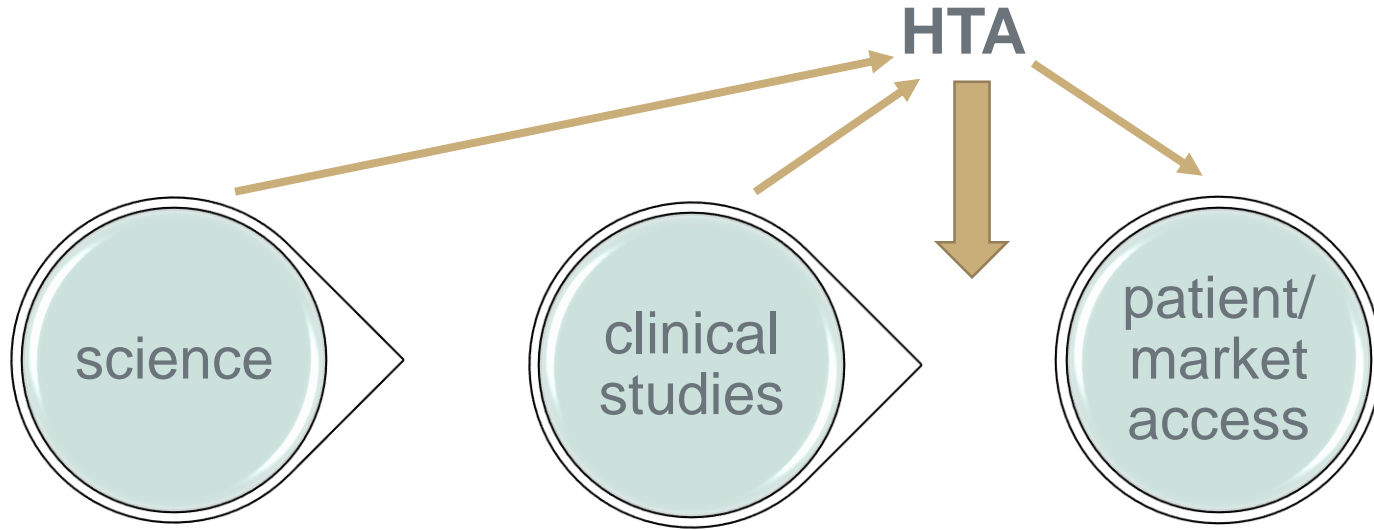
COST EFFECTIVE



**COST/QALY**

# HTA in the drug development process

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## Support therapeutic value and cost-effectiveness

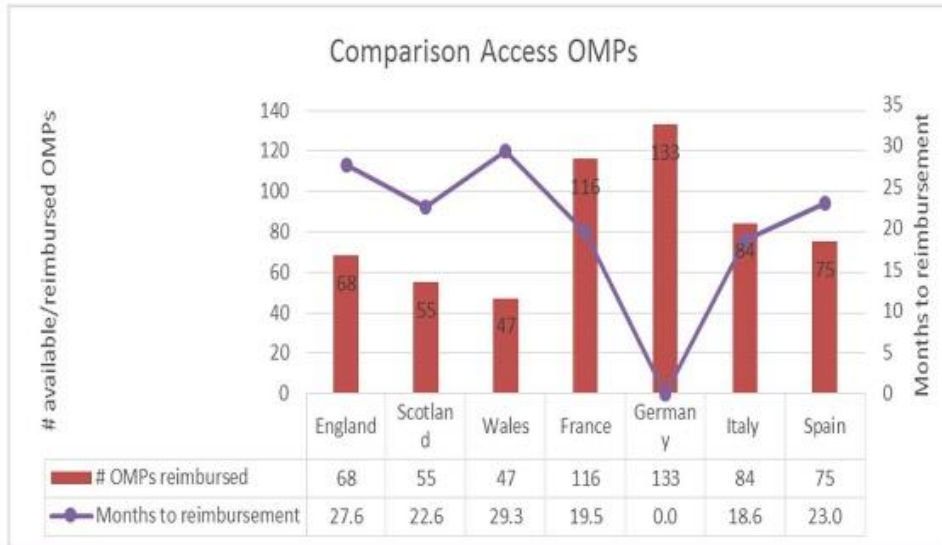
- Outcome parameters
- Data from comparative treatment and/or natural history data
- QOL and/or patient reported outcomes (PRO's)
- Patient subgroups

## Potential outcomes

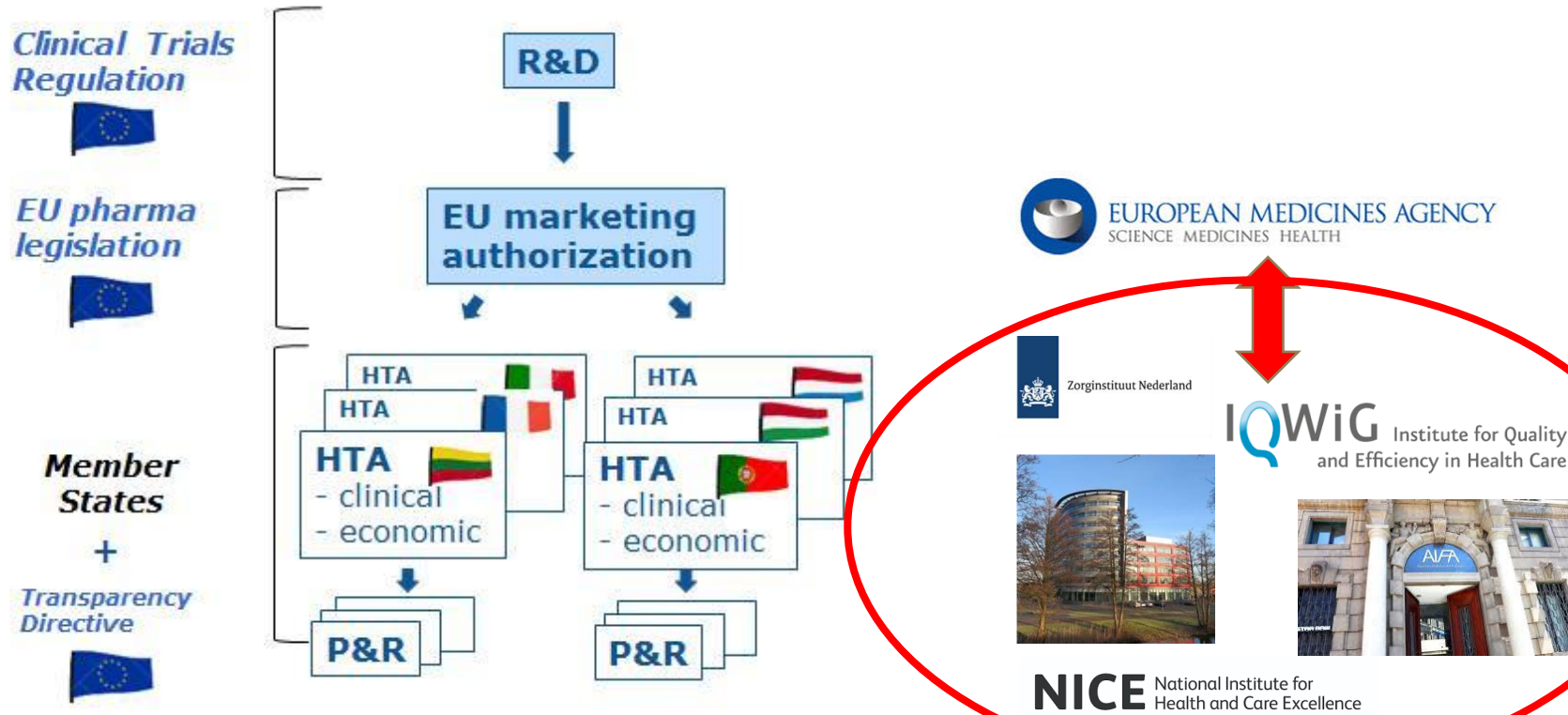
- Full reimbursement
- Conditional reimbursement
- Alternative financing

# Country variability in OMP access/reimbursement

## Comparison among countries



# National patient/market access decision making





# EU collaboration on HTA... and procurement



## EU collaboration

- Improve the availability of innovative health technologies for EU
- Ensure efficient use of resources and strengthen the quality of HTA across EU
- Improve business predictability



## Cross-country collaboration

“The BeNeLuxA Initiative aims for sustainable access to, and appropriate use of, medicines in the participating countries. We strive to increase patients’ access to high quality and affordable treatments.”

# Linking registration with patient/market access (HTA)



25 June 2014  
EMA/295485/2014  
Press Office

[Press release](#)

Outcome report on first European collaboration between regulators and HTA organisations: improving the contribution of regulatory assessment reports to health technology assessment



Mechanism of Coordinated Access  
to Orphan Medicinal Products



# QandA

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