



2014
Presidenza Italiana del Consiglio
dell'Unione Europea

The Italian approach to early and managed access



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Milan, 22st September 2014

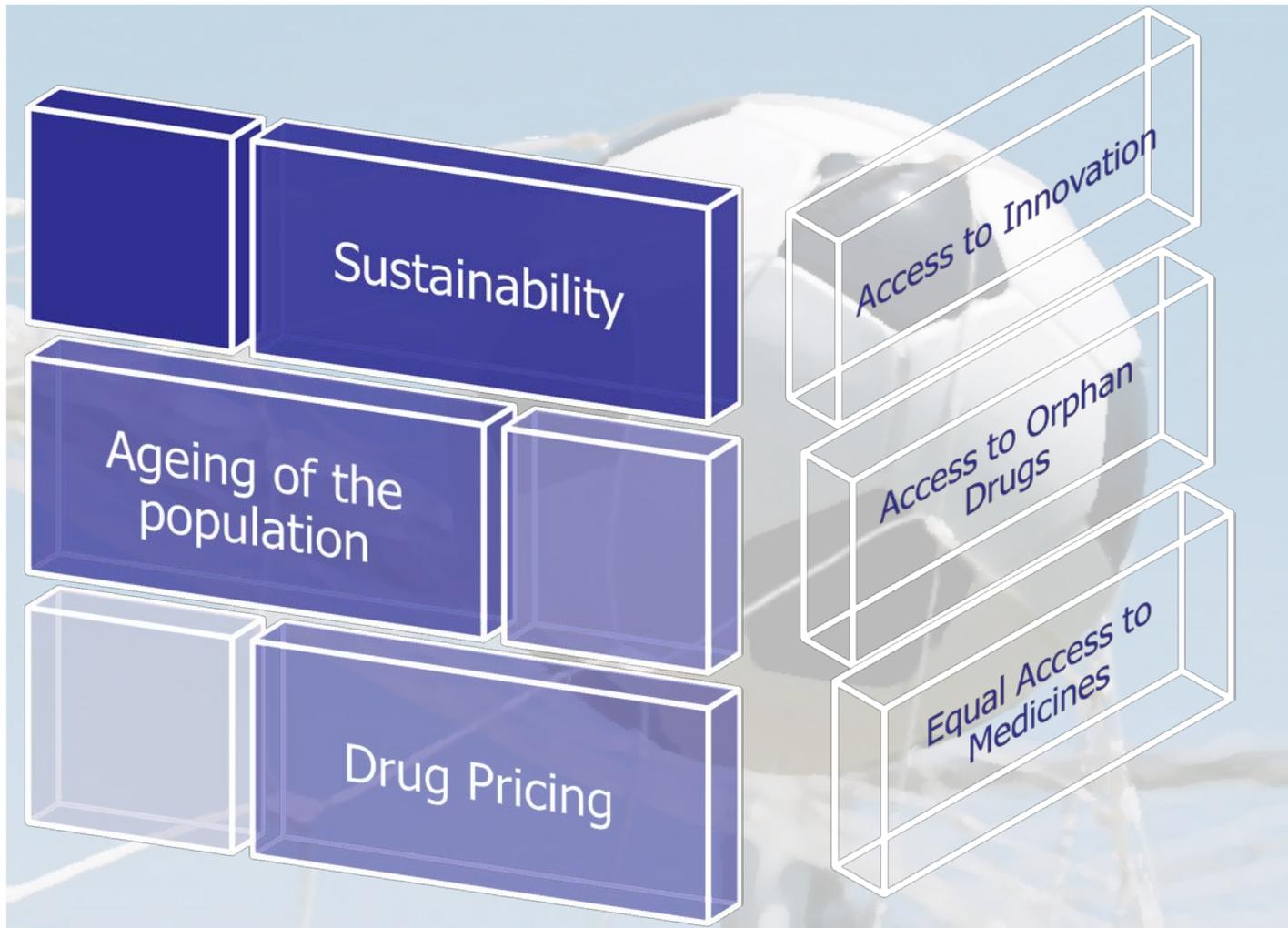


Public Declaration of transparency/interests*

Interests in pharmaceutical industry	NO	Currently	Last 2 years	More than 2 years but less than 5 years ago	More than 5 years ago (optional)
Direct interests:					
Employment with a company	X				
Consultancy for a company	X				
Strategic advisory role for a company	X				
Financial interests	X				
Ownership of a patent	X				
Indirect interests:					
Principal investigator	X				
Investigator	X				
Individual's Institution/Organisation receives a grant or other funding	X				
CME Courses				X	

***Luca Pani**, in accordance with the Conflict of Interest Regulations approved by AIFA Board of Directors (26.01.2012) and published in the Italian Government Official Journal on 20.03.2012 according to 0044 EMA/513078/2010 on the handling of the conflicts of interest for scientific committee members and experts

Some of the current challenges:



Innovation: a matter of size, structure, complexity, singularity and price?

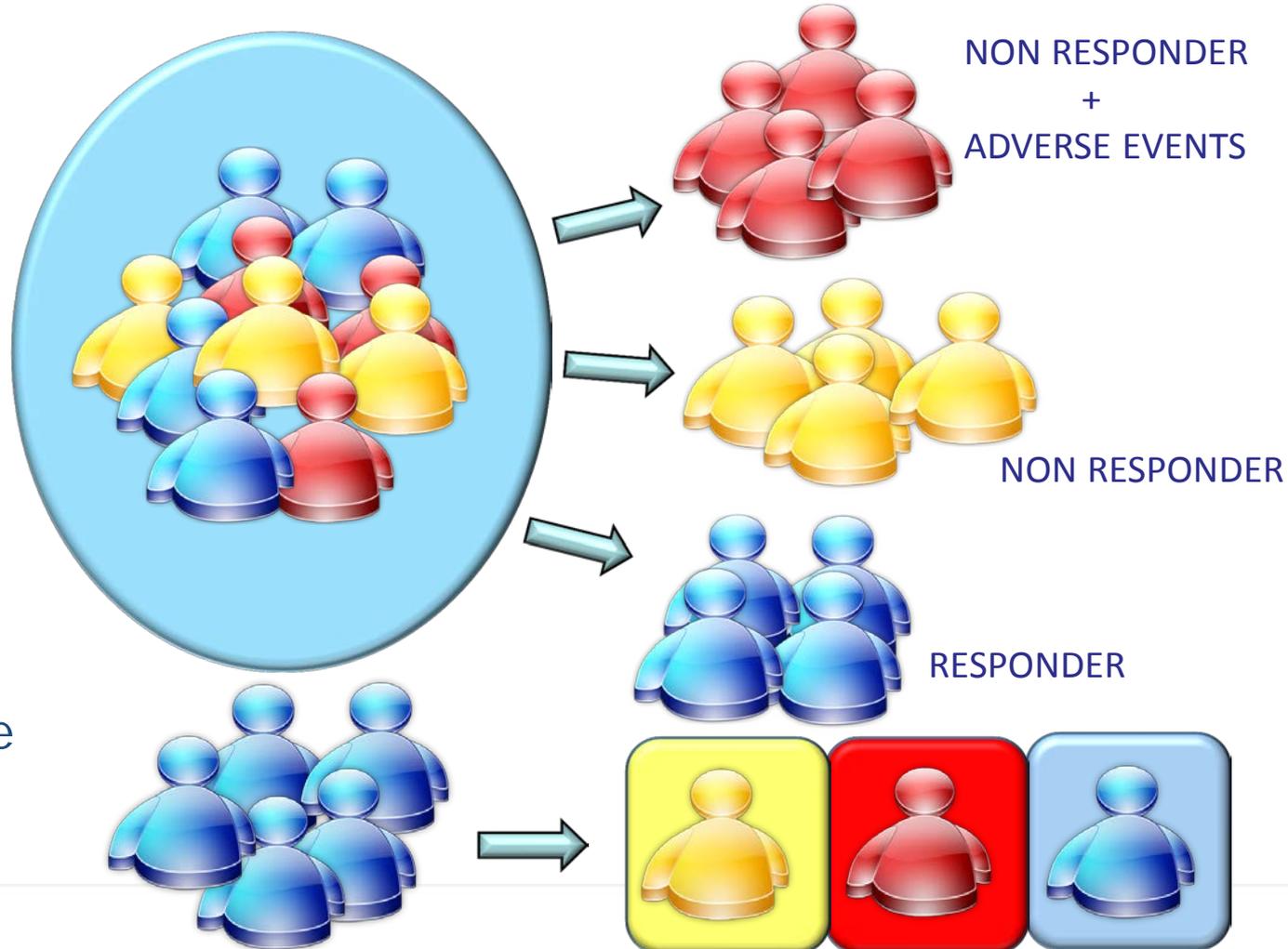
FROM

«Salami-slicing»

Stratification

1 Disease

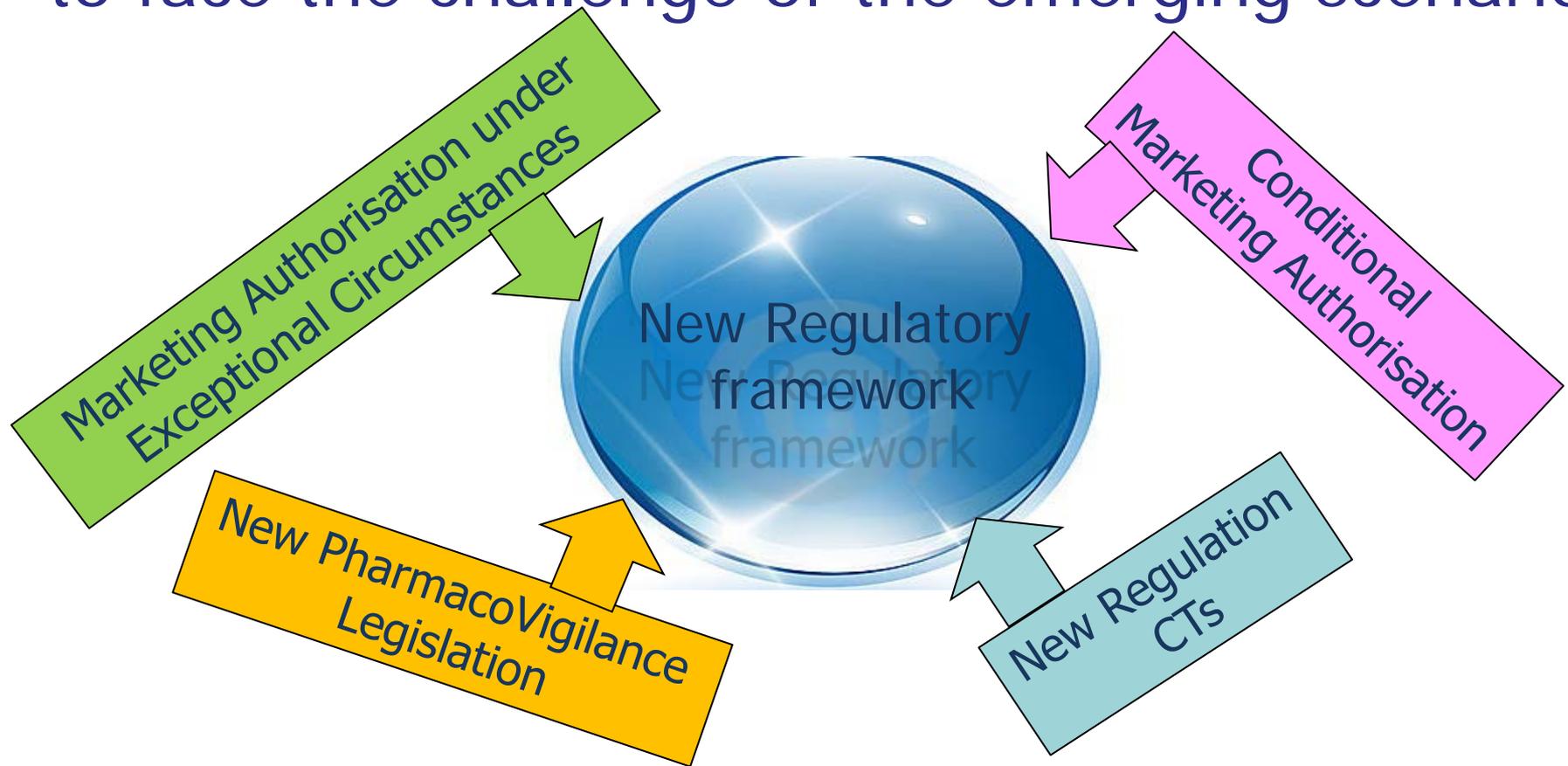
1/plus Treatment(s)



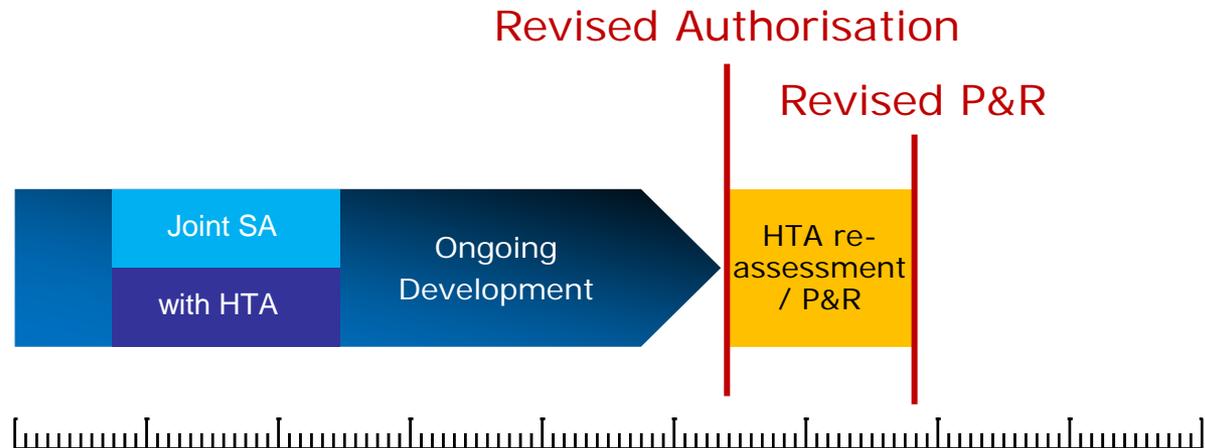
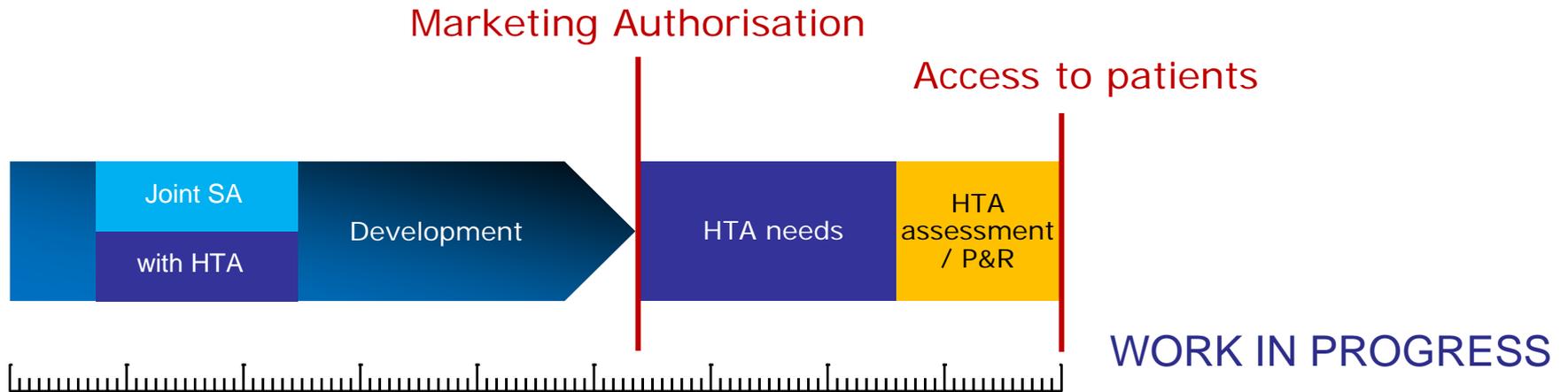
TO

Precision medicine

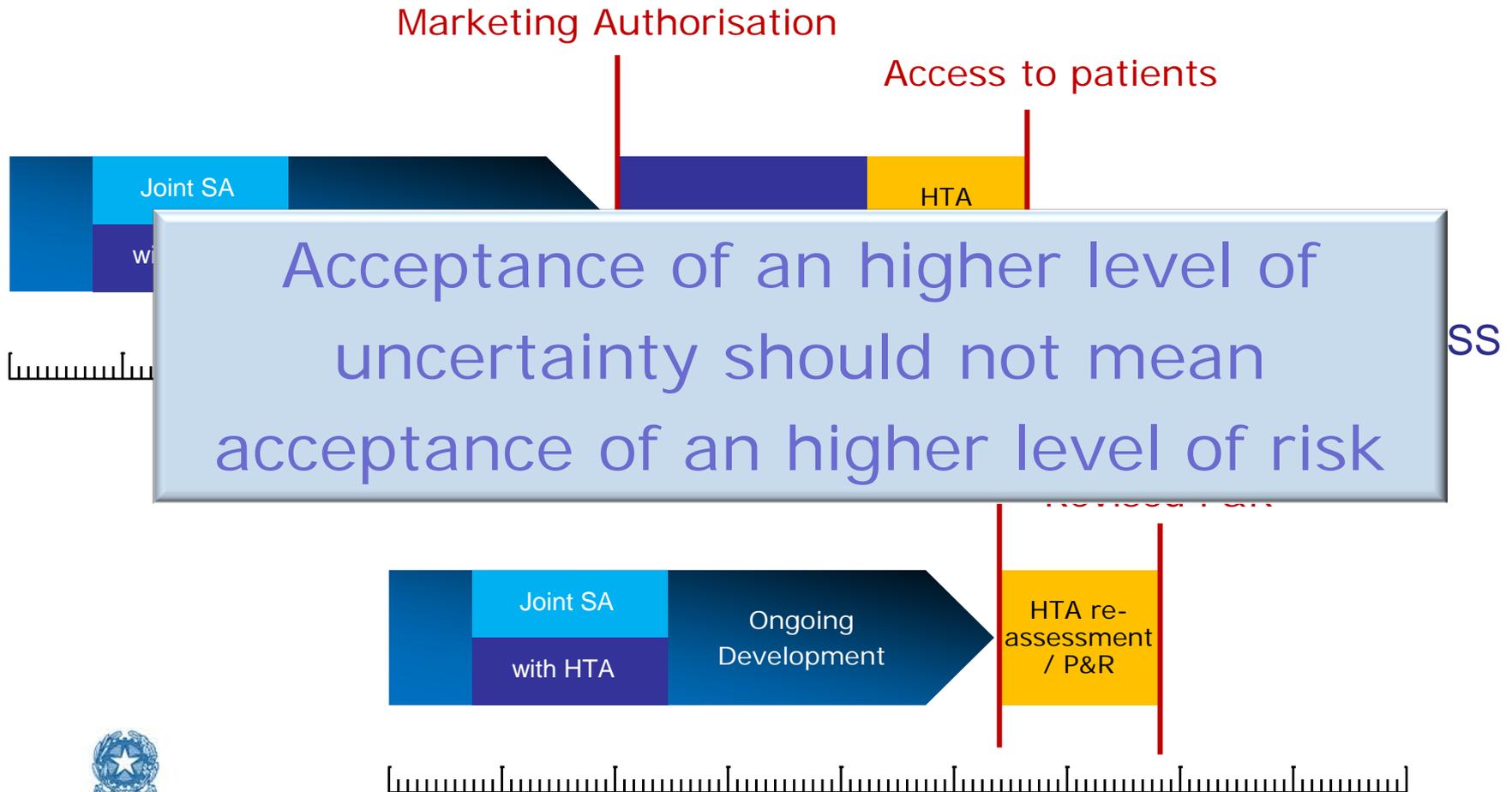
The Regulatory tools available to face the challenge of the emerging scenario



Progressive Patient Access Scheme Scenario



Progressive Patient Access Scheme Scenario



A life cycle approach for regulatory, HTA and payer purposes



The Italian Strategy

**Clinical
development**

**Market
entry**

**Real world
effectiveness
and safety**

**Further
regulatory/
policy
actions**

Early
dialogue/scientific
advice

Conditional
Reimbursement
(MEAs)

Monitoring
Registries

Re-assessment



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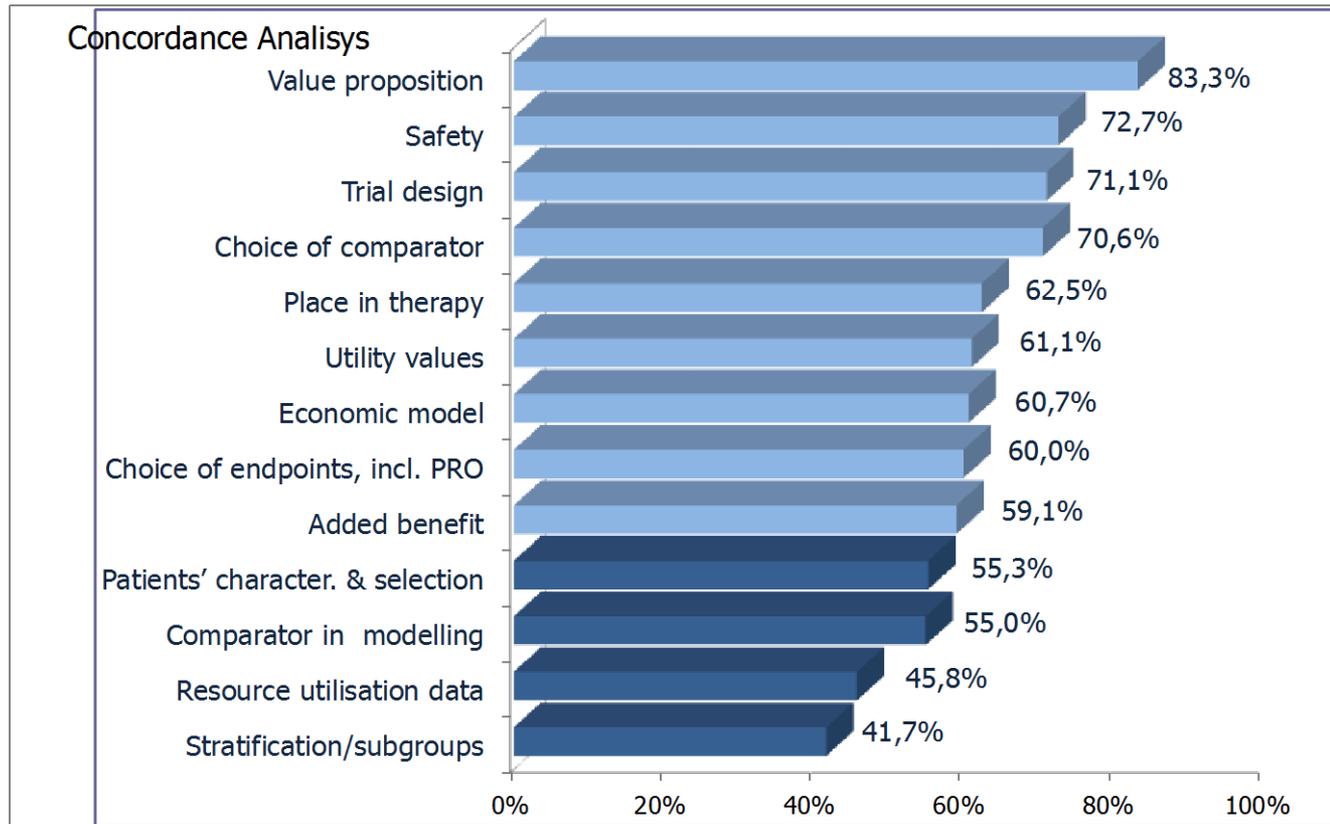
HTA Scientific Advice procedures: the Italian Experience

- National HTA Scientific Advice or National Joint Scientific Advice (Regulatory + HTA)
- Joint Parallel EMA/HTA Scientific Advice
- EUnetHTA Early Dialogues

From 2011 to 2013, a total of 21 HTA-SAs were performed



HTA Scientific Advice procedures



The analysis showed a lower concordance between AIFA and manufacturers for issues related to target population, stratification/subgroups, choice of comparator(s) in modeling and resource utilization data collection

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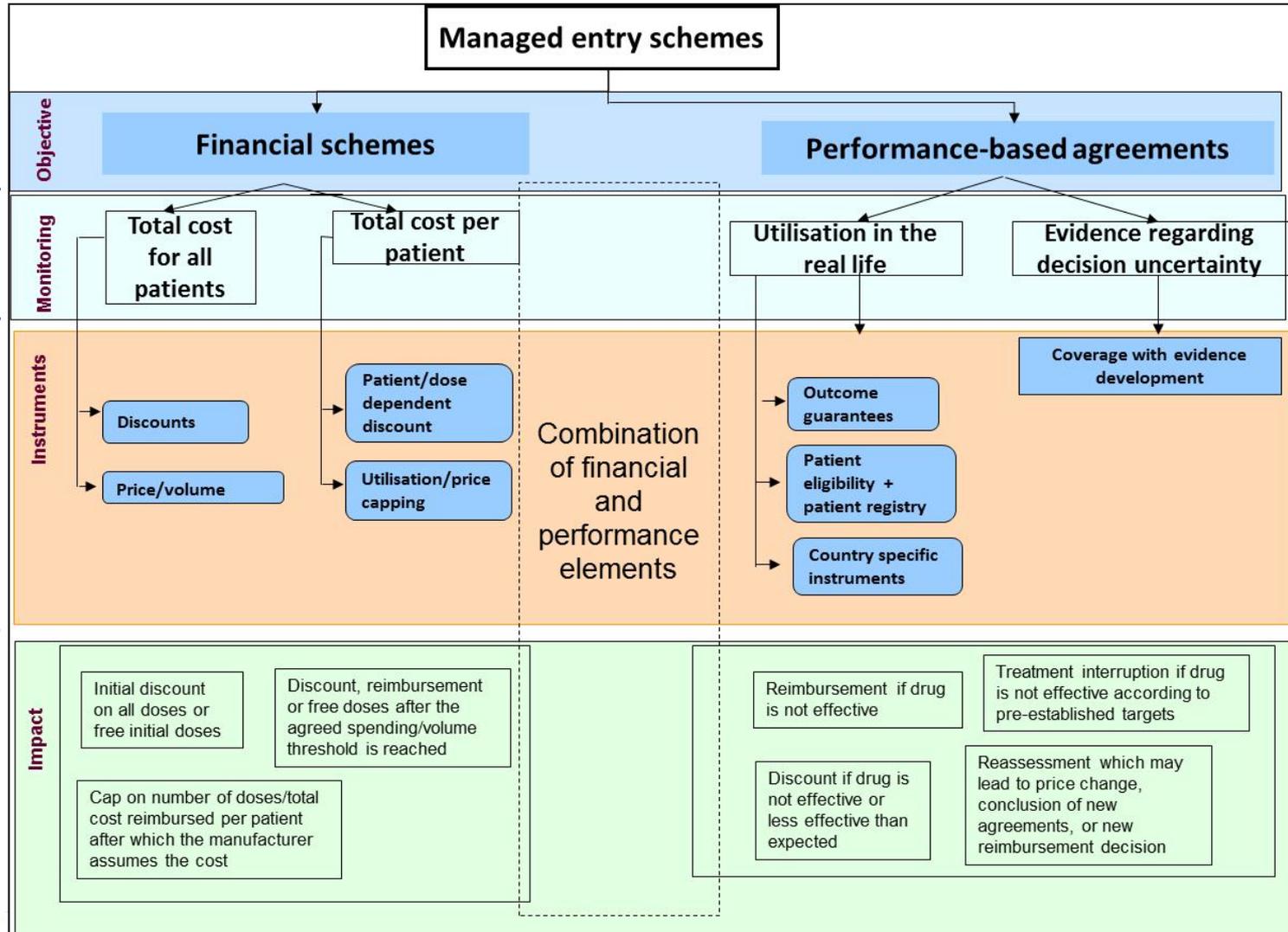
Re-assessment



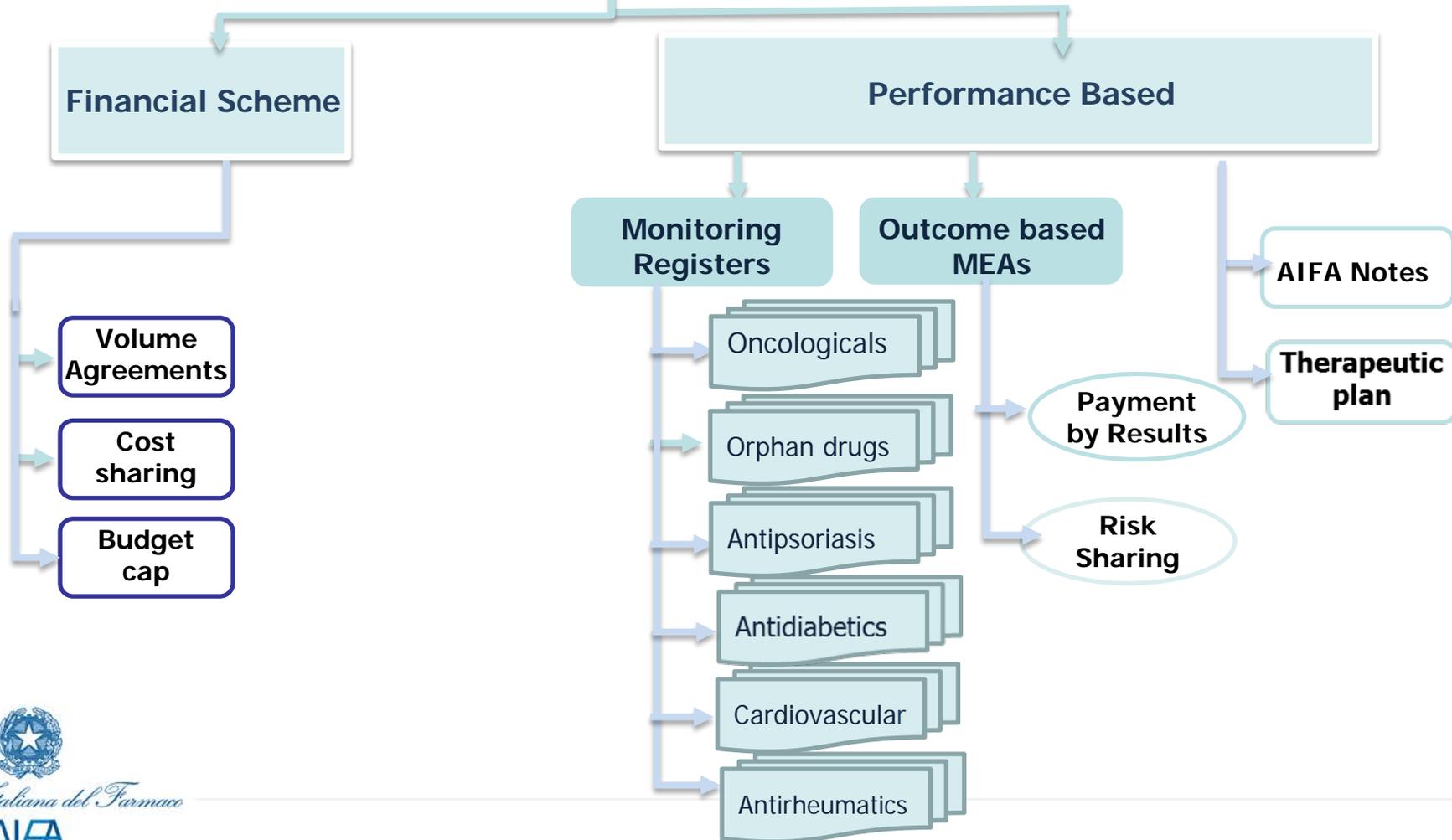
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MEAs Taxonomy



Managed Entry Agreements: the Italian Experience



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AIFA Monitoring Registries

For each therapeutic indication, patients eligible for treatment are registered in specific dynamic **Monitoring Databases (Registries)** in order to:

- Evaluate the utilisation in clinical practice (effectiveness)
- Collect epidemiologic data
- Get information on the safety profile
- To collect ex-post evaluation about missing knowledge

AIFA Monitoring Registries track the eligibility of patients and the complete flow of treatments. This tool guarantees appropriateness use of medicines according to their approved indications.

Data collected through Registries are owned by AIFA.
Maintenance costs are covered by pharmaceutical companies



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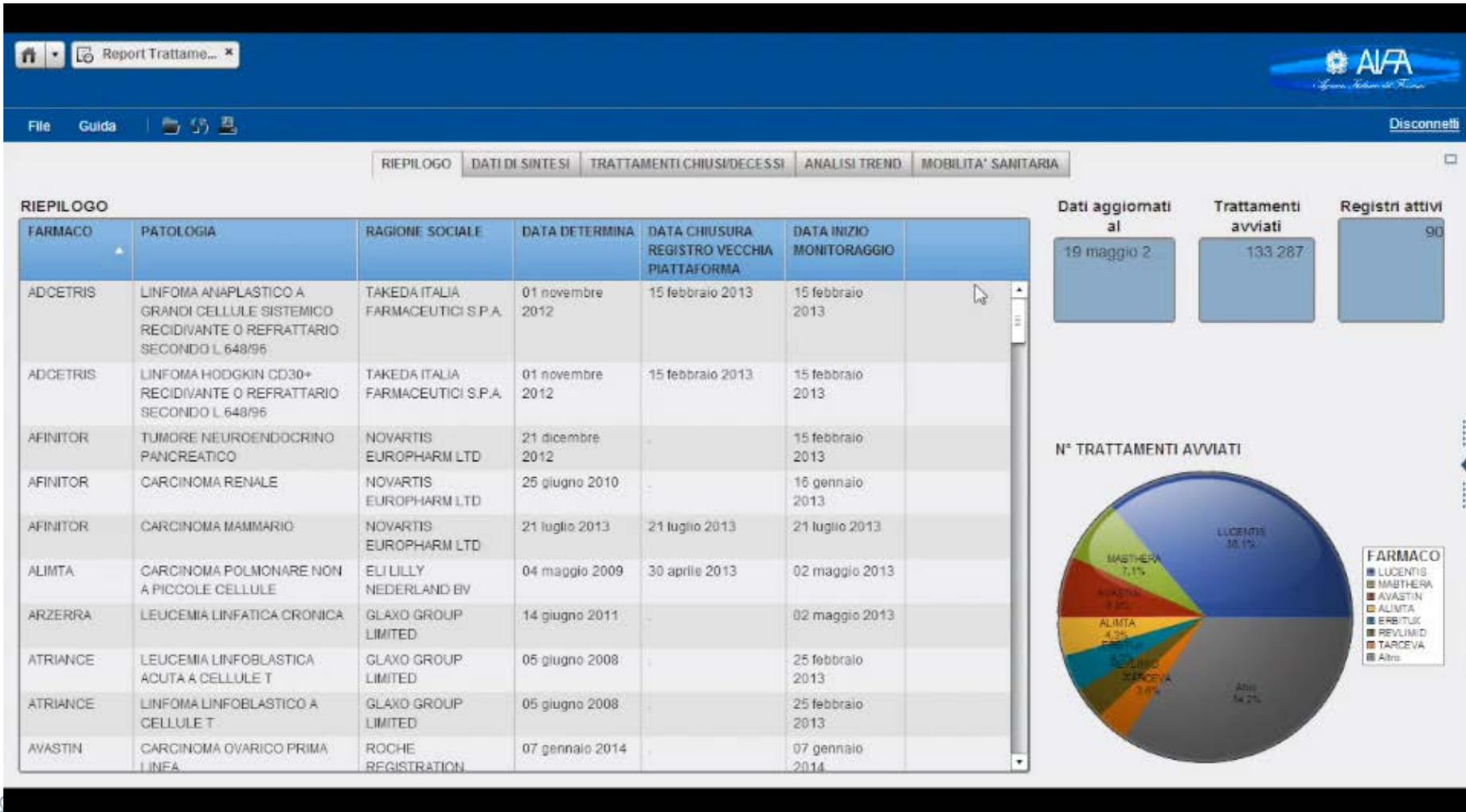
More than 300,000 unique individual treatments are on record as of today

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The evolution of AIFA Monitoring Registries



Pros & Cons of Regulatory Registries

- Pros:

- Negotiation and access to reimbursement for every single indication
- Savings on pharmaceutical expenditure for non-responding patients
- Early access to new therapies
- Data collection on real clinical practice
- Cost-efficacy optimization for each indication until clinical practice provides evidence about the best place in therapy

- Cons:

- Increasing administrative workload for healthcare professionals



The evolution of Monitoring Registries

They should be intended as common evidence Generators in real life treatments, to represent an opportunity and a starting point for a new type of cooperation between Patients, HCPs, Academia, Regulators, HTAs, Payers and Industry in order to achieve synergy, strategy and consistency



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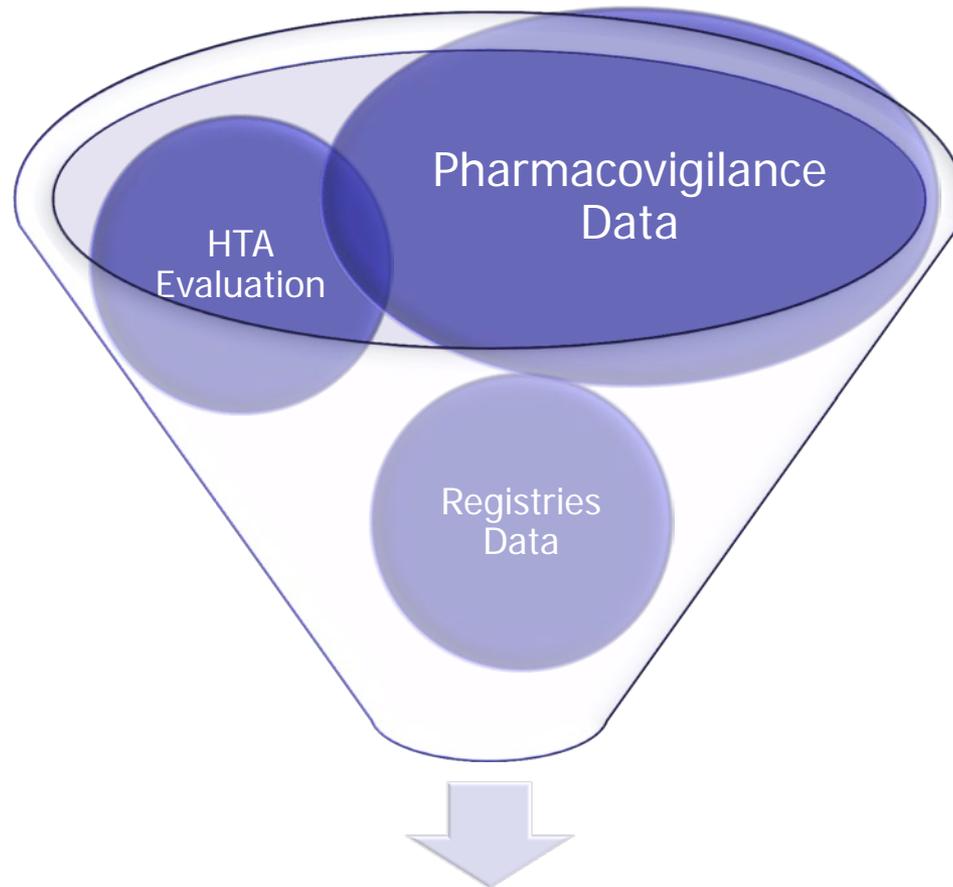
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Reassessment and sharing of information

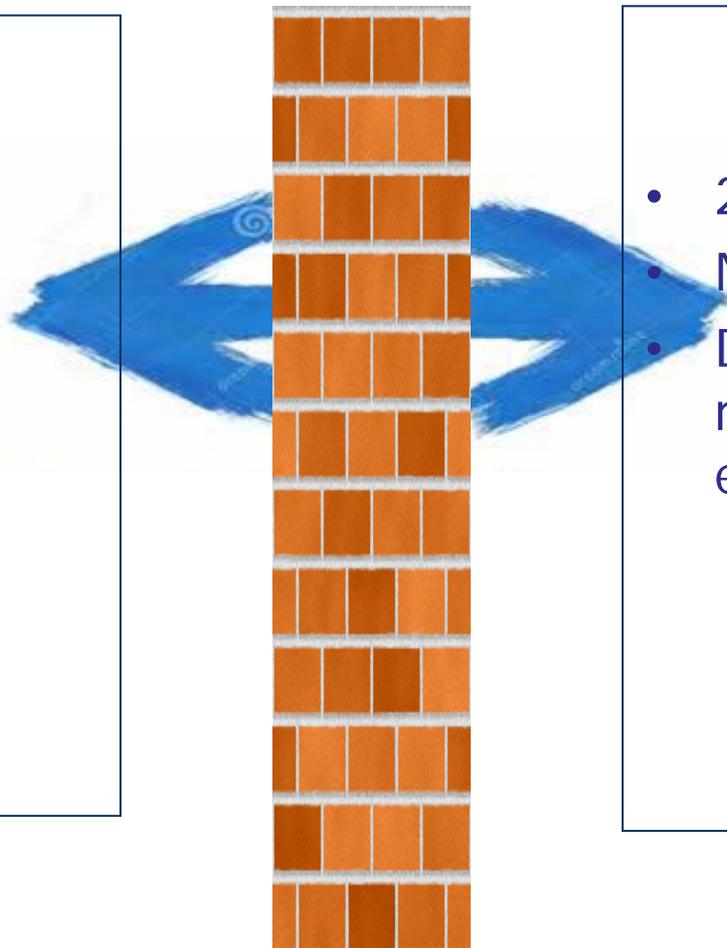
Can we take down the wall between:

Regulators

- 1 Centralized Procedures
- 1 EU Legislation
- Well defined assessment methodology

Payers

- 28 different systems
- National competency
- Different methodologies and elements of evaluation



Can we take down the wall between:

Regulators

- 1 Centralized Procedures
- 1 EMEA Regulation
- Defined assessment methodology

Towards a global coalition

Payers

- 28 different systems
- National
- Different technologies and methods of evaluation

New synergy and cooperation



The case of the new Hepatitis C treatment drugs:

- ❑ New treatments will be able to eradicate HCV infection
- ❑ Clear added therapeutic benefit versus Standard of Care
- ❑ Demonstrated cost-effectiveness in almost all subpopulation

but...

- ❑ High (?) prevalence of HCC in several European countries
- ❑ High price proposal
- ❑ Un-sustainability of expenditure by public healthcare systems



“Informal meeting on evaluation and pricing of new hepatitis C medicines”

Brussels, September the 17th 2014

- Objective: share information regarding **evaluation** and **pricing negotiations** of new hepatitis C medicines

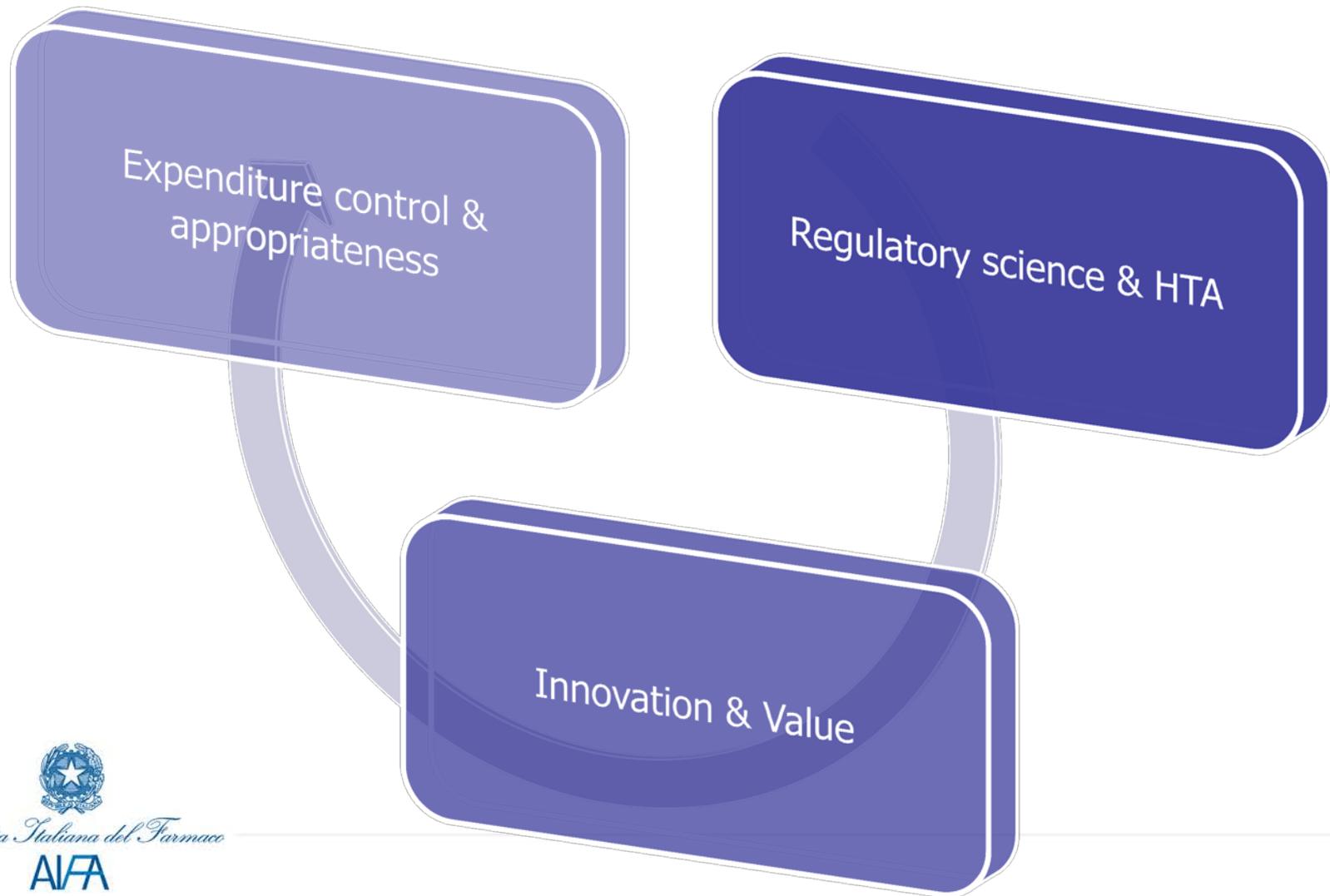
→ 26 MS represented + European Commission



%

- Evaluation achieved in most MS
 - According to national HTAs, majority of MS chose to **prioritize** certain indications or patients subgroups
- Pricing negotiation:
 - Ongoing in most MS
 - Some MS legislation prohibit information sharing
 - Shared view: **major unprecedented impact on health expenditures**
- Reflexion on a common approach:
 - Proposition: Ministers to evaluate about the relevance of a common letter to manufacturer(s)
 - Follow-up technical reflection among MS on financing of expensive disruptive drugs.

Are we ready for EU integrated pathways?



Thank you!



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