Managed Entry Agreements as a Way to Implement Outcomes of Assessment and Enable Patient Access to Innovation

Paolo D. Siviero

Head of the Office for Pharmaceutical Policy Organisation

Italian Medicines Agency

Agenzia Italiana del Farmaco

AIFA

24th Annual EuroMeeting

26-28 March 2012

Copenhagen, Denmark

DIA®

www.diahome.org

Disclaimer

The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to Drug Information Association, Inc. ("DIA"), its directors, officers, employees, volunteers, members, chapters, councils, Special Interest Area Communities or affiliates, or any organization with which the presenter is employed or affiliated.

Public Declaration of Interests*

The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to AIFA or any of its committees, working parties or expert groups.

I'M NOT RECEIVING ANY COMPENSATION AND/OR REIMBURSEMENT FOR THIS SPEECH

Activity for a company related to a single product/group of products	NO	Current or last year	More than one year but less than 5 years ago	More than 5 years ago
Employment	X			
Consultancy	X			
Principal Investigator	X			
Member of a steering committee or advisory board, or similar body	X			
Investigator (not principal) for a medicinal product development	X			
Financial interests in a pharmaceutical company	X			
I own a drug patent	X			
I work for an organisation that receives grants or other funding from a pharmaceutical company (I do not receive personal gain)	X			

Agenzia Italiana del Farmaco
AIFA

*Paolo Siviero, DOI 2012 in accordance with Conflict of Interest Regulations approved by AIFA Board of Directors (26.01.2012) and 0044 EMA/513078/2010 on the handling of the conflicts of interest for the members of scientific committees and experts

How to guarantee patient's access to new treatments?

How to cope with uncertainty when deciding on pricing and reimbursement?

How to guarantee the overall budget sustainability?

Balancing innovation and outcomes

To ensure

- Rapid access to new potentially beneficial health technologies
- Obtain best value for money
- Ensure affordability

healthcare payers are adopting a range of innovative reimbursement approaches called Managed Entry Agreements*.

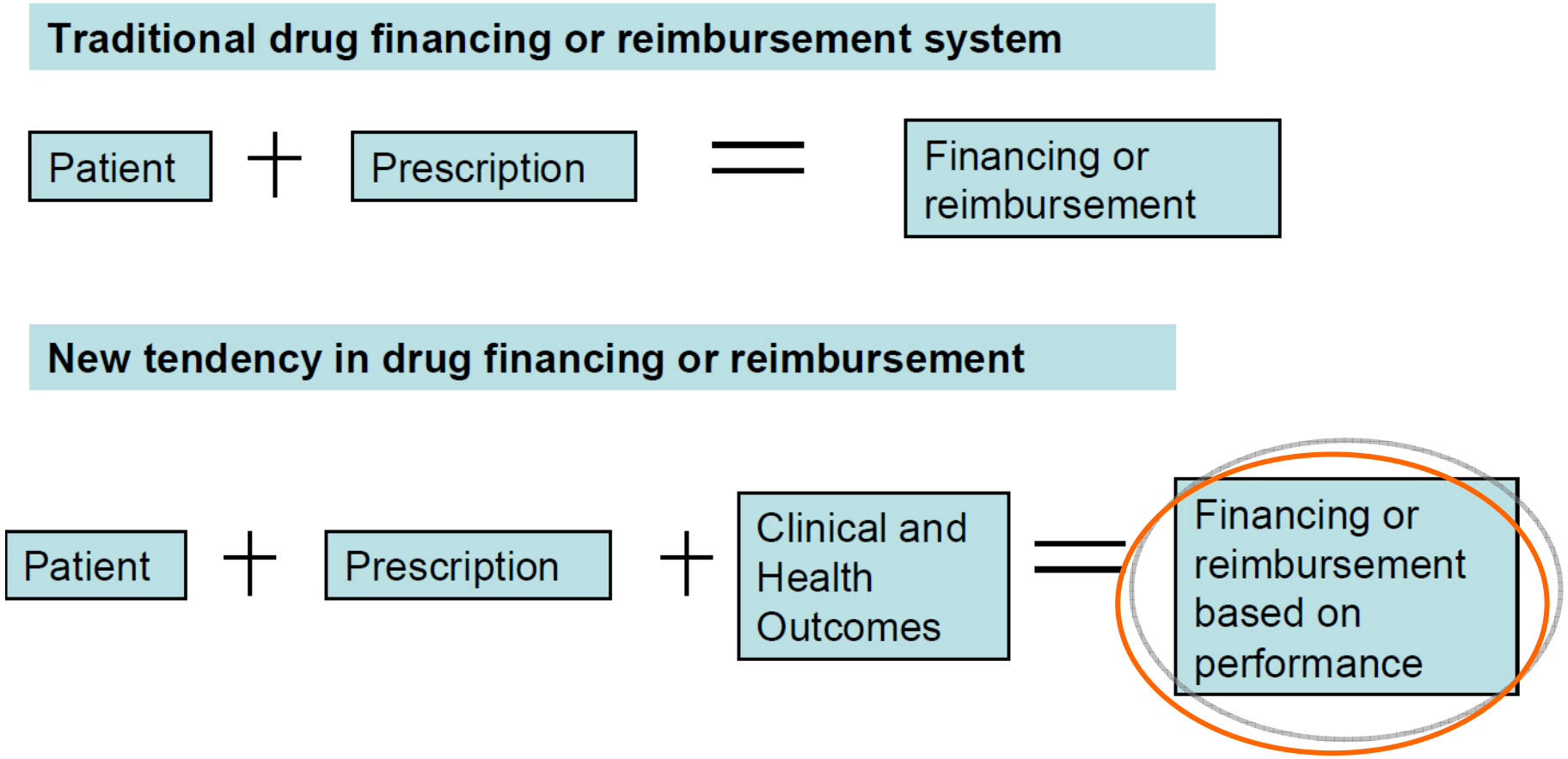
Some of these agreements link coverage of medical products to:

- The collection of additional evidence
- And/or to measures of health outcomes in the "real world" that is, outside the context of highly controlled clinical trials.

Avoiding exclusion from reimbursement of medicines which could be of some help to some patients

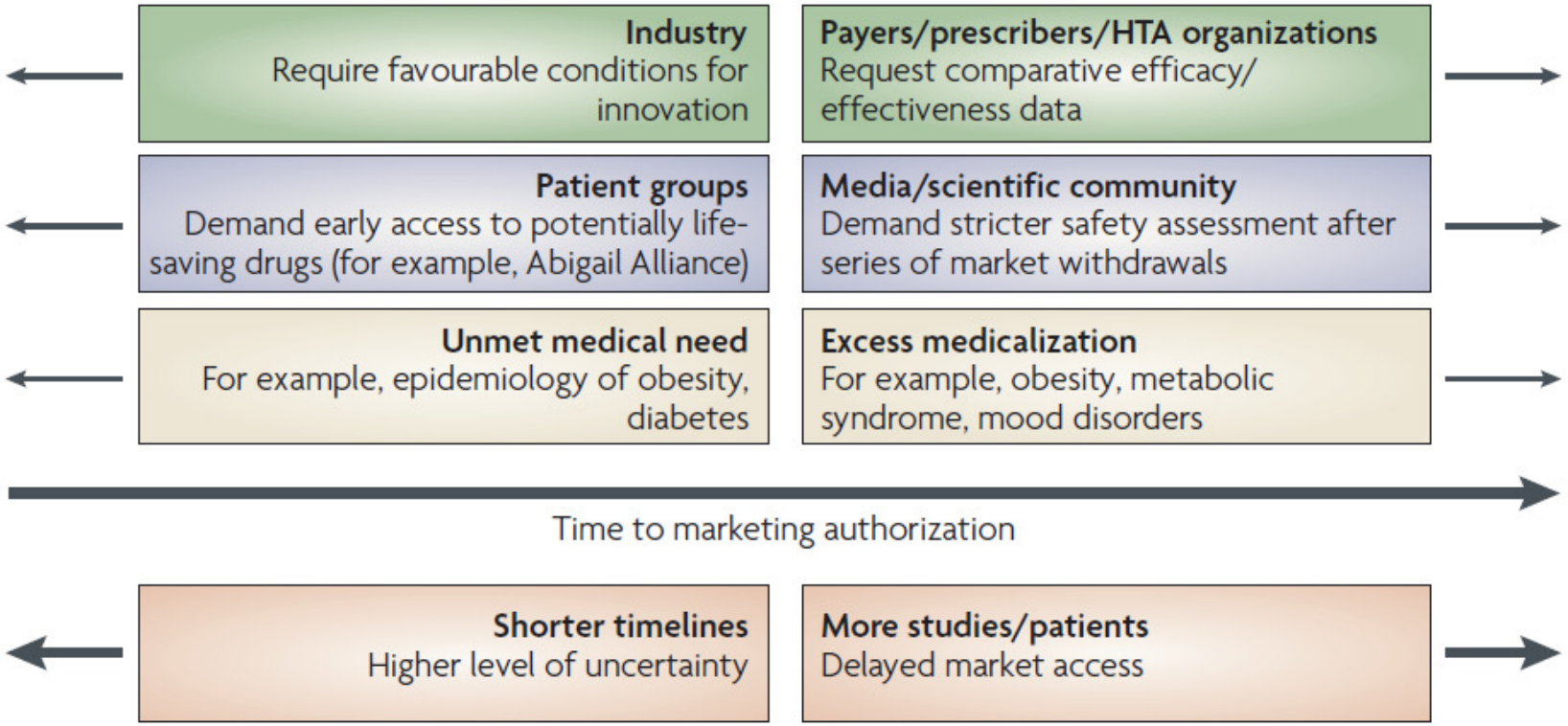
Avoiding unnecessary expenses to NHS helping to optimise allocation of expenditure and system sustainability

Figure 1: Change in drug financing or reimbursement systems



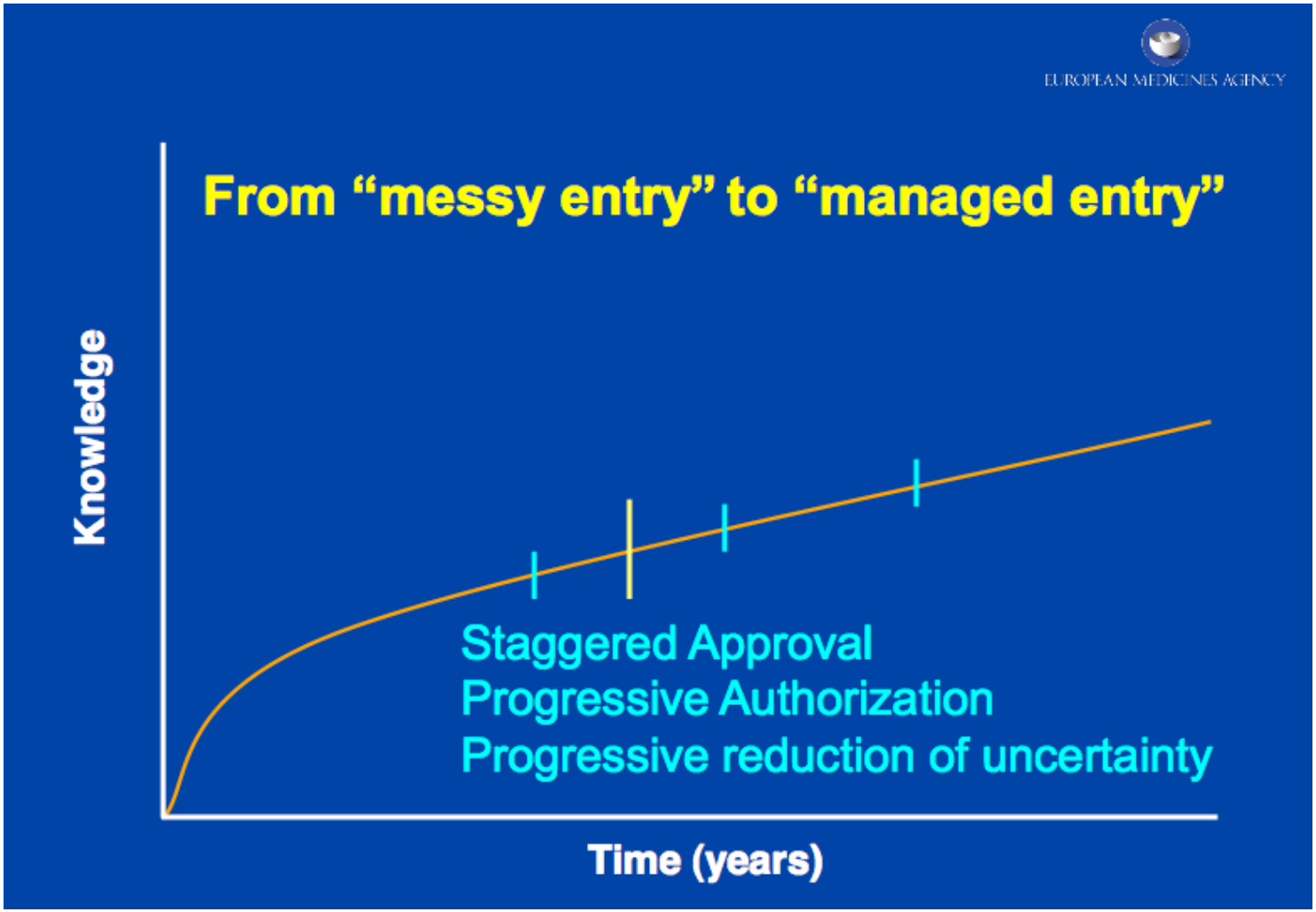
Fonte: Eminet 2009. Risk Sharing Schemes for Pharmaceuticals: Terminology, Classification and Experiences.

Balancing early market access to new drugs with the need for benefit/risk data



Eichler H. et al. Balancing early market access to new drugs with the need for benefit/risk data. Nat Rev Drug Discov. 2008; 7(10):818-26

Gap between efficacy and effectiveness



Hans Georg Eichler

Managed Entry Agreements

MANAGING BUDGET IMPACT

Management of the process of adoption to address concerns about budget impact (*e.g. capping total budget impact, discounting*).

MANAGING UNCERTAINTY RELATING TO CLINICAL AND/OR COST EFFECTIVENESS

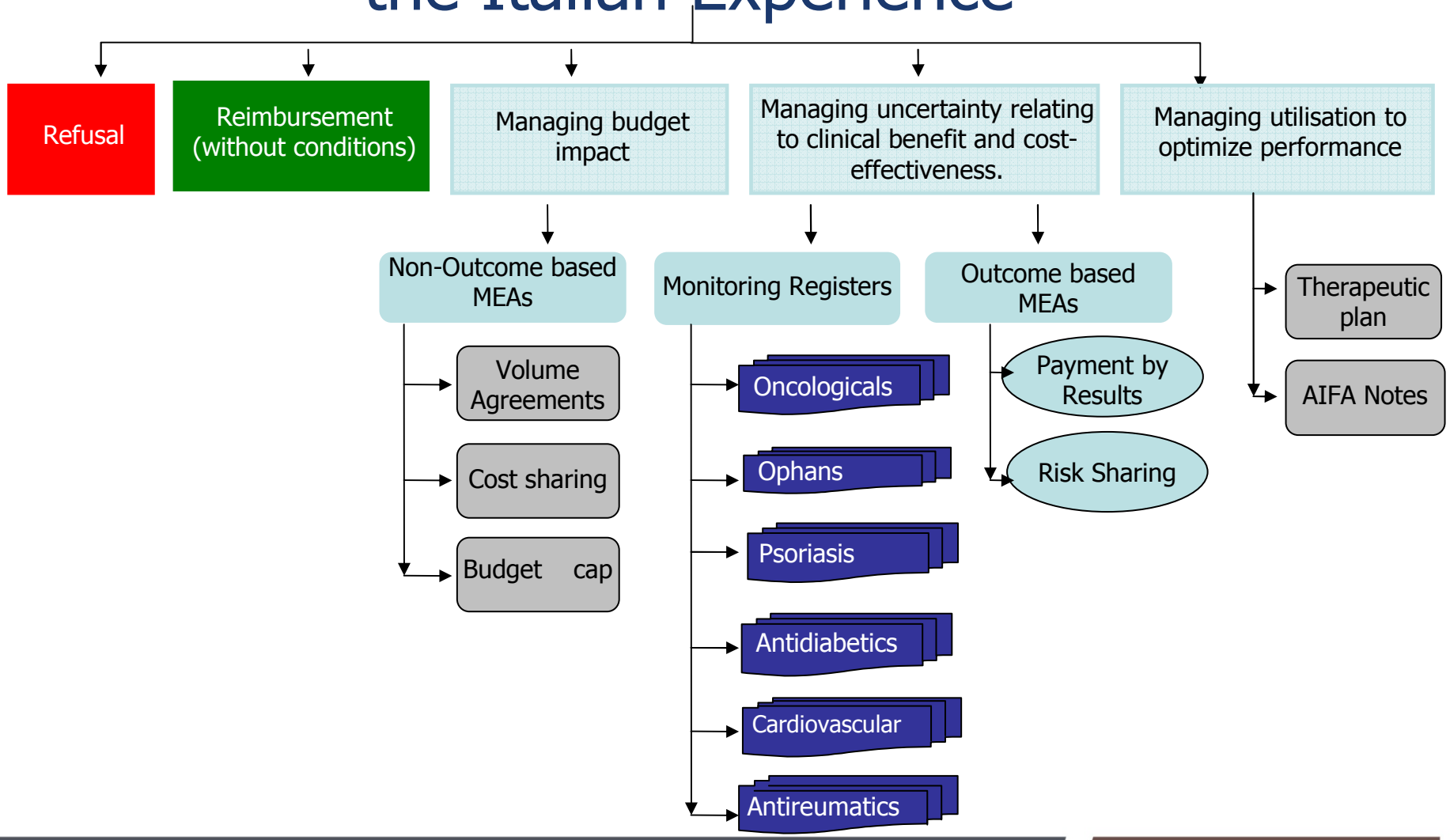
Management of uncertainty relating to the clinical and cost-effectiveness in the long term, in a real world-clinical setting (*e.g. through Coverage with Evidence Development*).

MANAGING UTILIZATION TO OPTIMIZE PERFORMANCE

Management of delivery systems to plan technology diffusion to targeted patients/ or by means of particular delivery mechanism.

* According to the *HTAi Forum Policy*

A range of approaches to Managed Entry: the Italian Experience



Volume based agreement

The Italian Medicines Agency negotiates a volume of sales, related to a target population, with the manufacturer. The volume of sales, exceeding the pre-set threshold, will have to be paid back by the manufacturer to the National Health Service.

AIFA Restricting Notes for prescription

Through this tool, called "AIFA Notes", the authorised therapeutic indication of a medicinal product is not fully reimbursed. In fact, the Italian Medicines Agency restricts the NHS reimbursability to the treatment of specific patient populations. This MEA is aimed at increasing the appropriateness of the use of medicines. The AIFA Note is reported by the general practitioner on the prescription form and this will allow the patient to get the medicinal product free of charge.

Therapeutic Plans

The therapeutic plan is a form in which the diagnosis and the treatment must be reported exclusively by specialised health care centres identified at regional level. This tool guarantees the reimbursement of certain medicines for the authorised therapeutic indications only under close monitoring of the specialists. Based on this document, the general practitioner will prescribe the medicine that will be delivered by the pharmacist to the patient free of charge.

AIFA Monitoring Registries

Patients eligible for treatment with pharmaceuticals are registered in specific **Monitoring 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 of use of medicines according to their approved indications.

MONITORING REGISTRIES

Agenxia Italiana del Farmaco

Programmi generali:

- Farmaci antineoplastici
- Farmaci orfani
- Farmaci per la psoriasi
- Farmaci antidiabetici
- Farmaci cardiovascolari
- Farmaci oftalmici
- Farmaci antireumatici NEW

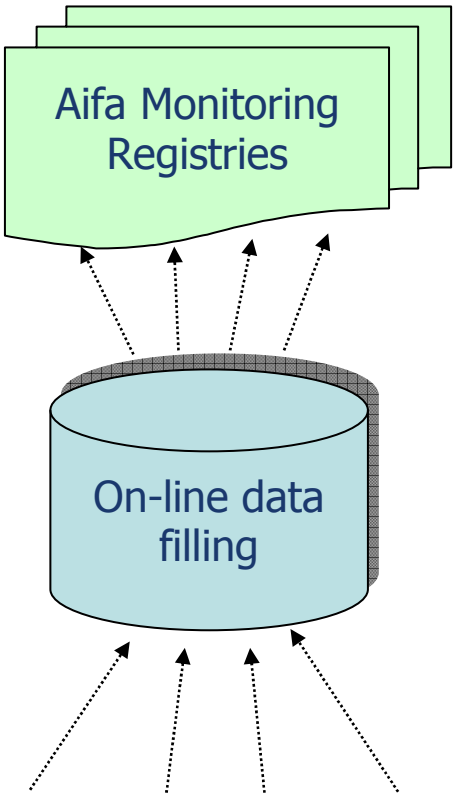
Progetti specifici:

- Toctino NEW
- Tysabri
- ADHD
- Xolair
- Xigris

- Oncology medicines
- Orphan drugs
- Psoriasis medicines
- Antidiabetic medicines
- Cardiovascular medicines
- Ophthalmic medicines
- Antirheumatic medicines

Aifa Monitoring Registries

Uncertainty or scarcity of evidence of the real use



Data collected by health professionals for eligible patients

Useful data on the effectiveness of medicines to support decisions for conditional reimbursement schemes.

Useful information on "real practice" and appropriateness.

- Hospitals
- Regions
- Local Health Units
- Pharmaceutical companies
- Other institutional bodies

* According to the *HTAi Policy Forum*

Models of conditional reimbursement

Three different ways to share responsibility and risk within pharmaceuticals companies and NHS (third payer)

1. Cost Sharing, discount on price of initial therapy cycle(s) for all eligible patients

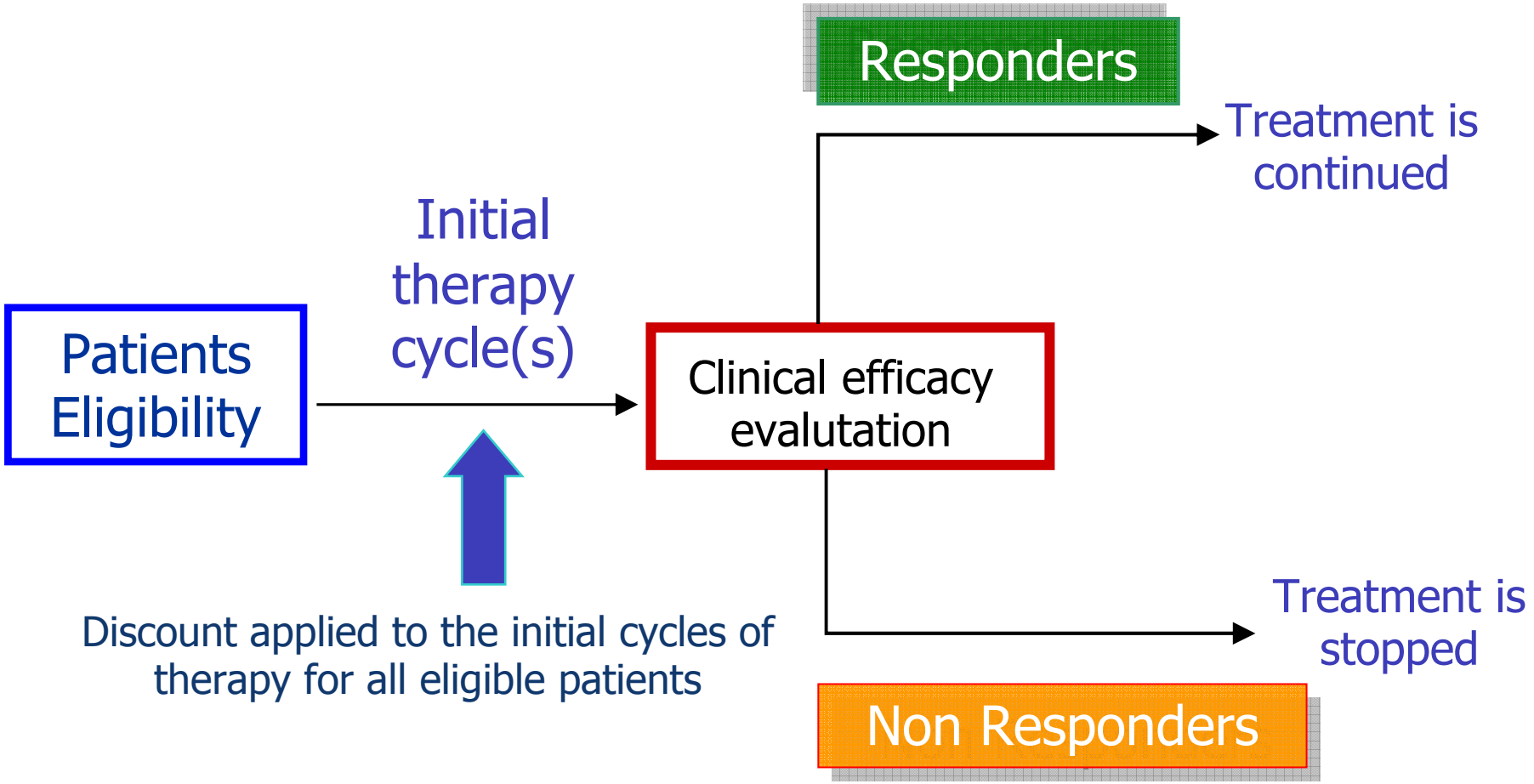
2. Risk Sharing, discount on price of initial therapy cycle(s) for non responder patients

3. Payment by Results, initial cycle(s) fully reimbursed by marketing authorization holder for non responder patients (fully reimbursed by NHS for responders

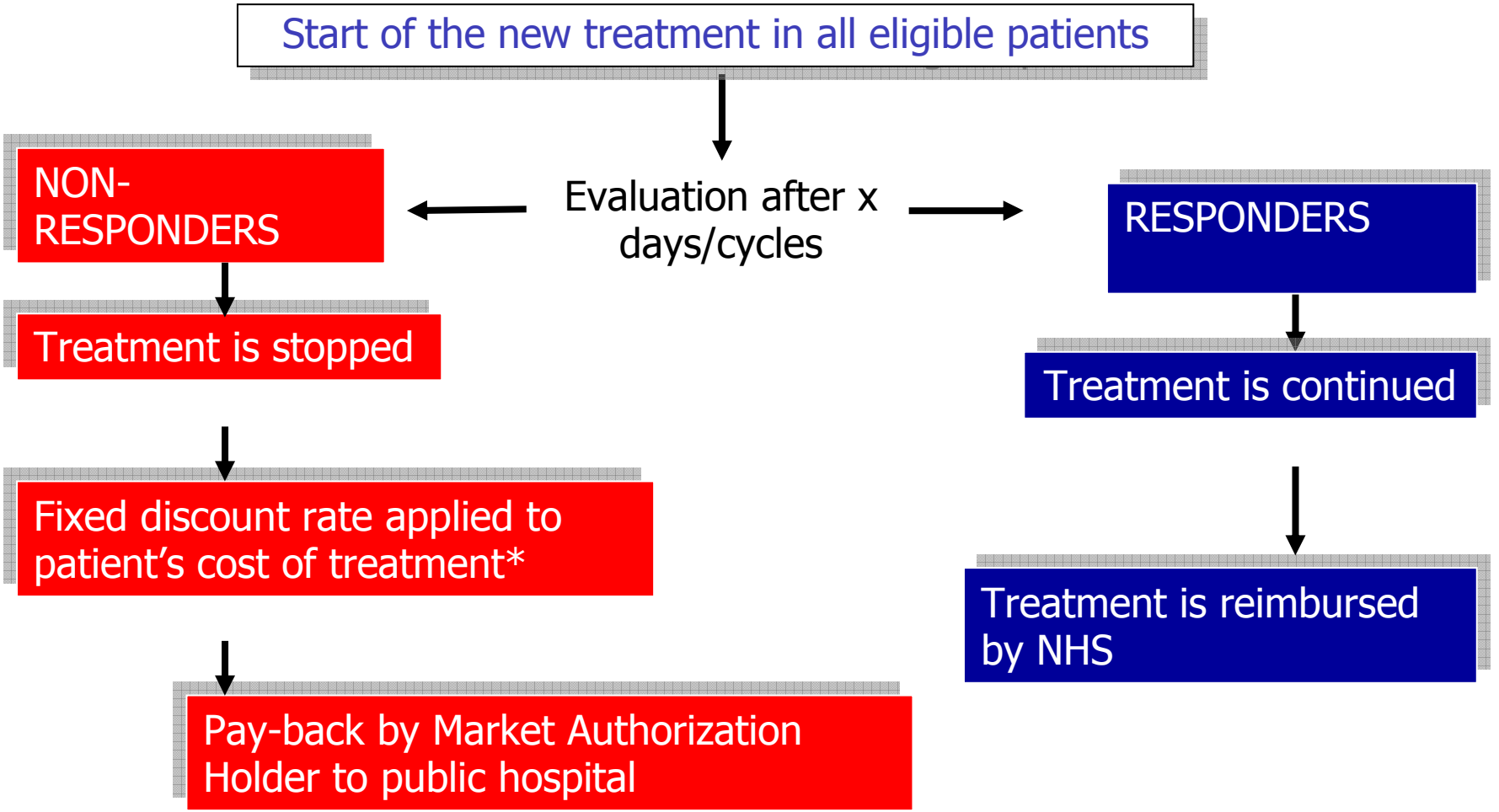
– Risk sharing and Payment by Results are performance based-agreements conditioned on clinical evaluation of specific endpoints, with limitations of cost if the effect is inappropriate.

The agreement is for a limited period of time, under specific conditions, waiting to be re-evaluated.

AIFA - Cost Sharing procedure

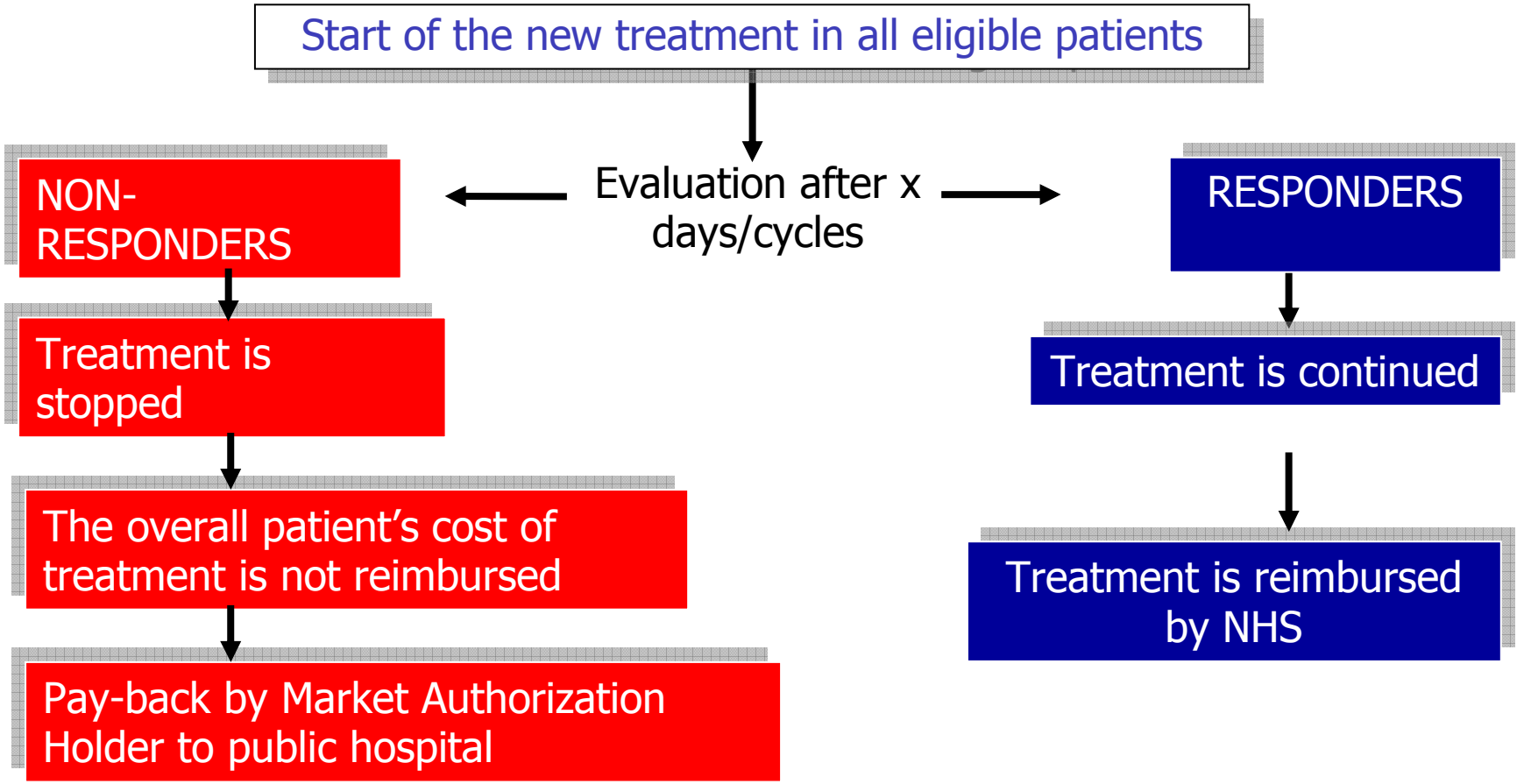


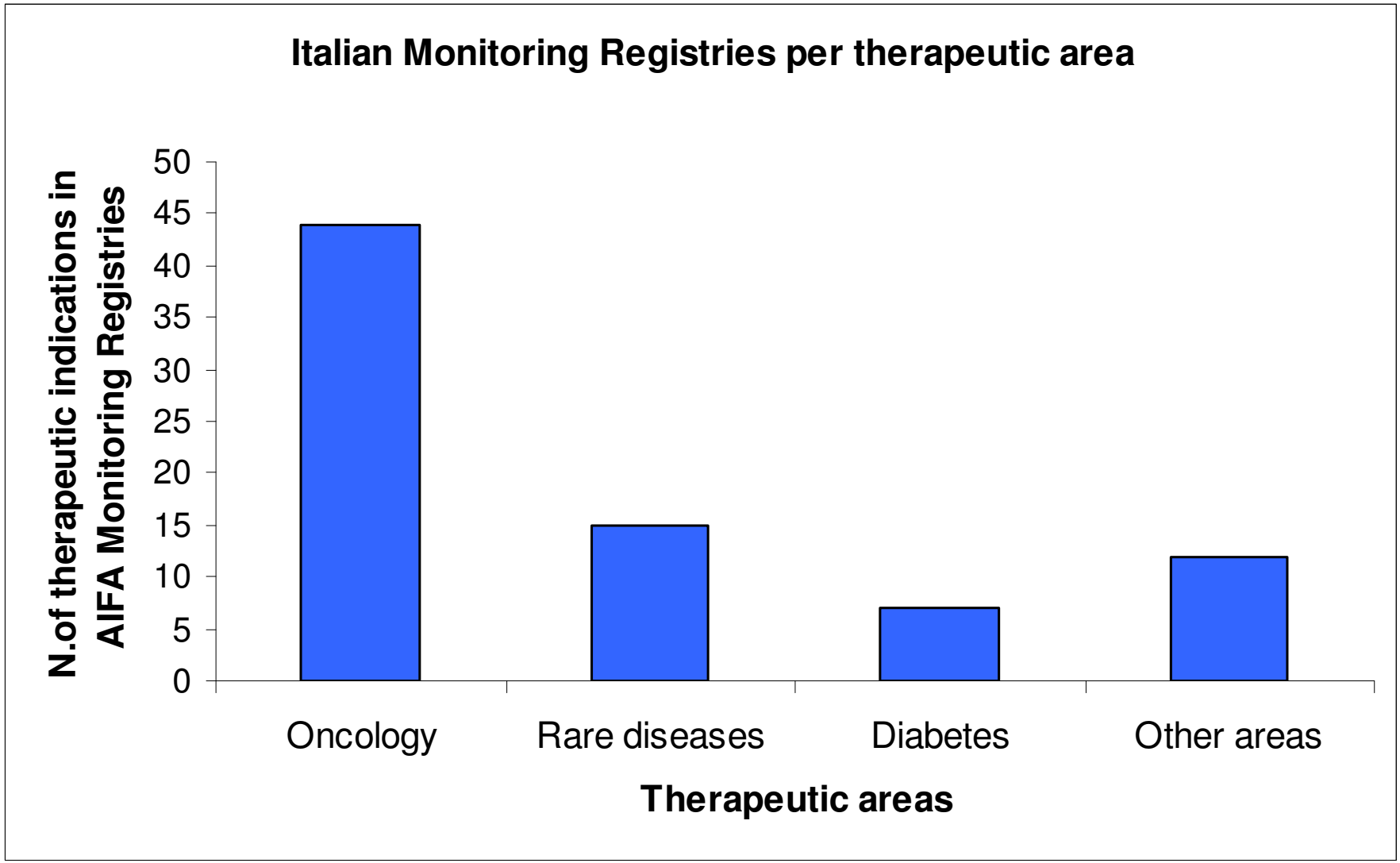
AIFA - Risk Sharing procedure



* predefined n. of initial packages

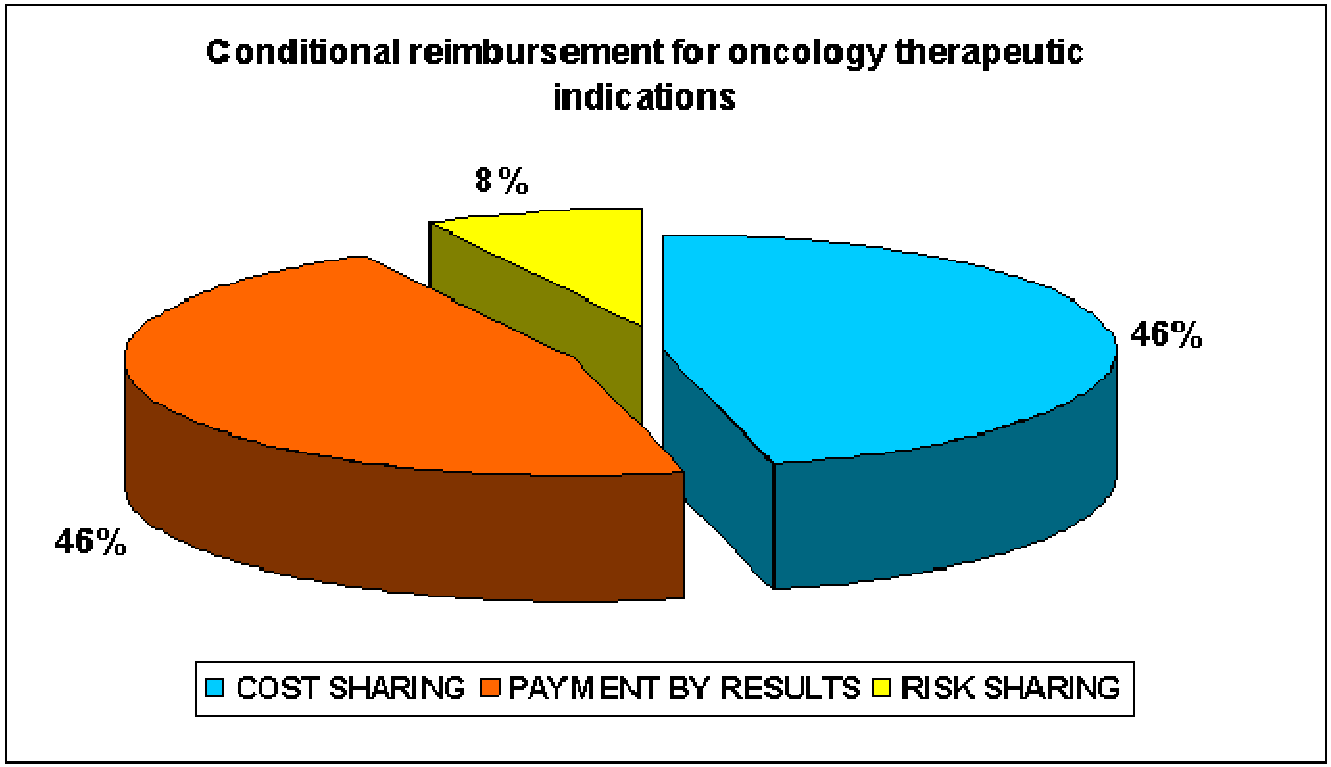
AIFA - Payment by Results procedure



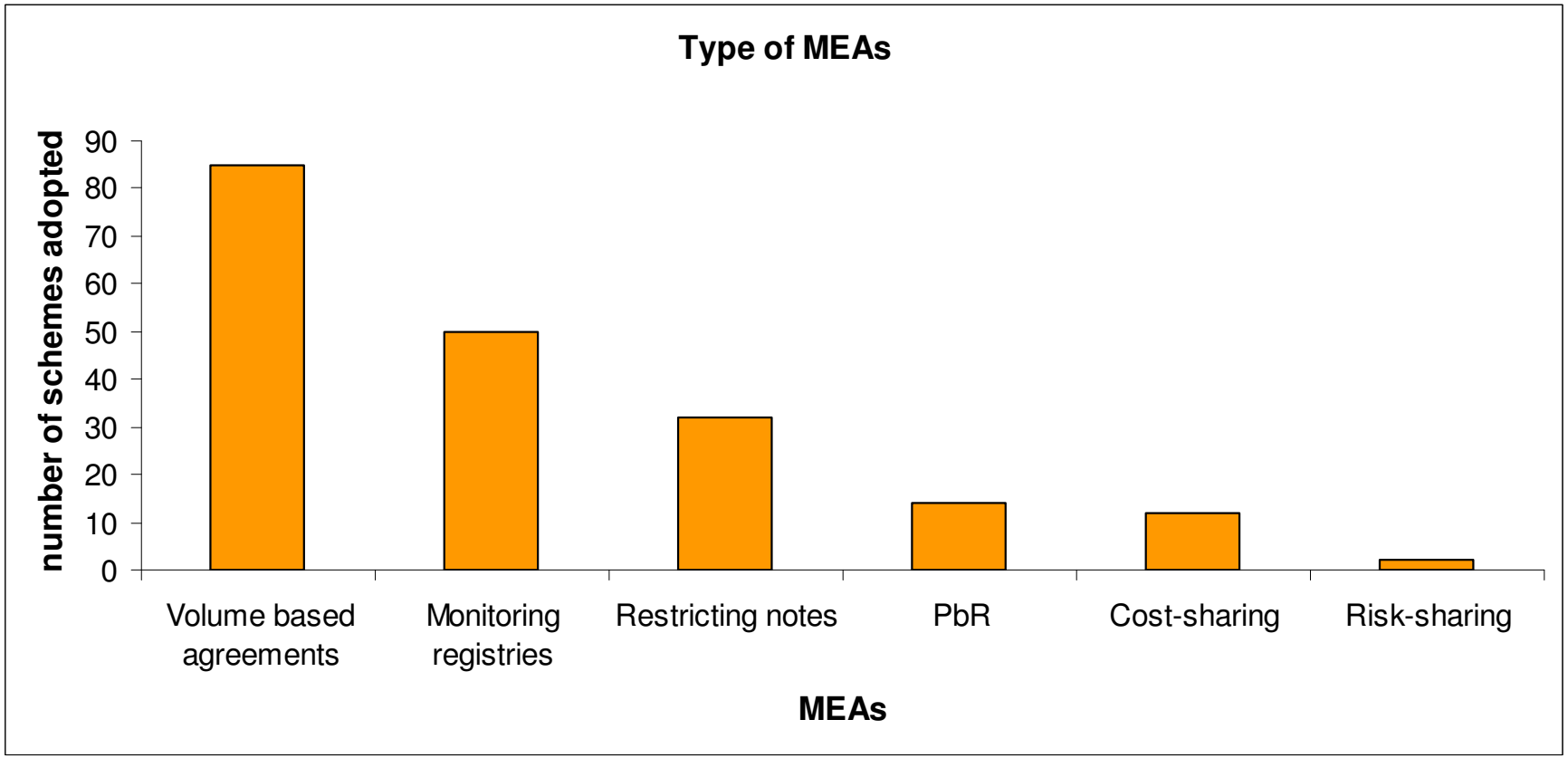

Italian Monitoring Registries per therapeutic area
N.of therapeutic indications in AIFA Monitoring Registries
50
45
40
35
30
25
20
15
10
5
0
Oncology
Rare diseases
Diabetes
Other areas
Therapeutic areas

33 oncology products are in place with monitoring registry; among these, 21 are subject to conditional reimbursement

(on the overall 26 therapeutic indications).



Source_ Aifa Databases 2011

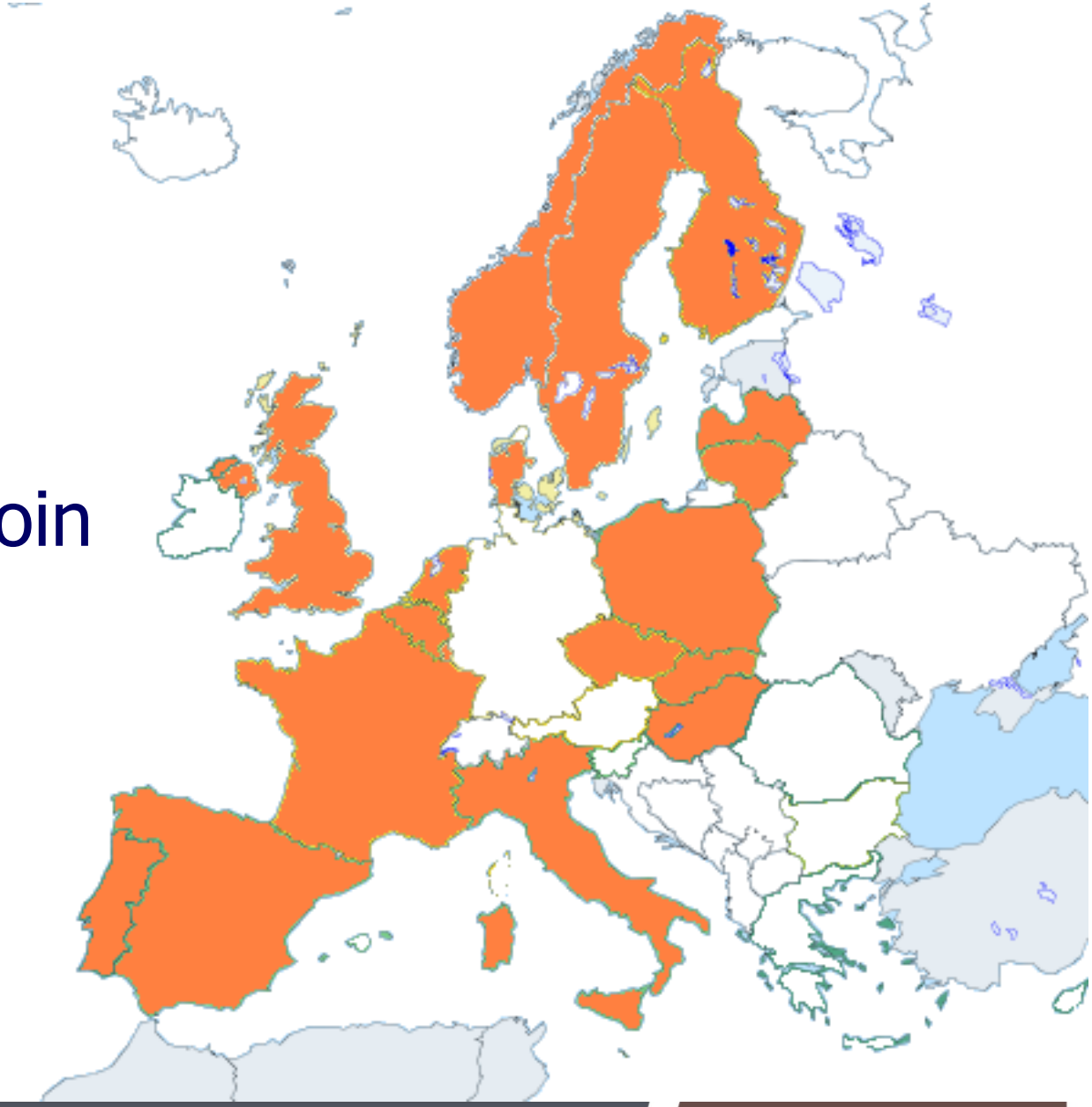

Type of MEAs
number of schemes adopted
90
80
70
60
50
40
30
20
10
0
Volume based agreements
Monitoring registries
Restricting notes
PbR
Cost-sharing
Risk-sharing
MEAs

EU Managed Entry Agreements Project

- CAPACITY BUILDING ON MANAGED ENTRY AGREEMENTS
- FOR INNOVATIVE MEDICINES: a project funded by the European Commission.

europa.eu

19 EU countries join MEAs Project



- An increasing number of countries consider Managed Entry Agreements as a valuable strategies to balance access to medicines and increasing costs.

- Managed Entry Agreements may play a key role in access to medicines in those cases where there are uncertainties related to the therapeutic benefits of medicines or where the costs of new medicines are high.

- *Objective*

  - To collect and analyse information about the Managed Entry Agreements used by the EU Member States.

  - The systematic analysis aims to support the decision making process of Competent Authorities for reimbursement purposes.

  - The findings, could foster knowledge exchange among European Member States.

- *Expected outcomes*

  - A sustainable collaboration will be established between MS and Stakeholders to collect the expected information and produce the foreseen reports.

  - The expected deliverables will improve the level of information on the different decision making processes used in the EU Countries and contribute outcome analysis.

  - The exchange of information can improve the methodologies used in the different MS.

Thank you

p.siviero@aifa.gov.it