Organisation for Economic Co-operation and Development

First Meeting of the Expert Group on Pharmaceuticals and Medical Devices

Managed entry agreements – state of play and possible improvements – Italian experience

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Paris, 27th March 2018

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Public Declaration of transparency/interests*

The view and opinions expressed are those of the individual presenter and should not be attributed to AIFA

xInterests in pharmaceutical industry	NO	Current	From 0 to 3 previous years	Over 3 preavious years
DIRECT INTERESTS:				
1.1 Employment with a company: pharmaceutical company in an executive role	x	☐	☐	☐ mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	x	☐	☐	☐ mandatory
1.3 Employment with a company: other activities	x	☐	☐	☐ optional
2. Consultancy for a company	x	☐	☐	☐ optional
3. Strategic advisory role for a company	x	☐	☐	☐ optional
4. Financial interests	x	☐	☐	☐ optional
5. Ownership of a patent	x	☐	☐	☐ optional
INDIRECT INTERESTS:				
6. Principal investigator	x	☐	☐	☐ optional
7. Investigator	x	☐	☐	☐ optional
8. Grant or other funding	x	☐	☐	☐ optional
9. Family members interests	x	☐	☐	☐ optional

*Gianluca Altamura, in accordance with the Conflict of Interest Regulations approved by AIFA Board of Directors (25.03.2015) and published on the Official Journal of 15.05.2015 according to EMA policy /626261/2014 on the handling of the conflicts of interest for scientific committee members and experts.

N.B. I am not receiving any compensation

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Agenda

① Pharmaceutical expenditure - Italian context

② Managed Entry Agreements (MEAs)

③ Registries

④ Pros & Cons

⑤ Critical issues & new goals

⑥ Q&A

Italian context

Italian National Health System (NHS): single-payer health care system

All citizens, without discrimination, have universal access to fair supply of health services (in implementation of Article 32 of the Constitution).

A share of the NHS Fund is dedicated to the pharmaceutical expenditure (14.85%).

Italian pharmaceutical expenditure

	Expenditure 2016	
Outpatient public expenditure (Class A)	10.652 billions (€)	22,7 B
Direct Distribution (Class A)	5.605 billions (€)	
Hospital expenditure (Class A, Class H, Class C)	6.487 billions (€)	
Outpatient private expenditure (Class A)	1.309 billions (€)	6,6 B
Class C with prescription (private expenditure)	3.014 billions (€)	
Class C without prescription (OTC - Over The Counter)	2.322 billions (€)	

Around 80% of pharmaecutical expenditure is reimbursed by NHS

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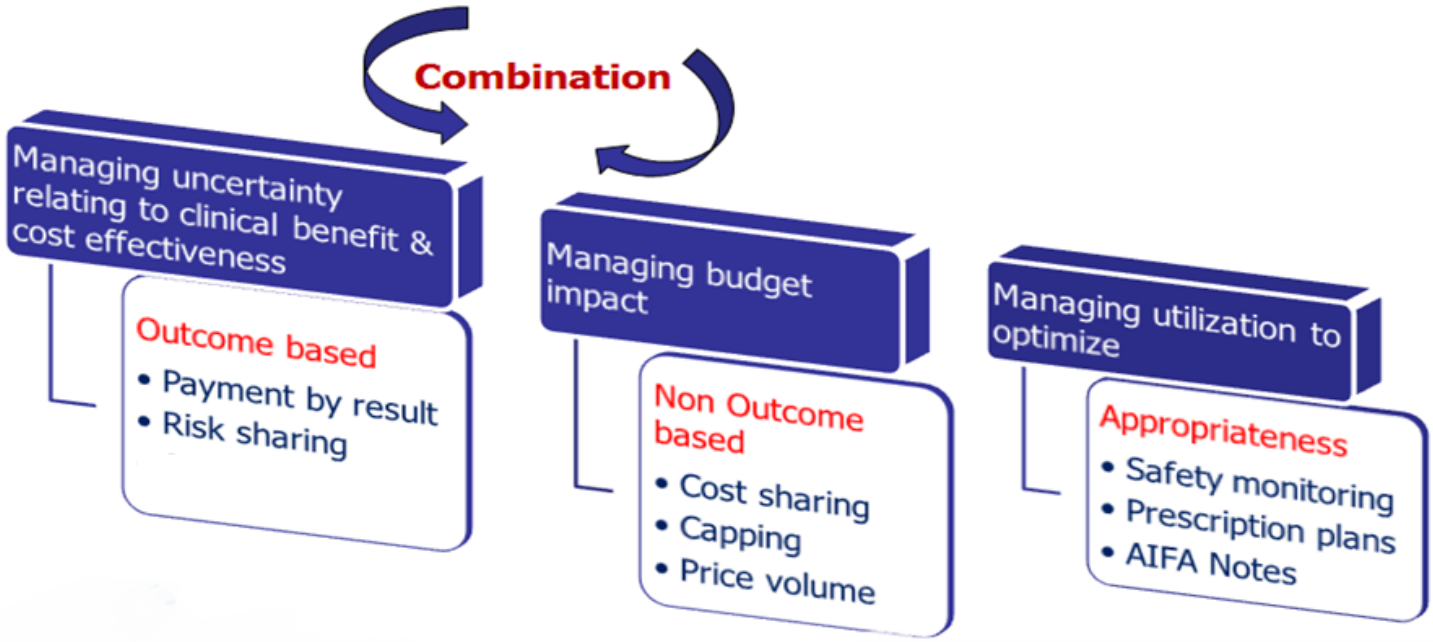
Reimbursement

Refusal

Reimbursement (without conditions)

Managed Entry Agreements (MEAs)



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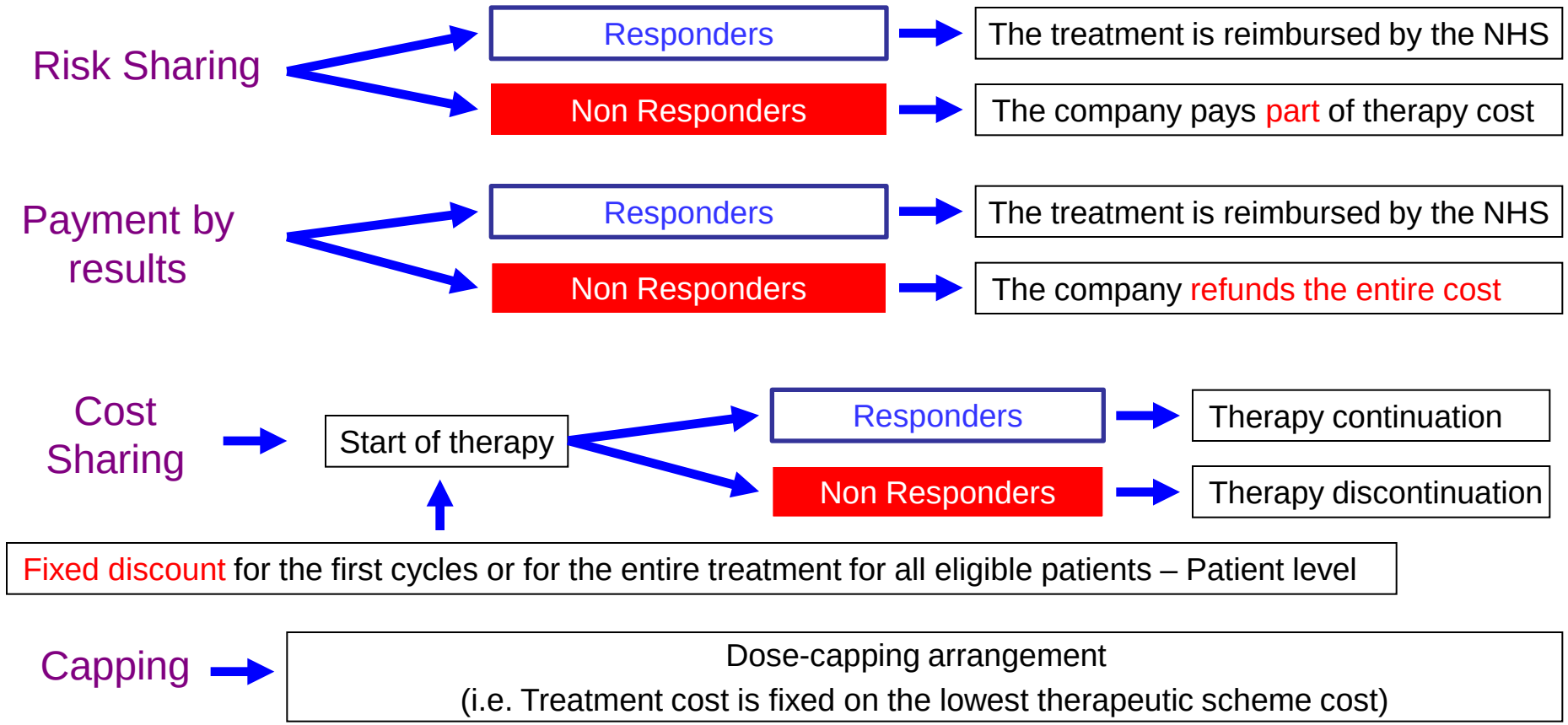
Conditional refund procedure



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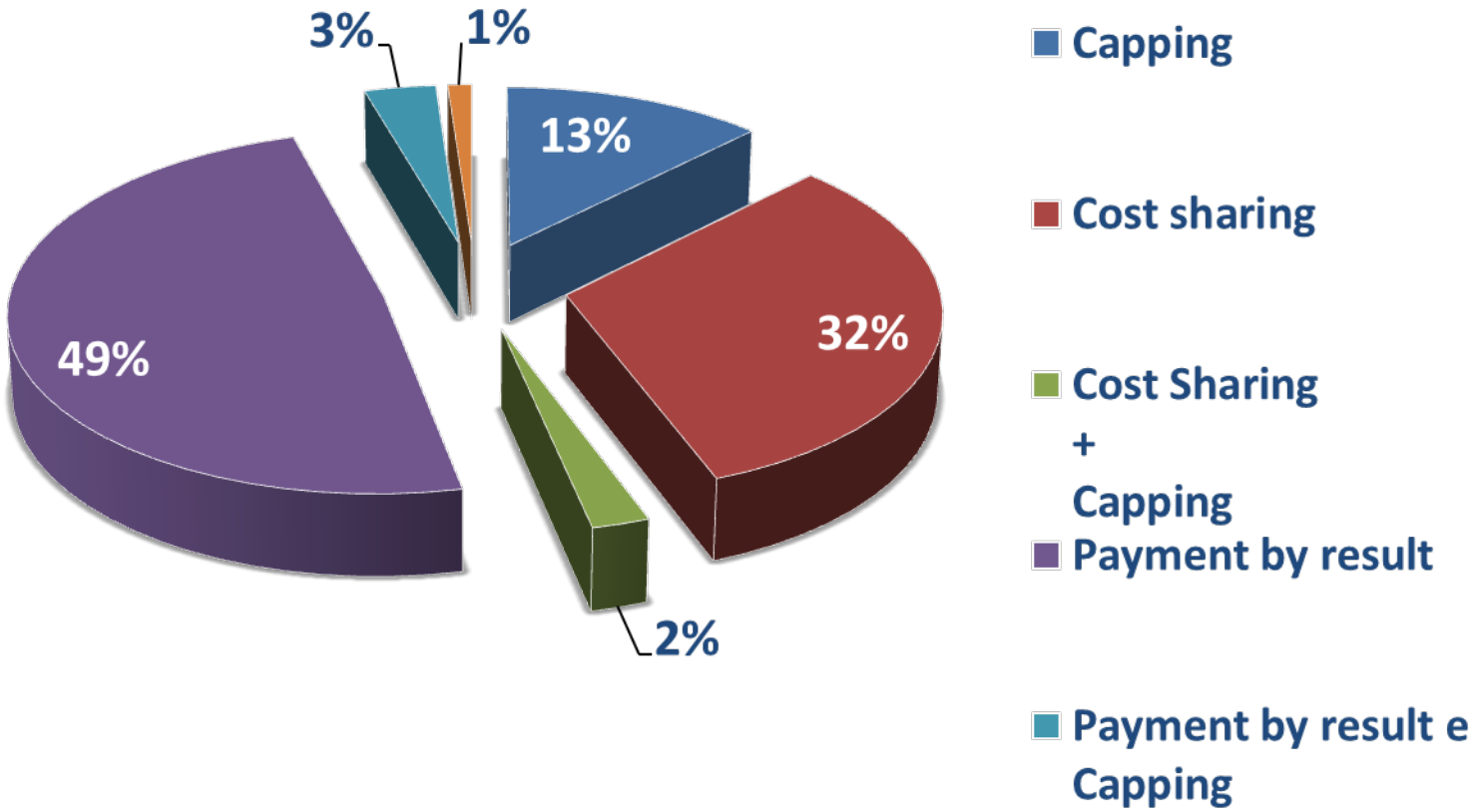
Current AIFA's MEAs (%) divided by type (88 MEAs)



*up to february 2018

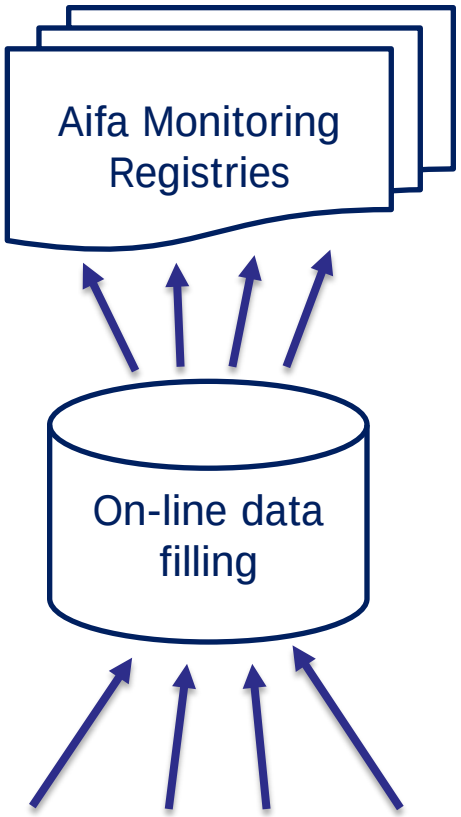
AIFA - Monitoring Registries

Patients eligible for treatment with pharmaceuticals under conditional reimbursement agreements are registered in specific Monitoring Registries in order to:

- evaluate the utilization in clinical practice (effectiveness)
- collect epidemiologic data
- gather information on the safety profile
- collect ex-post evaluation about missing knowledge
- manage Innovation Funds and Indication-specific pricing

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 new medicines
- the safety profile

To support decisions for :

- Conditional reimbursement schemes (Risk-/cost-sharing/ Pay-ment by results)
- renegotiating the price

<u>Useful information on “real practice” and appropriateness</u>

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

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The aim of a AIFA Registry

① Appropriateness of use

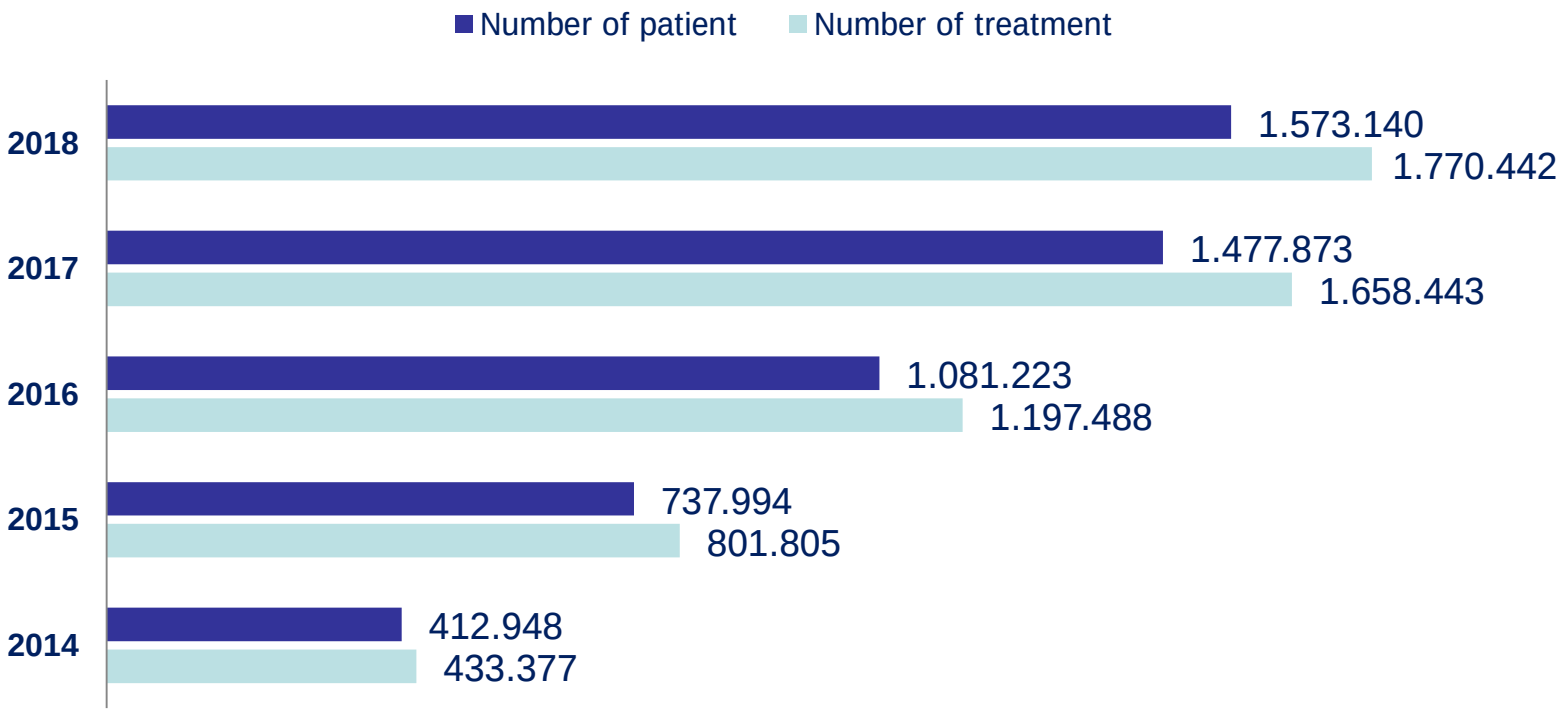
② Real world safety monitoring

③ Real world efficacy (Effectiveness)

④ Managed Entry Agreements' application

⑤ New Evidence generation

Number of patients and treatment in AIFA Registries over time



*up to march 2018

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Pros & Cons

① Access to reimbursement
② Individuation of non responder patients
③ Early access patient to new therapies
④ Collecting data on real clinical practice (RWD)
⑤ Optimizing the cost-efficacy of new therapies
⑥ Obtaining early drug activity indicators
⑦ Managing the expenditure controls and application of MEAs at patient level

① Complexity in implementing MEAs and activating new Registries
② Increasing administrative workload for HCP
③ Quality of data depends on the compliance of HCP
④ High number of new Registries coming: work in progress

Critical issues and new goals

- At present, MEAs (including financial agreements) are applicable through registers at the end of each treatment
- Ensure the application of financial agreements during treatment to ensure greater sustainability of the System
- Registries required to support MEAs may pose several hurdles even when systematic Real World Data collection is largely possible (variable quality of the information entered in registries, administratively complex, struggle to define precise-data collection periods and endpoints and consequent issues during the negotiation process).
- Simplification and availability of registries at the moment of market access
- Do not delay any longer, to publish Registries data
- AIFA is currently finalizing publication of data collected through registries on specific therapeutic areas (e.g. Cardiovascular and infection disease areas).

Critical issues and new goals
Indication-specific Pricing (MEA)

- ✓ Indication-specific MEAs: agreement applied to different indications, or patients sub-groups, in order to value the relative benefit and the relative cost
- ✓ The MEA will be choosen depending on clinical benefit, duration od response, median duration of therapy, etc. in each indication (or sub-groups)
- ✓ The discounted cost delivered by the MEA will be selected/negotiated in relation to the estimated budget impact for each indication or the comparison with the cost of the alternatives available for the specific indication

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Q&A

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