Aggiornamento sulla piattaforma AIFA dei Registri

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Genova, 04 marzo 2016

Agenzia Italiana del Farmaco

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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

Interests 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

*Entela Xoxi, 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.

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127 Registri - 32 AZF

Tutti *drug product-based*

21 registri con *data collection* standardizzati per indicazione terapeutica

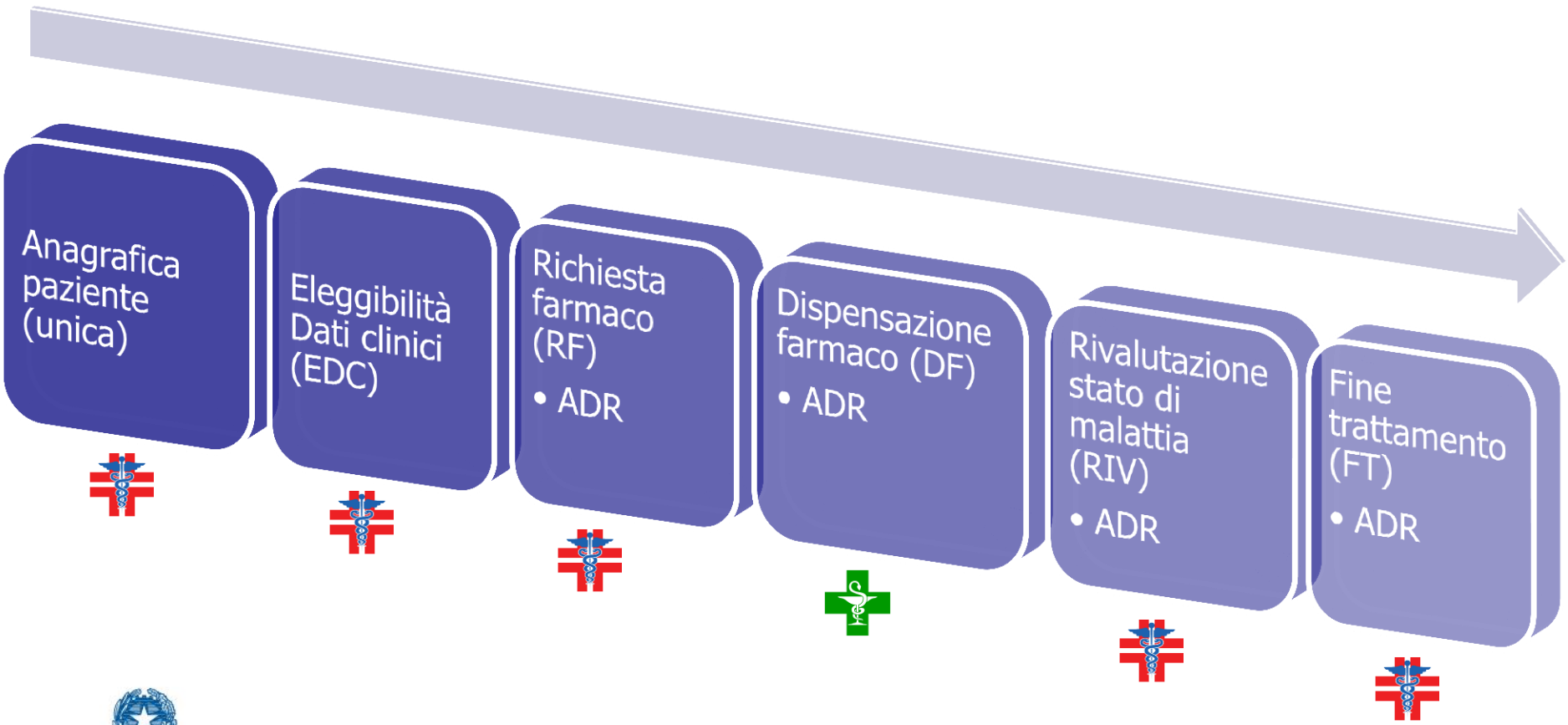
>850,000 Pazienti

~ 24,000 Medici

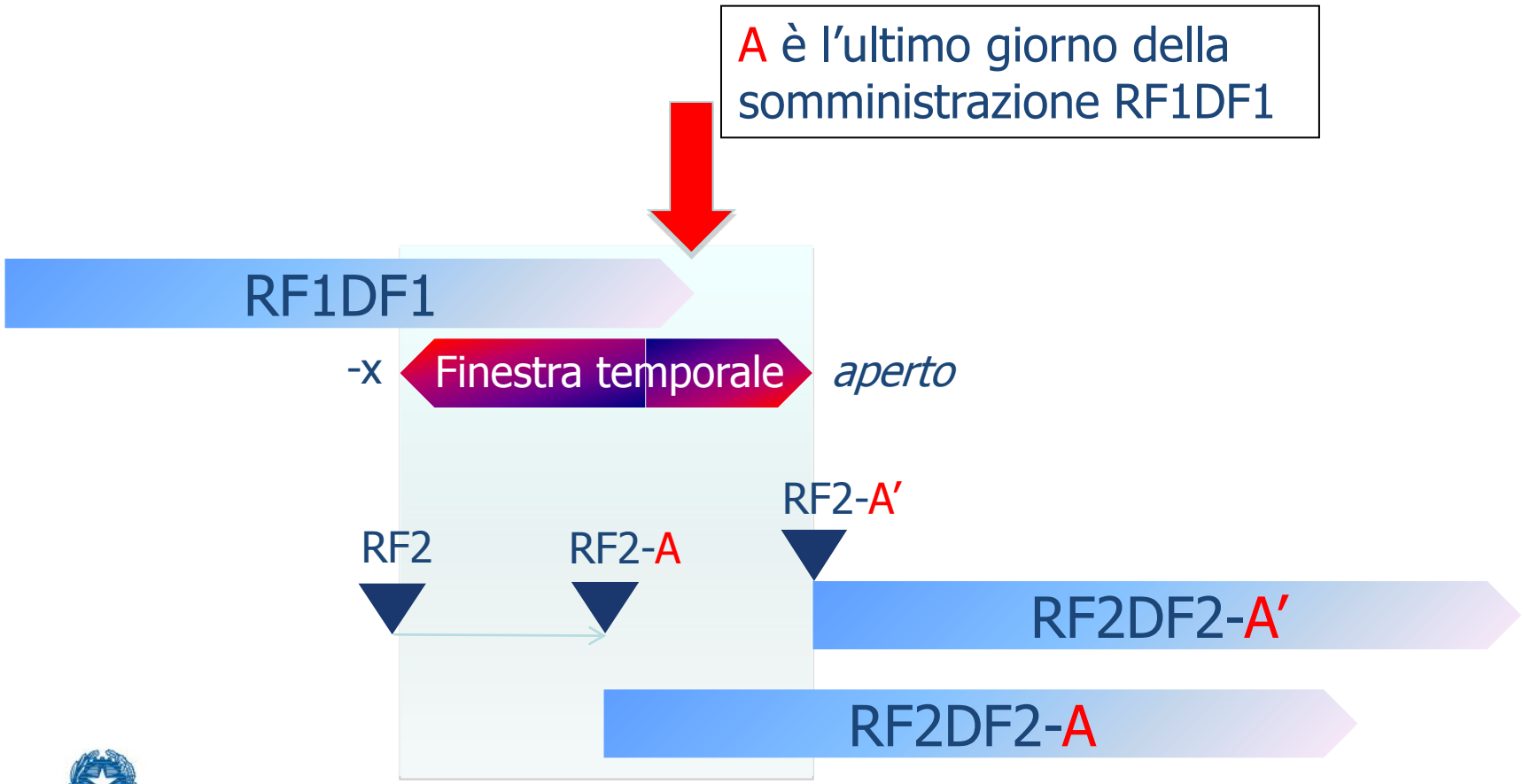
~ 1,325 Farmacisti

~ 900 DS & 48 Approvatori regionali

Trattamento



PRESCRIZIONE & DISPENSAZIONE



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MANAGED ENTRY AGREEMENTS

① Performance-based (PB)

Payment by results

Risk sharing

② Financial-Based (FB)

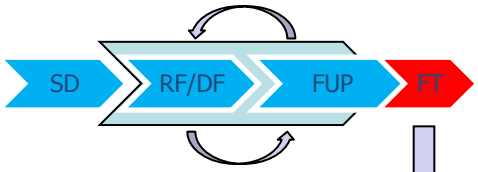
Cost Sharing

Capping

Volume/price

③ Combinazione PB AND FB

PAYBACK FLOW



Trattamento Rimborsabile

Richiesta di Rimborso

Valutazione Trattamenti

L'AZF effettua una analisi dei dati del singolo trattamento

Il sistema effettua una valutazione automatica del trattamento

Il Farmacista effettua la Richiesta di Rimborso (RdR) per uno specifico trattamento

Collezione di trattamenti relativi allo stesso registro per una specifica farmacia

Trattamento non Rimborsabile

- Data Analysis
- Condizionamento futuri trattamenti

Il Farmacista effettua la una valutazione di congruenza della Proposta Ricevuta

Valutazione Proposta di Pagamento

Proposta di Pagamento

Rappresenta l'offerta economica a rimborso per un insieme di trattamenti provenienti da diverse RdR

Nel caso in cui la Farmacia non accetti la Proposta di Pagamento (PdP) questa torna in carico all'AZF per eventuali modifiche

AZF registra a sistema i dati del pagamento effettuato

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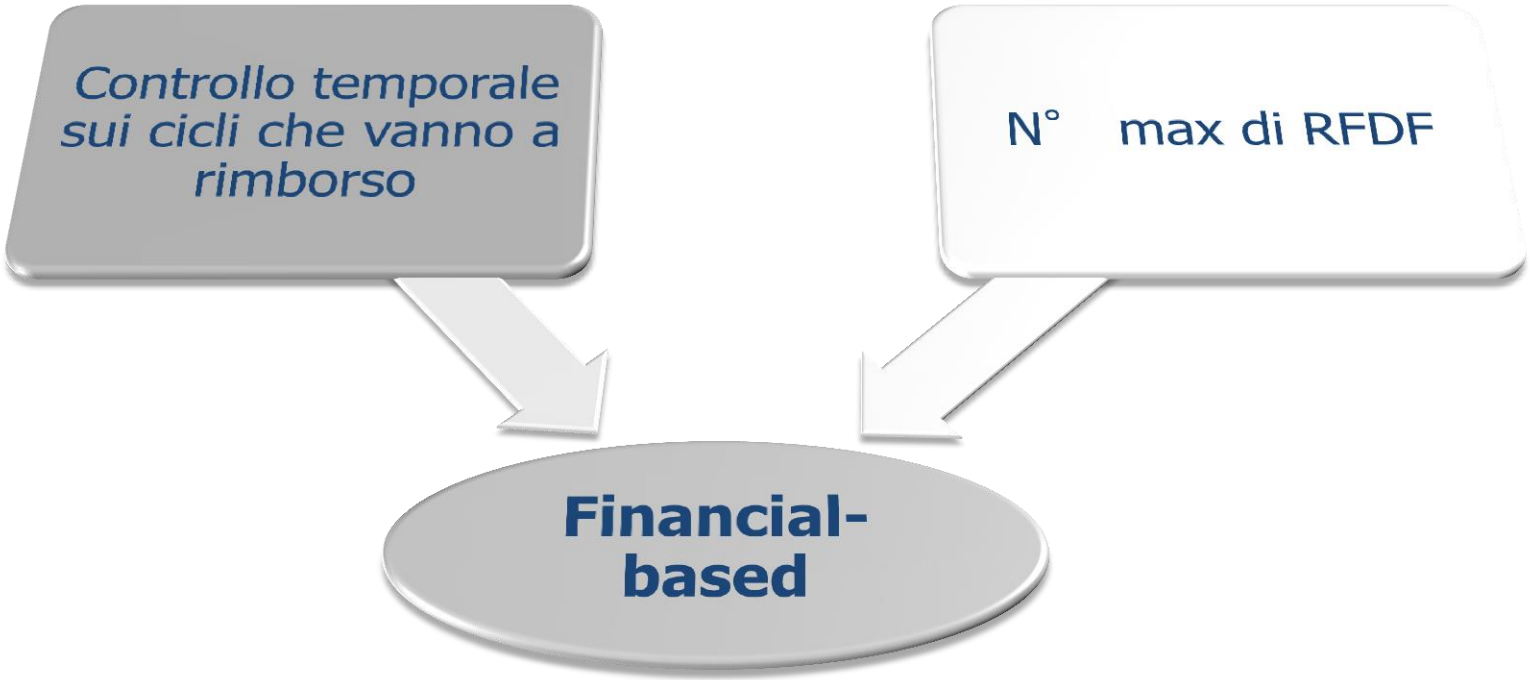
PERFORMANCE-BASED RISK SHARING

FINANCIAL-BASED



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1. SAS reporting amministrativo: Regioni
    a. Epatite C
    b. Trattamenti Registri
    c. Trattamenti PT
    d. Confezioni
    e. Rimborsi presunti (Determinazione 17/03/2014)
    f. Rimborsi attivi (MEAs)

2. Reporting user: Medico e Farmacista

In programmazione

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1. Area riservata per gli utenti
2. Analisi *in progress* della piattaforma AIFA *web* attuale ai fini di rendere più facile l'operabilità degli utenti (Ufficio IT e nuovo fornitore)

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- Registro Cineca Tysabri: *in progress*
- Diversi registri soggetti ad analisi
- Documento sui criteri di individuazione di apertura e chiusura registro: *in progress*

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NL 2016

'Innovation for the benefit of the patient: *early interaction between market authorization, health technology assessment and payer in order to optimize patient access to innovative medicines'*

Amsterdam, 29 February - 2 March 2016

11:00-11:30h Introduction objective 1: For which products are early access schemes/"adaptive pathways" useful and advisable.
Suzanne Hill, Senior Advisor, Essential Medicines and Health Products, World Health Organization, (WHO) Geneva, Switzerland

15:00-15:30h Introduction objective 2: How can standards and requirements for market authorization and HTA be aligned at an earlier stage and which preconditions should be stipulated during the adaptive pathways process ("procedures and assessments")
Audun Hågå, Director General Norwegian Medicines Agency (NOMA)

09:15-09:45h Introduction objective 3:
What are necessary conditions to come to an acceptable outcome of the pathway for the payer ("managed entry schemes and exit")
Entela Xoxi, Co-ordinator AIFA Registries, Italian Medicines Agency (AIFA)

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And I feel that we ought to keep an eye on the concerns of marketing authorization holders as well.
Concerns about the administrative burdens on both the registration process as well as on reimbursement. This often hampers timely access for patients. Shouldn't we work on better alignment of these two worlds?

My question for you today is: how can we kill two birds with one stone?

Improve flexibility in the system, on the one hand, to provide better access. And counter the ever increasing prices on the other? The Italian Medicines Agency has very promising and interesting experiences in this field. And I am very glad that they will be sharing these experiences with us here in Amsterdam.

Of course, we invited you together for a reason. We feel that early interaction between EU market authorization and national reimbursement requirements is needed in order to facilitate early access for patients.

I see three important steps in this regard.

Today we are making the first step, which is getting to know each other.

The second step is to improve the coordination and cooperation between market authorization, Health Technology Assessment and Pricing & Reimbursement.
And the third step is to share each other's knowledge and documentations.

Pagina web istituzionale dei Registri:
http://www.agenziafarmaco.gov.it/it/content/registri-farmaci-sottoposti-monitoraggio

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