The Empowerment and the Engagement of citizens and patients in healthcare

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Roma, 26 gennaio 2017

Agenzia Italiana del Farmaco
AIFA

Public Declaration of transparency/interests*

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

Interests in pharmaceutical industry	NO	Current	From 0 to 3 previous years	Over 3 previous 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

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*Mario Melazzini, in accordance with the Revised 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. NB For this talk I receive NO compensation.

AIFA and Patient Empowerment

- AIFA believes that patient empowerment is a strategy that, through a process of information and education, can provide patients or their representatives the skills and the critical tools that enable them to effectively contribute to the decision making processes.

- AIFA therefore considers that the Patient's Empowerment is an important tool to enable patients to exercise their rights, to be an active part of the system and to be informed on all aspects that may help to improve health choices.

AIFA opened the doors (OPENAIFA)

- AIFA launched OpenAIFA initiative: a series of meetings with all the stakeholders to ensure a direct and transparent dialogue.

- Patient organizations, scientific societies, pharmaceutical companies and any other interested party may submit a request for participation in the meetings that take place on a monthly basis.

- **IN 5 YEARS**

DAYS	MEETINGS	UNIVERSITY (other)	SCIENTIFIC SOCIETY	CONSULTING FIRMS	PATIENTS ORGANIZATIONS	OTHER	PHARMCEUTICAL COMPANIES
47	236	13	12	26	28	47	113

Transparent Communication

- Targeted publications,
- Information campaigns,
- Dedicated website:

Pregnancy and lactation, Antimicrobial use,

- Brochure: Drugs use and Summer,

Paediatric use,

Prescription report.

Aifa's Therapeutic Algorithms

The purpose of these new tools is to allow patients to benefit from the most appropriate therapy available and under NHS.
This tool is intended for the citizen as guarantee of independence, transparency and accountability:

- Algorithm for **Hepatitis C**
- Algorithm for **Diabetes**
- Algorithm for **Hypertension**
- Algorithm for **Osteoporosis**

CONCEPT PAPER

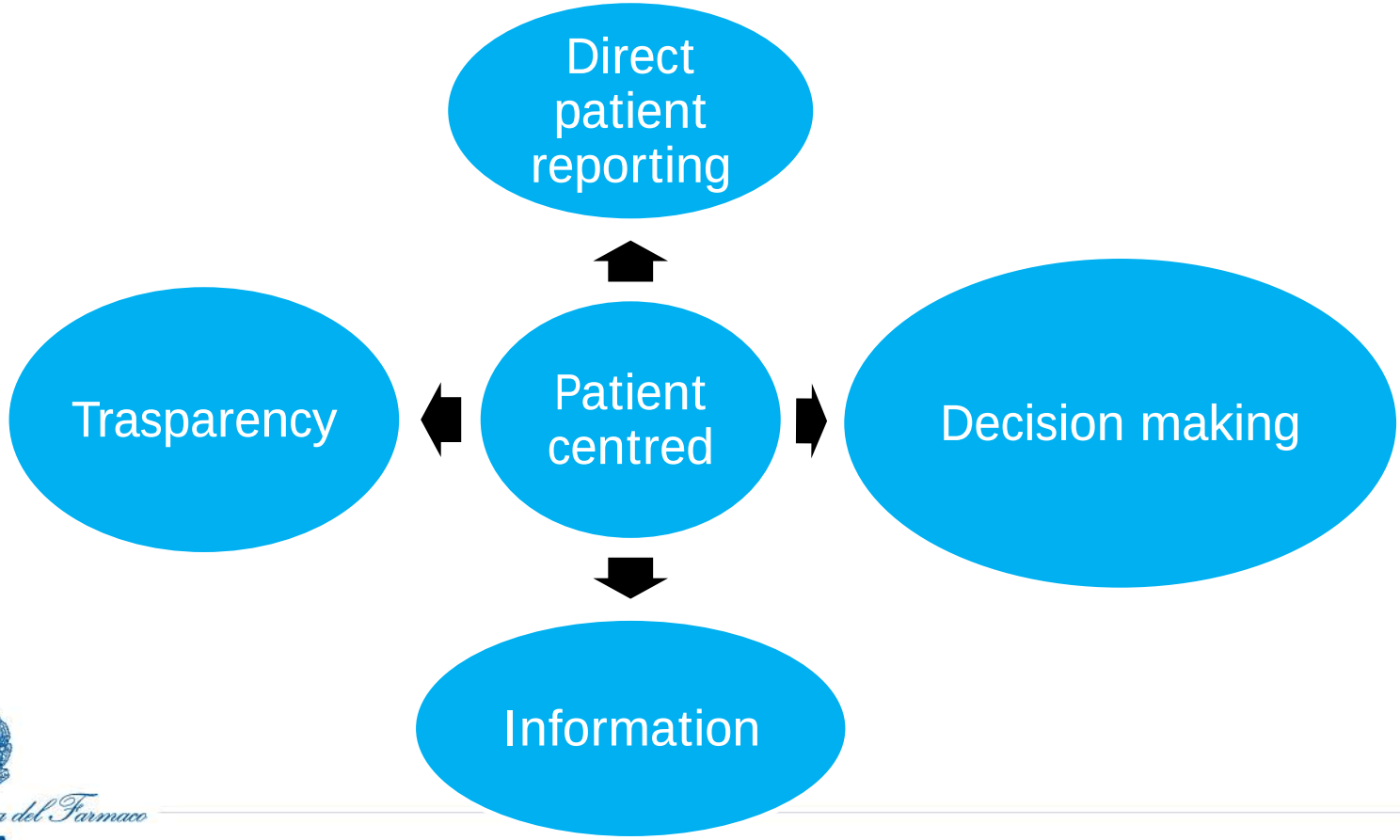
Concept Papers represent the official position of the Agency. These documents are finalized after a 90 days phase of Public Consultation (PC). During the PC also the patients are invited to send their comments to AIFA.

Other Initiatives

- Participation to discussion tables and AIFA's Committee meetings. E.g. updating of criteria for the HCV drugs

- Transparent Information on available drugs: Aifa's Drug Database

The new pharmacovigilance legislation and patients
REGULATION (EU) No 1235/2010



Representatives of patient organizations in the PRAC

Appointed by each Member State:

- 1 member + alternate
- 27 + EEA countries non voting members

Appointed by the European Commission following a public call for expressions of interest:

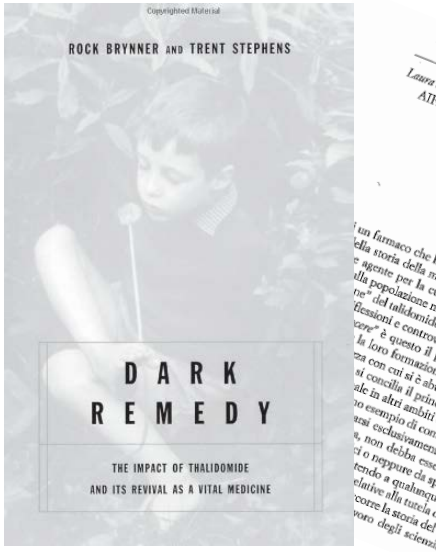
- 1 patient organisations[1] rep + alternate
- 1 healthcare professionals[1] rep + alternate
- 6 members to ensure relevant expertise available

[1] *Criteria for involvement in EMA activities*

Role of patients and pharmacovigilance

Pharmacovigilance monitors the way the medicines work, and their risk-benefit balance and Patients have a key role in building a better system of pharmacovigilance

“Feedback from the established systems is consistently that patient reporting is equal quality to professional reporting and that is actually adds value because it is based on the direct experience of the users and providers richer detail”



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The importance of direct patient reporting of suspected adverse drug reactions: a patient perspective” Anderson et al. British Journal of Clinical Pharmacology, Volume 72, Issue 5, pp 806-822, November 2011

Role of patients and pharmacovigilance

- Patients have a key role in building a better system of pharmacovigilance.
- Listen to the people enriches pharmacovigilance: it is important that patients be given the opportunity to report directly to the health authorities.
- Literature shows how under-known problem of all pharmacovigilance systems, could be reduced through the reporting citizen.

[Blenkinsopp A. et al. Br J Clin Pharmacol 2006]
[Ecouter les patients enrichit la pharmacovigilance. La Revue Prescrire 2008]
van Grootheest K et al. Drug Saf 2003

Patient involvement in R&D

Research program
Provide patients, health professionals and consumers feedback on the relevance of the research topic. They can help to identify new research topics.

Development of questions' research
Define questions useful to patients, health professionals and consumers and applicability in the real world.

Selection of outcomes and comparators
Identify outcomes of interest to patients, health professionals and consumers.

Recruiting
Develop approaches to maximize the potential of a large and significant representation of patients in research.

Translation and dissemination of results
Helping patients, health professionals and consumers understand the search results.

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Clinical Trial Regulation

D.M.8/3/2003

(D. Lgs. 211/2003)

Tissues / Cells
2004/23/EC

PhVig legislation

ATMPs
1394/2007CE

D.M.
17/12/2004

(D. Lgs. 200/2007)

Blood
2002/98/EC

Paediatrics
1901/2006

Regulation
536/2014

(Medical Devices
93/42/EC)

(D.M. 15/11/2011)

D.M. 8/2/2013

D.M. 27/04/2015

D.M. 19/03/1998 e
D.M. 7/11/2008

D.M.
14/07/2009

D.L. 158/2012

Det. AIFA 15/06/2015

D.M. 20/03/2008

D.P.R. 439
21/09/2001

UE Regulation 536/2014 topics

- Simplification
- Coordination
- New Role of Ethics Committees
- Patient
- Transparency

Regulation UE 536/2014 and Patients

- **Protocol**: where patients are involved in the design of the clinical trial, a description of their involvement;
- **Assessment**: Member States should ensure the involvement of a layperson, in particular patients or patients' organisations;
- Support in identifying potential growth areas for research (profit and independent);
- **Focus**: Vulnerable populations, emergency trials.

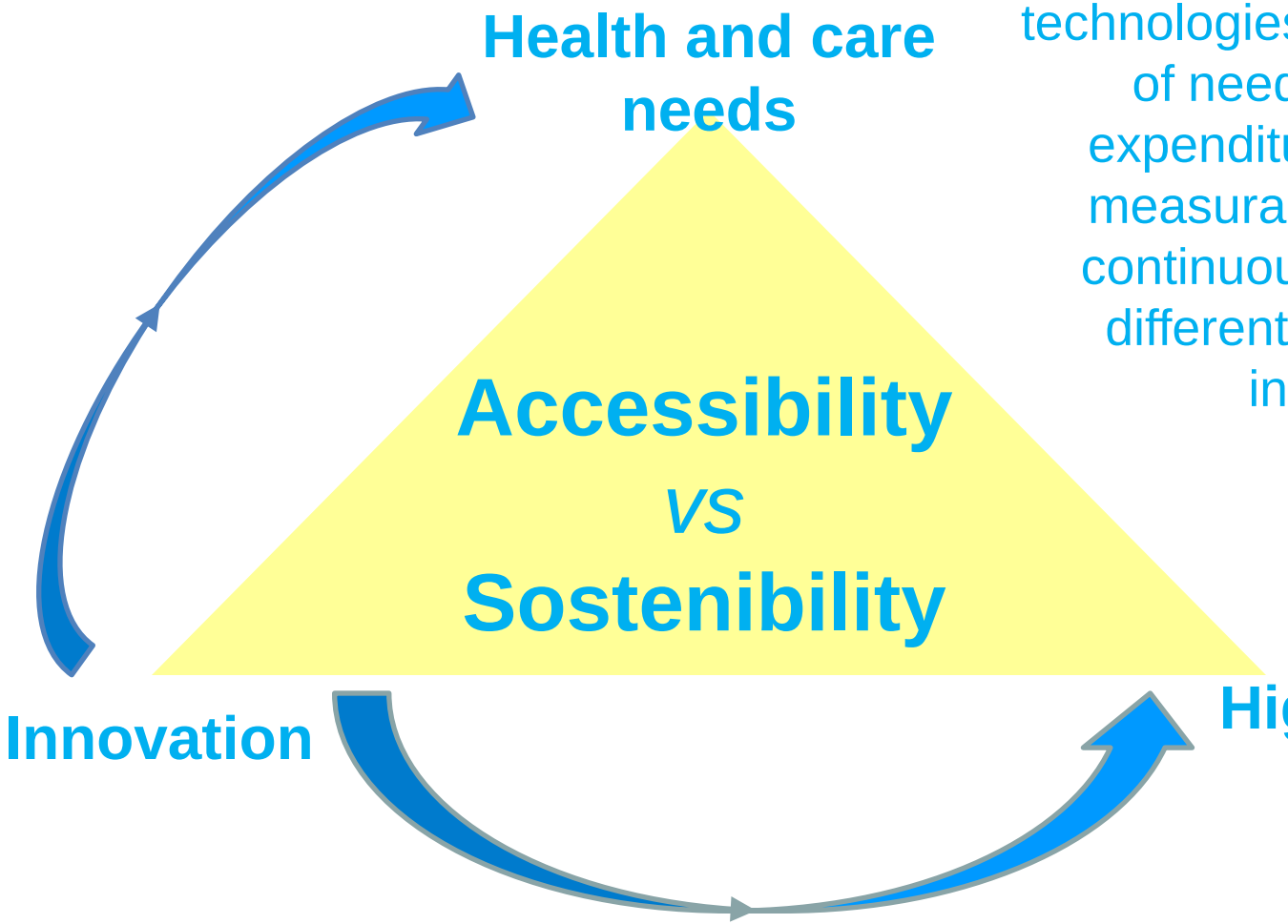
Patients' need

Incorporate patients' values and preferences into the scientific review process which could influence benefit risk decision making.

Patients are the ultimate beneficiaries of medicines and, therefore, their views should be heard.

UE Regulation 536/2014 and transparency data

Clinical Trial will be recorded in a publicly accessible and free of charge available database



The impact of health technologies on the satisfaction of needs and the total expenditure is not directly measurable: innovation is continuous and impacts of different innovations are interrelated

http://kff.org/health-costs/issue-brief/health-care-costs-a-primer/
May 2012 – Health Care Costs: a Primer

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Sustainability of care: the near future

- New therapies for HCV and HIV;
- Monoclonal antibodies for Alzheimer's disease and dementia;
- New cancer drugs;
- Immunotherapies;
- 3D printed drugs;
- Gene therapies.

Sustainability is an essential condition to ensure rapid access to new high-cost drugs to all those who may learn from a real advantage.

NHS will be able to repay all these new therapies?

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The Costly Paradox of Health-Care Technology

In every industry but one, technology makes things better and cheaper. Why is it that innovation increases the cost of health care?

By Jonathan S. Skinner on September 5, 2013

EMA's tools

The EU framework provides a set tools that allow access to the drug

- Conditional approval
- Exceptional circumstances
- Accelerated assessment
- Compassionate use
- Treatment on a named-patient basis

Adaptive pathways

The concept of AP is based on an approach consisting of a quick approval for a population of restricted patients, for therapeutic high-demand areas. Robust pharmacovigilance systems across the EU and the transition to proactive pharmacovigilance, the real-time monitoring are key tools of this approach.

PRIME PROJECT

To optimize the development and accelerated evaluation of innovative drugs and of most interest to the public health.

Better interaction and early dialogue with the developers of medicine.

Eligibility to PRIME: Preliminary clinical evidence in patients with unmet medical needs.

AIFA's Strategy

Early dialogue/scientific advice

Conditional Reimbursement (MEAs)

Monitoring Registries

Re-assessment

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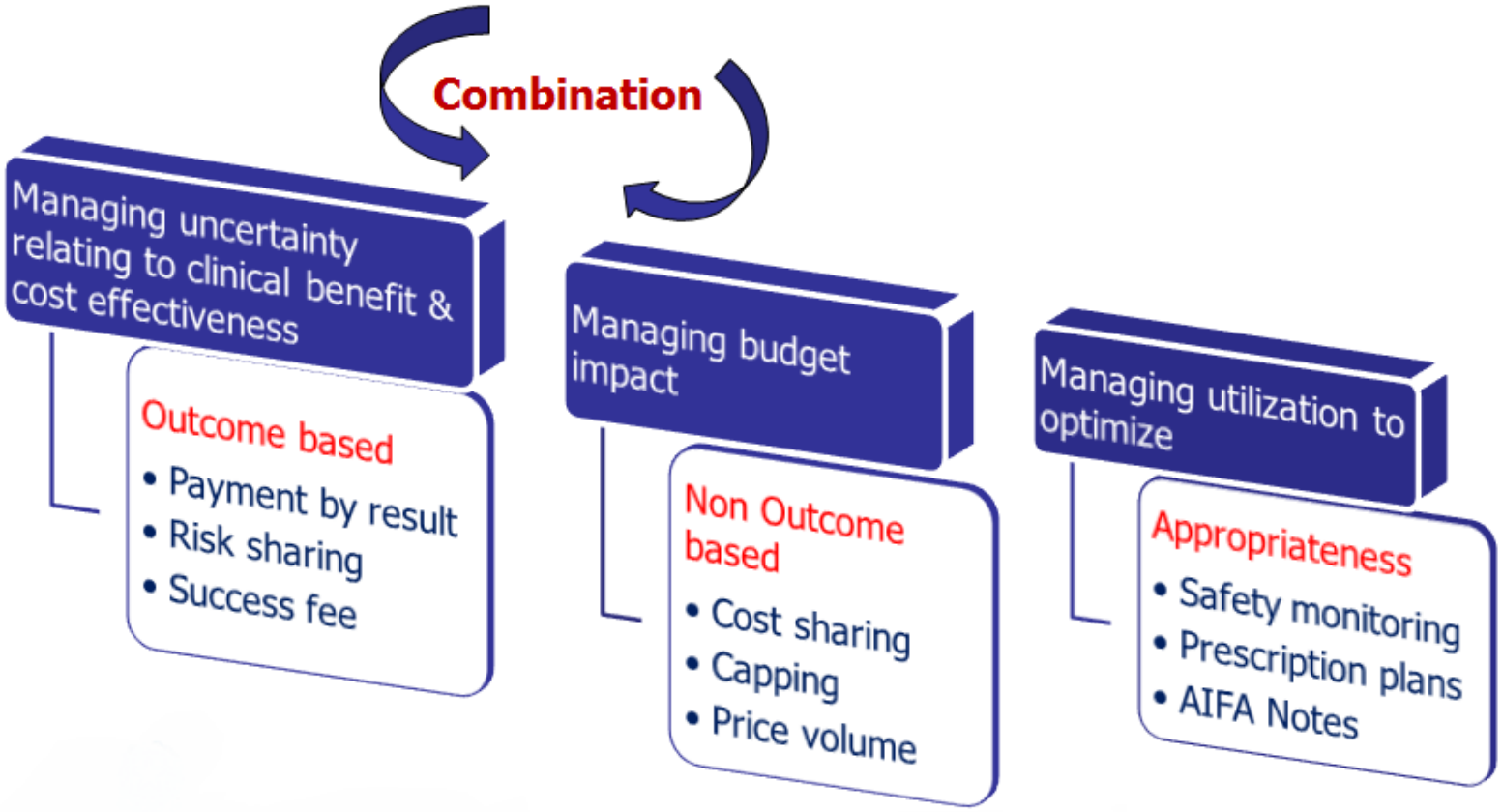
AIFA's Strategy



The independent research on drugs
AIFA 2016

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BANDO AIFA 2016
PER LA RICERCA INDIPENDENTE SUI FARMACI

The promotion of independent research on drugs represents one of the strategic tasks assigned to the Italian Medicines Agency by legislation. The general aim of the program is to support clinical research on drugs in areas of interest for the National Health Service (NHS) and where commercial support is normally insufficient.

AIFA- EUPATI MoU

In July 2014 Aifa signed an important MoU with Eupati to work towards the creation of a EUPATI Patient Expert Training Course in Italian. The collaboration between AIFA and EUPATI helps to increase the effectiveness of the training process for citizens. The long-term goal is to build competencies and expertise that could provide a solid and qualified contribution of patients to the drug regulatory process.

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Member of National Liason Team after the signing of the Memorandum of Understanding with the Italian Medicines Agency (AIFA) on 03 July 2014.

AIFA and the Scientific Board EUPATI

The collaboration between AIFA and EUPATI is aimed to go beyond the five year horizon of the official duration of the EUPATI project

Aifa is a member of the board together with patient organizations, academia, non-profit, institutions, pharmaceutical companies and other stakeholders with key roles in the national context .

Activities: consider the feasibility of initiatives based on the results in terms of social and health progress and in terms of ability to contribute to patient empowerment

Patient Empowerment: four EUPATI guidelines

AIFA commented Eupati guidance documents on patient involvement with aim to support the integration of patient involvement across the entire process of medicines research and development with regulatory agencies, health technology assessment (HTA) bodies, ethics committees and the pharmaceutical industry.

- Guidance for patient involvement in industry-led medicines R&D
- Guidance for patient involvement in regulatory processes
- Guidance for patient involvement in HTA
- Guidance for patient involvement in ethical review of clinical trials

Patients' empowerment

Encouraging patient empowerment is an added value for the patient and for the scientific community