EUPATI Patients-Regulator-Industry Workshop 20 July 2016
Patient involvement: Italian Medicine Agency approach
**Public Declaration of transparency/interests**

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

*Silvia Cammarata*, 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.

<table>
<thead>
<tr>
<th>Interests in pharmaceutical industry</th>
<th>NO</th>
<th>Current</th>
<th>From 0 to 3 previous years</th>
<th>Over 3 previous years</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DIRECT INTERESTS:</strong></td>
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<tr>
<td>1.1 Employment with a company: pharmaceutical company in an executive role</td>
<td>X</td>
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<tr>
<td>1.2 Employment with a company: in a lead role in the development of a medicinal product</td>
<td>X</td>
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<tr>
<td>1.3 Employment with a company: other activities</td>
<td>X</td>
<td></td>
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<tr>
<td>2. Consultancy for a company</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>3. Strategic advisory role for a company</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Financial interests</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>5. Ownership of a patent</td>
<td>X</td>
<td></td>
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<tr>
<td><strong>INDIRECT INTERESTS:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>6. Principal investigator</td>
<td>X</td>
<td></td>
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<tr>
<td>7. Investigator</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>8. Grant or other funding</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>9. Family members interests</td>
<td>X</td>
<td></td>
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</table>
Welcome to the Italian Medicines Agency (AIFA)

- AIFA is the only national authority responsible for drugs regulation in Italy.
- A public body operating autonomously, transparently and according to cost-effectiveness criteria, under the direction of the MoH and under the vigilance of the MoH and the MoE.
AIFA’s Core Mission

• To promote and protect public health through a safe and appropriate use of drugs

AIFA’s Broader Mission

• AIFA cooperates with the Regional Authorities, the National Institute of Health, Research Institutes, Patients’ Associations, Health Professionals, Scientific Associations, the Pharmaceutical Industry, Drug Distributors and with all Regulatory Authorities Worldwide

• Promote pharmaceutical culture and knowledge
What we are doing AND what has been done
We opened the doors
OPENAIFA 4 years and ½ - 225 meetings- 44 dedicated days about 112 hours

Since 2012 we have met with representatives of 11 scientific societies, 24 consulting firms, 26 associations/ federations of patients, 3 Federations of Centres, 44 associations / federations, 107 pharmaceutical companies and 13 from health professionals and academia

Meetings with our stakeholders with the aim to establish a direct dialogue, to optimize regulatory decision paths and to know the impact in real life

http://www.agenziafarmaco.gov.it/it/content/open-aifa
Transparent Communication

Targeted publications, information campaigns, dedicated site (Pregnancy and lactation, Antimicrobial use, Drugs use and Summer, pediatric use, prescription report)
La Banca Dati Farmaci

La Banca Dati Farmaci è prodotta dall’Agenzia Italiana del Farmaco (AIFA), è l’unica banca dati ufficiale che permette la consultazione dei Rilievi delle Caratteristiche del Prodotto (RCP) e dei Fogli Illustrativi (FI) aggiornati dei farmaci autorizzati in Italia. È inoltre possibile stampare copie di ogni documento presente nella Banca Dati, acquistando in questo modo utili informazioni che riguardano i farmaci autorizzati all’immissione in commercio in Italia. Tutti i documenti pubblicati sono stati controllati ed approvati dall’Agenzia Italiana del Farmaco o dall’Agenzia Europea dei Medicinali (EMA, European Medicines Agency).

Open Information

SPC and PL

% Stakeholder 2010-2015

- Int. Parl.
- Altre
- Infermiere
- Associazioni
- Autorità
- AMAGS
- Farmacista privato
- Medico specialista
- Farmacista pubblico
-Citadino/paziente
Therapeutic Algorithms

Able to define the optimum logical path for the definition of personalized therapy for the treatment of disease: HCV, T2 Diabetes, Hypertension

- The purpose of these new tools is to allow patients to benefit from the most appropriate therapy available and under NHS.

- The final therapeutics decision is of the medical doctor but the doctor can share the decision with the patient in order to implement the compliance

Free Access Online: http://www.agenziafarmaco.gov.it/it/content/algoritmi-terapeutici
Agency’s Position on specific topics

Concept Paper are documents which, finalized after a 90 days phase of Public Consultation, represent the position of AIFA. During the PC also the patients can send to AIFA their comments.

1 CP on biosimilars - open until september;
1 PP on antibiotic use in cystic fibrosis;
1 CP on new oral anticoagulants;
1 CP on Gonadotrophins;
1 CP on the pharmacological management of ADHD.
Trend Reports ADRs from Patients/Citizens

<table>
<thead>
<tr>
<th>Year</th>
<th>% reports from patients</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td>2001</td>
<td>0.1%</td>
<td>7.478</td>
</tr>
<tr>
<td>2002</td>
<td>0.1%</td>
<td>9.401</td>
</tr>
<tr>
<td>2003</td>
<td>0.2%</td>
<td>6.238</td>
</tr>
<tr>
<td>2004</td>
<td>0.2%</td>
<td>6.476</td>
</tr>
<tr>
<td>2005</td>
<td>0.4%</td>
<td>5.709</td>
</tr>
<tr>
<td>2006</td>
<td>0.3%</td>
<td>6.548</td>
</tr>
<tr>
<td>2007</td>
<td>0.5%</td>
<td>10.753</td>
</tr>
<tr>
<td>2008</td>
<td>0.3%</td>
<td>12.813</td>
</tr>
<tr>
<td>2009</td>
<td>0.3%</td>
<td>15.914</td>
</tr>
<tr>
<td>2010</td>
<td>7.7%</td>
<td>21.981</td>
</tr>
<tr>
<td>2011</td>
<td>1.1%</td>
<td>23.730</td>
</tr>
<tr>
<td>2012</td>
<td>2.0%</td>
<td>31.323</td>
</tr>
<tr>
<td>2013</td>
<td>5.3%</td>
<td>43.814</td>
</tr>
<tr>
<td>2014</td>
<td>0.7%</td>
<td>55.305</td>
</tr>
</tbody>
</table>
Participation in discussion table and AIFA’s Committee meetings

- Discussion Table on new DAAs

- Patients organisations were involved in the debate on the drug Ivacaftor (Kalydeco) in 2015 and on the discussion related to the generic form of cyclosporine
Patients’ empowerment

Encouraging patient empowerment is an added value for the patient and for the scientific community.
AI FA- 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 help 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.
A sustainable and efficient education system in progress for citizen

In future, the participation of the patients in the regulatory decision is seen as an important issue. AIFA is intending to increasingly involve patients into its processes but it can be difficult to find knowledgeable patients who can fulfil this role.

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

Such a collaboration is expected to translate in an education system in progress for citizen and/or their relatives, coordinated by the EUPATI National Platform (ENP) in collaboration with AIFA
AI FA & EUPATI
local projects for the empowerment of patients

• Local project developed under the collaboration umbrella AI FA-EUPATI, will empower patients to express their needs with the necessary competence in regard to the regulatory decision.

AI FA and EUPATI are cooperating in order to organize a **12 month Training Course in Italian language** to be held in Italy for Patients and Patient Representatives on the Medicines Research & Development Process, under the leadership of AI FA.
AI FA & EUPATI continuity and consolidation

*AI FA*, in collaboration with the Italian EUPATI National Platform, will support the continuity and the consolidation of such a patients’ educational system, initially promoted by EUPATI, by providing faculties and expertise provision.

- In October 2014, the Italian NLT formed the Executive Committee and the Scientific Board of the Italian EUPATI National Platform.
- AI FA support it and participates in the activities of the Scientific Board;
- In April 2015 AI FA participated to the launch of the Italian EUPATI National Platform in Rome.
- In April 2016 AI FA participated to the Eupati WS in Italy and helped to spread the toolbox.
“Is It Enough?”
Disclaimer

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They are not intended to be an official and/or binding regulatory position.