Italian post-marketing registries

Entela Xoxi

Budapest Conference - October 16, 2012
Public Declaration of transparency/interests*

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

<table>
<thead>
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<th>Interests in pharmaceutical industry</th>
<th>NO</th>
<th>Currently</th>
<th>Last 2 years</th>
<th>More than 2 years but less than 5 years ago</th>
<th>More than 5 years ago (optional)</th>
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<td>Direct interests:</td>
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<td>Employment with a company</td>
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<td>Strategic advisory role for a company</td>
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<td>Financial interests</td>
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<td>Indirect interests:</td>
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<td>Individual’s Institution/Organisation receives a grant or other funding</td>
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*Entela Xoxi, in accordance with the Conflict of Interest Regulations approved by AIFA Board of Directors (26.01.2012) and published on the Official Journal of 20.03.2012 according to 0044 EMA/513078/2010 on the handling of the conflicts of interest for scientific committee members and experts

N.B. I am not receiving any compensation
Outlines of this talk

① e-Prescription
② Collecting data
③ Registers’ factory
④ Regional dashboard
⑤ The benefits of all the actors involved
Electronic drug prescriptions

Change of mentality is essential in life
Collecting data: more info from the real world

A necessity for:
- Academy;
- Regulatory;
- Pharma industry.

Required for:
- Health economic data;
- Experiences data;
- Patient-reported outcomes;
- Reimbursement data;
- Safety surveillance data.
• Registries;

• **Drug** & Pathology analysis;

• National context;

• Appropriateness & Managed Entry Agreements.
AIFA Drugs Registries

monitoraggio-farmaci.agenziafarmaco.it

Eligibles 450,780
MEAs 25

Updated 28/09/2012
# Figures

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
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<tr>
<td>Hospital structures enabled</td>
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<td>Drugs (total monitoring)</td>
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<td>Drugs (active monitoring)</td>
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<td>Therapeutic indications</td>
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<td>Eligible patients</td>
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<td>Pharma companies</td>
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<td>MEAs</td>
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Updated 28/09/2012
Data entry
Algorithm

- **Treatment**
  - Disease evaluation
    - First cycles for all eligibles
  - **Responders**
    - Treatment continues, supported by NHS
  - **Non responders**
    - Stops treatment supported by NHS
MEAs: Performance - based risk-sharing arrangements

PBRSAs are payment schemes – they involve a plan by which the performance of the product is tracked in a defined patient population over a specified period of time and the level of reimbursement is based on the health and costs outcomes achieved.

ISPOR performance based Risk sharing arrangements TF Report
AIFA’s MEAs rules

Eligible:

- Cost sharing (CR, special discount)

Non responder:

- Payment by results (PbR, total refund);
- Risk sharing (discount).
MEA’s application

Pharmacist

Valid orders
Refund requests

MEA’s rules

Pharmaceutical Company

YES - NOT

DB

DB
Highlights of an eMEAs application

i. The system provides an indication of a 'credit' in favor of the pharmacy based on the count of packs dispensed registered in the system;

ii. Communicating all the requests, dispensing, revaluation and end treatment records is a mandatory condition;

iii. Pharma company analyze the requests received and check the real situation and has the right to verify each request and accept or decline the payment of refund (or discount) specially in situations of particular problems. In these cases controls will be activated, with the support of AIFA, to verify the correctness of the requests and the actual enforceability of repayments.
Regional dashboard

Cuscotto Informativo Regionale Registri CIRR
Business intelligence software: Enterprise

Is an analysis tool which creates interactive reports & charts to dynamically examine the data at different levels of aggregation.
Analysis outcomes

**Clinical**: eligible patients, treated patients, duration of treatment, end of therapy, ADR, per drug or therapeutic indication;

**Economic**: dispensed drugs per marketing authorisation, expenditure (per treated patient, pathology, difference among prescription sites), expenditure reimbursed by MEAs.
Multi-tier review

**Space:** region, local health unit, clinical site;

**Time:** year, semester, month;

**Clinical:** therapeutic indication;

**Treatment:** register, drug.
Exchange of data between:

- Clinicians;
- Pharmacists;
- Local healthcare units & Regions;
- Pharma companies;
- Regulatory: AIFA
Properly managed registries can produce a wealth of valuable data about

a. Patients;

b. Institutions of health care, communities and payers;

c. Pharma Industry.
Patients’ benefits

- Rapid access to new drugs, supported by NHS;

- Monitoring of prescriptions and tolerability.
Institutions of health care, communities and payers benefits

• Balance between:
  - rapid access to market and appropriateness;
  - costs and efficacy;

• New sources of relevant clinical data.
Pharmaceutical companies’ benefits

- Access to market for a drug, supported by NHS;

- New sources of relevant data.
Nationwide experiment in drug monitoring

Is a complex approach combining

regulatory, clinical & IT aspects

Main objective: effective growth of patient protection
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