Cooperation against counterfeit medicines
The institutional coordination schemes in Italy

Domenico Di Giorgio

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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>
<tr>
<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>
<td>NO</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>Ownership of a patent</td>
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<td>Indirect interests:</td>
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<td>Principal investigator</td>
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<td>Investigator</td>
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<tr>
<td>Individual’s Institution/Organisation receives a grant or other funding</td>
<td>NO</td>
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*Domenico Di Giorgio, 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>
In Italy the phenomenon of pharmaceutical counterfeiting has a low incidence in the legal distribution network (pharmacies, authorized stores), but it is growing in the illegal ones (Internet, sex shops, food supplement stores), due to the involvement of international organised crime.

The establishment (in 2007) of a collaborative network was a priority for the Italian Medicines Agency.

Partnership via the national anticounterfeiting task-force IMPACT ITALIA helped to solve many cases.
IMPACT Italia TASKFORCE | 2007

IMPACT Italia, the national anticounterfeiting Task force, has been established in 2007 to combat counterfeit medical products. IMPACT Italia Secretariat is composed, since the establishment of the working group on counterfeit prevention, by four branches of the Italian public administration.
IMPACT Italia TASKFORCE | 2007

- Italian Medicines Agency|AIFA
  - Research, Clinical Trials, Registration, Post Marketing Surveillance
- Police Carabinieri NAS
  - Legal and investigative activity on pharmaceutical crime
- Laboratories Natl. Health Inst. (ISS)
  - Official medicines control lab (OMCL) - Laboratory analysis on suspect samples
- Ministry of Health
  - Track and trace system, distribution, Medical Devices, cosmetics, dietary supplements
2 Memoranda of understanding with the Directorate general for the fight against counterfeiting to support AIFA activities:
March 2010, support for the publication of the book “Counterfeit medicines. Facts and Practical advice”
December 2010, support for the following activities:
- IT Intelligence project about e-pharmacies
- webinar for operators training
- communication
- handbook for operator
MANAGEMENT OF INPUTS | 1

1. SIGNAL SUSPECTED ILLEGAL IMPORT
   - AIFA Offices involved:
     - GMP
     - Pharma. Vig.

2. Inspection
   - AIFA, NAS
   - SAMPLING
   - Police Carabinieri NAS
   - OMCL ISS

3. Customs Agency Anti-Fraud
   - Ministry of Economic Development

4. USMAF
   - Industries
   - Pharmacies
   - Health prof.
   - Patients

5. ANALYSIS IMPORT/EXPORT

6. RESULTS OF ANALYSIS JUDICIAL AUTHORITY
   - Ministry of Health

7. SEIZURE 50 TONS OF API ILLEGALLY IMPORTED
   - IPPOCRATE PROJECT

**Process Flow:**
- **Signal:** AIFA, NAS
- **Inspection:** AIFA, NAS, OMCL ISS
- **Customs:** Agency Anti-Fraud, Ministry of Economic Development
- **Analysis:** Import/Export
- **Seizure:** 50 TONS OF API ILLEGALLY IMPORTED
- **IPPOCRATE Project**
MANAGEMENT OF INPUTS | 2

1. SIGNAL SUSPECTED FALSIFICATION
   - Italian Medicines Agency (AIFA)

2. SAMPLING
   - Police Carabinieri NAS
   - Customs Agency Anti-Fraud

3. RESULTS OF ANALYSIS
   - OMCL ISS
   - Ministry of Economic Development

4. VOLUNTARY WITHDRAWAL
   - USMAF
   - Industries
   - Pharmacies
   - Health prof.
   - Patients

AIFA Offices involved:
- Pharma.Vig.
- Product quality

Judicial Authority

Italian Medicines Agency (AIFA)

Pharmacies

Industries

Health prof.

Patients

Voluntary Withdrawal

Ministry of Health

Anti-Fraud

Ministry of Economic Development

OMCL

USMAF

VOLUNTARY WITHDRAWAL
IT ACTIVITIES

Italian Medicines Agency | AIFA

Police Carabinieri
NAS

OMCL
ISS

Ministry of Health

Customs Agency
Anti-Fraud

Ministry of Economic Development

USMAF

Industries

Pharmacies

Health prof.

Patients

IT INTELLIGENCE
WHO Project
Convey
Italian Competition Authority

CYBER SPACE
ILLEGAL
AND FAKE E-PHARMACIES

LegitScript:
BLOCKED MORE THAN 100 ILLEGAL E-PHARMACIES
INTERNATIONAL NETWORK

Single Points of Contact (SPOCs) model: the national points may relate to the international ones, sharing inputs and investigative data via Council of Europe (AIFA), Working Group of EU Enforcement Officers (NAS, AIFA), Official Medicines Control Laboratories (ISS), WHO-IMPACT (AIFA, MoH), Permanent Forum on International Pharmaceutical Crime (NAS). Cooperation with private agencies (as LegitScript or PSI – Pharm. Security Institute) is also considered.
EVOLUTION OF THE COOPERATION MODEL

Single Points of Contact (SPOCs): enforcement model, mainly reactive activities

Community of Practice (CoP): social sciences model, learning context

The evolution of the cooperation scheme was fostered through training and community tools (web based)
RESTRICTED WEB AREA
RESTRICTED WEB AREA

Access is allowed for officials identified by AIFA, USMAF, customs, ISS, NAS, with authentication username and password.
When a new document (EG case study, report, legislation dossier, blacklist, alert, newsletter...) is published, the system automatically generates an e-mail to all users.
“FOOD SUPPLEMENTS” OPERATION

In the framework of the agreement on “measures to apply in case of infringement or conflict with legislation”, signed in December 2011 between Ministry of Health and AIFA, the parties have planned and performed in March 2012 a control operation on the market. The operation was conducted in March in 5 different cities: Milan, Trento, Bologna, Florence and Rome.
The AIFA Counterfeit Prevention Unit organized a web training in order to encourage the involvement of Carabinieri NAS and to explain some relevant aspects:
- Legal dietary supplements and legislation
- Fake dietary supplements and the recent cases
- Operating procedures
“FOOD SUPPLEMENTS” OPERATION

The Unit has prepared two documents:

- a list of illegal products, mostly fake supplements that contain derivatives of active pharmaceutical ingredients, reported from European Agencies;

- a guide on the requirements of legal supplements.

During the day was created a point of contact for information about products, with the help of experts in the sector.
"FOOD SUPPLEMENTS" OPERATION

Every joint team checked the offer of at least five non pharmaceutical shops (EG sex shops, dietary supplements shops).
22 of the suspect products were sampled and analyzed by the Italian OMCL (National Institute of Health); 4 of them were classified as “illegal medicines”.
Police forces followed up to the results of the operation with seizures and investigations.
"FOOD SUPPLEMENTS" OPERATION

Sex shop “Magic America” (Bologna)
“GOLDEN ROOT +”
Presented as stimulant
2 cps, 450 mg.
Price € 25,00.
Lab analysis
demostrated the
contamination with
sildenafil and
yohimbine (alkaloid)
CONTACTS

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