

# Cooperation against counterfeit medicines

The institutional coordination schemes in Italy

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*Agenzia Italiana del Farmaco*  
AIFA

# Public Declaration of transparency/interests\*

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Interests in pharmaceutical industry	NO	Currently	Last 2 years	More than 2 years but less than 5 years ago	More than 5 years ago (optional)
Direct interests:					
Employment with a company	NO				
Consultancy for a company	NO				
Strategic advisory role for a company	NO				
Financial interests	NO				
Ownership of a patent	NO				
Indirect interests:					
Principal investigator	NO				
Investigator	NO				
Individual's Institution/Organisation receives a grant or other funding	NO				

\*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



## FRAMEWORK

- ❑ 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

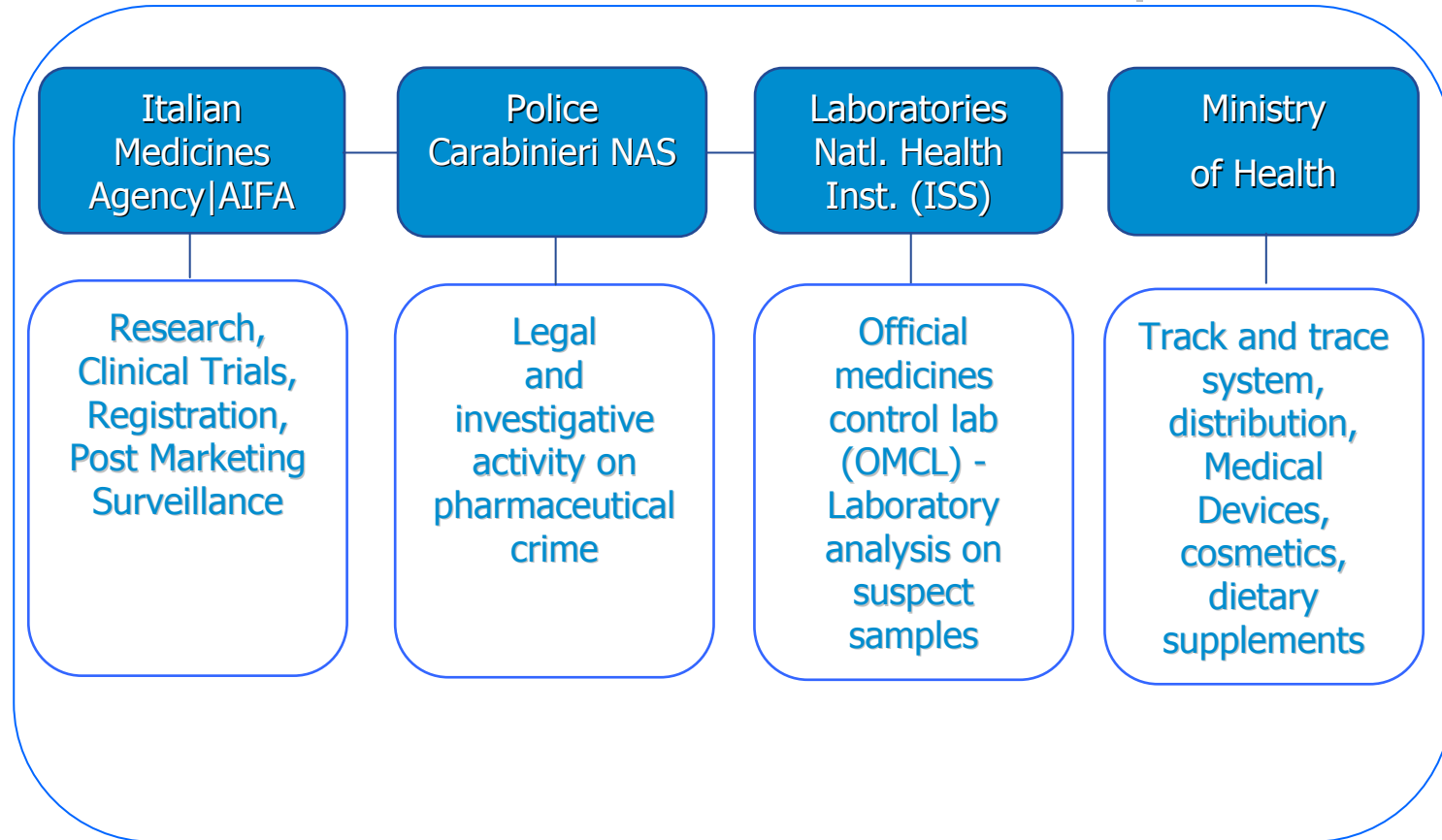


## IMPACT Italia TASKFORCE | 2007

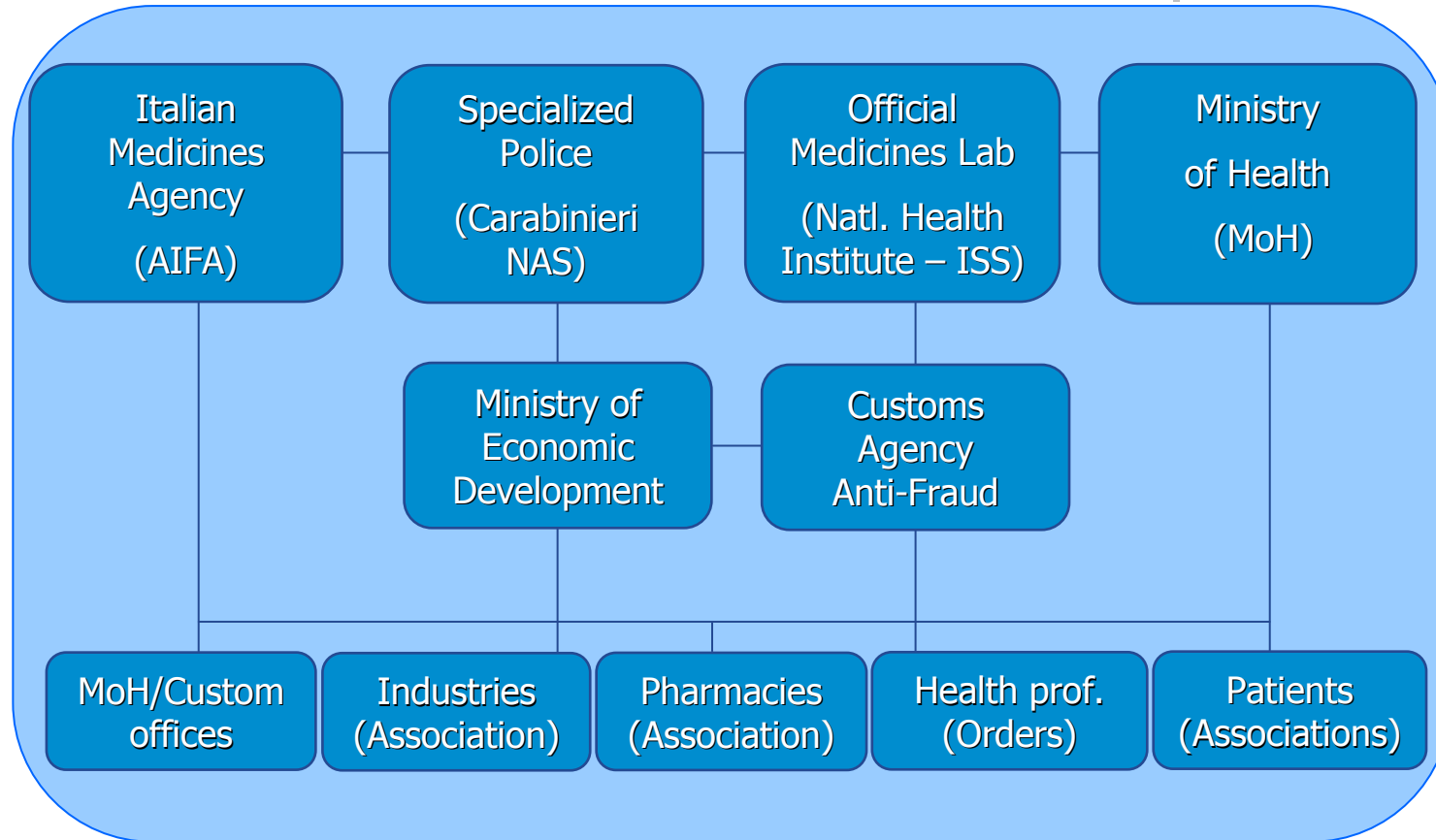
IMPACT Italia, the national anticounterfeiting Task force, has been established in 2007 to combat counterfeit medical products. IMPACT Italia Secretariat is composed, since the establishment of the working group on counterfeit prevention, by four branches of the Italian public administration.



# IMPACT Italia TASKFORCE | 2007



# INVOLVED STAKEHOLDERS | 2013



# FORMAL AGREEMENTS | EXAMPLE

Italian  
Medicines  
Agency | AIFA

Ministry of  
Economic  
Development

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:

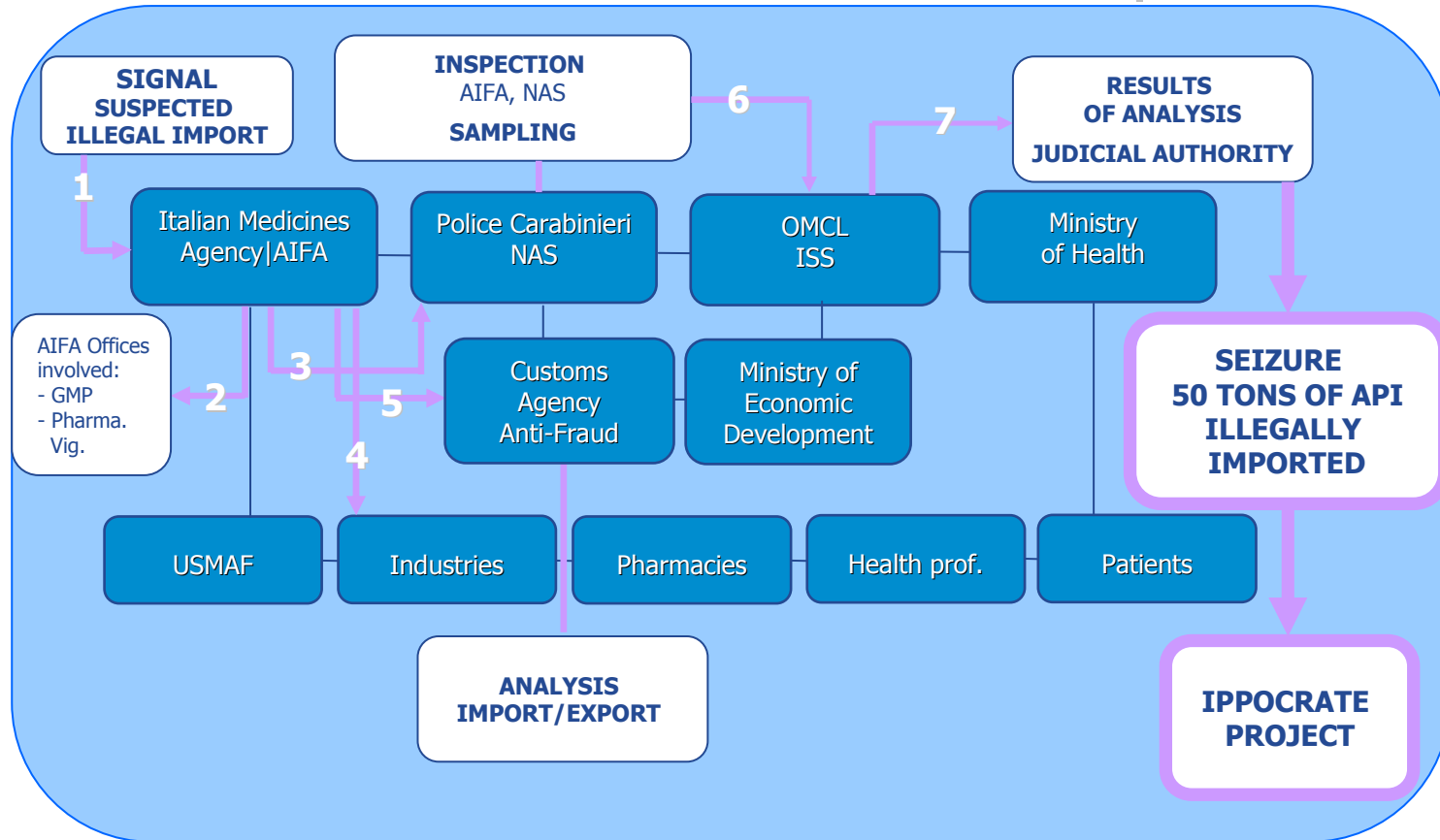
- IT Intelligence project about e-pharmacies
- webinar for operators training
- communication
- handbook for operator



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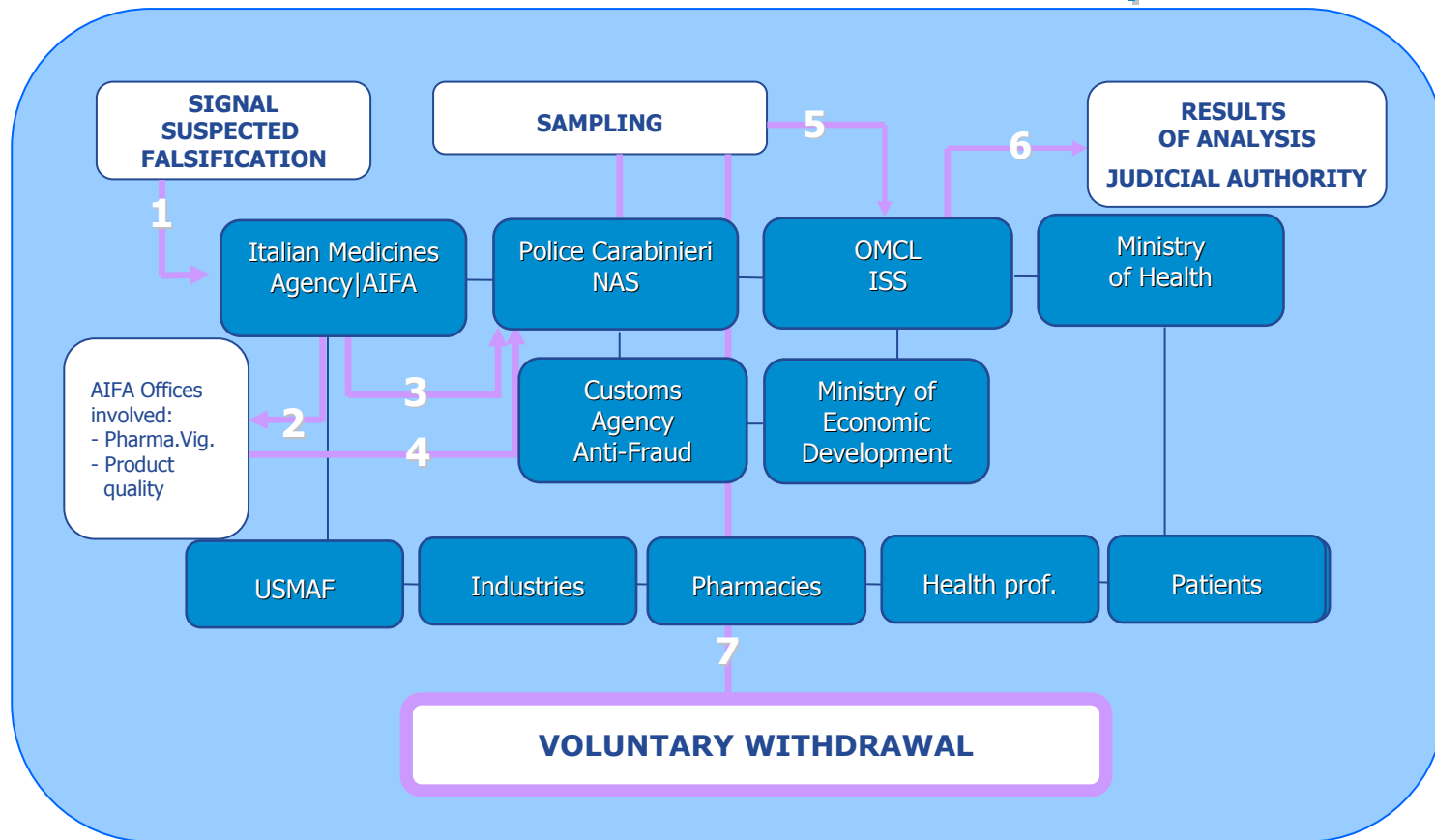
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# MANAGEMENT OF INPUTS | 1

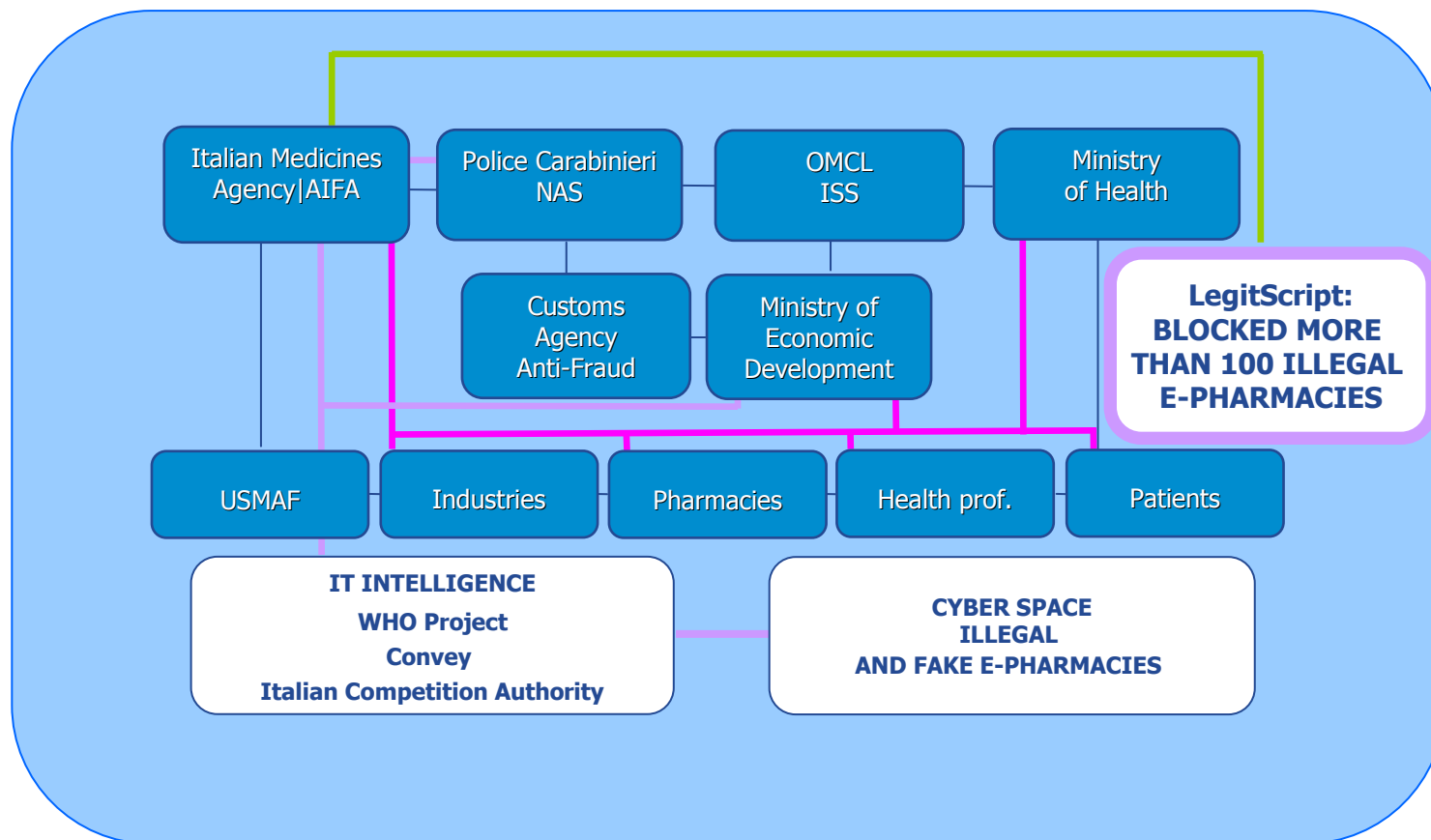




# MANAGEMENT OF INPUTS | 2



# IT ACTIVITIES



# 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

The screenshot displays the IMPACT Italia website interface. At the top, the logo and tagline "La task-force nazionale contro la contraffazione farmaceutica" are visible. The main content area features a section titled "Farmaci contraffatti" with an image of pills and a text block explaining the issue. Below this, a "Task Force" banner lists collaborating institutions: the Ministry of Health, the Carabinieri Command for Health Protection, the Italian Agency for Medicines (AIFA), and the Superior Institute of Health (ISS). The central focus is the "Impact - Area di lavoro collaborativa" section, which contains an "Autenticazione" (Authentication) form with fields for "UserName" and "Password", and an "Accedi" (Access) button. A footer note identifies the unit as "ISS - Unità informatica dipartimento del farmaco".

# RESTRICTED WEB AREA

## Impact - Area di lavoro collaborativa

**Autenticazione**

UserName

Password

ISS - Unità informatica dipartimento del farmaco

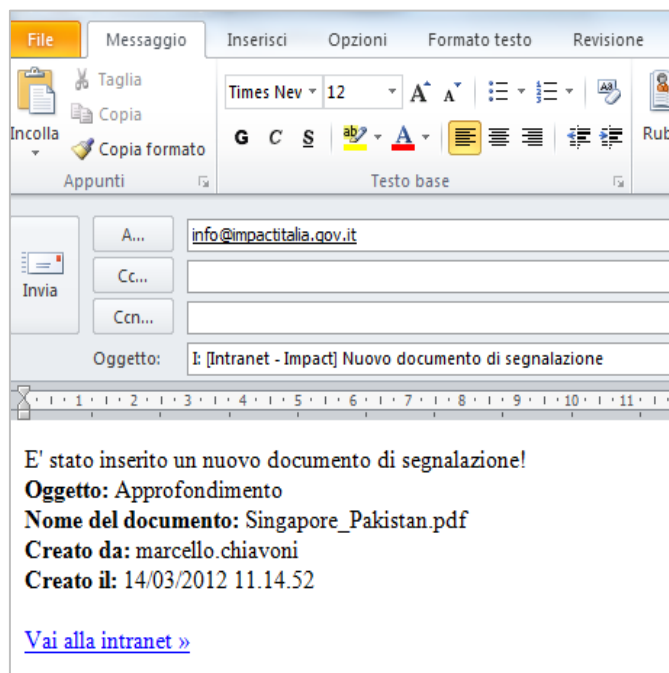
Access is allowed for officials identified by AIFA, USMAF, customs, ISS, NAS, with authentication username and password.



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# RESTRICTED WEB AREA



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.





# "FOOD SUPPLEMENTS" OPERATION

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

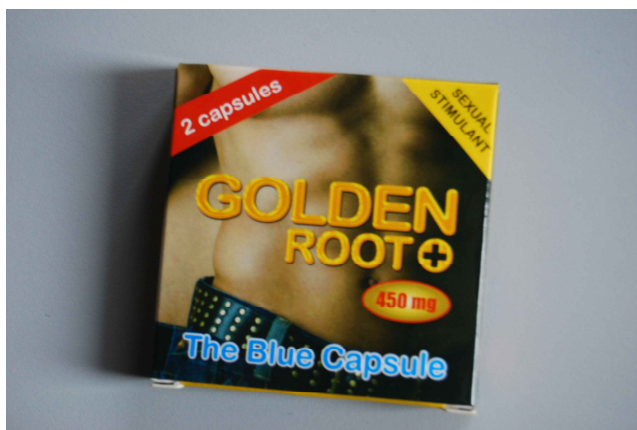
Every joint team checked the offer of at least five non pharmaceutical shops (EG sex shops, dietary supplements shops).

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.



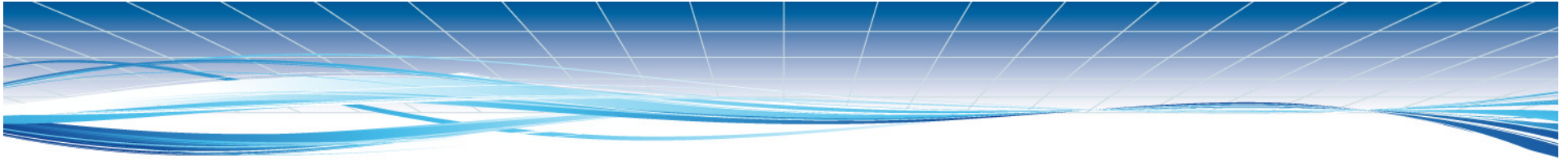
# "FOOD SUPPLEMENTS" OPERATION



Sex shop "Magic America" (Bologna)  
"GOLDEN ROOT +"  
Presented as stimulant  
2 cps, 450 mg.  
Price € 25,00.

Lab analysis  
demonstrated the  
contamination with  
sildenafil and  
yohimbine (alkaloid)





## **CONTACTS**

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