

# A EU operation to develop and enlarge expertise in tackling the trade of fake medicine through the internet

















## About the project

**OPERATION HIPPOCRATES** is a project co-funded by the European Commission which aims to develop and strengthen expertise in tackling the trade of fake medicine through the internet and to exchange best practices.

The project will support operators in their prevention activities through the delivery of reliable and useful information on key aspects, as for instance:

- Customs/pharmaceutical national or international laws on importation;
- Medicines, composition, pharmaceutical forms and active pharmaceutical ingredients;
- Characteristics of different types of health products (medical devices, cosmetics, dietary supplements, herbal products, regulatory issues);
- Recent case studies.

The project, implemented by **Codacons** together with **Associazione ISES** Association of Romanian consumers, **ANPCPPSR**, and Lithuanian, **VARTOTOJU BALSAS**, will have a duration of 2 years.

During these three days of training in Rome, participants from Italy, Lithuania and Romania will share opinions and experiences in order then to be trainers in their national courses on the recognition and investigation of fraud arising from the trade in fake medicines on the internet.

In addition, an e-learning course in each project language will be developed. The aim is to disseminate more widely the objectives of the project and to raise public awareness on the issues addressed.

For more information you can visit the website <u>www.hippocrates-project.eu/en</u>

Mr. CARLO RIENZI, CODACONS President



#### **Operation Hippocrates**

Training course
May 27, 28 and 29 2014
Stadio Domiziano
Via di Tor Sanguigna 3, Rome



#### 27 May 2014 What are medicines?

09:00 - 09:30

09:30 - 09:45

09:45 - 10:15

10:15 - 10:45

10:45 - 11:15

11:15 - 11:45

11:45 - 12.15

12:15 - 12:45

Welcome to participants

Presentation of the training programme

Gianluca Di Ascenzo (Vice-President Codacons)

Presentation of the project "Operation Hippocrates" Dolores Forgione (ISES)

The value of medicines

Achille P. Caputi (Full Professor of Pharmacology – Faculty of Medicine and Surgery – Messina University)

Coffee break

Medicines: definitions (active ingredients, excipients, synthetic and biological medicines, pharmaceutical forms, ATC codes...)

Piergiorgio Zuccaro (Former Executive - Department of Medicines Istituto Superiore di Sanità)

Ethical, SOP, OTC, nutraceuticals and herbal: pharmaceutical and regulatory aspects

Gianluca Trifirò (Department of Clinical and Experimental Medicine Messina University and Department of Medical Infomatics and Epidemiology Erasmus University Medical Center Rotterdam, NL)

The importance of GoodManufacturingPractices and Good DistributionPractices

Riccardo Ballerini (Managing Director Pharma D&S)



## 27 May 2014 What are medicines?

12:45 - 13:30

13:30 - 14:30 14:30 - 15:00 Lunch

Open discussion

Why medicines in pharmacies?

Luigi D'Ambrosio Lettieri (Vice President FOFI)

15:00 - 15:30

**Devices and cosmeceuticals** 

Marcella Marletta\* (Chief of the General Directorate of medical devices, of pharmaceutical service and of treatments security – Ministry of Health)

15:30 - 16:30

Why we should say no to fake medicines Round Table

16:30 - 17:30

Wrap up of the day and closure

<sup>\*</sup> to be confirmed



#### 28 May 2014 E-commerce

12:40 - 13:00

09.00 - 09.30The value of auality Arturo Zanni (Chief Executive - Sanofi) 09:30 - 10:00From the e-commerce revolution to the black market Gianluca Arnesano (Social Media Strateaist Senior Competence Communication) 10:00 - 10:30 Identification of the internet paths Matteo G.P. Flora (Associazione Informatici Professionisti – Italian Computer Society) 10:30 - 11:00 Coffee break 11:00 - 11:20 Which rules for e-commerce? Marco Ramadori (President Codacons) 11:20 - 11:40 SIAC - The anti counterfeiting service Gen. B. Gennaro Vecchione (Commander of the Special Units of the Guardia di Finanza) 11:40 - 12.00Import regulations Edoardo Francesco Mazzilli (General Directorate antifraud and controls - Investigations offices Agenzia delle Dogane e dei Monopoli) 12.00 - 12:20 Unfair commercial practices Jacopo Berti (Italian Competition Authority) 12:20 - 12:40 The privacy issues on health data Riccardo Giannetti (President Pharmasoft)

A new device for the identification of take medicines

Renato Ostorero (Responsible for New Projects GI.BI.EFFE)

Carmelo Lo Duca (President GI.BI.EFFE)



#### 28 May 2014 Trade of medicine through the internet

14:00 -14:30

The national legal framework - Italy

Gianluca Di Ascenzo (Vice-President Codacons)

14:30 - 15:00

The national legal framework - Lithuania

Asta Zlatkiene (Chief Specialist of the Pharmacy department Pharmacy Activities Division Ministry of Health of Republic of Lithuania)

Vida Kevaliene (State Drug Control Service of the Lithuanian Ministry of Health Inspection Division, Chief Specialist)

Loreta Adomonyte (Quality department Manager, Responsible Pharmacist Ltd "Tamro")

15:00 -15:30

The national legal framework - Romania

Tania Radulescu (Medical Director - Hospitals Administration and Medical Services - Bucharest Hall) Ramona Bulcu (Prosecutor - The High Court of Cassation and Justice)

Laurentiu Mihai (Executive Director - Romanian Generic Medicines Manufacturers)

15:30 -16:30

Consumers protection laws

Round table and open discussion

16:30 -17:30

Wrap up of the day and closure



# 29 May 2014 Trade of fake medicine through the internet

09:00 - 09:20

Trade of fake medicine through the internet: a global concern

Domenico Di Giorgio (Unit for counterfeit prevention AIFA)

09:20 - 09:40

Fake medicines: a public health threat

Maria Cristina Gaudiano (Department of chemical medicines quality, Anti counterfeiting Unit Istituto Superiore Sanità)

09:40 - 10:00

European regulation and initiatives (Pangea III, IV, V, Impact)

Col. Vito Antonio Rosario Diomeda (Vice officer N.A.S. Carabinieri – Health protection unit)

10:00 - 10:20

The economical, image, individual and community damage

Enrico Maccallini (General Directorate for the counterfeit Italian patent and trademarks office – Ministry of Economic Development)

10:20 - 10.45

Coffee break

10:45 - 11.15

The Italian experience in the prevention of and fight against trade of fake medicine through the internet

Antonio Longo (President Movimento difesa del cittadino)



# 29 May 2014 Trade of fake medicine through the internet

#### 11.15 - 11:45

## The Lithuanian experience in the prevention of and fight against trade of fake medicine through the internet

Evaldas Visockas (Chief inspector of Violation Prevention Division Customs Department under the Ministry of Finance of the Republic of Lithuania)

Laura Breškiene (Deputy head of Information analysis division Customs criminal service)

Jurgita Šerenaite Kaukeniene (Chief Inspector of the Training and Methodology Division)

#### 11:45 - 12:15

## The Romanian experience in the prevention of and fight against trade of fake medicine through the internet

Corneliu Vișoianu (Advisor of the Prime Minister -Romanian Government) Sorin Stanica (Chief Police Inspector - General Inspectorate of Romanian Police)

#### 12:15 - 13:00

Case studies

Codacons, Vartotoju balsas, A.N.P.C.P.P.S.

13:00 - 14:00

Lunch

14:00 - 14:20

Citizens' role: information and reports

Luigi Gabriele (Public Affairs Associazione Codici)

14:20 - 15:00

Case studies

Codacons, Vartotoju balsas, A.N.P.C.P.P.S.

15:00 - 15:30

15:30 - 17:00

Train the trainers activity

Valeria Graziussi (Codacons)

Closing remarks – Wrap up of the training and closure



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#### About the training

#### **Background**

There is an alarming increase of medicinal products detected in the European Union which are falsified in relation to their identity, history or source. Those products usually contain substandard or falsified ingredients, or no ingredients or ingredients, including active substances, in the wrong dosage becoming a threat to public health.

Directive 2001/83/EC of the European Parliament and of the Council sets the rules for manufacturing, importing, placing on the market, and the wholesale distribution of medicinal products in the Union. Now this Directive has been amended by Directive 2011/62/EU.

#### **Objectives**

- To increase participants' awareness
- To develop and strengthen the expertise in tackling the trade of fake medicine through the internet
- To improve co-operation and exchange best practices in the field
- To develop the train-the-trainer methodology

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