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Presidenza Italiana del Consiglio
dell'Unione Europea

Ministero della Salute

CONFERENCE ON ELECTRONIC HEALTCARE

MINISTERIAL CONFERENCE

Semester of Italian Presidency of the European Council

Carla Collicelli General Vice-Director of CENSIS Foundation

Traceability of medicinal products: new chances

Rome, 7-8 October 2014

HEALTHCARE CHALLENGES NOWADAYS

Economic crysis	Sustainability
Essential changes	Chronicity, growing demand
Technological Innovation	E-health, development of therapies and drugs

ETHICS GETS IMPORTANCE IN PUBLIC AFFAIRS' MANAGEMENT

It is a form of ethics which should be conveyed by:

- self-regulation rules
- verification of competences
- control on processes
- verifications of efficacy
- cost-benefit analysis from the common good point of view
- damages compensation

COUNTERFEITING OF PHARMACEUTICAL PRODUCTS

IT IS A GROWING PROBLEM, EVEN IF IN EUROPE AND ITALY IS STILL LIMITED

LAST CENSIS VALUATION ABOUT ITALY

- 21,4 MILLION OF EURO IN 2013 (VS 21,3 IN 2010)
- EQUAL TO 0,3% OF THE TOTAL AMOUNT ON THE NATIONAL COUNTERFEITING
- GROWTH OF + 0,5% BETWEEN 2010 AND 2012

SUMMARY

EUROPEAN LAW

IDENTIFICATION OF PACKAGE UNITS IN EUROPE

- PRICE DISPLAY
- DISPLAY OF HEALTH INSURANCE SCHEME
- IDENTIFICATION CODE

AN ITALIAN PROPOSAL

THE CENTRAL ROLE OF THE CITIZEN-USER

BENEFITS

MEDICINAL PRODUCTS SAFETY EUROPEAN DIRECTIVE

THE DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 8TH JUNE 2011, IN BRIEF, ESTABLISHES IMPORTANT PROVISIONS ON SAFETY AND COSTS CHARGE FOR DRUGS:

a. SAFETY FEATURES BY WHICH THE WHOLESALE DISTRIBUTORS AND OTHER SUBJECTS AUTHORIZED TO PROVIDE DRUGS TO THE PUBLIC CAN VERIFY THEIR AUTHENTICITY (ANTICOUNTERFEITING IN A WIDE SENSE) THROUGH THE IDENTIFICATION OF INDIVIDUAL PACKAGE UNITS
b. SAFETY FEATURES THAT GARANTEE THE PACKAGING INTEGRITY THROUGH A DEVICE (SEAL)
c. COSTS CHARGE- THE COSTS STATED IN BULLETS A) AND B) – AND RELATED DATABASE, ARE BEARED BY HOLDERS OF MANUFACTURING AUTHORIZATION FOR PHARMACEUTICAL PRODUCTS

MEDICINAL PRODUCTS SAFETY EUROPEAN DIRECTIVE

THE DIRECTIVE RECOMMENDS THAT THE SAFETY FEATURES OF MEDICINAL PRODUCTS BE HARMONIZED WITHIN THE EU, TAKING INTO ACCOUNT ALL THE RISK PROFILES AND ENSURING THE OPERATION OF THE INTERNAL DRUGS MARKET IN ALL THE STATES

IT'S CLEARLY IMPORTANT TO KNOW WHICH ARE THE STARTING SYSTEMS IN THE MEMBER STATES OF UE

A FIRST SURVEY SHOWED THAT EVEN IF THERE ARE SOME ACCURATE CONTROL SYSTEMS, THE ARE STILL SITUATIONS AND AREAS WHERE NO CONTROL OR SOLUTIONS HAVE BEEN APPLIED TO SOLVE THIS KIND OF PROBLEMS

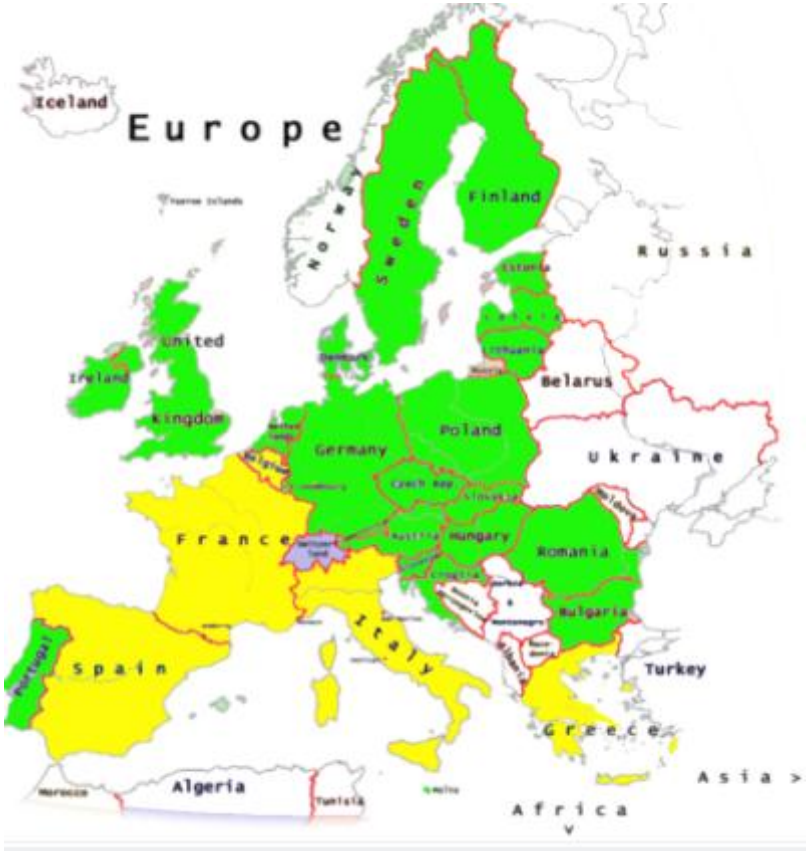
SECURITY CODES OF MEDICINES IN EUROPEAN COUNTRIES

THE IDENTIFICATION ELEMENTS OF MEDICINES' PACKAGES CAN BE SUMMARIZED AS FOLLOWS:

- DISPLAY OF MEDICINAL PRODUCT'S PRICE;
- DISPLAY OF HEALTH INSURANCE SCHEME ;
- ASSIGNATION OF A PRODUCT'S IDENTIFICATION CODE.

THE SITUATION FOUND IN THE SURVEY ON THE 28 EU COUNTRIES SHOWS A CERTAIN BACKWARDNESS IN INFORMATION AND SECURITY CODING

SECURITY CODES OF MEDICINES IN EUROPEAN COUNTRIES



PRICE DISPLAYED ON THE PACKAGE

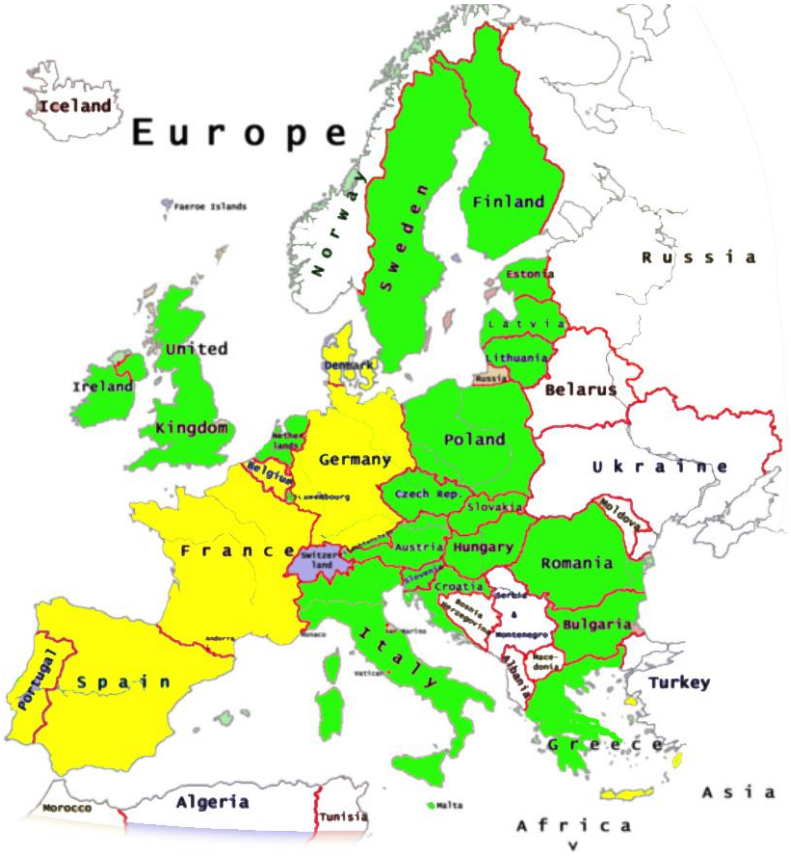
MANDATORY

BELGIUM, FRANCE, GREECE, ITALY, SPAIN

OPTIONAL

AUSTRIA, BULGARIA, CYPRUS, CROATIA, DENMARK, ESTONIA FINLAND, GERMANY, IRELAND LATVIA, LITHUANIA, LUXEMBOURG, MALTA, NETHERLANDS, POLAND, PORTUGAL, CZECH REPUBLIC, ROMANIA, SLOVAKIA, SLOVENIA, SWEDEN, HUNGARY, U.K.

SECURITY CODES OF MEDICINES IN EUROPEAN COUNTRIES



REFUND CONDITIONS DISPLAYED ON THE PACKAGE

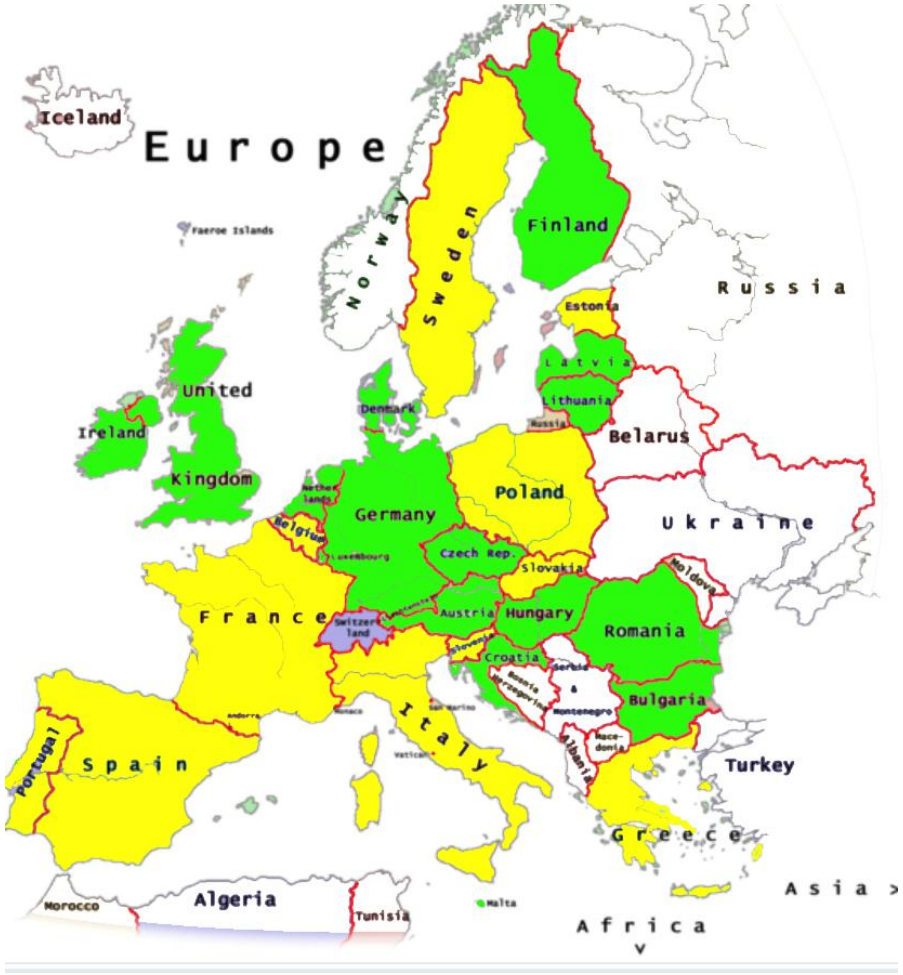
MANDATORY

BELGIUM, DENMARK, FRANCE, GERMANY, PORTUGAL AND SPAIN

OPTIONAL

AUSTRIA, BULGARIA, CYPRUS, CROATIA, ESTONIA, FINLAND, GREECE, IRELAND, ITALY, LATVIA, LITHUANIA, LUXEMBOURG, MALTA, NETHERLANDS, POLAND, CZECH REPUBLIC, ROMANIA, SLOVAKIA, SLOVENIA, SWEDEN, HUNGARY, U.K.

SECURITY CODES OF MEDICINES IN EUROPEAN COUNTRIES



CODE DISPLAYED ON THE PACKAGE

MANDATORY

BELGIUM, ESTONIA, FRANCE, GREECE, ITALY, POLAND, PORTUGAL, SLOVAKIA, SLOVENIA, SPAIN, SWEDEN

OPTIONAL

AUSTRIA, BULGARIA, CYPRUS, CROATIA, DENMARK, FINLAND, GERMANY, IRELAND, LATVIA, LITHUANIA, LUXEMBOURG, MALTA, NETHERLANDS, CZECH REPUBLIC, ROMANIA, HUNGARY, U.K.

SYSTEM OF MAXIMUM EFFICIENCY AND LOW MANAGEMENT COST

THANKS TO THE PAST YEARS EXPERIENCE IT IS NOW CLEAR THAT AN INTEGRAL CONTROL SYSTEM FOR DRUGS AND FOR THE CERTIFICATION OF MEDICINAL PRODUCTS WITH INFORMATIVE SERVICES TO THE CONSUMERS HAS TO HAVE MAXIMUM EFFICIENCY AND EASY IMPLEMENTATION FEATURES

FURTHERMORE THE COST FOR THE SYSTEM IMPLEMENTATION HAS TO BE VERY LOW AND COMMENSURATE WITH THE VALUE OF THE MEDICINAL PRODUCTS PUT IN THE MARKET

SYSTEM OF MAXIMUM EFFICIENCY AND LOW MANAGEMENT COST

FOLLOWING A STUDY MADE BY CENSIS AND CONSAFE INTRODUCED TO THE ITALIAN MINISTRY OF HEALTH, A PROPOSAL FOR AN EUROPEAN CODING SYSTEM (EITHER ON THE LABEL OR DIRECTLY ON THE CASE) HAS BEEN FORMULATED

A DOUBLE CODE TO BE USED ONE IN OVERT, ONE IN COVERT, ONE FOR THE DISTRIBUTION AND ONE FOR THE FINAL CONSUMER

THE IT MANAGEMENT COST OF THE 2 CODES FOR THE ENTIRE VALIDITY PERIOD OF THE INDIVIDUAL MEDICINAL PRODUCT HAS BEEN ASSESSED AS FOLLOWS:

11.00 euro

per 1000 package units

THIS COST INCLUDES ALL DIRECT AND INDIRECT COSTS WITH A UNIVERSAL COVERAGE

CONFORMITY TO THE EUROPEAN DIRECTIVE

1. Seal
2. Code
3. Batch number and expiry date
4. Database managed by manufacturers and institutions

FULL WARRANTY OF SAFETY AND TRANSPARENCY

DATABASE

It is the guarantee and protection point for the citizen and all the tasks related to the safety and certification of the coded product are assigned to it

It generates codes and manages them in all phases

It exchanges data in a European network with national databases

CODE

It has strict and precise features imposed by a rule wich has to be observed at every stage, from the production to the final use.

It doesn't require restrictions about the support to be used, and therefore the solutions are chosen on a functionality and / or cost basis

It requires the full respect of quality standards, therefore it has to be committed to specialized companies according to the solution type chosen for the support

SEAL

It strictly follows the operational provisions established by the European Union

It is subject to the approval of the local Ministry when it has to receive the marketing authorization

MAIN FUNCTIONS OF THE SYSTEM

PRINTING
CENTRE codes

codes on support

PHARMACEUTICAL INDUSTRY

coded medicinal products

DEPOSITARIES

CENTRAL DATABASE

MIN. OF HEALTH DATABASE

EUROPEAN NETWORK

coded medicinal products

DISTRIBUTORS

coded medicinal products

PHARMACIES

coded medicinal products

CITIZENS

SYSTEM OF MAXIMUM EFFICIENCY AND LOW MANAGEMENT COST

BY COMPARISON WAY WE CAN CONSIDER THE COST OF THE

ITALIAN PHARMACEUTICAL OPTICAL LABEL (BOLLINO) PER 1000 PIECES

	Euro
PRINTING, CONTROL NUMBERING AND DELIVERY	9.00
WATER-MARKED TRIPLEX PAPER, SILICONE ADHESIVE PAPER	3.70
IPZS GROSS MARGIN	13.30

TRANSFER PRICE FROM IPZS TO THE INDUSTRY 26.00 EURO

WITH THE NEW SYSTEM FOR THE ITALIAN PHARMACEUTICAL INDUSTRIES THE COST OF THE EUROPEAN CODED SUPPORT WOULD DECREASE OF

- 46%

INDUSTRIAL SIGNIFICANCE PROBLEM

- CONSIDERING THE ESSENCE AND THE AIMS CONTAINED IN THE DIRECTIVE, WE CAN IMAGINE AN IMPLEMENTATION SYSTEM WHICH IS ABLE TO COMPREHEND FURTHER ISSUE DEVELOPPED IN THE EUROPEAN PHARMACEUTICAL SECTOR NOWADAYS

- IN THE NEW EUROPEAN CONTEXT THE TRACEABILITY OF PHARMACEUTICAL PRODUCTS IS CHARACTERIZED BY AN INDUSTRIAL MARK, WHILE IN THE PAST IT WAS MORE FOCUSED ON HEALTHCARE FEATURES

- THE NEEDED IMPLEMENTING DECREES (RELATED TO THE DIRECTIVE ISSUED ON THE SUBJECT) HAVE NOT BEEN PREPARED YET

- THE PROPOSAL HAS NO EFFECT ON PHARMACEUTICAL INDUSTRIES AND ON COSTS OF APPLICATIONS FOR THE ADAPTATION REQUIRED TO BE IN CONFORMITY WITH THE LAW PROVISIONS

THE CENTRAL ROLE OF THE CITIZEN/PATIENT IN THE SYSTEM

THE PROPOSED SOLUTION STRONGLY PROMOTES THE IMPORTANT ROLE OF THE CITIZEN / PATIENT, WHICH WILL GET ACCESS TO ALL INFORMATION:

- ON THE PHARMACEUTICAL PRODUCT IN GENERAL (UPDATED PATIENT INFORMATION LEAFLET...)
- ON THE PACKAGE UNIT(VALIDITY PERIOD, POST MARKETING PROVISIONS, AUTHENTICITY AND ORIGIN CONTROL, STORAGE INSTRUCTIONS, ...)
- THIS COULD BE DONE AT ANY TIME, EVEN DURING THE ADMINISTRATION OF THE DRUG

BENEFITS OF THE CODING SYSTEM FOR THE STAKEHOLDERS

AN INTEGRATED SYSTEM WOULD ALSO BE ABLE TO GENERATE SIGNIFICANT BENEFITS IN TERMS OF EUROPEAN HOMOGENEITY TO ALL THE SUBJECTS INVOLVED, STARTING FROM THE PHARMACEUTICAL INDUSTRY, WHICH MAY HAVE A FURTHER INSTRUMENT TO STUDY THE MARKET, TO IMPLEMENT FOCUSED RECALLS, TO OBTAIN REDUCTIONS OF INSURANCE POLICIES AND TO MANAGE THE INTERNAL AND MARKET STOCKS IN REAL TIME

EVEN DISTRIBUTORS, PHARMACIES, HEALTH CENTRES WOULD RECEIVE BENEFITS AND ADVANTAGES BY TRACKING THE PRODUCT WITH SIMPLE OPERATIONS, FROM WHEN THE PRODUCT IS TAKEN IN CHARGE UNTIL ITS FINAL SALE

THE SYSTEM INCREASES THE VALUE OF THE MINISTERIAL DATABASES AS A TOOL FOR THE COLLECTION OF ALL THE INFORMATION FOR EPIDEMIOLOGICAL EVALUATION AND CONTROL OF PHARMACEUTICAL SPENDING

RECOMMENDATIONS

IN THIS PHASE THE DIRECTIVE SHOULD BE PUT INTO EFFECT TOGETHER WITH THE EVALUATION OF ACTIONABLE PROPOSALS WHICH SHOULD BE ABLE TO FOCUS AND DEFINE THE FOLLOWING POINTS:

1. THE PROCESS OF DATABASE, DATA CONSULTATION AND DATA FEEDING SYSTEMS

2. CODING MODELS ON DIFFERENT SUPPORTS

3. ALL THE AVAILABLE SEAL MODELS

CONFERENCE ON ELECTRONIC HEALTCARE

Thank you for the attention!

www.censis.it

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Carla Collicelli Vicedirettore Fondazione CENSIS