ARES SPA PORPOSAL TO

THE PUBLIC CONSULTATION IN PREPARATION OF A LEGAL PROPOSAL TO COMBAT COUNTERFEIT MEDICINES FOR HUMAN USE

Key Ideas For Better Protection Of Patients Against The Risk Of Counterfeit Medicines

Introduction

ARES Spa is glad to have the opportunity to take part in this Public Cosultation of the European Commission.

ARES has been working for years in the field of pharmaceuticals in Italy and with our system and the collaboration – started in 1988 - of Italian Mint (Istituto Poligrafico e Zecca dello Stato) we have been able to completely shoot down pharmaceutical counterfeiting and theft in our Country.

We believe it is necessary and urgent to undertake a decisive action at a global level against counterfeiting (but also theft and recycling of stolen pharmaceuticals) this is the reason why we are moving in this direction, improving the system we will be introducing later on.

We are firmly convinced that these fraudulent activities must be strongly faced from Public Institutions because they negatively impact public health and the national health systems (as well as the Treasury): in this sense our goals totally coincide with the goals conveyed by European Commission through this initiative.

ARES's project **eliminated** the recycling of the stolen and counterfeited pharmaceuticals being sold in the public sector. The law was enacted by the Italian National Health Service (Servizio Sanitario Nazionale italiano).

Exeperience of drug traceability in Italy

ARES's successful system for drug traceability in Italy, created in collaboration with the Istituto Poligrafico e Zecca dello Stato (Italian Mint), has proved an important starting point for the research, study and experimentation of integrated traceability systems.

This system has been improved in 2001 and then in 2004 and 2006, until today.

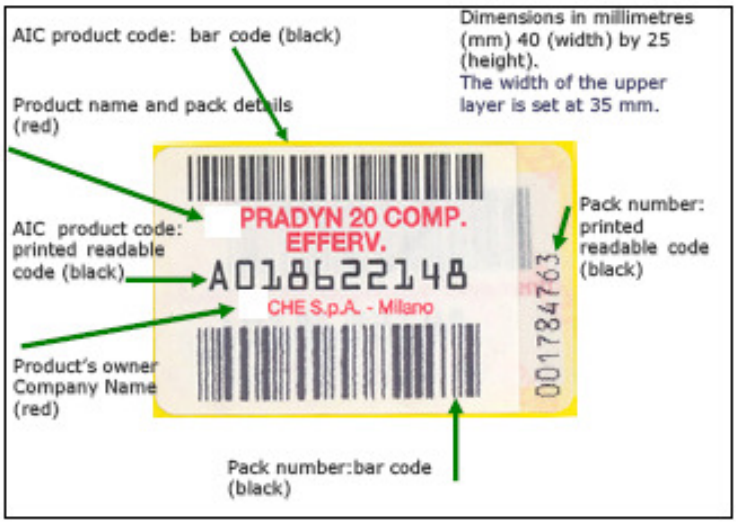
The system lays down that:

- every single pack must be made unique by the application of a specific identification tag (called "label");
- the transfers of packs from one phase to the next of the production and distribution chain must be documented and memorized in a data bank managed directly by the Ministry of Health; and
- the actual production of the tags, as indicated by the data bank of the Ministry, is to be undertaken by the Italian Mint, which guarantees that they are originals.

The packs of medicines that go onto the market bear self-adhesive labels – with specific identification systems – that enable the definite identification of every single pack.

These items were designed in such a way as to prevent both their duplication and removal. The adhesive labels and where to affix them were also the subject of careful study.

In practical terms, these elements have been subdivided into six areas, for each of which the following requirements in terms of size and content have been determined.



This track and trace system has enabled:

- the combating of possible fraudulent activities (the cloning or counterfeiting of drugs) that negatively impact public health, the national health system and the Treasury;
- the prevention and repression of other illegal activities related to the selling-on of packs previously stolen by monitoring the transfers of drugs from one point in the distribution chain to the next;
- the ability to follow the packs of drugs along the distribution channel has provided valuable epidemiological information and vital data on trends in major diseases, so enabling the authorities to take the necessary decisions on investments and to prepare the appropriate measures.

The technological choices were also "spot on":

- the cost of the means used (a three-layer tag, one of which in watermarked paper), compatible with the value of the item concerned;
- the set-up and preparation costs, compatible with the value of the item concerned;
- the affixing of the tags on the packs of pharmaceutical products;
- the optical reading of the identification codes on the individual packs (bar code) at all stages of the primary, intermediate and final distribution systems;
- the management of pack movement data.

The reasons for the success of this system can be understood by analyzing the questions that ARES's research and development department asked when they first began the feasibility study for the system.

These questions were:

- Why, in spite of the numerous traceability systems on the market today, do theft, counterfeiting and recycling continue to be perpetrated with great harm to society, above all in sensitive sectors linked to citizens' well-being?
- What will have to be the key features of the "traceability system for drugs in Italy" that will enable the elimination of any possibility of introducing onto the Italian market drugs that are counterfeit or that have been stolen and recycled?

The answer to the first question came from the analysis of the characteristics of the most commonly used traceability systems.

Even today, many of these are largely based on increasingly sophisticated methods or technologies – holograms, IR inks, RFID, DNA, etc. – that enable the product to be identified with certainty (or almost). However, such methods have the serious drawback that they cannot be used by ordinary people who are not able to access laboratories equipped with the sophisticated equipment required in order to certify the originality of the identification tag, which, in turn, certifies the product. Other systems focus on special systems of printing with optical or magnetic reading devices – matrix codes, laser systems, etc. – that enable local memorization, on the individual product, of the "history" of that particular item, so allowing one to work back up the logistical chain simply by reading that particular code. These systems are undoubtedly valid, until the code becomes illegible for reasons that range from simple inappropriate handling (rubbing, scraping, tearing, etc.) to fraud.

Moreover, also these codes necessitate the use of sophisticated equipment. Yet other systems are based on the use of electronic archives that store important data on the product and that can be accessed using the identification code assigned to it during production. These systems allow information about the originality of the product in question to be provided after first accessing the data bank, also by telephone.

However, they cannot prevent product duplication or cloning.

It was clear that it was not right to go for just any identification system (even a very sophisticated one), or the simple local memorization of the key data, or the use of a straightforward data bank in order to resolve the issues relating to traceability.

The answer to the second question was that the only way forward was to develop a system that integrated all of these: It was necessary to create an integral security system that would utilize various methods, integrating them into a coherent system.

Therefore, it was necessary to focus on:

- creating identification systems that were both technologically appropriate (performance/costs) to the type of product to be traced and easily legible also for the ordinary user. This meant being able to use any sort of identification technology – RFID, IR, UV, holograms, DNA, etc. – on the condition that it met the needs of that particular product;
- creating data banks that were sufficiently well equipped to handle the mass of information generated during the production phase and the subsequent movements of the products;
- creating an autonomous body with the function of being the "certifier" of the validity and accuracy of the data transmitted by the various elements of the production and distribution chain of the products;
- simplifying the procedures for reading and storing/transmitting data, so as to make the system viable without having to make too high an investment;
- making use of existing networks and standards – Internet – to link all the users of the service.

The result of the application of our system was the complete eradication of the theft, counterfeiting, and recycling of packs of pharmaceutical products in the Italian market for medicines.

Our proposal: SITRIS

This philosophy, which has proved a winning one for Italian pharmaceuticals sector, is the one that has led our Company to create the new SITRIS integral traceability and re traceability security system. The system – in its current shape – is managed in partnership with:

Technology innovation, integrate solutions addressed to consumer and business markets, advanced web infrastructures, spread of fixed and mobile broadband, products and technologies integration.www.telecomitalia.it

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The system is divided in two distinct parts:

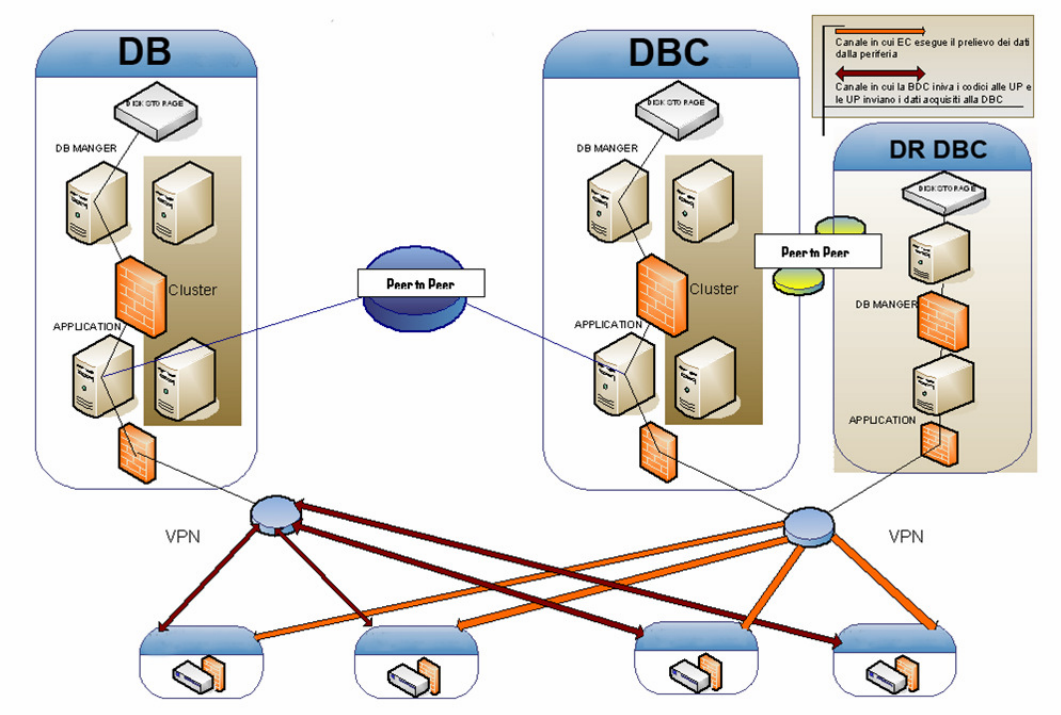
a) Data control (a standard part of the system, carried out by means of peripherals installed in the producer's company)

b) Products codification (distinct from the data control system; it is completely flexible and can be adapted to the needs of any company)

Data control includes:

- Central DataBank (which generates and releases unique and unrepeatible codes and then manages these codes during all steps of the chain)
- Central DataBank of Certification (parallel DB which certificates the codes, verifies and double-checks the originality of the pharmaceuticals during all steps of the chain)
- Peripherals (the peripheral unit installed at the producer's manufactoring which constantly communicates with both DBs)

Data are gathered from peripherals installed in every part of the production and distribution chains and are continuously communicated to the central databank and the central databank of certification so that products can be automatically and systematically certified at every stage.



The security system ensures:

- data control procedures are respected at all times and at all levels of reception and transmission
- mechanism to verify alarm operation in case of anomalies are systematically managed and controlled
- set procedures are launched in cases of alarm at any point of the global network
- the inspection network is properly organised and managed.

The networks are Internet and Extranet with the crypted H24 security functions.

The system:

- gets the identification code from the central databank and matches them to the products to be marketed
- verifies and controls the code numbers received, those used and those destroyed during manufacture
- transmits to the central databank the analytical downloading of the products with the codes pallets, the single box, or the packaging code.

In all cases the central databank registers all the codes for each individual packet.

Identificative Supports:

It is possible to use any identification tag currently available on the market (RFID, holograms, ultraviolet ink, infrared ink, fluorescent polymers, barcodes, micro texts, chemical codes, special glues, laser, fusion, heat-shrinking, anti-refill tops, audio-software, CDs…)

The code is the only reference of a single product and identify its typology and characteristics. Any identification method in use prior to the adoption of SITRIS can be incorporate into it.

The code accompanies the products in all stages of the distribution chain till it reaches the end user, and even up to the disposal phase, if envisaged.

The system keeps track of the processes in the life cycle of the product through a unique, reliable and continuously updated register.

SITRIS code is composed by 14 alphanumeric fonts, is unique and will never be repeated twice. More than 182 billions of billions of unique codes can be generated. To give an idea, using 1,000 computers creating 3.000.000 transactions per second, getting to the last unique SITRIS code would take almost 2,000 years.

The system complies with the ISO 27001 standard.

SITRIS has been introduced and reported in:

Indiachem, Mumbay 2006

La Semaine De La Traçabilité, Paris 2007

IMPACT/WHO Meeting, Prague 2007

Reconnaissance International Meeting, Prague 2007

Reconnaissance International Meeting, Minneapolis 2007

SITRIS has been introduced to:

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advancing security, serving justice, building peace
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