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Counterfeit medicine. A threat to health. Legal situation

Title in Spanish: *El medicamento falsificado. Una amenaza para la salud. Situación legal*

Carlos del Castillo Rodríguez[1,*], María Jesús Lozano Estevan

[1]Facultad de Farmacia, Universidad Complutense de Madrid

ABSTRACT: The existence of substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products is an unacceptable risk to public health, becoming an emerging problem in recent years. However, we should be aware that the phenomenon of counterfeiting is not a novelty since such practice coexists with human beings since time immemorial. In the present work we will do a partial analysis of counterfeiting situation from a legislative point of view and will analyze how various legal and non-legal instruments have been used trying to resolve this issue in the European context.

RESUMEN: La existencia de medicamentos falsificados es una realidad. Se trata de un problema emergente en los últimos años. Sin embargo, hemos de ser conscientes que el fenómeno de la falsificación no es un hecho novedoso ya que tal práctica convive con el ser humano desde tiempos pretéritos. En el siguiente texto se realizará un análisis parcial de la situación de los mismos desde su punto de vista legislativo y se analizará cómo se han utilizado diversas herramientas jurídicas y no jurídicas para intentar solventar esta problemática existente a nivel comunitario.

[*]**Corresponding Author:** carlcast@ucm.es
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1. INTRODUCTION

Medicines are medical products subject to state intervention in all their phases (1), being multi-dimensional products (2). According to Valverde (3): "there must be a need of moving towards a free global movement of medicines taking into account the specific problems of developing countries". The legal regulation of medicines can not be understood without a detailed regulation of persons, both natural and legal persons involved in the circulation and supply of medicines (4).

Nowadays, worldwide, there is an irregular supply of medicines. This activity is a great threat that has to be controlled by the public administration as guarantor of citizens' rights.

We should understand that the movement of counterfeit medicines is an emerging problem in both developed and developing countries. Although in Spain the distribution chain is secure, health authorities should be alert to the emergence of possible counterfeit medicines, especially sold online through websites. The community pharmacist occupies the best position to exercise pharmacovigilance and detection activities of counterfeit medicines since at present there is a large number of consumption in developed countries due to the population's feeling of insecurity.

Although health authorities in developed countries had proved the existence of spurious/falsely-labelled/falsified/ and counterfeit medicines, they thought they could only be purchased by users via Internet. There was no evidence that might be found in legal distribution channels, at least in the European Union.

However, in 2007, the British health authorities detected more than two million doses of Zyprexa imported, nearly half of them were acquired by patients. This medicine did not contain the doses indicated in its fact sheet (5).

For this reason, and given the health alert that occurred, it was decided to regulate/change urgently issues related to distribution and import of medicines in the European Union in order to ensure proper distribution channel of the medicines

2. SITUATION OF COUNTERFEIT MEDICINES IN SPAIN

After the need of promulgation of Royal Decree 1/2015, of July 24, amending law of guarantees and rational use of medicines and health products (6), it has been set a clear and necessary definition of counterfeit medicine. The metioned Act defines counterfeit medicine as: "Medicines that are deliberately and fraudulently mislabelled with respect to:

1. º Its identity, including packaging and labeling, name or composition in regard to any of its components, including excipients and the dosage of those ingredients;

2. ° its source, including the manufacturer, country of manufacturing, country of origin and the holder of the marketing authorization; or,

3. ° its history, including records and documents in relation with the distribution channels used."

This problem is by no means trivial. The existence of counterfeit medicines is not new. There is plenty of historical data (7) demonstrating the use of these medicines since time immemorial. It is true that this problem has lived with human beings from almost its origin, but the most significant rise has occurred in the last forty years when population started to consume medicines, most of time, almost everyday.

For this important reason, several European institutions enacted different guidelines that were transposed into Spanish law in relation to our Constitution in the field of health protection, preventing the entry of these medicines into the legal distribution channel. The European Commission noticed the growing dimension of this problem and, during the first months of 2008, made an inquiry about the key ideas to better protect patients against the risk of counterfeit medicines publishing in December 2008 a proposal amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply system of medical products which are falsified in relation to their identity, history or source.

The Commission made a proposal to amend pharmaceutical legislation (8) against counterfeit medicines in order to prevent the spread of these through the legal supply system. For this, the Commission introduced additional guidelines related to products, in particular on safety features for medicines subject to prescription; new rules regarding distribution and import of medicines and active pharmaceutical ingredients (API's); and rules regarding the quality of manufacturing and the authenticity of the mentioned API's.

On the other hand, it should be noted the importance of Directive 2011/62/EU (9) amending Directive 2001/83/EC (10) that established a European code relating to medical products for human use, as regards the prevention of the entry of counterfeit medicines in the legal supply system.

This new European directive had as its main purpose to stop the massive emergence of counterfeit medicines in the European Union in both illegal, in most cases, and legal (11) channels including a definition of counterfeit medicine and making in-depth analysis on rational use of medicines and their distribution within the Union European in order to prevent the proliferation of counterfeit medicines.

However, we should be aware of the existence of other "non-legislative" weapons that enable the eradication of this phenomenon at least in Spain and, consequently, on many occasions, in the European Union. From our point of view, health workforce education is the most essential component for health promotion in most constitutions worldwide.

It is desirable to emphasize the importance of health workforce education in connection with counterfeit medicines. The health workforce education is defined by the World Health Organization as "a set of information and education activities that encourage people to enjoy good health, to know how to attain it, to do everything as possible individually and collectively in order to maintain health and to ask for help if needed."

Furthermore, this definition could be extended, from our point of view, considering the Spanish legal system, specifically to Law 44/2003, of 21 November, on Health Profession (12) Planning which highlights the educational role that health professionals should have with their patients.

We have abovementioned the existence of several initiatives both from a legislative and non-legislative point of view used by authorities and health professionals to try to partially eradicate the proliferation and development of the problem of counterfeit medicines both in legal and illegal distribution channels.

The aim of this work is not to describe in detail the methods and initiatives of combating the rapid rise; however, we would like to show some of them due to the importance they have had in the possible modification of both Spanish and EU regulation.

The first initiative we would like to emphasize is the National Strategic Plan 2012-2015 for medicines coordinated by the Spanish Medicine Agency's and Health Products. This initial strategy was articulated as a response from all sectors involved in order to shield the pharmaceutical channel against attempts to introduce counterfeit medicines.

After the term of the previous strategy (2008-2011) and after the approval of Directive 2011/62/EU, a new overall Strategic Plan, with the same principles as the previous strategy, was designed; however, this new one raised new performances based on the changes in recent years in order to strengthen their effectiveness. The main objective is to protect the health of patients preventing them from consuming counterfeit medicines.

Secondly, we would like to indicate that group IMPACT (The International Medical Product Anti-Counterfeiting Task Force) published a document entitled “Anti- counterfeit Technologies for the Protection of Medicines”. This work shows the various technologies available to, to the extent possible, try to alleviate the proliferation of counterfeit medicines (13).

Finally, and from a more global perspective, we highlight the publication in 2014 of the document entitled National Guidelines for Pharmacists by the International Pharmaceutical Federation (FIP) in order to combat counterfeit medicines and provide member institutions a plan to facilitate the development of a national guideline for pharmacists on counterfeit medicines (already done, as stated above, in Spain both in 2007-2011 and 2011-2015).

In the first part of the mentioned guideline different definitions of counterfeit medicines and their extension to counterfeit medical devices are reviewed; and it also includes an analysis of the extent of the problem from an international perspective. Then, the document provides a list of thirty-two medicines most likely to be adulterated,

and reviews the consequences for personal and public health. Furthermore, this document also provides a tool for visual inspection to facilitate the detection of counterfeit medicines.

It is true that the occurrence of such medicines has considerably increased in recent years due to the emergence of new technologies that allow the purchaser/patient buying medicines through telematics channels. In many of these cases, the purchaser ignores the existing rules on the sale of such products and because both the comfort of acquiring them and the anonymity that occurs in this purchase, he/she prefers to use this channel without being aware that most of the time he/she is buying a counterfeit medicine. It is for this reason that European health authorities have tried to stop this indiscriminate selling enabling pharmacies legally established to sell online some medicines that before patients only could buy in the pharmacy.

However, at present the society is fully linked due to the rapid expansion of the Internet phenomenon that provides users large amounts of information, sometimes excessive, and allows the purchase of products through the network.

Consequently, this outrageous commercialism has caused the sale of different types of goods, including medicines. This fact has led to a regularization of the market to try to eradicate criminal acts.

Moreover, in the field of European Public Health it is worth noting the full respect of the European authorities on the responsibilities of Member States for the organization and delivery of health services, such as pharmaceutical services. We must be aware that pharmacies are health institutions (private property and public interest) (14) and in Spain are distributed following a demographic and geographical (15) criterion ensuring access to medicines to almost the entire population (16). In Spain dominates the so-called "Mediterranean model" pharmacies which enables citizens a high degree of accessibility to medicines.

However, given the massive proliferation of illegal sale of medicines (counterfeit and unauthorized) to the public through Internet and with the objective of public protection and risks' reduction, the Royal Decree 870/2013 was approved, regulating the online selling of non-prescription medicines (17) to the public and regulating also the Law 29/2006 of July 26 on sale of medicines for human use through websites for later publishing a single text (Royal Legislative Decree 1/2015 of 24 July that approves the revised text of the law on guarantees and rational use of medicines and health products) which encompasses most part of the comprehensive regulation on abovementioned medicines.

On the other hand, it should be noted that in Spain the sale of medicines are also done by post (18). However, this fact is not similar to the one of selling medicines online. The Spanish Constitutional Court allowed this type of sale (19) under strict conditions.

BAES says that allowing the sale of prescription medicines by post and telematic procedures to specific patients, does not mean that it is possible to dispense these medicines outside the official circuit and for this reason, the Court strengthens the essential role of health professional.

It is clear that the main aim of the promulgation of the Royal Decree was to strengthen the telematic channel in order to make it safer when dispensing medicines. However, we should notice that only, at least in Spain, may be online dispensed non-prescription medicines of human use following industrial manufacturing.

As regards online sale of non-prescription medicines, Spanish legislation protects the rational use of medicines, establishing a series of guarantees to ensure that the supply and demand of medicines is done from a health public interest facility, as in the case of the pharmacy, and with the performance of a skilled professional, both health and scientifically, of medicines as pharmacists.

The second Additional Provision and sole Transitional Provision of the mentioned Royal Decree show that pharmacies before starting distance selling of non-prescription medicines for human use manufactured industrially through websites (20) must, firstly, have been published a common logo on the website, and secondly be running the websites of the Spanish Agency for Medicines and Health Products and the competent authorities of the Autonomous Communities.

Pharmacies interested in telematics salling shall send their notifications to the competent authorities of their autonomous region, so that the latter will be able to implement their websites.

In addition, pharmacies should inform about the beginning of their telematics activity, data on pharmaceutical holder of the pharmacy that offers such a service, and the date of the beginning of the activity, web address and should describe the procedures for sending the patient medication.

However, pharmacies that plan to provide this service must be aware that it is a "virtual" extension thereof. Consequently, the pharmacist must perform the legal and ethical measures that regulate their professional work in the field of medicines dispension. They should also meet a number of requirements described below.

Firstly, as we have showed in the previous parragraphs, they can only perform this service, pharmacies which have been legally authorized prior notification of such activity to the competent authority of the Autonomous Community in which it is located. Orders are directly made to the pharmacy through the web address given and it can not offer or link to self-medication or self-diagnostic tools that avoid the obligatory advice of the pharmacist.

Secondly, dispensing can be only made by a pharmacist, prior personalized advice, located in a pharmacy legally established and without the involvement of intermediaries.

Thirdly, it may occur that the buyer is located in

another Member State of the European Union. In this case, the sale must follow the Spanish law, as well as the enforceable one in the country of destination.

On the other hand, it is important to highlight the problems that may arise at the time of the medicines delivery. The pharmacist in charge of dispensation of medicines is the person responsible of this expedition which may only be sent from the pharmacy responsible for the dispensation, indicating, among others, data and expenses of mailing, and the address.

It is also important that after delivering the medicine in the address where the user has indicated, refunds are not permitted unless the medicines have been delivered by mistake, do not correspond with the order or have been damaged during the transport.

With regard to means of payment, the web can offer different ways according to the needs of the author. These means can be: a) credit/debit card; b) bank transfer; c) payment gateways; d) cash on delivery payment.

In addition, we should consider that when dispensing non-prescription medicines, the pharmacist is using Internet technology. Consequently, he/she must know that such mean facilitates the transmission of information and transactions but at the same time it is important to know that this is a mean that requires the development and use of a series of measures to take advantage of all abilities it can eventually provide.

On the one hand, pharmacies should have a technology infrastructure (hardware and software) for dispensingnon-prescription medicines for human use through websites . In addition, the infrastructure developed for the website of the pharmacy must ensure the availability of services offered during the period established for it, as well as an adequate level of usability, presenting structured information so that it offers easy, intuitive and fast navigation.

The records of purchases and forms exchanged between the user and the pharmacy during the purchase process should be stored in a secure system that guarantees that the information is kept for a minimum period of two years (the maximum required by law).

The information used in dispensing through websites of non-prescription medicines for human use is related to the user's health. For this reason there must be included security measures described in Royal Decree 1720/2007 (21), of 21 December, which approves the Regulation implementing Organic Law 15/1999, of 13 December (22), on the Protection of Personal Data. It is also recommended conducting a daily backup of the system and of the users and purchases data recorded on the web. Thus, the legal compliance of service record will be guaranteed for at least two years against possible failures.

All these requirements are not a simple list of exigencies to enable the performance of these services. It is an effective and safe way to ensure users/patients the accessibility to non-prescription medicines for human use through Internet and to regulate exhaustively this sale to deal with the problem of illegal purchase of medicines through telematics channels that in many cases are the entry mechanism of the reported counterfeit medicines.

3. CONCLUSION

The counterfeiting of medicines is a major problem worldwide, affecting in varying degrees to all countries. Adequate legislation and clear definition concerning counterfeit medicine is necessary. Today we need a harmonized at international level in terms of definition of counterfeit medicine, although various attempts to carry out coordination at the local level to be necessary to ensure adequate regulation, control and research. There are several initiatives at both international and European Union level to eradicate counterfeit drugs. In this paper we have analyzed European standards and the various national and international strategic plans that have been established to try to resolve this emerging problem.

In our view, it is necessary to provide more information to patients and healthcare professionals about the risk involved in the use of these drugs. It is essential to raise awareness of irrigation there to buy drugs by telematics ways, since there is a possibility that they are false.

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