

Protecting European Patients Against the Entry of Falsified Medicinal Products into the Legal Supply Chain *

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Abstract

Examining the compatibility with the Community law of the conditions for the retail of medicinal products, the Court of Justice of the European Union recognized the particular nature of medicinal products, whose therapeutic effects distinguish them substantially from other goods. The Court of Justice also said that the people's health and life rank foremost among the values and interests protected by the TFEU and that Member States are responsible for deciding on the level of public health protection they wish to provide and the measures to be implemented in order to achieve this level. In this context, this article examines the evolution of the legislative process regulating the internal market for medicinal products in order to ensure a high level of protection of public health against falsified medicines and to present the legislative initiatives that have been taken at EU level taking account of new risk profiles, measures meant to ensure, at the same time, the functioning of the internal market of medicinal products.

This article aims to address consumers' right to have access to safe, effective, quality and innovative medicinal products as a right of the European patient. Ensuring the free movement of medicinal products on the EU market must not violate or restrict this fundamental right of the patient.

The falsification of medicines is a global problem and requires increased and effective international coordination and cooperation to ensure the effectiveness of the strategies to combat counterfeiting, especially in relation to the sale of such products on the Internet. In this respect, the European Commission and the Member States have to cooperate closely and to support the ongoing work of international fora on this subject, such as the Council of Europe, Europol and the UN. In addition, in close cooperation with the Member States, the Commission cooperates with the competent authorities of third countries to effectively combat the trade in counterfeit drugs globally.

Keywords: *patient rights, European legislation, the European Union, counterfeit medicinal products, public health, legislative initiatives, internal market, legal supply chain*

Introduction

Before establishing a Community code on medicinal products for human use [1], the trade with medicinal products within the European Union was hindered by the disparities between certain national provisions, which directly affected the functioning of the internal market. To reduce the disparities in the field of medicinal products for human use was necessary to draw near the relevant laws, establishing rules for monitoring medicinal products and specifying the obligations of the competent authorities of the Member States to ensure compliance with the legal requirements.

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Although the main objective of rules governing the production, distribution and use of medicinal products must be to safeguard public health, however, the means by which this goal is achieved, should not prevent the development of the pharmaceutical industry or of the trade in medicinal products in the European Union.

Considering its importance for health services, the pharmaceutical sector is subject to strict regulations. The existing regulatory framework in this sector should not include unnecessary regulatory constraints that restrict and limit competition.

The complex mechanisms of the pharmaceutical sector are subject to constant and careful analysis both at the level of the European Commission and of the Competition Council. Overseeing the rules regulating and governing the freedom of competition on the pharmaceutical market and the direct and clear intervention if violations of the regulatory framework are found guarantees the existence of a competitive environment in the pharmaceutical sector in the European Union. As mentioned above, the regulatory framework in which the business operation in the pharmaceutical sector functions must not contain constraints.

The pharmaceutical sector is vital to the health of European citizens, who must have access to innovative, safe and affordable medicinal products. The functioning of the pharmaceutical sector at Community level is based on four dimensions: regulation, integration, competition and innovation.

In terms of regulation, the EU level concerns in terms of competition in the pharmaceutical market pay particular attention to the rules on authorization and marketing, on pricing and reimbursement of medicinal products and to those relating to patents.

The patient's right to have access to innovative medicinal products

At EU level there are legislative initiatives designed to create a business environment that promotes research, innovation and the competitiveness of the pharmaceutical sector.

The pharmaceutical industry is currently experiencing an important phase of consolidation. This includes, on the one hand, an increasing concentration among (large) innovative firms and the acquisition of biotech companies.

On the other hand, the generic landscape is undergoing substantial changes in the form of the acquisitions of generic companies by originator companies and through mergers and the acquisition activities within the generic industry.

On average, consumers do not have access to generic medicines earlier than seven months after the date on which innovative medicines have lost exclusivity. This is due, in part, to pharmaceutical companies that use various techniques to extend the commercial life cycle of their products.

When the original products compete with generic medicines, prices go down and become accessible to a larger number of patients. In some cases, prices may decrease considerably.

The European Commission aims to provide safe, effective and affordable medicinal products for patients in Europe and to create, at the same time, a business environment that stimulates research, encourages significant innovation and supports the competitiveness of the industry.

Directive 2001/83/EC has been an important step in achieving the objective of free movement of medicines. Since the adoption of the Community code relating to medicinal products for human use, given the experience, especially by the Committee for Proprietary Medicinal Products additional measures have been necessary in order to cancel any remaining barriers to the free movement of patented drugs.

In 2005 came into force significant changes in the pharmaceutical regulatory framework, which had the objective of facilitating the market entry of generic medicines [2], for example, the introduction of so-called Bolar provisions [3]. Some new rules (namely the new harmonized rules on data and market exclusivity) basically entered into force only in 2013 because the new protection periods were applied for the innovative product for which authorization was applied for and approved after these rules became effective in 2005.

Any action by public authorities in the pharmaceutical sector should aim at creating a competitive environment to ensure the access to medicinal products for European citizens to innovative, safe and affordable medicinal products, without unnecessary delay. In this respect, both competition law enforcement and regulatory

measures can improve market performance for the benefit of consumers and should be considered in this regard.

To facilitate the movement of medicinal products and to prevent the duplication of controls from one Member State to another, the minimum requirements for the manufacture and imports from third countries were established, as well as the conditions for granting their authorization.

Since many operations involving the wholesale distribution of medicinal products for human use may be carried out simultaneously in several Member States, it is necessary to exercise control over the entire chain of distribution of medicinal products, from their manufacture or import into the Community to their supply to the public. This ensures that the storage, transport and handling of these products is carried out appropriately. The measures taken in this respect facilitated the withdrawal of inadequate products from the market and allowed to take more effective measures against counterfeit products.

Although all persons involved in the wholesale distribution of medicinal products must have a special permit, pharmacists and persons authorized to supply medicinal products to the public and which limit themselves to this activity are exempt from obtaining this authorization. However, controlling the whole medicinal products distribution chain and avoiding the entry into the legal supply chain of counterfeit medicines requires that pharmacists and persons authorized to supply medicinal products to the public keep records showing transactions in the received products.

The parallel trade in products is a legal form of trade on the internal market. It is „parallel” as it involves products that are essentially similar to products marketed through the sales networks of original producers or suppliers, but which takes place outside and often parallel to those networks.

Parallel trade is a result of differences in prices between pharmaceutical products [4], for example, when Member States establish or otherwise control the price of products sold on their markets. In principle, parallel trade creates healthy competition and price decreases for consumers and is a direct consequence of the development of the internal market which guarantees the free movement of goods.

Although the safety and the first marketing of medicines are regulated by EU law, the principles of legality of parallel trade in these products have been established as a result of decisions of the Court under the provisions of the Treaty on the free movement of goods [5].

Regarding medication, when necessary information to protect public health is already available to the competent authorities of the Member State of destination as a result of first placing on the market of a product in that Member State, a parallel imported product is subject to licenses granted on the basis of a proportionally „simplified” procedure (as opposed to a procedure for granting marketing authorization), if the imported product has been granted a marketing authorization in the Member State of origin and whether the imported product is essentially similar to a product which has received marketing authorization in the Member State of destination.

In an attempt to balance the rights of parallel traders and the need to maintain public interest objectives such as public health, the Commission has introduced guidelines on parallel imports in the *Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted* (2003) [6].

In addition, we must distinguish between parallel trade and reimport. For example, in the case of pharmaceutical products, re-importation designates transactions through which are imported medicinal products from a Member State in which they are authorized, after having been previously obtained by a pharmacy in another Member State from a wholesaler in the Member State of import.

In this regard, the Court held that a product manufactured in a Member State which is exported and then reimported into the concerned Member State is an imported product in the same way as a product manufactured in another Member State [7]. The Court noted, however, that these findings do not apply if it is found that such products were exported solely for the purpose of re-importation in order to avoid legislation such as that at issue [8].

The risks of the entering of counterfeit medicinal products in the legal supply chain

The field of medicinal products is one of the most regulated areas of activity within the European Union, with about 80 000 pages of EU regulations applicable to medicinal products for human use.

When examining the compatibility with Community law of the conditions for the retail supply of medicinal products, the the Court of Justice recognized the specific nature of medicinal products, whose therapeutic effects distinguish them substantially from other goods. The Court also stated that the health and life of humans rank foremost among the values and interests protected by the TFEU and that Member States are responsible for deciding on the level of public health protection they wish to provide and the measures to be implemented to achieve this level.

Taking account of new risk profiles, legislative initiatives which have been taken at EU level include measures to ensure, at the same time, the internal market of medicines.

The counterfeiting of medicines is a global problem and requires increased and effective international coordination and cooperation to ensure the effectiveness of strategies to combat counterfeiting, especially in relation to the sale of such products on the Internet. In this respect, the European Commission and Member States have to cooperate closely and support ongoing work in international fora on this subject, such as the Council of Europe, Europol and the UN. In addition, in close cooperation with the Member States, the Commission cooperates with the competent authorities of third countries to effectively combat trade in counterfeit drugs globally.

The threat that falsified medicines pose to public health is also recognized by the World Health Organization (WHO), which has established the International Medical Products Anti-Counterfeiting Taskforce ("IMPACT"). IMPACT has developed the Principles and Elements for National Legislation against Counterfeit Medical Products, which were endorsed by the IMPACT General Meeting in Lisbon on 12 December 2007. The European Union participated actively in IMPACT.

An impact assessment conducted in 2008 by the European Commission brought before the authorities alarming elements regarding falsified medicinal products entering the legal supply chain.

The European Commission held between 11 March 2008 - 9 May 2008 a public consultation on "*Key ideas for better protection of patients against the risk of counterfeit medicines*". In response to this consultation, the Commission received 128 contributions from stakeholders. Of these, 103 were from industry (pharmaceutical industry, distributors, suppliers of active ingredients, consultants), 15 from citizens, patients (patient groups), and academics, and 10 from health professionals, pharmacists and health insurers.

In terms of regions, of the 128 stakeholder contributions, 20 contributions were received from EU-wide associations, 30 from Italy, 14 from the UK, 9 from Germany, 4 each from France and Switzerland, 3 each from Poland, Ireland and the Netherlands, 2 each from Malta and Denmark, 1 each from Austria, Sweden and Spain and 18 from third countries.

13 stakeholder contributions were from global associations or could not be attributed to the regions. Thirty national and regional authorities profited from this stakeholder consultation to inform the Commission about their views on the matter. The respondents unanimously welcomed the initiative, stressing the need for urgent and decisive measures and the fact that the issue of counterfeit medicines is in exponential growth.

The "multilayered" approach the Commission, based on an identification of the various possible points of entry for falsified medicines, has also been well received. A summary of the responses was published on the Commission's website [9].

The above analysis [10] has highlighted the increasing number of falsified medicines seized in customs (2.7 million in 2006 to 2.5 million in 2007, representing an increase of 384% compared to 2005), the counterfeiting with fatal effects of medicines for serious diseases (heart, cancer) and the introduction to the legal supply chain of fake drugs, including online purchase.

The European Commission estimated that annually are sold to Europe, through legal distribution circuit, 1.5 million boxes of counterfeit medicinal products.

The fact that their volume increases on average by 10-20% per year is even more worrying. With a growth rate of 10%, the number of boxes of falsified medicines in the legal distribution circuit could reach 42 million by 2020. According to other, more pessimistic estimates, the growth rate is 30%, which would bring this number to 192 million.

The standardization of European law in the field of counterfeit medicinal products

The existing provisions of Directive 2001/83/EC on the Community code relating to medicinal products for human use [11] were in some respects insufficient to address these concrete causes. Given the length of time between the proposed amendments to Directive 2001/83/EC and their effective implementation, the need for action from European Commission at the time was clear.

Considering all these alarming aspects, the European Parliament and the Council adopted Directive 2011/62 /EU on the prevention of the entry into the legal supply chain of falsified medicinal products [12].

As the stated aim of the Directive is to protect public health, it provides the legal basis for which the *counterfeiting of medicinal products is a criminal act* which deprives patients of safe and quality medical treatment.

To this end, Directive 2011/62/EU on falsified medicinal products decided upon the clear definition of some terms, the clarification of certain responsibilities and the elimination of any confusion, for the simplification of implementation. The legal document proposes relevant enforcement measures, safety aspects for medicinal products and harsh penalties, differentiated according to the degree of the crime and its effects.

Directive 2001/83/EC of the European Parliament and of the Council provides, inter alia, the rules for the manufacture, importation, marketing and wholesale distribution of medicinal products in the European Union and the rules relating to active substances.

The measures of the Directive to include the mandatory application on the packaging of medicinal products of safety features, the increased controls and inspections of factories producing active pharmaceutical substances, increasing the

strictness of distributor records, the obligation of producers and distributors to report medicinal products presumed fake, and the centralized regulation of online pharmacies.

Past experience shows that no falsified medicines reach patients only through illegal means, but also via the legal supply chain. This poses a particular threat to public health and can lead to the distrust of patients, including in the legal supply chain. To respond to this increasing threat, Directive 2001/83/EC had to be changed.

Persons procuring, holding, storing, supplying or exporting medicinal products are allowed to operate only if they meet the requirements for obtaining a wholesale distribution authorization in accordance with Directive 2001/83/EC.

However, the distribution network of medicinal products is increasingly complex and involves many players which are not necessarily wholesale distributors as referred to in that Directive.

To ensure the reliability of the supply chain, medicines legislation should address all actors in the supply chain. This includes not only wholesale distributors, whether or not they physically handle drugs but also intermediaries who are involved in the sale or purchase of medicinal products without selling or purchasing those products themselves, and without owning and physically handling the medication.

Any actor in the supply chain who packages medicinal products must hold a manufacturing authorization. For the safety features to be effective, the manufacturing authorization holder who is not the original manufacturer of the medicinal product must be permitted to remove, replace or cover those safety features under strict conditions.

The strict conditions stated in the Directive provide appropriate mechanisms to prevent falsified medicinal products from entering the supply chain, in order to protect both patients and the interests of marketing authorization holders and producers.

Manufacturing authorization holders who repackage medicinal products are liable for damages in the cases and under the conditions laid down in Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.

To increase reliability in the supply chain, wholesale distributors should verify that their supplying wholesale distributors are holders of a wholesale distribution authorization. To ensure transparency, the list of wholesalers that have been established

after inspection by a competent authority of a Member State to comply with applicable Union legislation will be published in a database created at the level of the Union.

The provisions on inspections and controls of all actors involved in the manufacture and supply of medicinal products and their ingredients have been clarified and specific provisions apply to different categories of actors. These provisions do not prevent Member States from performing additional inspections, where considered appropriate.

To help ensure the functioning of existing mutual recognition agreements with third countries whose application depends on efficient and comparable inspection and enforcement throughout the Union and, also, to provide a similar level of protection of human health throughout the Union and to avoid distortions in the internal market, harmonized principles and guidelines for inspections of manufacturers and wholesale distributors of medicinal products and active substances must be strengthened.

Medicinal products can be introduced into the EU with no intention of being imported, that is with no intention of being released for free circulation. If these drugs are falsified, they pose a risk to public health in the Union.

In addition, those falsified medicinal products may reach patients in third countries. Member States should take measures to prevent the circulation of such counterfeit drugs entering the Union.

When adopting provisions supplementing this obligation on Member States to adopt the measures mentioned above, the Commission must take into account the available administrative resources and the practical implications and the need to maintain swift trade flows for legitimate medicinal products. Those provisions should be without prejudice to customs legislation, the division of powers between the Union and the Member States or to the distribution of responsibilities within Member States.

The risk assessment should consider aspects such as the price of medicines; reported previous cases of falsified medicinal products in the EU and in third countries; the implications of falsification on public health, given the specific characteristics of the products concerned; and the severity of the conditions intended to be treated.

The supply of medicinal products to the population via the internet

The illegal sale of medicinal products to the public via the Internet constitutes a serious threat to public health because in this way counterfeit drugs may reach the public. It was therefore necessary to address this threat in Directive 2011/62/EU.

In this regard, account was taken of the fact that specific conditions for the supply of medicinal products to the public have not been harmonized at EU level and, therefore, Member States may impose conditions for supplying medicinal products to the public within the Treaty on European Union (TFEU).

The Court of Justice of the European Union, analyzing the compatibility with Community law of the conditions for the supply of retail drugs, held that the Member States are responsible for deciding on the level of public health protection they wish to provide and means to be implemented to achieve this level.

The Court also stated that Member States should have discretion as regards the supply of medicinal products to the public on their territory. Given the particular risks to public health and the power given to Member States to determine the level of protection of public health, the Court has recognized that Member States may, in principle, restrict the retail sale of medicinal products to pharmacies only.

In view of the foregoing and the provisions of the Court, Member States may impose conditions justified by the protection of public health for the retail supply of drugs sold remotely through information society services. However, those conditions should not unduly restrict the functioning of the internal market.

Without prejudice to national legislation prohibiting the remote offer for sale to the public of medicinal products subject to medical prescription via the Internet, the Member States must ensure that products are offered for sale remotely to the public by means of information society services as defined in Directive 98/34/EC [13].

For online sales of medicinal products, natural or legal person who offers the medicinal product must be authorized or have the right to provide medicinal products to the population remotely as well, in accordance with the national law of the Member State where the person concerned is established.

The Internet site offering the medicinal product should contain at least the contact details of the competent authority or the notified authority, a hyperlink to the Internet site

of the Member State of establishment and the common logo clearly displayed on every page of the Internet site related to the remote offer for sale of medicinal products to the public.

So that the functioning of the internal market not be unduly restricted, but also for public health protection, for the retail supply of medicinal products sold online, the Directive proposes the creation of a common logo that can be recognized throughout the Union and allowing the identification of the Member State of establishment of the person offering the medicinal products for remote sale to the public. The logo shall be clearly displayed on the Internet site offering the medicinal products for remote sale to the public.

To harmonize the functioning of the common logo, the Commission adopts implementing acts concerning the technical, electronic and cryptographic requirements for the verification of the authenticity of the common logo and the Community logo design. If necessary, these acts shall be adjusted to take account of technical and scientific progress.

Each Member State must create a website that provides information on national legislation applicable to the remote offering for sale of medicinal products to the public by means of information society services, including information that there might be differences between Member States with respect to the classification of medicinal products and the conditions of their supply. Also, Internet sites of the Member States should provide information on the purpose of the common logo, the list of persons offering medicinal products for sale at a distance to the public by means of information society services and their website address.

This site should also provide general information on the risks related to medicinal products supplied illegally to the public via information society services, and a hyperlink to the internet site of the competent authority in that Member State.

The European Medicines Agency (EMA) created a website that provides information on the purpose of the common logo, general information on the risks related to medicinal products supplied illegally to the public via information society services, information on the European Union legislation applicable to falsified medicinal products, as well as hyperlinks to the Internet sites of the Member States. EMA website explicitly

states that websites contain information on persons authorized or entitled to remotely supply medicinal products by means of information society services in the Member States.

The population should be assisted to identify sites which are legally offering medicinal products for sale to the public remotely. To provide comprehensive information to the public, all these sites must be interconnected.

In addition, in cooperation with the European Medicines Agency and the Member States, the Commission must organize awareness campaigns to warn consumers about the risks of purchasing medicinal products from illegal sources via the Internet.

Without prejudice to Directive 2000/31/EC and the requirements of Title VII of Directive 2011/62/EU, Member States must ensure that unauthorized persons offering medicinal products for sale to the public remotely, by means of information society services, and operating on their territory, are subject to effective, proportionate and dissuasive sanctions.

The right of patients to be protected against counterfeit medicines

To prevent drugs that are suspected to present a danger to health from reaching the patient, Member States use a system that includes the receipt and handling of notifications of suspected falsified medicinal products, as well as suspected quality defects of medicinal products. The system includes also recalls of drugs made by holders of marketing authorizations or withdrawals of drugs from the market ordered by the competent national authorities from all relevant actors in the supply chain, both during normal working hours and beyond.

The system also allows, if necessary, with the assistance of healthcare professionals, medicinal product recalls from patients who received such products.

If it is suspected that the product in question poses a serious risk to public health, the competent authority of the Member State where the product was initially identified transmits without delay a rapid alert notification to all Member States and all actors in the supply chain of the Member State in question.

If it is suspected that falsified medicinal products have reached patients, urgent public announcements are made within 24 hours to recover these products from the

patients. Such notices shall contain sufficient information on the suspected quality defect or falsification and the risks involved.

Enlightening in this respect is the case of Pegasys, which we will present in the following. In November 2013, the Police and the National Agency for Medicines and Medical Devices (NAMMD) started an investigation after three pharmacies in the country were found counterfeit syringes with serum hepatitis B and C.

The Syringes with counterfeit hepatitis serum, on which the investigation was initiated, were found in two pharmacies in Pitesti and in one of Ialomita County. The investigation was initiated as a result of complaints received from patients.

Roche Romania SRL, the drug manufacturer, informed the National Agency for Medicines and Medical Devices (NAMMD) in September 2013 on the identification in Germany by the quality department of F. Hoffmann-La Roche, Basel Ltd. of a box of counterfeit Pegasys 180 mg / 0.5 ml. After this information, constant communication with NAMMD continued related to occurrence of suspected counterfeit boxes in Romania.

The producing company Roche Romania SRL has shown that by November there were no reported cases of counterfeit suspicions of possible penetration in Romania.

The company informed, also in the context of counterfeit Pegasys syringes, that the counterfeit medicinal product presents easily observable differences from the original, asking the patients suspecting that the product they hold could be counterfeit to immediately address the doctor, the pharmacist or directly the NAMMD.

"Patient safety is a priority for Roche. (...) We note that Pegasys (peginterferon alfa-2a) is released in pharmacies only on prescription issued by the gastroenterologist or infectious disease specialist and is intended solely for the treatment of viral hepatitis B and C, not some cancers," said Roche Romania.

Regarding the product found in Germany, on the site of Bucharest Medical College [14] was posted at the end of October a notice to health professionals, which stated that the countries where were distributed counterfeit syringes are unknown.

The same notice stated that the chemical analysis of the counterfeit product confirms that it does not contain peginterferon alfa-2a (Pegasys active substance), that

the counterfeit product has no efficacy and safety and counterfeit pre-filled syringe should not be used.

The Medical College also recommend those holding any product which they suspect is counterfeit or whose authenticity they cannot confirm or if they suspect that a patient could have been given a counterfeit product to immediately contact NAMMD.

After dozens of boxes of counterfeit Pegasys were released in November on prescription in pharmacies in several counties and irregularities were noticed by several people with hepatitis, the forgery came to the attention of the national authorities.

In the context of the investigation started, the Ministry of Health recommended that patients using the product Pegasys 180 µg/0.5 ml solution for injection in pre-filled syringe, when buying it in the last two weeks, to immediately contact the treating physician to determine the appropriate therapeutic management.

In the same context, the Ministry of Health asked NAMMD to take "*all legal steps required to manage the situation, so that patients do not suffer*".

The medicinal product that came to the attention of the Romanian authorities is Pegasys - indicated for the treatment of chronic hepatitis B. Following the analysis proved that the product sold in Romania does not contain peginterferon alfa - 2a (Pegasys active substance), but glucose, water and cellulose fibers solution, therefore it has no efficacy and safety when administered. Moreover, doctors say that subcutaneous glucose administration can lead to tissue necrosis.

The press release issued by NAMMD in this case shows that "*due to information received from the National Agency for Medicines and Medical Devices (NAMMD) on the possibility of the presence on the pharmaceutical market in Romania of counterfeit boxes with the label Pegasys 180 µg/0.5 ml solution for injection in pre-filled syringe (peginterferon alfa-2a), we draw your attention to the need of visual inspection of the product before administration, as the counterfeit medicinal product presents easily identifiable differences to the original medicinal product Pegasys.*" [15].

In this case, the counterfeiting of a drug for a serious chronic disease, we can speak of a criminal act because for patients with hepatitis B and C, interferon vials mean life expectancy.

Counterfeit drugs could endanger patient response to treatment and even his/her life.

The interest in counterfeiting this medicinal product is obviously economic because one vial has an average price of 750 RON, the entire sum being paid by the state through national health programs. Therefore, the investigation of the national health authority was doubled by that of the Organized Crime.

Conclusions

The legal analysis conducted in this paper results, unequivocally, that the European Union is strongly committed to ensuring a high level of protection, competitiveness and innovation in public health.

With regard to medicines and treatment, the main Community objectives are to ensure the quality, safety and efficacy of medicinal products, the authorization and monitoring of medicinal products available on the market and the free movement of medicinal products on the EU market.

Fighting the penetration of falsified medicinal products in the legal supply chain without hampering the functioning of the internal market of medicinal products is a goal that can not be sufficiently achieved by the Member States and can therefore be better achieved by the Community.

All these goals are achieved by the European bodies by improving and updating the legislation on medicinal products, stimulating the development of innovative medicinal products that offer therapeutic benefits and respond to health needs left uncovered.

When referring to the implications of a falsification of on public health, we must consider both the specific characteristics of the products in question, and the severity of the conditions intended to be treated with such medicinal products. Another aspect to be taken into consideration when introducing counterfeit medicines into the legal distribution chain is the price of counterfeit medicines. Counterfeiting of medicines for serious chronic diseases, for example, lead to reimbursement by the state of the full price of the medicinal product in question and, in addition, to tax evasion produced by the people introducing the forgeries to the legal distribution network, which endangers the lives of patients, by the lack of the necessary treatment.

Counterfeit drugs are illegal in terms of EU pharmaceutical legislation as they do not comply with EU rules on medicinal products. They pose a major threat to European patients and European industry and the public and stakeholders are deeply concerned about the steady increase of these products detected in the European Union in recent years.

Another concern is the fact that the risk profile has changed. The number of falsifications of innovative and life-saving medicines is increasing. In addition, to increase volume, these products are channeled through the legal supply chain to patients. Thus, in 2007, thousands of packets of counterfeit life-saving drugs have reached patients in the EU.

Even if you the exact number of existing or future cases is unknown, there is a noticeable trend clearly threatening the high level of public health protection in the European Union. *We believe that this trend can have disastrous consequences for consumer patient confidence in the pharmaceutical industry and the policy makers.*

The assessment of policy options, starting from a baseline of "non-action" on falsified medicinal products entering the legal distribution chain and estimates based on existing data, which are limited, were revealed the direct and indirect costs to society of non action, which could reach, depending on the scenario, between 9.5 billion and 116 billion by 2020.

Given the objective pursued, namely the elimination, by all means, of the risk of falsified medicines entering the legal supply chain, the European Commission compared the costs of non-action costs for achieving the chosen policy options and estimated the costs which will be incurred by 2020 by all actors involved in the distribution of medicines on the internal market.

Thus, manufacturers and importers of drugs will bear between EUR 6.8 billion and 11 billion, depending on the safety technique chosen. The costs for distributors who remove or modify the safety features are based on the volume of their business. Moreover, depending on the chosen approach, pharmacies are going to bear costs of about 157 million. The estimated costs for wholesale distributors of drugs are about 280 million, and for wholesale distributors who engage only in export activity of approximately EUR 403 million. It has been estimated, too, that other traders in the

distribution chain will have to bear costs amounting to approximately EUR 5 million. Manufacturers of active pharmaceutical ingredients will face costs of about 320 million, the bulk of these costs will be borne by producers in third countries.

Unfortunately, the costs the patients consumers of these counterfeit medicinal products have to bear can not be estimated, the danger that they have on human health and life can not be quantified.

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