EUROPEAN PARLIAMENT 2009 - 2014

*Committee on the Environment, Public Health and Food Safety*

**2008/0261(COD)**

12.3.2010

# AMENDMENTS
# 51 - 122

**Draft report**
**Marisa Matias**
(PE430.883v02-00)

on the proposal for a directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source

Proposal for a directive – amending act
(COM(2008)0668 – C6-0513/2008 – 2008/0261(COD))

AM_Com_LegReport

**Amendment 51**
**Marisa Matias**

**Proposal for a directive – amending act**
**Citation 1**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| Having regard to the Treaty ***establishing the European Community***, and in particular Article ***95*** thereof, | Having regard to the Treaty ***on the Functioning of the European Union***, and in particular ***Articles 114 and 168*** thereof, |

Or. en

*Justification*

*This amendment aligns the legal basis to the Treaty on the Functioning of the European Union. The aim of this Directive is not only to establish the functioning of the internal market for medicinal products (Article 114) but to ensure as well a high level of protection of public health in the EU (Article 168).*

**Amendment 52**
**Cristian Silviu Buşoi**

**Proposal for a directive – amending act**
**Recital 3 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(3a) In the light of this Directive the Commission should submit every year to the European Parliament and to the Council a statistical report with reliable and accurate data on the current situation, trends and developments concerning falsified medicines, including details of where, how and by whom the falsified products were detected, the country from which they came, and the falsified element itself (identity, source and/or ingredient/components) in the Member States.*** |
| | ***This report should clearly distinguish*** |

***falsification problems from patent infringement.***

Or. en

*Justification*

*Neither the impact assessment study, nor other European Commission reports, sufficiently focus on and explain the origin and main sources of falsified products. It is important not to confuse patent violations or disputes with the problem of falsification of medical products. Reliable data and statistics with details where 'counterfeit' products were detected, which country they came from, and the 'counterfeit' element itself (identity, source and/or ingredient/components) are needed.*

**Amendment 53**
**Peter Liese, Thomas Ulmer**

**Proposal for a directive – amending act**
**Recital 3 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(3a) In the light of this Directive the Commission should submit every year to the European Parliament and to the Council a statistical report with reliable and accurate data on the current situation, trends and developments in counterfeiting/falsified medicines, including details of where, how and by whom the counterfeit products were detected, the country from which they came, and the 'counterfeit' element itself (identity, source and/or ingredient/components) in the Member States.*** |

Or. en

*Justification*

*Neither the impact assessment study, nor other European Commission reports, sufficiently focus on and explain the origin and main sources of 'counterfeit' products. It is important not to confuse patent violations or disputes with the problem of counterfeiting of medical products. Reliable data and statistics with details where 'counterfeit' products were detected,*

*which country they came from, and the 'counterfeit' element itself (identity, source and/or ingredient/components) are needed.*

**Amendment 54**
**Michail Tremopoulos, Michèle Rivasi**

**Proposal for a directive – amending act**
**Recital 3 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(3a) The Commission should submit every year to the European Parliament and to the Council a report on the current situation and trends in the falsification of medicinal products, and update the measures on the application of the safety features accordingly.*** |

Or. en

*Justification*

*To tackle and remedy the problems of falsified medicinal products it is essential to understand and identify their origin and main sources. As such, annual reporting should be introduced. On the basis of these findings, the rules on applying the safety features should be updated accordingly.*

**Amendment 55**
**Jo Leinen**

**Proposal for a directive – amending act**
**Recital 3 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(3a) Within three years of the entry into force of this Directive, the Commission should present to the European Parliament and the Council an assessment report providing detailed data on the extent and sources of counterfeit medicinal products in the legal supply*** |

***chain in the Union.***

Or. en

*Justification*

*It is necessary to have a clear overview of the extent and principle sources of counterfeit risks in order to potentially recast or adapt the directive.*

**Amendment 56**
**Marisa Matias**

**Proposal for a directive – amending act**
**Recital 4 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(4a) This Directive is to apply without prejudice to Directive 95/46/EC and should retain clear and effective safeguards whenever personal data is processed.*** |

Or. en

**Amendment 57**
**Françoise Grossetête, Frédérique Ries**

**Proposal for a directive – amending act**
**Recital 4 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(4a) The European Union should support the drafting of an international agreement stepping up the penalties for falsifying medicinal product, and of an additional protocol to the Palermo Convention against Transnational Organised Crime.*** |

Or. fr

*Justification*

*The falsification of medicinal products has become an operation organised by international crime networks and efforts to tackle this threat to public health cannot be limited to measures taken within our European borders alone.*

**Amendment 58**
**Oreste Rossi**

**Proposal for a directive – amending act**
**Recital 4 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(4a) It is well known that the internet represents one of the main routes for falsified medicinal products to enter the European market. In view of the difficulty of pinpointing the actual physical address of internet sites and, therefore, of granting them certification of authenticity with complete certainty and of verifying the quality, safety and efficacy of the pharmaceutical, the internet sale of all types of medicinal product should be prohibited, unless they have been authorised under national legislation in force on the date of entry into force of this Directive.*** |

Or. it

*Justification*

*Although the internet sale of medicinal products is permitted in some Member States, its high and verified rate of illegality is incompatible with the goal of ensuring a high standard of public health protection in the EU. The Commission proposal to deem internet sales part of the illegal chain of supply is therefore to be endorsed. However, Member State legislation under which such practice is legal and is in force at the date on which this Directive enters into force should continue to have effect.*

**Amendment 59**
**Jorgo Chatzimarkakis**

**Proposal for a directive – amending act**
**Recital 4 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(4a) A legitimate mail order pharmacy should be connected to a legally registered pharmacy, thereby ensuring that a legitimate mail order pharmacy must comply with all legal requirements for any pharmacy establishment in the Member State where it is legally based. The identification of the chief pharmacist should be a legal requirement for all legitimate mail order pharmacies. A mail order pharmacy can only dispense an ordered prescription medication if the original prescription has been obtained by the respective mail order pharmacy in advance. Member States should ensure that all mail order provision for pharmaceutical products is continuously regulated by designated national agencies.*** |

Or. en

*Justification*

*Mail order pharmacies must adhere to the same provisions as a legally registered pharmacy, thus ensuring customers receive the same quality and safety of product. Every mail order pharmacy must register a chief pharmacist, legally responsible for the sales. Member States' pharmacy regulatory bodies should routinely monitor all mail order pharmacies, liaising closely with the European Association of Mail Service Pharmacies (EAMSP). The EAMSP could act as a centre for expertise and best-practice.*

**Amendment 60**
**Jorgo Chatzimarkakis**

**Proposal for a directive – amending act**
**Recital 4 b (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(4b) European citizens should be made aware of the health risks associated with ordering products from illegal websites. The Commission, in co-operation with the Member States, should adopt measures to increase awareness among the general public of the risks associated with purchasing medicinal products on the internet from any websites other than legitimate mail order pharmacies. Public awareness campaigns should inform citizens about how to identify legitimate mail order pharmacies and the risks related to buying from illegal websites.*** |

Or. en

*Justification*

*Public awareness campaigns are crucial in informing European customers about the risks of buying medicinal products from illegitimate mail order pharmacies. Specialist marketing techniques will be required for running these public awareness campaigns to ensure that clear, easily understandable messages about the legal and illegal activities of websites selling medicinal products are conveyed. For example, using the same advertisements could create confusion among consumers and should therefore be avoided throughout.*

**Amendment 61**
**Judith A. Merkies**

**Proposal for a directive – amending act**
**Recital 4 c (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(4c) It is useful to introduce a definition of the concept of 'falsified medicinal product' in order to distinguish such products from legal but unauthorised*** |

***medicinal products. Furthermore, authorised or otherwise legitimate products with quality defects and medicinal products that due to mistakes in the manufacturing or subsequent handling do not comply with the requirement of Good Manufacturing Practices or Good Distribution Practices should not be confused with falsified medicines.***

Or. en

*Justification*

*The deliberate falsification of a medicinal product is a criminal offence. It should not be considered equivalent to GMP non-compliance or quality defects which can occur in normal manufacturing conditions and are handled in a transparent manner between the medicinal product manufacturer and the authorities with a constant care for public health protection.*

**Amendment 62**
**Marisa Matias**

**Proposal for a directive – amending act**
**Recital 5**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (5) Today's distribution network for medicinal products is increasingly complex and involves many players which are not necessarily wholesale distributors as defined in Directive 2001/83/EC. In order to ensure reliability in the distribution chain, pharmaceutical legislation should address all actors in the distribution chain: this includes not only distributors who procure, hold, store and supply products, but also persons who are involved in transactions without handling the products. They should be submitted to proportionate rules in order to exclude, by all practical means, the possibility that medicinal products which are falsified in relation to their identity, history or source to enter the | (5) Today's distribution network for medicinal products is increasingly complex and involves many players which are not necessarily wholesale distributors as defined in Directive 2001/83/EC. In order to ensure reliability in the distribution chain, pharmaceutical legislation should address all actors in the distribution chain: this includes not only distributors who procure, hold, store and supply products, but also persons who are involved in transactions without handling the products***, such as traders or brokers***. They should be submitted to proportionate rules in order to exclude, by all practical means, the possibility that medicinal products which are falsified in relation to their identity, |

| | |
|---|---|
| legal supply chain in the Community. | history or source to enter the legal supply chain in the Community. |

Or. en

*Justification*

*Replaces amendment 7 of the draft report.*

**Amendment 63**
**Jorgo Chatzimarkakis**

**Proposal for a directive – amending act**
**Recital 6 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(6a) Counterfeit medicinal products are often found to have been supplied in response to orders placed over the Internet. In accordance with the provisions of the TFEU, particularly Article 168 thereof, Member States are responsible for regulating the marketing of medicinal products at the last level of trade, particularly in pharmacies. This also includes regulating the marketing of medicinal products by mail order and over the Internet. The case law of the Court of Justice permits Member States to impose an absolute ban on the supply of prescription medicines by mail order, in accordance with the wide margin of discretion which they enjoy on account of the dangers associated with this method of marketing.*** |

Or. en

*Justification*

*The directive must respect the established allocation of powers. Rules on pharmacies and the marketing of medicines at the last level of trade are a matter for the Member States. The vast majority of Member States prohibit mail-order trading in prescription medicines, and the Court of Justice has upheld this (Judgment of 11.12.2003, C-322/01, Deutscher*

*Apothekerverband).*

**Amendment 64**
**Oreste Rossi**

**Proposal for a directive – amending act**
**Recital 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of prescription medicinal products should be established at Community level. ***When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated.*** | (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of prescription medicinal products should be established at Community level. |

Or. it

**Amendment 65**
**Peter Liese**

**Proposal for a directive – amending act**
**Recital 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for | (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for |

| | |
|---|---|
| medicinal products, safety features designed to ensure the identification, authentication and traceability of prescription medicinal products should be established at Community level. When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community ***and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated***. | medicinal products, safety features designed to ensure the identification, authentication and traceability of prescription medicinal products should be established at Community level. When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and***/or*** past incidences in the Community. |

Or. en

*Justification*

*A straightforward approach is needed to protect patients from counterfeit medicines. A risk assessment of products or product categories is key to ensuring an effective allocation of the available resources to combat counterfeit. Consequently, the Commission shall assess the risk profile of prescription medicinal products and on this basis decide whether safety features are necessary. Strictly analyzing the incentive for counterfeiters (price) and the previous experience (past incidents) prevents an ineffective drain on resources which would be needed in other areas.*

**Amendment 66**
**Pilar Ayuso**

**Proposal for a directive – amending act**
**Recital 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of | (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the ***unique*** identification, authentication and |

| | |
|---|---|
| prescription medicinal products should be established at Community level. When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. | traceability of prescription medicinal products should be established at Community level. When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. |

Or. en

*Justification*

*For the purposes of absolute clarity the only types of safety feature that will enable authentication and traceability of individual packs are those that identify the pack uniquely.*

**Amendment 67**
**Michail Tremopoulos, Michèle Rivasi**

**Proposal for a directive – amending act**
**Recital 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of ***prescription*** medicinal products should be established at Community level. When introducing obligatory safety features for ***prescription*** medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of | (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of medicinal products should be established at Community level. When introducing obligatory safety features for medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past |

| | |
|---|---|
| falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. | incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. |

Or. en

*Justification*

*The status of prescription products and OTC products is not harmonised in the EU. As such, a differentiation between those makes little sense. According to a recent study by Pfizer reported in the German press, 45% of all falsified medicines are diet pills, 35% drugs against influenza, and 25% drugs against erection problems [note: the figures do not add up]. If this were roughly correct, it would show that OTC drugs are a key target for falsifications. As any falsified drug could have a detrimental effect on human health, all drugs should be covered, based on the risk assessment of Art 54(4).*

**Amendment 68**
**Sylvana Rapti**

**Proposal for a directive – amending act**
**Recital 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of ***prescription*** medicinal products should be established at Community level. When introducing obligatory safety features for ***prescription*** medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of | (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of medicinal products should be established at Community level. When introducing obligatory safety features for medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of |

falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated.

the specific characteristics of the products concerned or of the severity of the conditions intended to be treated.

Or. en

*Justification*

*It is important to guarantee the authenticity of both prescription medicines and non prescription medicines that when counterfeited could have a disastrous effect on human health especially because it seems there is a growing trend at national and at European level towards switching medicines from prescription to non-prescription status.*

**Amendment 69**
**Paolo Bartolozzi**

**Proposal for a directive – amending act**
**Recital 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of ***prescription*** medicinal products should be established at Community level. When introducing obligatory safety features for ***prescription*** medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. | (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of medicinal products should be established at Community level. When introducing obligatory safety features for medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. |

Or. it

*Justification*

*It is important to guarantee the authenticity of all categories of medicinal product, be they ethical products or OTC ones. All pharmaceuticals are special products which, if counterfeited, may have a disastrous impact on human health. Moreover, the 'switching' of pharmaceuticals, or in other words their changing from the ethical category to the OTC one, is becoming increasingly widespread in Europe. It should not be forgotten either that major profits can be made from the counterfeiting of OTC medicinal products.*

**Amendment 70**
**Elena Oana Antonescu, Rareş-Lucian Niculescu**

**Proposal for a directive – amending act**
**Recital 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| 7. In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of prescription medicinal products should be established at Community level. When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. | 7. In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of prescription ***and over-the-counter*** medicinal products should be established at Community level. When introducing obligatory safety features for prescription ***and over-the-counter*** medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. |

Or. ro

*Justification*

*The Commission proposal fails to ensure compliance with safety standards regarding over-the-counter medicinal products. Given the growing consumption thereof in Europe, it is important to introduce provisions protecting all patients, through whatever channels they obtain medicinal products.*

**Amendment 71**
**Jorgo Chatzimarkakis**

**Proposal for a directive – amending act**
**Recital 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of prescription medicinal products should be established at Community level. When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. | (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features ***or any other technical measure*** designed to ensure the identification, authentication and traceability of prescription medicinal products should be established at Community level. When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines ***and well-established use products***. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. |

Or. en

*Justification*

*Technical measures such as printing holograms or special varnish may be used too. The particularities of well-established brands should equally be taken into account. They are based on the same, well known formula. Both generic and well-established brands belong to the lower price segment and are rarely counterfeited owing to their low profit margin. They*

*should also be examined.*

**Amendment 72**
**Linda McAvan**

**Proposal for a directive – amending act**
**Recital 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of prescription medicinal products should be established at Community level. When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. | (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of prescription medicinal products should be established at Community level. When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines ***and those products that are subject to a managed distribution chain***. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. |

Or. en

*Justification*

*Certain products (for example immunoglobulins) are delivered directly by the manufacturer to the hospital or other end-using healthcare setting. As the risk of a counterfeit product entering this chain is very low, there is a case for these products to be exempted from having to carry safety features.*

**Amendment 73**
**Thomas Ulmer**

**Proposal for a directive – amending act**
**Recital 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification**,** authentication ***and traceability*** of prescription medicinal products should be established at Community level. When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. | (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification ***and*** authentication of prescription medicinal products should be established at Community level. When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. |

Or. de

*Justification*

*Each Member State should be responsible for deciding whether a specific medicinal product must be traceable throughout the supply chain from the manufacturer to the pharmacy. Traceability is not required in order to recognise falsified products, and involves a considerable additional burden which would result in disproportionate costs for small and medium-sized enterprises in particular.*

**Amendment 74**
**Dagmar Roth-Behrendt**

**Proposal for a directive – amending act**
**Recital 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of prescription medicinal products should be established at Community level. When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products***, such as generic medicines***. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. | (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of prescription medicinal products should be established at Community level. When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. |

Or. en

*Justification*

*There shall be no anticipated exemption for generic medicines when introducing safety features for prescriptive medicinal products.*

**Amendment 75**
**Holger Krahmer**

**Proposal for a directive – amending act**
**Recital 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (7) In order to take account of new risk | (7) In order to take account of new risk |

| | |
|---|---|
| profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of prescription medicinal products should be established at Community level. When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. | profiles, while at the same time ensuring the functioning of the internal market for medicinal products, ***mandatory*** safety features designed to ensure the identification, authentication and traceability of prescription medicinal products should be established at Community level. When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated.<br><br>***No later than five years after the date of entry into force of this Directive, the Commission should submit to the European Parliament and to the Council an assessment report on the application of the safety features referred to in point (o) of Article 54 of Directive 2001/83/EC and their estimated contribution to the reduction of the number of falsified medicines in the legal supply chain in Europe. The report should include an assessment of the safety features to other categories of medicines, including medicinal products not subject to medical prescription as defined in Title VI of Directive 2001/83/EC.*** |

Or. de

*Justification*

*The impact of the envisaged safety features should be assessed after five years. If it shown that there has been a reduction in falsified medicines in the legal supply chain, the EU-wide harmonised safety features could, where appropriate, be extended to non-prescription medicines. At this point in time it is reasonable and adequate to limit the application of safety features to prescription medicines. Unnecessary regulatory burdens should be avoided, to*

*prevent unnecessary costs for European citizens.*

**Amendment 76**
**Elżbieta Katarzyna Łukacijewska**

**Proposal for a directive – amending act**
**Recital 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of prescription medicinal products should be established at Community level. When introducing ***obligatory*** safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. | (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of prescription medicinal products should be established at Community level. When introducing safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. |

Or. pl

*Justification*

*1. We cannot use the word 'obligatory' because in this context it applies to all prescription products. Safety features should be applied on the basis of a risk assessment as regards falsification of the product, and therefore not all medicines will be subject to the application of safety features.*

*2. The date on which the five-year period begins needs to be changed in the text of the directive. It should be the date on which the enforcement provisions relating to the safety features enter into force, not the date on which the directive enters into force.*

**Amendment 77**
**Theodoros Skylakakis**

**Proposal for a directive – amending act**
**Recital 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of prescription medicinal products should be established at Community level. When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. | (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, ***mandatory*** safety features designed to ensure the identification, authentication and traceability of prescription medicinal products should be established at Community level. When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines ***and excipients***. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated.<br><br>***No later than five years after the date of entry into force of this Directive, the Commission should submit to the European Parliament and to the Council an assessment report on the application of the safety features referred to in point (o) of Article 54 of Directive 2001/83/EC and their estimated contribution to the reduction of the number of falsified medicinal products in the legal supply chain in Europe. No later than 18 months after the date of entry into force of this Directive, the Commission should submit an assessment report on the safety features of over-the-counter medicinal products in accordance with Title VI of Directive 2001/83/EC.*** |

Or. el

*Justification*

*The impact of the projected safety features must be assessed at the latest after five years, thereby helping to reduce the number of counterfeit medicinal products. At the same time it is necessary to examine the possibility of extending the harmonised safety features to over-the-counter medicinal products medicines, the possible falsification of which is also a public health hazard. If they are to be included, this must be done without delay so as to avoid creating any grey areas which might detract from the effectiveness of the operational programme.*

**Amendment 78**
**Thomas Ulmer**

**Proposal for a directive – amending act**
**Recital 7**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of prescription medicinal products should be established at Community level. When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated. | (7) In order to take account of new risk profiles, while at the same time ensuring the functioning of the internal market for medicinal products, safety features designed to ensure the identification, authentication and traceability of prescription medicinal products should be established at Community level. When introducing obligatory safety features for prescription medicinal products, due account should be taken of the particularities of certain products or categories of products, such as generic medicines ***and homeopathic medicines***. This includes the risk of falsifications in view of their price and past incidences in the Community and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated.<br>***No later than five years after the date of entry into force of this Directive, the Commission should submit to the European Parliament and to the Council*** |

***an assessment report on the application of the safety features referred to in point (o) of Article 54 of Directive 2001/83/EC and their estimated contribution to the reduction of the number of falsified medicines in the legal supply chain in Europe. The report should include an assessment of the safety features of other categories of medicines, including medicinal products not subject to medical prescription as defined in Title VI of Directive 2001/83/EC.***

Or. en

*Justification*

*Homeopathic medicines (if subject to medical prescription) should be added referring to the principle of proportionality. Here it will be up to the Commission to define if safety features are mandatory on a risk basis approach as described in Article 54a - point 4 - subparagraph 3 lit. a to e. This element should be enlarged for other low risk products groups. As there is no higher risk of falsification related to these products (low turn-over, low price) compared to the same homeopathic products not subject to prescription in other Member States they should be exempted in general.*

**Amendment 79**
**Elżbieta Katarzyna Łukacijewska**

**Proposal for a directive – amending act**
**Recital 7 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(7a) No later than five years from the date of entry into force of the enforcement provisions relating to safety features, the Commission should submit to the European Parliament and the Council an assessment report on the application of the safety features referred to in point (o) of Article 54 of Directive 2001/83/EC and their estimated contribution to the reduction of the number of falsified medicines in the legal supply chain in Europe. The report should include an*** |

***assessment of the safety features of other categories of medicines, including medicinal products not subject to medical prescription as defined in Title VI of Directive 2001/83/EC.***

Or. pl

*Justification*

*1. We cannot use the word 'obligatory' because in this context it applies to all prescription products. Safety features should be applied on the basis of a risk assessment as regards falsification of the product, and therefore not all medicines will be subject to the application of safety features.*

*2. The date on which the five-year period begins needs to be changed in the text of the directive. It should be the date on which the enforcement provisions relating to the safety features enter into force, not the date on which the directive enters into force.*

**Amendment 80**
**Marina Yannakoudakis**

**Proposal for a directive – amending act**
**Recital 7 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(7a) Safety features will be grouped so as to reflect the particularities of certain products or categories of products. They will be considered equivalent when they offer the same or a higher level of efficiency for ascertaining identification, authentication, traceability and absence of tampering, as well as the same level of technical difficulty for duplication. When removing, replacing or covering the safety feature, this point should also be applicable to the new safety feature.*** |

Or. en

*Justification*

*To implement a risk-based approach, safety features have to be categorised according to the*

*risk involved in the falsification of the different types of medicinal products. This amendment ensures that this is possible following a technology-neutral stance. Moreover, to ensure original and new safety features used by re-packagers are indeed equivalent or of a higher standard of feature, this directive has to introduce the different categories of equivalent or a higher feature according to specific criteria.*

**Amendment 81**
**Marisa Matias**

**Proposal for a directive – amending act**
**Recital 7 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(7a) When removing, replacing or covering the safety feature, the new safety features will be considered equivalent to the original safety features when they offer the same level of efficiency for ascertaining identification, authentication, traceability and absence of tampering, as well as the same level of technical difficulty for duplication.*** |

Or. en

*Justification*

*Replaces amendment 9 of the report.*

**Amendment 82**
**Pilar Ayuso**

**Proposal for a directive – amending act**
**Recital 7 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(7a) Safety features should be grouped so as to reflect the particularities of certain products or categories of products. They should be considered equivalent when they offer the same level of efficiency for ascertaining unique identification,*** |

***authentication, traceability and absence of tampering, as well as the same level of technical difficulty for duplication. When removing, replacing or covering the safety feature an equivalent safety feature should be replaced.***

Or. en

*Justification*

*For the purposes of absolute clarity, the only types of safety feature that will enable authentication and traceability of individual packs are those that identify the pack uniquely.*

**Amendment 83**
**Antonyia Parvanova**

**Proposal for a directive – amending act**
**Recital 7 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(7a). Over-the counter (OTC) medicinal products should be the subject of regular risk analysis study carried out by national authorities. Depending on the results of this risk analysis study, OTC medicinal products may be integrated into the scope of Directive 2001/83/EC. For that purpose, the marketing authorisation holders have the right, as soon as this Directive has entered into force, to submit their OTC medicinal products to the provisions included in this Directive***. |

Or. en

*Justification*

*OTC medicinal products should be submitted to a specific follow-up and be submitted to the requirements of this directive, depending on the results of the risk analysis studies carried out by the national authorities.*

**Amendment 84**
**Paolo Bartolozzi**

**Proposal for a directive – amending act**
**Recital 7 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(7a) Member States, in consultation with stakeholders, should be free to determine the particular aspects of technologies for combating counterfeiting of pharmaceuticals which they consider most appropriate for their pharmaceutical distribution systems, taking account of the authentication seal adopted by this Directive.*** |

Or. it

*Justification*

*This Directive will require the use of an authentication seal on the packaging of pharmaceuticals, which will make it possible for wholesalers and pharmacists to check the authenticity of the pharmaceuticals. The characteristics of the safety system will have to be decided at national level on the basis of the specific needs of the national pharmaceuticals distribution system. National initiatives already implemented or being implemented must be respected.*

**Amendment 85**
**Esther de Lange, Cristina Gutiérrez-Cortines**

**Proposal for a directive – amending act**
**Recital 7 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(7a) The use of technologies that allow the authentication and tracing of medicinal products at the level of individual dosage forms (e.g. the capsule, tablet or tamper-evident immediate packaging of liquids) can also be very valuable in terms of allowing better monitoring of products on the market.*** |

Or. en

*Justification*

*The use of technologies that allow the authentication and tracing of medicinal products at the level of individual dosage forms, as a complement to the safety features proposed for the packaging of medicinal products, will allow early detection of falsified products and in that way help to further reduce the health and safety risks that falsified products pose to patients.*

**Amendment 86**
**Thomas Ulmer**

**Proposal for a directive – amending act**
**Recital 7 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(7a) Member States, working together with stakeholders, should be free to determine the particular aspects of medicines authentication which they consider most appropriate for their medicine distribution system, taking into account the safety features adopted pursuant to this Directive.*** |

Or. en

*Justification*

*This Directive will require safety features to be added to medicines packages, which will allow medicines to be authenticated by wholesalers and pharmacists. Specific features of the authentication process should be determined at national level, according to the needs of the medicine distribution system in each State. National initiatives already implemented, or in the process of being implemented, should be respected.*

**Amendment 87**
**Sylvana Rapti**

**Proposal for a directive – amending act**
**Recital 7 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(7a) Member States, working together with stakeholders, should be free to determine the particular aspects of medicines authentication which they consider most appropriate for their medicine distribution system, taking into account the safety features adopted pursuant to this Directive.*** |

Or. en

*Justification*

*The Directive will require safety features to be added to medicines packages which will allow medicines to be authenticated by wholesalers and pharmacists. Special features of the authentification process should be determined at national level according to the needs of the medicine distribution system in each State.*

**Amendment 88**
**Jorgo Chatzimarkakis**

**Proposal for a directive – amending act**
**Recital 7 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(7a) Member States, in cooperation with stakeholders, should be permitted to regulate the particular aspects of authentication of medicines in the way in which they consider most appropriate for their market in medicinal products, taking account of the safety features established in accordance with this Directive.*** |

Or. en

**Amendment 89**
**Crescenzio Rivellini**

**Proposal for a directive – amending act**
**Recital 7 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(7a) Member States, together with stakeholders, should be free to determine the particular aspects of technologies for combating counterfeiting of pharmaceuticals which they consider most appropriate for their pharmaceutical distribution systems, taking account of the authentication seal adopted by this Directive.*** |

Or. it

*Justification*

*This Directive will require the use of an authentication seal on the packaging of pharmaceuticals, which will make it possible for wholesalers and pharmacists to check the authenticity of the pharmaceuticals.*

*The characteristics of the safety system will have to be decided at national level on the basis of the specific needs of the national pharmaceuticals distribution system in order to guarantee the highest and most effective level of protection for the public. National initiatives already implemented or being implemented must be respected.*

**Amendment 90**
**Françoise Grossetête**

**Proposal for a directive – amending act**
**Recital 8**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (8) Any actor in the supply chain who packages medicinal products has to be a holder of a manufacturing authorization. In order for the safety features to be effective, the manufacturing authorization holder should ***only*** be permitted to remove, replace or cover these features ***under*** strict | (8) Any actor in the supply chain who packages medicinal products has to be a holder of a manufacturing authorization. In order for the safety features to be effective, the manufacturing authorization holder should ***not*** be permitted to remove, replace or cover these features. ***Except in*** |

| | |
|---|---|
| conditions. | ***exceptional cases governed by*** strict conditions ***as stipulated in paragraph (2) of Article 54a, the manufacturing authorisation holder may only place the original medicinal product container inside another package if this makes it possible to preserve intact the original container and the integrity and effectiveness of the initial safety arrangements throughout the entire distribution chain.*** |

Or. fr

*Justification*

*In the interests of ensuring the optimal safety standards desired by all, the medicinal product must not be manipulated. Once the product has been packaged by the marketing authorisation holder, it must remain intact until it reaches the patient, in line with the current requirements of the European food safety strategy. However, it should, in certain cases, still be possible to place the original product in another container while preserving intact the initial safety arrangements.*

**Amendment 91**
**Marisa Matias**

**Proposal for a directive – amending act**
**Recital 8**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (8) Any actor in the supply chain who packages medicinal products has to be a holder of a manufacturing authorization. In order for the safety features to be effective, the manufacturing authorization holder should only be permitted to remove, replace or cover these features under strict conditions. | (8) Any actor in the supply chain who ***labels and*** packages medicinal products, ***or makes changes to the labelling or packaging,*** has to be a holder of a manufacturing authorization. In order for the safety features to be effective, the manufacturing authorization holder should only be permitted to remove, replace or cover these features under strict conditions. |

Or. en

*Justification*

*Replaces amendment 10 of the draft report.*

**Amendment 92**
**Frédérique Ries**

**Proposal for a directive – amending act**
**Recital 8**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (8) Any actor in the supply chain who packages medicinal products has to be a holder of a manufacturing authorization. In order for the safety features to be effective, the manufacturing authorization holder should only be permitted to remove, replace or cover these features under strict conditions. | (8) Any actor in the supply chain who ***labels or*** packages medicinal products ***or inserts changes to the labelling or packaging of medicinal products*** has to be a holder of a manufacturing authorization. In order for the safety features to be effective, the manufacturing authorization holder should only be permitted to remove, replace or cover these features under strict conditions. ***The strict conditions should provide adequate safeguards against falsified products entering the distribution chain and also reflect a strict duty of care of those manufacturing authorisation holders towards the original manufacturer and the marketing authorisation holder of the products and to consumers of the products.*** |

Or. en

*Justification*

*Patients and others actors in the supply chain must be explicitly informed via a label on the pack where original safety features have been removed and replaced.*

**Amendment 93**
**Françoise Grossetête**

**Proposal for a directive – amending act**
**Recital 9**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (9) These manufacturing authorisation holders ***should*** be held strictly liable for | (9) These manufacturing authorisation holders ***must*** be held strictly liable for |

| | |
|---|---|
| damages to patients caused by products placed by them on the market which are falsified in relation to their identity. | damages to patients caused by products placed by them on the market which are falsified in relation to their identity. |

Or. fr

*Justification*

*Responsibility is the keystone of the protection arrangements. All those concerned should therefore be left in no doubt as to their duties and rights.*

**Amendment 94**
**Paolo Bartolozzi**

**Proposal for a directive – amending act**
**Recital 11 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(11a) The European public should be made aware of the risks run when purchasing pharmaceuticals through illegal channels. In particular, information campaigns should be promoted at both national and European level. The Commission, in conjunction with the Member States, should adopt effective measures to improve public awareness of the risks arising from purchases of pharmaceuticals over the internet.*** |

Or. it

*Justification*

*The internet is the main source of counterfeit pharmaceuticals. Members of the public should be strongly discouraged from acquiring pharmaceuticals through illegal distribution channels. It would therefore be desirable to organise education campaigns on the subject at both national and European level.*

**Amendment 95**
**Crescenzio Rivellini**

**Proposal for a directive – amending act**
**Recital 11 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(11a) The European public should be made aware of the risks run when purchasing pharmaceuticals through illegal channels, especially in terms of their danger to health. In particular, information campaigns should be promoted at both national and European level. The Commission, in conjunction with the Member States, should adopt effective measures to improve public awareness of the risks arising from purchases of pharmaceuticals over the internet.*** |

Or. it

*Justification.*

*The internet is the main source of counterfeit pharmaceuticals. Members of the public should be strongly discouraged from acquiring pharmaceuticals through illegal distribution channels. It would therefore be desirable to organise education campaigns on the subject at both national and European level.*

**Amendment 96**
**Elena Oana Antonescu, Rareş-Lucian Niculescu**

**Proposal for a directive – amending act**
**Recital 11 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(11a) European citizens should be made aware of the risks of purchasing medicinal products from illegal suppliers. An information campaign should be organised by the Member States and at EU level. The Commission and Member States should adopt measures to make the*** |

***public aware of the risks of purchasing medicinal products over the internet.***

Or. ro

*Justification*

*Citizens who purchase medicinal products from illegal suppliers cannot be as well informed as medical experts of the resulting risks to their health. An information campaign could discourage the purchase of medicinal products through illegal channels if consumers were given specialist information concerning the possible risks involved.*

**Amendment 97**
**Jorgo Chatzimarkakis, Holger Krahmer**

**Proposal for a directive – amending act**
**Recital 11 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(11a) European citizens should have their attention drawn to the risks which arise when medicinal products are ordered from illegal suppliers. In particular, public information measures should be promoted in the Member States and throughout Europe. The Commission and Member States should adopt measures to increase awareness among the general public of the risks related to purchasing medicinal products on the Internet.*** |

Or. en

**Amendment 98**
**Peter Liese, Thomas Ulmer**

**Proposal for a directive – amending act**
**Recital 11 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(11a) European citizens should be made aware of the risks of ordering medicinal products from illegal suppliers. In*** |

***particular, awareness campaigns should be promoted at Member States and EU level. The Commission together with the Member States should adopt measures to increase awareness among the general public of the risks related to purchasing medicinal products on the internet.***

Or. en

*Justification*

*The Internet is the main source of counterfeit medicines. Citizens should be strongly discouraged from ordering medicines through illegal channels. Therefore awareness campaigns in this regard should be undertaken at Member State level and EU level.*

**Amendment 99**
**Françoise Grossetête, Frédérique Ries**

**Proposal for a directive – amending act**
**Recital 11 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(11a) The Commission and the Member States should adopt measures such as awareness campaigns to inform the public more fully of the risks of purchasing pharmaceutical products online.*** |

Or. fr

*Justification*

*The internet is the principal source of falsified medicinal products. The public should be strongly discouraged from purchasing medicinal products through illegal channels.*

**Amendment 100**
**Cristina Gutiérrez-Cortines, Amalia Sartori, Françoise Grossetête, Thomas Ulmer**

**Proposal for a directive – amending act**
**Recital 12**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (12) Falsified active pharmaceutical ingredients pose the risk of sub-standard active pharmaceutical ingredients. This risk should be addressed. In particular, manufacturers of medicinal products should ensure ***either by themselves of through a body accredited for that purpose*** that the supplying manufacturer of active pharmaceutical ingredients complies with good manufacturing practices. | (12) Falsified active pharmaceutical ingredients pose the risk of sub-standard active pharmaceutical ingredients. This risk should be addressed ***by combining an effective inspection system with a system ensuring the traceability of active pharmaceutical ingredients.*** In particular, manufacturers of medicinal products should ***themselves*** ensure that the supplying manufacturer of active pharmaceutical ingredients complies with good manufacturing practices. |

Or. en

*Justification*

*To ensure that public health is properly protected, the competent authorities of the Member States should inspect production sites, in cooperation with the EMEA. In cases where there were a number of different accredited private bodies, there would be uncertainty about the effectiveness of inspections and confusion as to who was responsible for ensuring the accuracy of inspection findings, and the ambiguous relationship between firms being inspected and the bodies inspecting them could give rise to a risk of corruption.*

**Amendment 101**
**Cristina Gutiérrez-Cortines, Amalia Sartori, Françoise Grossetête, Thomas Ulmer**

**Proposal for a directive – amending act**
**Recital 13**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (13) ***The*** manufacture of active pharmaceutical ingredients should be subject to good manufacturing practices irrespective of whether those ingredients | (13) ***In order to ensure sufficient protection of public health the*** manufacture of active pharmaceutical ingredients should be subject to good |

| | |
|---|---|
| were manufactured in the Community or imported. With regard to the manufacture of active pharmaceutical ingredients in third countries, it should be ensured that ***the rules for the manufacture of active pharmaceutical ingredients intended for export to the Community, including inspection and enforcement, provide for a level of protection of public health equivalent to that provided for by Community legislation***. | manufacturing practices ***and should comply with the information submitted within, or supplied to, the Marketing Authorisation Application*****,** irrespective of whether those ingredients were manufactured in the Community or imported. ***Therefore*****,** with regard to the manufacture of active pharmaceutical ingredients in third countries ***intended for medicinal products marketed in the Union***, it should be ensured ***through repeated, mandatory inspections and enforcement by the Union's competent authorities or by authorities with mutual recognition agreements covering active pharmaceutical ingredients in force, that manufacture is taking place in compliance with both of the above-mentioned requirements.*** |

Or. en

*Justification*

*Certainty as to the source and quality of active pharmaceutical ingredients is of essential importance. To ensure compliance with good manufacturing practice, thorough inspections of production facilities need to be carried out on a regular basis.*

**Amendment 102**
**Thomas Ulmer**

**Proposal for a directive – amending act**
**Recital 13**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (13) The manufacture of active pharmaceutical ingredients should be subject to good manufacturing practices irrespective of whether those ingredients were manufactured in the Community of imported. With regard to the manufacture of active pharmaceutical ingredients in third countries, it should be ensured that the rules for the manufacture of active | (13) The manufacture of active pharmaceutical ingredients should be subject to good manufacturing practices irrespective of whether those ingredients were manufactured in the Community of imported. With regard to the manufacture of active pharmaceutical ingredients ***or excipients*** in third countries, it should be ensured that the rules for the manufacture |

| | |
|---|---|
| pharmaceutical ingredient intended for export to the Community, including inspection and enforcement, provide for a level of protection of public health equivalent to that provided for by Community legislation. | of active pharmaceutical ingredients ***or excipients*** intended for export to the Community, including inspection and enforcement, provide for a level of protection of public health equivalent to that provided for by Community legislation. |

Or. en

*Justification*

*Excipients originating from other industries than the pharmaceutical industry cannot be subject to GMP. Many excipients for example come from food industry. And there are also quality assuring steps in this sector; as for example the measures which had been introduced regarding the products where TSE might be an issue. They also are the base for guaranteeing the safety of the medicinal products sector. As there had been attempts to separate the measures of both sectors; the experience made at that time clearly showed that this did not function.*

**Amendment 103**
**Judith A. Merkies**

**Proposal for a directive – amending act**
**Recital 13**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (13) The manufacture of active pharmaceutical ingredients should be subject to good manufacturing practices irrespective of whether those ingredients were manufactured in the Community or imported. With regard to the manufacture of active pharmaceutical ingredients in third countries, it should be ensured that the rules for the manufacture of active pharmaceutical ingredients intended for export to the Community, including inspection and enforcement, provide for a level of protection of public health equivalent to that provided for by Community legislation. | (13) The manufacture of active pharmaceutical ingredients should be subject to good manufacturing practices irrespective of whether those ingredients were manufactured in the Community or imported. With regard to the manufacture of active pharmaceutical ingredients in third countries, it should be ensured that the rules for the manufacture of active pharmaceutical ingredients intended for export to the Community, including inspection and enforcement, provide for a level of protection of public health equivalent to that provided for by Community legislation. ***Pharmaceutical excipients, other than active pharmaceutical ingredients, used in drug*** |

***product manufacturing should be subject to appropriate controls by the manufacturing authorisation holder such that the excipients are checked and verified by the manufacturing authorisation holder to be suitable for use in the production of drug products in accordance with Good Manufacturing Practices and that the verification provides for an adequate level of protection of public health.***

Or. en

*Justification*

***The inclusion of excipients within the scope is relevant provided that excipients are addressed separately from active pharmaceutical ingredients and that specific requirements will apply which are different from those applicable to active pharmaceutical ingredients.*** *The Manufacturing Authorisation Holder holds responsibility for ensuring that the quality of excipients is fit for purpose and this provision is already embedded in EU Good Manufacturing Practices (GMP) for medicinal products for human use*[1].

**Amendment 104**
**Marisa Matias**

**Proposal for a directive – amending act**
**Recital 13 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(13a) Active pharmaceutical ingredients manufactured in plants based in third countries should be subject not only to inspections carried out on the grounds of non-compliance but also to risk analysis and intelligence-based targeted inspections and searches.*** |

Or. en

[1] Directive 2003/94 of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational products for human use, OJ L 262, p.22-26

*Justification*

*Replaces amendment 12 of the report.*

**Amendment 105**
**Vittorio Prodi**

**Proposal for a directive – amending act**
**Recital 13 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(13a) Where good manufacturing practices for excipients or equivalent systems are already in place and well-regulated, they should be taken into account in this Directive.*** |

Or. en

*Justification*

*Excipients in other applications, such as food, already have GMP equivalent systems in place like HACCP and/or ISO9001/ISO22000 and mandatory EDQM certification. Moreover, the EFfCI GMP (cosmetics) is already well accepted by pharmaceutical manufacturers worldwide when auditing the producers of excipients. These should be enough to satisfy their safety and quality criteria: new mandatory GMP for these excipients would not offer patients any additional security.*

**Amendment 106**
**Marisa Matias**

**Proposal for a directive – amending act**
**Recital 14**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (14) In order to facilitate enforcement and control of Community rules relating to active substances used as starting material, the manufacturers ***or*** importers of those substances should notify their activity. | (14) In order to facilitate enforcement and control of Community rules relating to active substances used as starting material, the manufacturers, importers ***or distributors*** of those substances should notify their activity. |

Or. en

**Amendment 107**
**Horst Schnellhardt**

**Proposal for a directive – amending act**
**Recital 14 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(14a) Counterfeit medicinal products are often found to have been supplied in response to orders placed over the Internet. In accordance with the provisions of the Treaty, particularly Article 168 of the TFEU, Member States are responsible for regulating the marketing of medicinal products at the last level of trade, particularly in pharmacies. This also includes regulating the marketing of medicinal products by mail order and over the Internet. The case law of the Court of Justice permits Member States to impose an absolute ban on the supply of prescription medicines by mail order, in accordance with the wide margin of discretion which they enjoy on account of the dangers associated with this method of marketing.*** |

Or. de

*Justification*

*The directive must respect the established allocation of powers. Rules on pharmacies and the marketing of medicines at the last level of trade are a matter for the Member States. The vast majority of Member States prohibit mail-order trading in prescription medicines, and the Court of Justice has upheld this.*

**Amendment 108**
**Marisa Matias**

**Proposal for a directive – amending act**
**Recital 15**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (15) To ensure a similar level of protection of human health throughout the Community, and to avoid distortions in the internal market, the harmonised principles and guidelines for inspections of holders of manufacturing and wholesaler authorisations of medicinal products as well as manufacturers of active substances should be strengthened. This should also help to ensure the functioning of existing mutual recognition agreements which rely on efficient and comparable inspection and enforcement throughout the Community. | (15) To ensure a similar level of protection of human health throughout the Community, and to avoid distortions in the internal market, the harmonised principles and guidelines for inspections of holders of manufacturing and wholesaler authorisations of medicinal products as well as manufacturers ***and distributors*** of active substances should be strengthened. This should also help to ensure the functioning of existing mutual recognition agreements which rely on efficient and comparable inspection and enforcement throughout the Community. |

Or. en

**Amendment 109**
**Marisa Matias**

**Proposal for a directive – amending act**
**Recital 15 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(15a) Member States should impose effective sanctions for acts related to falsified medicines. Those sanctions should at least be equivalent to those typically applied for illegal acts related to narcotics. The Commission may issue general guidelines for such an effective criminal sanctions regime. Specific provisions should be included in Directive 2001/83/EC for enforcing the new safety feature requirements. In cases of authorised or otherwise legitimate medicinal products with quality defects*** |

***due to mistakes in the manufacturing or subsequent handling, the relevant Union or national legislation shall apply.***

Or. en

**Amendment 110**
**Horst Schnellhardt**

**Proposal for a directive – amending act**
**Recital 15 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(15a) It is necessary for the operation of the internal market to establish EU-wide harmonised safety features for medicinal products. The technical implementation of these features and the design of the test methods should, however, be left to the Member States in accordance with the principle of subsidiarity.*** |

Or. de

*Justification*

*The Member States alone should be responsible for the technical implementation of the verification procedures. This ensures that the solutions found are appropriate and tailored to the respective national distributions systems.*

**Amendment 111**
**Marisa Matias**

**Proposal for a directive – amending act**
**Recital 16**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (16) ***The measures necessary for the implementation of this Directive should be adopted*** in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the | ***(16) In accordance with Article 291 TFEU, rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers shall be*** |

| | |
|---|---|
| exercise of implementing powers conferred by the Commission***.*** | ***laid down in advance by a Regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of that new Regulation, given the necessity of adopting and implementing this Directive as soon as possible, control by Member States should be carried out in accordance with the provisions of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission, insofar as those provisions remain compatible with the amended Treaties. References to those provisions should nevertheless be replaced with references to the rules and principles set out in the new Regulation as soon as that Regulation enters into force.*** |

Or. en

**Amendment 112**
**Jorgo Chatzimarkakis**

**Proposal for a directive – amending act**
**Recital 17**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (17) In particular the Commission should be empowered to adopt ***measures regarding*** safety features that shall appear on the packaging of medicinal products subject to medical prescription and to adopt detailed rules for medicinal products introduced without being placed on the market. ***Since those measures are of general scope and are designed to amend non-essential elements by supplementing it, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.*** | (17) In particular the Commission should be empowered to adopt ***delegated acts in accordance with Article 290 TFEU in respect of*** safety features ***or any other technical instrument able to confirm the authenticity of the drug*** that shall appear on the packaging of medicinal products subject to medical prescription and to adopt detailed rules for medicinal products introduced without being placed on the market. ***A standardised form of safety feature or a standardised safety measure within the Union should be found.*** |

Or. en

*Justification*

*In the current discussion, only several types of codification are considered. It should also be borne in mind that a standardized safety measure has not necessarily to be a safety feature, such as a 2D-Bar-Code or a RFID-Code, but it could be a safety measure, such as a special hologram or varnish, as well. Such a solution might be less expensive and technically easier to implement.*

**Amendment 113**
**Marisa Matias**

**Proposal for a directive – amending act**
**Recital 17**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| (17) In particular the Commission should be empowered to adopt ***measures regarding*** safety features that shall appear on the packaging of medicinal products subject to medical prescription and to adopt detailed rules for medicinal products introduced without being placed on the market. ***Since those measures are of general scope and are designed to amend non-essential elements by supplementing it, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.*** | (17) In particular the Commission should be empowered to adopt ***delegated acts in accordance with Article 290 TFEU in respect of*** safety features that shall appear on the packaging of medicinal products subject to medical prescription and to adopt detailed rules for medicinal products introduced without being placed on the market***.*** |

Or. en

*Justification*

*This amendment aligns the old so-called "comitology procedure" to the new procedure under Article 290 of the Treaty on the Functioning of the European Union.*

**Amendment 114**
**Françoise Grossetête, Frédérique Ries**

**Proposal for a directive – amending act**
**Recital 17 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(17a) 36 months at the latest after entry into force of this Directive, the traceability procedure for medicinal products should be harmonised at EU level. Hence, each medicinal product should be unequivocally identified by means of a serial number on its individual packaging.*** |

Or. fr

*Justification*

*It is important to harmonise traceability procedures for medicinal products in such a way as to meet the expectations and requirements of the medical community and of patients in a suitable and effective manner.*

**Amendment 115**
**Jorgo Chatzimarkakis, Holger Krahmer**

**Proposal for a directive – amending act**
**Recital 18 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(18a) The Member States should cooperate to enforce existing restrictions on illegal trading in medicinal products, including by means of Europol.*** |

Or. en

**Amendment 116**
**Peter Liese, Thomas Ulmer**

**Proposal for a directive – amending act**
**Recital 18 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(18a) Member States should collaborate, including through Europol, to enforce existing restrictions on the illegal internet supply of medicines.*** |

Or. en

*Justification*

*There is considerable scope for collaboration among Member States in order to tackle the illegal supply of medicines through the internet, including the exchange of best practice and technological know-how. Such collaboration should include Europol which has acquired considerable expertise in areas related to European cybercrime.*

**Amendment 117**
**Sylvana Rapti**

**Proposal for a directive – amending act**
**Recital 18 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(18a) Furthermore, Member States should collaborate, making use of the services of Europol, to enforce the existing restrictions on the illegal internet supply of medicines.*** |

Or. en

*Justification*

*The collaboration between Member States, including the exchange of best practices, is very important with a view to tackling the illegal supply of medicines through the internet. Europol possesses considerable expertise in areas related to cybercrime.*

**Amendment 118**
**Elena Oana Antonescu, Rareş-Lucian Niculescu**

**Proposal for a directive – amending act**
**Recital 18 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(18a) The Member States should collaborate, within Europol and elsewhere, in enforcing existing rules designed to restrict the illegal activities of those supplying medicinal products over the internet.*** |

Or. ro

*Justification*

*Use should be made of the experience acquired by Europol and of available infrastructures, for example to control the circulation within the EU of illegal pharmaceutical products.*

**Amendment 119**
**Paolo Bartolozzi**

**Proposal for a directive – amending act**
**Recital 18 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***Member States should cooperate with each other, and with Europol, to step up the existing restrictions on the illegal supply of pharmaceuticals over the internet.*** |

Or. it

*Justification*

*Cooperation among Member States to combat the illegal distribution of pharmaceuticals over the internet is certainly wide-ranging and includes, for example, exchanges of best practices and technological know-how. This cooperation should also extend to Europol, which has acquired considerable experience in fields relating to on-line crime.*

**Amendment 120**
**Peter Liese, Thomas Ulmer**

**Proposal for a directive – amending act**
**Recital 18 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(18a) Counterfeit medicinal products are often found to have been supplied in response to orders placed over the Internet. In accordance with the provisions of the Treaty, particularly Article 168 of the TFEU, Member States are responsible for regulating the marketing of medicinal products at the last level of trade, particularly in pharmacies. This also includes regulating the marketing of medicinal products by mail order and over the Internet. The case law of the Court of Justice permits Member States to impose an absolute ban on the supply of prescription medicines by mail order, in accordance with the wide margin of discretion which they enjoy on account of the dangers associated with this method of marketing.*** |

Or. de

**Amendment 121**
**Thomas Ulmer**

**Proposal for a directive – amending act**
**Recital 18 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(18a) Counterfeit medicinal products are often found to have been supplied in response to orders placed over the Internet. In accordance with the provisions of the Treaty, particularly Article 168 of the TFEU, Member States*** |

***are responsible for regulating the marketing of medicinal products at the last level of trade, particularly in pharmacies. This also includes regulating the marketing of medicinal products by mail order and over the Internet. The case law of the Court of Justice permits Member States to impose an absolute ban on the supply of prescription medicines by mail order, in accordance with the wide margin of discretion which they enjoy on account of the dangers associated with this method of marketing.***

Or. de

*Justification*

*The directive must respect the established allocation of powers. Rules on pharmacies and the marketing of medicines at the last level of trade are a matter for the Member States. The vast majority of Member States prohibit mail-order trading in prescription medicines, and the Court of Justice has upheld this (Judgment of 11.12.2003, C-322/01, Deutscher Apothekerverband).*

**Amendment 122**
**Thomas Ulmer**

**Proposal for a directive – amending act**
**Recital 18 a (new)**

| *Text proposed by the Commission* | *Amendment* |
|---|---|
| | ***(18b) It is necessary for the operation of the internal market to establish EU-wide harmonised safety features for medicinal products. The technical implementation of these features and the design of the test methods should, however, be left to the Member States in accordance with the principle of subsidiarity.*** |

Or. de

*Justification*

*The Member States alone should be responsible for the technical implementation of the verification procedures. This ensures that the solutions found are appropriate and tailored to the respective national distributions systems.*