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Committee on the Internal Market and Consumer Protection

2008/0261(COD)

6.4.2010

OPINION

of the Committee on the Internal Market and Consumer Protection

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

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
(COM(2008)0668 – C6-0513/2008 – 2008/0261(COD))

Rapporteur: Regina Bastos

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SHORT JUSTIFICATION

There is an increase in the European Union of medicinal products which are falsified in relation to their identity, history or source. Falsified medicinal products may contain sub-standard or falsified ingredients, no ingredients or ingredients in the wrong dosage, including active ingredients.

They pose a major threat to European patients and European industry, and there are strong concerns in the public and amongst policy makers about the steady increase of these products detected in the European Union in the last year.

The Commission wishes to establish an effective legislative basis for the fight against falsified medicinal products on the internal market of the European Union by introducing better safety features and track and trace systems of medicinal packaging, simplifying procedures, enhanced transparency and communication, better data collection and evaluation procedures, more involvement of stakeholders and the establishment of best practices.

Though your rapporteur for opinion welcomes the proposal, she is of the view that there is room for further improvement, mainly with regard to consumer protection issues**.** She therefore proposes amendments along the following lines:

- For reasons of legal certainty and clarity, there should be a definition of the term 'falsified medicinal product' in the text of the Directive with a clear focus on consumer protection.

- As it is estimated that the majority of falsified medicines enters the internal market via internet sales, the limited focus on the legal supply chain seems to be insufficient. Therefore, the rapporteur calls on the Commission to report to the European Parliament and to the Council every two years on the impact of the measures established by this Directive as well as the need for further harmonisation, in particular regarding sales of medicinal products through the internet and 'over-the-counter' sales of such products.

- Via public information campaigns, consumers of medicinal products should be made aware of the new safety features for medicines and the dangers of purchasing medicinal products from unlicensed internet sites.

- The information entering in the Community database should be as specific as possible. Furthermore, the database should contain cases of falsified medicinal products which have been discovered on the Union market.

- The processing of data during several stages of the track and trace process should take place in accordance with existing Community and national legislation on data protection and should not be available for any commercial purpose.

- The falsification of medicinal products is a severe organised criminal activity which endangers human lives. Therefore, sanctions against falsification should reflect this. Without violating the principle of subsidiarity, it is important to strengthen the

provisions on sanctions in the Directive.

- Finally, with the Lisbon Treaty, which entered into force on 1 December 2009, the comitology procedure is obsolete. Therefore, Directive provisions as regards comitology have to be replaced by provisions with reference to one of the new procedures foreseen in the Treaty on the Functioning of the European Union (Art.290 or 291 TFEU). The responsible Committee on the Environment, Public Health and Food Safety is asked to clarify this issue.

AMENDMENTS

The Committee on the Internal Market and Consumer Protection calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

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

Text proposed by the Commission	*Amendment*
	(3a) Experience shows that, when consumers purchase medicinal products on the internet, they cannot always verify the authenticity of the source. The Commission, in coordination with the Agency and the Member States, should launch campaigns to raise awareness among consumers of the risks they run in obtaining medicines over the internet from unlicensed sites. Furthermore, the Commission should report every two years to the European Parliament and to the Council on the impact of the measures provided for in this Directive and the need for further harmonisation, with particular regard to the sale of medicines on the internet, whereby the decision on whether or not to authorise the sale of medicines on the internet rests with each Member State.

Justification

The majority of falsified products enter the market via illegal online sites. Consumers should

have the possibility to safely obtain medicinal products via the internet, whereby it will be for each Member State to authorise the sale of medicines on the internet in accordance with the subsidiarity principle, subject to compliance with all the relevant European legislation.

Amendment 2

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

Text proposed by the Commission	*Amendment*
	(3b) After the adoption of this Directive, the Commission should, in cooperation with the Agency and Member State authorities, launch campaigns informing and raising awareness among consumers of the risk involved in purchasing falsified medicinal products, focusing in particular on the authentication measures and safety features (such as holograms and safety seals) shown on the packaging of medicinal products or elsewhere.

Justification

The increasing number of falsified medicinal products indicates that consumers are not aware of the risks involved in purchasing falsified medicinal products, in particular from illicit websites. One of the problems that has been reported is the lack of knowledge among consumers of the legislation in force. Well-informed consumers could contribute to the detection of falsified medicinal products on the market.

Amendment 3

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

Text proposed by the Commission	*Amendment*
	(3c) Within two years after the date of adoption of this Directive, the Commission should submit a comprehensive evaluation of the situation regarding 'over-the-counter' medicinal products (OTCs), focusing on the question of whether and in what form OTCs should be included in the scope of this Directive.

Justification

Further evaluation is needed of the possible dangers of OTCs in order to decide whether they should be included in the scope of this Directive.

Amendment 4

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

Text proposed by the Commission	*Amendment*
	(4a) Citizens of the Union should be made aware of the danger to their health of ordering products from non-controlled internet websites or from the illegal supply chain. The Commission, together with the Member States and in cooperation with patients' and consumers' organisations, should adopt measures to increase awareness among the general public of the risks involved in purchasing medicinal products via the internet.

Justification

Patients and consumers' organisations should be involved in such European and national initiatives to raise public and patients' awareness of counterfeit medicines. Patients' organisations have the experience to provide relevant, accurate and accessible information for the communities that they know well. For example, patients should be encouraged to know their medicines – to assess their quality and provenance, to be vigilant for signs that may indicate a counterfeit medicine, any differences in the medicine itself or its packaging, and to encourage them to go to a health professional if they have any concerns.

Amendment 5

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	(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 legal supply chain in the Community.	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. ***All actors*** should be *subject* 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 *might* enter the legal supply chain in the Community.

Justification

All actors in the distribution chain should be subject to the same rules, level of requirements and responsibility in order to ensure the identification, authenticity and uninterrupted traceability of medicinal products from the factory to the consumer.

Amendment 6

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. 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. ***Safety features (other than serialisation***

numbering) should be grouped in categories based on equivalence and, in general, manufacturing authorization holders should adopt a specific feature or features to use within a particular category. Safety features should be considered equivalent when they ensure the same level of protection in terms of ascertaining authenticity, absence of tampering and, where relevant, identification, and present the same level of technical difficulty of duplication.

Justification

In order to ensure the same level of protection it is necessary to clarify the scope of equivalent safety features designed to ensure the identification, authentication and traceability of prescription medicinal products when they are removed. They should be grouped according to complexity and the removal (or covering up) of these features will require replacement with a similar feature providing an equivalent level of protection and complexity.

Amendment 7

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

Text proposed by the Commission	*Amendment*
	(7a) The proposed safety measures and the data collected from identifying, authorising and tracing medicinal products should be used in accordance with existing Union and national legislation on data protection. This includes in particular information on distribution channels.

Justification

The data protection requirements must be met. Particularly, information on the distribution channels of medicinal products could be of commercial use to marketing authorisation holders and should therefore not be made available to them.

Amendment 8

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

Text proposed by the Commission	*Amendment*
	(18a) Member States should cooperate with Europol in the fields of justice and police cooperation, inter alia, in order to strengthen the application of existing restrictions regarding the illegal supply of medicinal products on the internet.

Justification

Cooperation between Member States, including exchanges of best practices and technological know-how, is important in order to address the illegal supply of medicinal products via the internet. Such cooperation should, however, also include Europol which has acquired significant technical expertise in sectors relating to combating cybercrime at EU level.

Amendment 9

Proposal for a directive – amending act
Article 1 – point -1 (new)
Directive 2001/83/EC
Article 1 – point 5 a (new)

Text proposed by the Commission	*Amendment*
.	***-1) In Article 1, the following point 5a is inserted after point 5:*** ***"5a. Falsified medicinal product:*** ***Any medicinal product that has been intentionally or deliberately falsified in relation to its:*** ***(a) identity, including its packaging, labelling, name and composition in terms of both ingredients, including excipients and active ingredients, and the dosage thereof; and/or*** ***(b) source, including the manufacturer, the country of manufacture, the country of origin and the marketing authorisation holder; and/or*** ***(c) history, including the registers and documents enabling the distribution chain to be identified.***

Infringements or disputes concerning patents must be distinguished from counterfeiting or falsification of medicinal products. Medicinal products (whether generic or branded) that are not authorised for marketing in a given country but are authorised elsewhere shall not be considered falsified. Sub-standard batches or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medicinal products shall not be considered falsified. The Commission shall be empowered to adopt delegated acts updating this definition on the basis of technical and scientific progress and/or international agreements. Those acts, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the procedure referred to in Article 290 of the Treaty on the Functioning of the European Union."

Justification

For reasons of legal certainty and clarity a definition of 'falsified medicinal product' should be introduced into the text of the Directive.

Amendment 10

Proposal for a directive – amending act
Article 1 – point 2 a (new)
Directive 2001/83/EC
Article 2 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	2a) In Article 2, the following paragraph 3a is inserted after paragraph 3:
	"3a. Nothing in this Directive shall affect the right of Member States to restrict or prohibit the sale of prescription medicines via the internet."

Justification

The vast majority of Member States currently restrict the sale of prescription medicines through the internet. Such restriction help, among other things, to minimise the opportunities for counterfeiters to make counterfeit medicines available to the general public. In the interests of public health, and in accordance with the principles of subsidiary, such restrictions should be allowed to stay in place.

Amendment 11

Proposal for a directive – amending act
Article 1 – point 9
Directive 2001/83/EC
Article 54a – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
(2) The safety features referred to in point (o) of Article 54 shall not be partly or fully removed or covered-up, unless the following conditions are fulfilled:	(2) The safety features referred to in point (o) of Article 54 shall not be partly or fully removed or covered-up, unless ***the identification, authenticity and traceability of the medicinal products are guaranteed and*** the following conditions are fulfilled:

Justification

The safety features should guarantee the identification, authenticity and uninterrupted traceability of the medicinal product from the factory to the consumer. The identification, authenticity and traceability of medicinal products must be guaranteed in all circumstances.

Amendment 12

Proposal for a directive – amending act
Article 1 – point 9
Directive 2001/83/EC
Article 54a – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) The manufacturing authorisation holder clearly indicates on the outer packaging when original safety features have been partly or fully removed or covered up;

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 13

Proposal for a directive – amending act
Article 1 – point 9
Directive 2001/83/EC
Article 54a – paragraph 4 – subparagraph 3 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) the complexity of the supply chain;

Justification

A risk-based approach is needed as regards the implementation of safety features for medical products (e.g. unit serialisation), evaluating the actual risk for counterfeiting, reimbursement fraud and added value for patient safety. Instead of solely focusing on product risks, authorities should also look into the risks associated with the complexity of the distribution chain, in order to obtain a realistic and balanced evaluation of counterfeiting risks for a certain product group. The risk of a counterfeit entering the legal supply chain usually rises with the number of players involved in the distribution of a specific product group.

Amendment 14

Proposal for a directive – amending act
Article 1 – point 9
Directive 2001/83/EC
Article 54a – paragraph 4 – subparagraph 3 – point b

Text proposed by the Commission	*Amendment*
(b) the number of incidences of falsifications ***in third countries and*** within the ***Community***;	(b) the number of incidences of falsifications ***worldwide, particularly*** within the ***Union***;

Justification

The situation in many third countries is quite different from the situation in Europe as regards monitoring and surveillance by the competent authorities and respect for intellectual property.

Amendment 15

Proposal for a directive – amending act
Article 1 – point 9
Directive 2001/83/EC
Article 54a – paragraph 4 – subparagraph 3 a (new)

Text proposed by the Commission	*Amendment*
	The safety features (other than serialisation numbering) shall be imposed through the identification of one or more categories of feature that must be used for particular products or categories of product. The Commission's Pharmaceutical Committee shall define categories comprising safety features offering equivalent efficiency and effectiveness, and features from the same category shall then be considered equivalent for the purposes of paragraph (2)(b) of this Article. Manufacturing authorisation holders shall have discretion as to which specific feature or features to use within a category, unless the Commission specifies reasons for requiring that a particular safety feature be used.

Justification

We consider that the basic level of security on all prescription medicines should be tamper-evident packaging in combination with a unique coding feature (storing product identification number, batch number, expiry date, and a unique serial code). Tamper-evident packaging is the safest way to ensure that the medicine inside the pack is the same as that inserted by the original manufacturer and a unique coding system is the most robust way to verify the authenticity of a product at the point of dispensing.

We believe that additional overt visual safety features should be required subject to the risk-based approach contained in the Commission proposal. It is important that the implementation of overt safety features provides flexibility for pharmaceutical companies to choose a specific technology or feature from a selection of available technologies that are grouped into categories of equivalence according to the level of protection offered.

Amendment 16

Proposal for a directive – amending act
Article 1 – point 9
Directive 2001/83/EC
Article 54a – paragraph 4 – subparagraph 5

Text proposed by the Commission	*Amendment*
The measures referred to in this paragraph shall take due account of the legitimate interests to protect information of a commercially confidential nature and of the protection of industrial and commercial property rights.	The measures referred to in this paragraph shall take due account of the legitimate interests to protect information of a commercially confidential nature and of the protection of industrial and commercial property rights. ***Member States shall ensure that the ownership and confidentiality of the data resulting from the use of safety features intended to demonstrate the authenticity of pharmaceutical products are respected. In particular, information concerning distribution channels shall not be made available for commercial use.***

Justification

The data protection requirements must be met. Particularly, information on the distribution channels of medicinal products could be of commercial use to marketing authorisation holders and should therefore not be made available to them.

Amendment 17

Proposal for a directive – amending act
Article 1 – point 9
Directive 2001/83/EC
Article 54a – paragraph 4 – subparagraph 5 a (new)

Text proposed by the Commission	*Amendment*
	The measures referred to in this paragraph shall take due account of at least all of the following:
	(a) The cost-effectiveness of the system, in order to ensure that any measure that is applied is based on a cost-benefit analysis.
	(b) The costs relating to the measures shall be shared proportionately by all the actors in the supply chain and take the price of the medicinal product concerned into consideration.
	(c) The independence of the system and the legitimate interest in protecting information of a commercially confidential nature and the protection of

industrial and commercial property rights and of personal data.

Justification

The additional costs related to safety features may jeopardize the ability to continue supplying the market and presenting low prices for patients and governments. Therefore any safety features that are to be implemented should comply with at least the following three principles:

a) Cost effectiveness of the system, in order to guarantee that any measure that is applied is based on a cost benefit analysis and that the system implemented ensures the continued duration of the system avoiding additional and unnecessary costs

b) Costs related to the measures should be applied proportionally to all actors of the supply chain and be linked to the price of the medicines concerned and not to volume.

c) Guaranteed independence of the system and the legitimate interests to protect information of a commercially confidential nature and the protection of industrial and commercial property rights, as well as the protection of confidential patient information.

Amendment 18

Proposal for a directive – amending act
Article 1 – point 9
Directive 2001/83/EC
Article 54a – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) Paragraphs 2 and 3 shall also apply to a manufacturing authorisation holder who partly or fully removes or covers-up safety features that are applied on a voluntary basis to medicinal products that are subject to medical prescription by the original manufacturer for the purposes referred to in paragraph 2 of this Article.

Amendment 19

Proposal for a directive – amending act
Article 1 – point 9
Directive 2001/83/EC
Article 54a – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	(4b) The Commission shall, in cooperation with the Agency and Member State authorities, launch an information campaign. The campaign shall raise consumer awareness of the authentication measures already in place, of the safety features (such as holograms and safety seals) on the packaging of medicinal products, and of the risks involved in purchasing falsified medicinal products. It shall focus in particular on unauthorised and unlicensed online sources.

Justification

The increasing number of falsified medicinal products indicates that consumers are not aware of the risks involved in purchasing falsified medicinal products, in particular from illicit websites. Well-informed consumers could contribute to the detection of falsified medicinal products on the market.

Amendment 20

Proposal for a directive – amending act
Article 1 – point 14
Directive 2001/83/EC
Article 85 c (new)

Text proposed by the Commission	*Amendment*
	Article 85c
	The Commission, together with the Member States, shall certify, and establish a register of accredited internet pharmacies. Such a register shall be accessible via a public database.
	The Commission shall establish a Union quality certification logo to be affixed on the webpages of the legitimate internet pharmacies.
	The Commission shall ensure that none of the non-accredited pharmacies use the Union logo, or trade in medicinal

products in the internal market.

Justification

The consumers confidence in buying medication via the internet pharmacies needs to be strengthen, and distribution of falsified medication on the internet minimised.

Amendment 21

Proposal for a directive – amending act
Article 1 – point 14
Directive 2001/83/EC
Article 85 d (new)

Text proposed by the Commission	*Amendment*
	Article 85d
	The Commission and Member States shall adopt delegated acts containing measures to increase awareness among the general public of the risks related to purchasing medicinal products on the internet, which may include:
	- warnings appearing at the top of the internet page in search engines in the event of a search for medicinal products on the internet;
	- information campaigns, in cooperation with the Member States and patients' and consumers' organisations;
	- providing an easily accessible list of accredited internet pharmacies;
	Those acts, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the procedure referred to in Article 290 of the Treaty on the Functioning of the European Union.

Justification

Patients and consumers' organisations should be involved in such European and national initiatives to raise public and patients' awareness of counterfeit medicines.

Patients' organisations have the experience to provide relevant, accurate and accessible

information for the communities that they know well. For example, patients should be encouraged to know their medicines – to assess their quality and provenance, to be vigilant for signs that may indicate a counterfeit medicine, any differences in the medicine itself or its packaging, and to encourage them to go to a health professional if they have any concerns.

Communications should stress that it is important to engage with health services and purchase prescription medicines and over-the-counter medicines from licensed sources, rather than self-diagnosing and self-medicating outside of the healthcare system. This information should reflect the recent EU developments on quality principles on information to patients endorsed during the Pharmaceutical Forum process.

Amendment 22

Proposal for a directive – amending act
Article 1 – point 15 – point c
Directive 2001/83/EC
Article 111 **–** paragraph 7

Text proposed by the Commission	*Amendment*
(7) If the outcome of the inspection as referred to in paragraph 1 is that the person does not comply with the principles and guidelines of good manufacturing practices or good distribution practices as provided for by Community legislation, the information shall be entered in the Community database referred to in paragraph 6.	(7) If the outcome of the inspection as referred to in paragraph 1 is that the person does not comply with the principles and guidelines of good manufacturing practices or good distribution practices as provided for by Community legislation, the information shall be entered in the Community database referred to in paragraph 6. ***Such information shall specify the principles, guidelines and rules not complied with. Cases where falsified medicines have been discovered on the Union market shall also be reported to this database.***

Justification

The information which enters the Community database should be as specific as possible.

Amendment 23

Proposal for a directive – amending act
Article 1 – point 17
Directive 2001/83/EC
Article 118b

Text proposed by the Commission	*Amendment*
The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by [***insert concrete date*** 18 months after publication] at the latest and shall notify it without delay of any subsequent amendment affecting them.	***Without prejudice to the principle of subsidiarity, Member States shall lay down the rules on penalties applicable to infringements of provisions of this Directive and shall take all measures necessary to ensure that they are implemented. Applicable penalties, which may be criminal penalties, shall take into account the threat to public health presented by the falsification of medicinal products. The penalties provided for shall*** be ***harmonised,*** effective, proportionate and dissuasive***, and shall cover, inter alia, the following forms of behaviour:*** ***(1) manufacturing falsified medicinal products, active substances, excipients, parts, materials and accessories;*** ***(2) supplying or offering to supply, including brokering, trafficking, keeping in stock, importing and exporting falsified medicinal products, active substances, excipients, parts, materials and accessories;*** ***(3) making false documents or tampering with documents;*** ***(4) aiding and abetting any of the above-mentioned infringements;*** ***(5) attempting to commit any of the above-mentioned infringements.*** The Member States shall notify those provisions to the Commission by [18 months after the publication] at the latest and shall notify it without delay of any subsequent amendment affecting them.

Justification

The falsification of medicinal products is a severe criminal activity which endangers human lives. Sanctions against falsification should reflect this. The threat to public health represented by the falsification of counterfeit medicines must be recognised when laying down the rules on penalties applicable. The penalties should therefore be superior to the ones applicable to the falsification or counterfeiting of other kind of good or products.

Amendment 24

Proposal for a directive – amending act
Article 1 – point 17
Directive 2001/83/EC
Article 118 b a (new)

Text proposed by the Commission	*Amendment*
	Article 118ba
	The Commission shall establish a network between the Commission, the Agency and the competent authorities of the Member States and involve patients' and consumers' organisations in order to ensure the exchange of information on the measures taken to combat the falsification of medicinal products, including on the penalties systems in place.

Justification

In order to understand correctly the phenomenon of counterfeited medicinal products e.g. factors leading to purchase of counterfeited medicines, and act effectively to fight counterfeiting, it is essential to establish cooperation with Patients´ Organisations. The latter can help in gathering important data on patients' behaviour such as reasons of purchasing falsified medicines.

Amendment 25

Proposal for a directive – amending act
Article 1 – point 17 a (new)
Directive 2001/83/EC
Article 127 c (new)

Text proposed by the Commission	*Amendment*
	17a) The following Article shall be inserted:
	"Article 127c
	The Commission shall by 30 June 2012 and thereafter every two years report to the European Parliament and to the Council on the impact of the measures provided for by this Directive and the need for further harmonisation. To that end, the Commission shall in particular assess whether specific harmonisation is needed

with regard to 'over-the-counter' sales of medicinal products and sales of such products through the internet. Furthermore, the market entry points of falsified medicinal products as well as the dangers of 'over-the-counter' medicinal products (OTCs) shall be evaluated. Where appropriate, the report shall be accompanied by legislative proposals. If necessary, it shall propose legislation designed to include OTCs in the scope of this Directive."

Justification

The majority of falsified products enter the market via illegal online sites. Consumers should have the possibility to safely purchase medicinal products via the internet and 'over-the-counter'. Furthermore, little data is given regarding the question where and when falsified medicinal products are most likely to enter the legal distribution chain.

Amendment 26

Proposal for a directive – amending act
Article 2 – paragraph 1 – subparagraph 3 – point -a (new)

Text proposed by the Commission	*Amendment*
	(-a) the provisions necessary to comply with Article 1(9) of this Directive in so far as it relates to Article 54a(5) and with Articles 54a(2) and 54a(3) to the extent they are referred to in Article 54a(5) of Directive 2001/83/EC as amended by this Directive from [insert date 6 months after publication of this Directive];

Justification

Given the growing risks to patients from counterfeit medicines, the introduction of interim measures to strengthen patient safety before entry into force are urgently required. Interim measures should require inter alia that manufacturing authorization holders, (including repackagers) who remove or cover up overt safety features applied on a voluntary basis by the originator, replace them with equivalent overt safety features, and be held strictly liable in the case of counterfeits entering the supply chain as a result of their actions.

Amendment 27

Proposal for a directive – amending act
Article 2 – paragraph 1 – subparagraph 3 – point b

Text proposed by the Commission	*Amendment*
(b) the provisions necessary to comply with Article 1(6***), (8) and (9)*** from [insert concrete date 48 months after publication].	(b) the provisions necessary to comply with Article 1(6) ***and (8)*** from [insert concrete date 48 months after publication].

Justification

Given the growing risks to patients from counterfeit medicines, the introduction of interim measures to strengthen patient safety before entry into force are urgently required. Interim measures should require inter alia that manufacturing authorization holders, (including repackagers) who remove or cover up overt safety features applied on a voluntary basis by the originator, replace them with equivalent overt safety features, and be held strictly liable in the case of counterfeits entering the supply chain as a result of their actions.

Amendment 28

Proposal for a directive – amending act
Article 2 – paragraph 1 – subparagraph 3 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) the provisions necessary to comply with Article 1(9) of this Directive except in so far as it relates to Article 54a(5) and with Articles 54a(2) and 54a(3) to the extent they are referred to in Article 54a(5) of Directive 2001/83/EC as amended by this Directive from [insert date 48 months after publication of this Directive].

Justification

Given the growing risks to patients from counterfeit medicines, the introduction of interim measures to strengthen patient safety before entry into force are urgently required. Interim measures should require inter alia that manufacturing authorization holders, (including repackagers) who remove or cover up overt safety features applied on a voluntary basis by the originator, replace them with equivalent overt safety features, and be held strictly liable in the case of counterfeits entering the supply chain as a result of their actions.

PROCEDURE

Title	Falsified medicinal products (amendment of Directive 2001/83/EC)
References	COM(2008)0668 – C6-0513/2008 – 2008/0261(COD)
Committee responsible	ENVI
Opinion by Date announced in plenary	IMCO 19.10.2009
Rapporteur Date appointed	Regina Bastos 14.9.2009
Discussed in committee	29.9.2009 4.11.2009 27.1.2010
Date adopted	17.3.2010
Result of final vote	+: 30 –: 0 0: 2
Members present for the final vote	Pablo Arias Echeverría, Cristian Silviu Buşoi, Lara Comi, António Fernando Correia De Campos, Jürgen Creutzmann, Christian Engström, Evelyne Gebhardt, Louis Grech, Małgorzata Handzlik, Malcolm Harbour, Philippe Juvin, Sandra Kalniete, Eija-Riitta Korhola, Kurt Lechner, Toine Manders, Gianni Pittella, Mitro Repo, Robert Rochefort, Zuzana Roithová, Heide Rühle, Christel Schaldemose, Andreas Schwab, Laurence J.A.J. Stassen, Catherine Stihler, Róża Gräfin Von Thun Und Hohenstein, Kyriacos Triantaphyllides, Bernadette Vergnaud
Substitute(s) present for the final vote	Regina Bastos, Cornelis de Jong, Othmar Karas, Sylvana Rapti, Wim van de Camp