***I

REPORT

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

Committee on the Environment, Public Health and Food Safety

Rapporteur: Marisa Matias
Symbols for procedures

* Consultation procedure
*** Consent procedure
***I Ordinary legislative procedure (first reading)
***II Ordinary legislative procedure (second reading)
***III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

In amendments by Parliament, amendments to the draft act are highlighted in **bold italics**. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the draft act which may require correction when the final text is prepared - for instance, obvious errors or omissions in a language version. Suggested corrections of this kind are subject to the agreement of the departments concerned.

The heading for any amendment to an existing act that the draft act seeks to amend includes a third line identifying the existing act and a fourth line identifying the provision in the that act that Parliament wishes to amend. Passages in an existing act that Parliament wishes to amend, but that the draft act has left unchanged, are highlighted in **bold**. Any deletions that Parliament wishes to make in such passages are indicated thus: [...].
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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a directive of the European Parliament and of the Council on 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))

(Odinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2008)0668),

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0513/2008),

- having regard to the Commission Communication entitled 'Consequences of the entry into force of the Treaty of Lisbon for ongoing interinstitutional decision-making procedures' (COM(2009)0665),

- having regard to Article 114 and Article 168(4)(c) on the Treaty of the Functioning of the European Union,

– having regard to Rule 55 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Industry, Research and Energy and the Committee on the Internal Market and Consumer Protection (A7-0148/2010),

1. Adopts the position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council, to the Commission and to the national parliaments.

Amendment 1

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 falsified medicinal products, including details of where, how and by whom the falsified products were detected, the country in which they originated, and the ‘falsified’ element itself (identity, source and/or ingredient/components) in the Member States and update the measures on the application of the safety features accordingly.

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 2

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

Text proposed by the Commission

(3b) After the adoption of this Directive, the Commission should, in cooperation with the European Medicines Agency ("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 4 a (new)

Text proposed by the Commission

(4a) This Directive is without prejudice to provisions concerning intellectual and industrial property rights and aims specifically to prevent falsified medicinal products from entering the legal distribution chain.

Amendment

Justification

This directive should focus on the consequences for public health and should not deal with possible problems related to intellectual Property Rights or Patent Rights.

Amendment 4

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

Text proposed by the Commission

(4b) This Directive is to apply without prejudice to Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data\(^1\) and should retain clear and effective safeguards whenever personal data are processed.

Amendment

\(^1\) OJ L 281, 23.11.1995, p. 31.
Amendment 5

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

Text proposed by the Commission

(4c) The falsification of medicinal products is a global problem, requiring effective and enhanced international coordination and cooperation in order to ensure that anti-falsification strategies are more effective.

Justification

Increased international cooperation and collaboration among governmental entities such as health, police, customs, local administrative units, judiciary, is essential to defeat the falsification of medicines.

Amendment 6

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

Text proposed by the Commission

(4d) The European Union should support the drafting of an international agreement increasing the penalties for falsifying medicinal products, and of an additional protocol to the United Nations Convention against Transnational Organised Crime (Palermo convention).

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 7
### Proposal for a directive – amending act

#### Recital 4 e (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
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<tbody>
<tr>
<td>(4e) The new draft Convention of the Council of Europe on the counterfeiting of medical products and similar crimes involving threats to public health, should be supported by the Commission and the Member States. Furthermore, the Member States should collaborate, including through Europol, to strengthen the enforcement of the rules designed to restrict trading in falsified medicinal products, including the supply via internet.</td>
</tr>
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</table>

**Justification**

This compromise amendment covers AM4 (Matias), 115 (Chatzimarkakis/Krahmer), 116 (Liese/Ulmer), 117 (Rapti), 118 (Antonescu/Niculescu), 119 (Bartolozzi)

### Amendment 8

#### Proposal for a directive – amending act

#### Recital 4 f (new)

<table>
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<tr>
<th>Text proposed by the Commission</th>
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<tr>
<td>(4f) It is well known that the internet represents one of the main routes by which falsified medicinal products enter the European market. Medicinal products purchased over the internet from sites that conceal their actual physical address are estimated to be falsified in more than 50 % of cases. Therefore, a distinction should be made between legitimate mail order or internet pharmacies and the illegal supply chain through non-controlled internet purchasing. In accordance with Article 168 TFEU, Member States are responsible for regulating the marketing of medicinal products at the last level of trade, particularly in pharmacies. That</td>
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responsibility also includes regulating the marketing of medicinal products by mail order or internet. Internet pharmacies should, in Member States in which they are allowed to operate, require a special authorisation by the competent authority. Member States should ensure that the internet sale of medicinal products is continuously monitored. 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 applicable to 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 may only dispense an ordered prescription medicinal product if the original prescription has been obtained by the respective mail order pharmacy in advance.

Justification

This compromise amendment covers AM5 (Matias), 58 (Rossi), 63 (Chatzimarkakis), 107 (Schnellhardt), 120 (Liese/Ulmer), 121 (Ulmer).

Amendment 9
Proposal for a directive – amending act
Recital 4 g (new)

Text proposed by the Commission

(4g) The European public should be made aware of the health risks of ordering products from non-controlled internet sites or from the illegal supply chain. The Commission, in cooperation with the Member States, should adopt measures to better inform the public of the risks of purchasing medicinal products online. Public awareness campaigns at national and European level should be conducted
to increase awareness of the risks and to inform citizens about how to identify whether internet pharmacies are officially registered and controlled by public authorities.

Justification

This compromise amendment covers AM6 (Matias), 60 (Chatzimarkakis), 94 (Bartolozzi), 95 (Rivellini), 96 (Antonescu/Niculescu), 97 (Chatzimarkakis/Krahmer), 98 (Liese/Ulmer), 99 (Grossetête/Ries)

Amendment 10

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

Text proposed by the Commission  Amendment

(4h) 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 errors in the manufacturing or subsequent handling do not comply with the requirements of good manufacturing practices or good distribution practices should not be confused with falsified medicinal products.

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 11

Proposal for a directive – amending act
Recital 5

Text proposed by the Commission

(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.

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, such as traders and brokers. 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 and brokers. All players should be clearly and unambiguously defined, as should their responsibilities, and 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 Union. In particular, such persons should have a valid licence for their business activities, which should be conducted in accordance with the good practice guidelines laid down by the Commission, in cooperation with the Agency and the Member State authorities, by analogy with those applying to manufacturers and distributors of medicinal products.

Justification

To ensure the safety of pharmaceutical products, due account needs to be taken of all those working in the sector and not just wholesale distributors. For the system to be able effectively to protect public health, it is essential for the responsibilities of the various stakeholders to be clearly identified and for all stakeholders to be subject to a rigorous accreditation, verification and good-practice system. This must apply to parallel traders as well.
Amendment 12

Proposal for a directive – amending act
Recital 7

Text proposed by the Commission

(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.

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 Union 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 Union 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. There is also a risk of falsification of non-prescription medicinal products. However, it is appropriate to first assess the effect of the safety features for prescription medicinal products before taking a decision on whether to extend the safety features to non-prescription medicinal products.

Justification

This compromise covers amendments 8 (Matias), 64 (Rossi), 65 (Liese), 66 (Ayuso), 67 (Tremopoulos), 68 (Rapti), 69(Bartolozzi), 70(Antonescu,Niculescu), 71(Chatzimarkakis), 72(LindaMcAvan), 73(Ulmer), 74(Roth-Behrendt), 75(Krahmer), 76(Lukacijewska),77(Skylakakis), 78(Ulmer), 79(Lukacijewska), 83 (Parvanova)

Amendment 13
Proposal for a directive – amending act
Recital 7 a (new)

Text proposed by the Commission Amendment

(7a) In order to ensure a similar and harmonised level of protection of public health throughout the European Union and to avoid distortions in the internal market, a clarification of the notion of equivalent safety features should be provided for.

Justification

This compromise amendment covers am 9 and 81 (Matias), 80 (Yannakoudakis), 82 (Ayuso)

Amendment 14

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

Text proposed by the Commission Amendment

(7b) 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.

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 15

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

**Text proposed by the Commission**

(7c) The proposed safety measures and the data collected from identifying, authorising and tracing medicinal products, in particular information on distribution channels, should be used in accordance with existing Union and national legislation on data protection.

**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 16

Proposal for a directive – amending act
Recital 8

**Text proposed by the Commission**

(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.

**Amendment**

(8) Any actor in the supply chain who labels or packages medicinal products or makes 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. Those strict conditions should provide adequate safeguards against falsified products entering the distribution chain and reflect a strict duty of care owed by those manufacturing authorisation holders to the original manufacturer and the marketing authorisation holder of the products and to consumers of the products.
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 17

Proposal for a directive – amending act
Recital 9

Text proposed by the Commission

(9) These manufacturing authorisation holders should 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.

Amendment

(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.

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 18

Proposal for a directive – amending act
Recital 12

Text proposed by the Commission

(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 or through a body accredited for that purpose that the supplying manufacturer of active pharmaceutical ingredients complies with good manufacturing practices.

Amendment

(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 ensure that the supplying manufacturer of active pharmaceutical ingredients complies with good manufacturing practices.

Justification

To ensure that public health is properly protected, the competent authorities of the Member States should inspect production sites, in cooperation with the European Medicines Agency.
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 19

Proposal for a directive – amending act
Recital 13

Text proposed by the Commission

(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.

Amendment

(13) In order to ensure sufficient protection of public health, the manufacture of active pharmaceutical ingredients should be subject to good manufacturing practices and should comply with the information submitted within, or accompanying, the marketing authorisation application, irrespective of whether those ingredients were manufactured in the Union 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 in force covering active pharmaceutical ingredients, that manufacture is taking place in compliance with both of the above requirements. Pharmaceutical excipients, other than active pharmaceutical ingredients, used in medicinal 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 medicinal products in accordance with good manufacturing practices and that the verification provides for an adequate level of
protection of public health.

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. 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.

Amendment 20

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

Text proposed by the Commission
(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.

Justification

Replaces amendment 12 of the report.

Amendment 21

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

Text proposed by the Commission
(13b) Where good manufacturing practices for excipients or equivalent

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systems are already in place and well-regulated, they should be taken into account in this Directive.

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 22

Proposal for a directive – amending act
Recital 14

Text proposed by the Commission

(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.

Amendment

(14) In order to facilitate enforcement and control of Union rules relating to active substances used as starting material, the manufacturers, importers or distributors of those substances should notify their activity.

Amendment 23

Proposal for a directive – amending act
Recital 15

Text proposed by the Commission

(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

Amendment

(15) To ensure a similar level of protection of human health throughout the Union, 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. enforcement throughout the Union.

Amendment 24
Proposal for a directive – amending act
Recital 15 a (new)

Text proposed by the Commission
(15a) Member States should impose effective sanctions for acts involving falsified medicinal products. Those sanctions should at least be equivalent to those typically applied for illegal acts involving 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 should apply.

Amendment 25
Proposal for a directive – amending act
Recital 15 b (new)

Text proposed by the Commission
(15b) It is necessary for the operation of the internal market to establish EU-wide harmonised safety features for medicinal products.

Justification

Amendment 26
Proposal for a directive – amending act

Recital 16

Text proposed by the Commission

(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 exercise of implementing powers conferred by the Commission.

Amendment

(16) In accordance with Article 291 TFEU, rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers shall be 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 the Member States should be exercised 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 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.

Amendment 27

Proposal for a directive – amending act

Recital 17

Text proposed by the Commission

(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

Amendment

(17) 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 medicinal product 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
it, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC. on the market. A standardised form of safety feature or a standardised safety measure within the Union should be found.

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 28

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

Text proposed by the Commission

(17a) Thirty-six months at the latest after the entry into force of this Directive, the traceability procedure for medicinal products should be harmonised at EU level. Thereafter, each medicinal product should be unequivocally identified by means of a serial number on its individual packaging.

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 29

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

Text proposed by the Commission

(-1) In Article 1, the following point 2a is inserted after point 2:
2a. Falsified medicinal product:

Any medicinal product with a false or misleading representation of:

a) its identity, including its packaging and labelling, name, composition in respect of any of its components, including excipients, and strength; and/or

b) its source, including the manufacturer, country of manufacture, country of origin, marketing authorisation holder; and/or

c) its history, including the records and documents relating to distribution channels.

The Commission shall be empowered to update this definition on the basis of technical and scientific progress and international agreements.

This definition does not include unintentional manufacturing errors.

This definition is without prejudice to infringements of legislation on intellectual and industrial property rights or patent rights.

Justification

This compromise amendment covers AM 16 (Mattas), 123 (Krahmer), 124 (Buşoi), 125 (Merkies), 126 (Weisgerber/Ulmer), 127 (Chatzimarkakis), 128 (Tremopoulos/Rivasi), 129 (Rossi), 130 (Buşoi), 131 (Merkies), 132 (Weisgerber/Ulmer), 133 (Krahmer), 134 (Tremopoulos/Rivasi), 135 (Chatzimarkakis), 136 (Rossi), 137 (Buşoi), 138 (Chatzimarkakis), 139 (Rossi), 140 (Krahmer), 141 (Tremopoulos/Rivasi), 142 (Merkies), 143 (Weisgerber/Ulmer), 144 (Buşoi), 145 (Weisgerber/Ulmer), 146 (Merkies), 147 (Chatzimarkakis), 148 (Rossi), 149 (Krahmer), 150 (Tremopoulos/Rivasi), 151 (Merkies), 152 (Weisgerber/Ulmer), 153 (Chatzimarkakis), 154 (Rossi), 155 (Krahmer), 156 (Tremopoulos/Rivasi)

Amendment 30

Proposal for a directive – amending act
Article 1 – point -1 a (new)
Directive 2001/83/EC
Article 1 – point 2 b (new)
(-1a) In Article 1, the following point 2b is inserted after point 2a:

2b. Active substance used as starting material:

Any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product. Such substances are intended to furnish pharmacological activity or have other direct effects in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

### Amendment 31

**Proposal for a directive – amending act**

**Article 1 – point -1 b (new)**

Directive 2001/83/EC

**Article 1 – point 3 a (new)**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td>(-1 b) In Article 1, the following point 3a is inserted:</td>
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<tr>
<td>3a. Excipient:</td>
<td></td>
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<tr>
<td>Any constituent of a pharmaceutical form apart from the active substance. Excipients include fillers, disintegrants, lubricants, colouring matters, antioxidants, preservatives, adjuvants, stabilisers, thickeners, emulsifiers, solubilisers, permeation enhancers, flavouring and aromatic substances, as well as the constituents of the outer covering of the medicinal products, such as gelatine capsules.</td>
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**Justification**

A definition on excipients is needed. As an excipient is an essential part of the finished medicinal product The definition is in accordance with the European Medicines Agency
Amendment 32

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

Text proposed by the Commission

17a. Trading of medicinal products:
All activities consisting of negotiating independently on behalf of another person the sale or the purchase of medicinal products, or billing or brokering medicinal products, apart from supplying medicinal products to the public, and not falling under the definition of wholesale distribution.

Amendment

17a. Trading of medicinal products:
All activities consisting of the sale, purchase or billing of medicinal products and active pharmaceutical ingredients, apart from the physical handling and supply of medicinal products to the public, and not falling under the definition of wholesale distribution.

Justification

Definitions used in the Directive should be easily understood and should not result in any uncertainty as to their meaning. Therefore, definitions must distinguish between trading and brokering, the former includes cases where the trader is owner of the product, the latter not, whereas both take no physical possession of products and therefore do not control their handling.

Amendment 33

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

Text proposed by the Commission

(1a) In Article 1, the following point 17b is inserted after point 17a:

17b. Brokering:
All activities in relation to sale or purchase of medicinal products, active pharmaceutical ingredients or excipients except for retail supply and wholesale
distribution as defined in point 17 of this Article, that do not include physical handling and that consist of mediating independently and on behalf of another legal or natural person.

Justification

A distinction between trading and brokering is necessary.

Amendment 34

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

Text proposed by the Commission

(1b) In Article 1, the following point 17c is inserted after point 17b:

17c. Managed distribution chain

System of distribution where the manufacturer delivers a medicinal product directly, without the involvement of third parties such as wholesale distributors or traders, to a healthcare setting in which the product is dispensed directly to the patient.

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. As such, it would be helpful to define what a Managed Distribution Chain means.

Amendment 35

Proposal for a directive – amending act
Article 1 - point 2
Directive 2001/83/EC
Article 2 - paragraph 3
(3) Notwithstanding paragraph 1 and Article 3(4), Title IV of this Directive shall apply to medicinal products intended only for export and to intermediate products and active substances used as starting materials.

**Amendment**

(3) Notwithstanding paragraph 1 and Article 3(4), Title IV of this Directive shall apply to medicinal products intended only for export and to intermediate products and active substances used as starting materials and excipients.

**Justification**

Falsified excipients can also pose an important risk to health and should be included in the scope of this directive.

**Amendment 36**

**Proposal for a directive – amending act**

**Article 1 – point 3 – point a**

Directive 2001/83/EC

Article 46 – point f - subparagraph 1

**Text proposed by the Commission**

(f) to comply with the principles and guidelines of good manufacturing practice for medicinal products and to use as starting materials only active substances, which have been manufactured in accordance with the detailed guidelines on good manufacturing practice for starting materials. To this end, the holder of the manufacturing authorization shall verify compliance of the active substances manufacturer with good manufacturing practices by himself or through a body accredited for this purpose by the competent authority of a Member State.

**Amendment**

(f) to comply with the principles and guidelines of good manufacturing practices for medicinal products and to use as starting materials only active substances which have been manufactured and distributed in accordance with the detailed guidelines on good manufacturing and distribution practices for starting materials. To this end, the holder of the manufacturing authorization shall verify compliance of the active substances manufacturer and distributor with good manufacturing practices by himself or through a body accredited for this purpose by the competent authority of a Member State.

**Justification**

This amendment inter alia 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 37**
Proposal for a directive – amending act
Article 1 – point 3 - point a
Directive 2001/83/EC
Article 46 – point f – subparagraph 1 a (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>The manufacturing authorisation holder shall ensure that excipients are assessed as being suitable for use in medicinal products following specific good manufacturing practices as developed by the Commission in accordance with Article 47. The manufacturing authorisation holder shall also ensure that the process by which the assessment is conducted is described in a quality system which is available for inspection by competent authorities.</td>
<td></td>
</tr>
</tbody>
</table>

Justification

Active Pharmaceutica Ingredients (API’s) and excipients have very different supply chain characteristics. Both excipients and active pharmaceutical ingredients should be subject to relevant good manufacturing practices developed at the European level taking into account their own specificities.

Amendment 38

Proposal for a directive – amending act
Article 1 – point 3 – point a a (new)
Directive 2001/83/EC
Article 46 – point f – subparagraph 2

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(aa) The second subparagraph of point (f) is replaced by the following:</td>
<td></td>
</tr>
<tr>
<td>The Commission shall adopt, by means of delegated acts in accordance with Article 121a and subject to the conditions of Articles 121b and 121c, a list of certain categories of excipients identified on a risk-based approach taking into account their source and their intended use. For these categories of excipients, the manufacturer shall apply the appropriate good manufacturing practices on the</td>
<td></td>
</tr>
</tbody>
</table>
basis of a formalised risk assessment in accordance with the applicable guidelines referred to in the second paragraph of Article 47, taking into account other suitable quality system requirements, and document that process.

Justification

This amendment inter alia 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 39

Proposal for a directive – amending act
Article 1 – point 3 – point b
Directive 2001/83/EC
Article 46 – point g

Text proposed by the Commission

(b) The following point (g) is added:

‘(g) to inform the competent authority of products he gets knowledge of which are or which are suspected to be falsified in relation to the identity, history or source of products manufactured by him.’

Amendment

(b) The following point (g) is added:

‘(g) to inform the competent authority of products he gets knowledge of which are or which are reliably suspected to be falsified in relation to the identity, history or source of products manufactured by him in the legal or illegal supply chain, including on the internet.’

Justification

The obligation for the holder of the manufacturing authorisation to inform the competent authorities of falsified products should be comprehensive so as to help to achieve the maximum level of transparency and traceability. This would also help to provide reliable data on the actual extent of the problem.

Amendment 40

Proposal for a directive – amending act
Article 1 - point 3 - point b a (new)
Directive 2001/83/EC
Article 46 - point g a (new)
(ba) The following point (ga) is added: 'The following point (ga) is added: 
'(ga) to verify the authenticity and quality of the active substances and the excipients.'

**Justification**

Excipients can also be falsified and can thus also result in risks for public health. Their quality and authenticity should therefore be verified.

**Amendment 41**

Proposal for a directive – amending act
Article 1 – point 3 – point b a (new)
Directive 2001/83/EC
Article 46 – paragraph 1 a (new)

**(ba)** In Article 46, the following paragraph is added:

The Commission shall submit every year to the European Parliament and to the Council a report with reliable and accurate data on the current situation and trends in the falsification of medicinal products. The report shall as a minimum include where, how and by whom the falsified products were detected, their origin, and an exact description of the nature of the falsification.

That report shall clearly distinguish falsified medicinal products from patent infringements.

**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.

**Amendment 42**
Proposal for a directive – amending act
Article 1 – point 4
Directive 2001/83/EC
Article 46b – paragraph 1

Text proposed by the Commission

(1) Member States shall take appropriate measures to ensure that the manufacture on their territory of active substances used as starting material, including active substances that are intended for export, complies with good manufacturing practices for active substances.

Proposal for a directive – amending act
Article 1 - point 4
Directive 2001/83/EC
Article 46b - paragraph 2 - point b

Text proposed by the Commission

(b) they are accompanied by a written confirmation from the exporting third country that the standards of good manufacturing practice applicable to the plant manufacturing the exported active substance are at least equivalent to those laid down by the Community, and that the plant is subject to control and enforcement ensuring that those good manufacturing practices cannot be circumvented.

Amendment

(1) Member States shall take appropriate measures to ensure that the manufacture and distribution on their territory of active substances used as starting material, including active substances that are intended for export, comply with good manufacturing practices for active substances.

(b) they are accompanied by a written confirmation from the exporting third country that the standards of good manufacturing practices applicable to the plant manufacturing the exported active substance are at least equivalent to those laid down by the Union, and that the plant is subject to regular strict and transparent control and efficient enforcement of good manufacturing practices including repeated and unannounced inspections, ensuring a protection of public health at least equivalent to that in the Union, and that in the event of findings relating to non-compliance, that information shall be supplied by the exporting third country to the Union without any delay.
Justification

The protection in third countries should be at least equivalent to that in the Community. In the event of non-compliance, this information should be immediately supplied by the exporting third country to the Community.

Amendment 44

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 47 – paragraph 3

Text proposed by the Commission

The principles of good manufacturing practice for active substances used as starting materials referred to in point (f) of Article 46 and in Article 46b shall be adopted in the form of detailed guidelines.

Amendment

The Commission shall adopt, by means of delegated acts in accordance with Article 121a and subject to the conditions of Articles 121b and 121c, the principles of good manufacturing and distribution practices for active substances used as starting materials and excipients referred to in point (f) of Article 46 and in Article 46b in the form of detailed criteria.

Justification

Replaces Amendment 26 of the draft report. This amendment inter alia 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 45

Proposal for a directive – amending act
Article 1 - point 7
Directive 2001/83/EC
Article 52a

Text proposed by the Commission

Importers and manufacturers of active substances used as starting materials established in the Community shall notify their address to the competent authority of the Member State where they are established.

Amendment

Importers, manufacturers and distributors of active substances used as starting materials established in the Union shall notify their address to the competent authority of the Member State where they are established.
Amendment 46

Proposal for a directive – amending act
Article 1 - point 7
Directive 2001/83/EC
Article 52b

Text proposed by the Commission

(1) Notwithstanding Article 2(1), and without prejudice to Title VII, Member States shall ensure that medicinal products not intended to be placed on the market are not introduced into the Community if there are reasons to believe that the products claim a falsified identity, history or source.

(2) The Commission shall adopt the necessary measures for the implementation of paragraph 1. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 121(2a).

Amendment

(1) Notwithstanding Article 2(1), and without prejudice to Title VII, Member States shall take the necessary measures to prevent medicinal products not intended to be placed on the market from being introduced into and from transiting through the Union if there are reasons to believe that the products are falsified.

(2) In order to establish the necessary measures referred to in paragraph 1, the Commission shall adopt by means of delegated acts in accordance with Article 121a and subject to the conditions of Articles 121b and 121c:

- the criteria to be considered and the verifications to be made by the national authorities when assessing a medicinal product intended for introduction into the Union in terms of identity, history or source;
- the documentation that is to accompany the medicinal product in order to facilitate enforcement, without prejudice to the applicable documentation requirements in accordance with customs legislation;
- the minimum extent of cooperation and the mechanisms between customs authorities and competent authorities for medicinal products. This shall include at least risk management concepts and triggers for inspections.
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 47

Proposal for a directive – amending act
Article 1 - point 7
Directive 2001/83/EC
Article 52 c (new)

Text proposed by the Commission

Amendment

Article 52c

The Commission shall study the possibilities for the authentication of individual dosage forms, as a method of detecting falsified medicinal products.

Justification

By studying the possibilities for the authentication of individual dosage forms, the Commission can raise the awareness of citizens on state-of-the-art techniques that help preventing pharmaceutical counterfeiting.

Amendment 48

Proposal for a directive – amending act
Article 1 – point 8
Directive 2001/83/EC
Article 54 – point o

Text proposed by the Commission

Amendment

(o) safety features making it possible to ascertain identification, authenticity and traceability of medicinal products, other than radiopharmaceuticals, subject to medical prescription as defined in Title VI.

(o) safety features making it possible to ascertain identification, authenticity and traceability of medicinal products, other than radiopharmaceuticals, subject to medical prescription as defined in Title VI. The decision on whether to extend the safety features to medicinal products not subject to medical prescription shall be based on an assessment by the Commission in accordance with Article 2(2a).
Justification

This compromise amendment covers AM 201 (Chatzimarkakis), 202 (Perello Rodríguez), 203 (Rapti), 204 (Tremopoulos/Rivasi), 205 (Bartolozzi), 206 (McAvan), 207 (Ulmer), 208 (Ayuso), 209 (Liese/Ulmer), 210 (Yannakoudakis), 211 (Grossetête/Ries), 212 (Chatzimarkakis/Leinen), 213 (Ulmer).

Amendment 49

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The safety features referred to in point (o) of Article 54 shall allow wholesale distributors or pharmacists or persons authorised or entitled to supply medicinal products to the public to perform all of the following:</td>
<td>1. The safety features referred to in point (o) of Article 54 shall allow wholesale distributors or pharmacists and persons authorised or entitled to supply medicinal products to the public to perform all of the following:</td>
</tr>
</tbody>
</table>

Justification

The amendments to this article are intended to facilitate its implementation or clarify the scope of the text proposed. It is also necessary, five years from the entry into force of these measures, to evaluate their effectiveness. Furthermore, the implementation of safety features should not be limited to the falsification of medicinal products.

Amendment 50

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) verify authenticity by assessing overt, covert or forensic devices;</td>
<td>a) verify authenticity;</td>
</tr>
</tbody>
</table>

Justification

The amendments to this article are intended to facilitate its implementation or clarify the scope of the text proposed. It is also necessary, five years from the entry into force of these measures, to evaluate their effectiveness. Furthermore, the implementation of safety features should not be limited to the falsification of medicinal products.
Amendment 51
Proposal for a directive – amending act
Article 1 - point 9
Directive 2001/83/EC
Article 54a – paragraph 1 – point b

Text proposed by the Commission

(b) identify individual packs;

Amendment

(b) identify individual packs by a single EU-wide standard;

Justification

In a number of Member States safety features are already in place. It should be possible for them to adapt to an EU standard for a certain transition period. However, given that the problem of counterfeit medicines doesn’t stop at national borders a patchwork of different national legal provisions is not fit to effectively protect patients. Thus, the safety features must be the same throughout the entire EU.

Amendment 52
Proposal for a directive – amending act
Article 1 - point 9
Directive 2001/83/EC
Article 54a - paragraph 1 - point c a (new)

Text proposed by the Commission

(ca) keep the additional costs as low as possible.

Amendment

Justification

Safety features need to be harmonised based on clear criteria. They should also ensure that the excipient is not falsified. Furthermore the additional costs should be as low as possible.

Amendment 53
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

(2) The safety features referred to in point (o) of Article 54 shall not be partly or fully

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: 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 54

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

Text proposed by the Commission

b) The manufacturing authorisation holder complies with point (o) of Article 54 by replacing the safety feature with a safety feature which is equivalent as regards the possibility to ascertain identification, authenticity and uninterrupted traceability of the medicinal product, and without opening the immediate packaging as defined in Article 1(23);

Amendment

(b) The manufacturing authorisation holder complies with point (o) of Article 54 by replacing the safety feature with a safety feature which is equivalent as regards the possibility to ascertain identification, authenticity and inviolability of the external packaging of the medicinal product, and without any changes to the immediate packaging as defined in Article 1(23) other than for the purposes set out in Article 55;

Justification

Amendment 55

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

Text proposed by the Commission

Safety features shall be considered

Amendment

Safety features shall be considered
equivalent where they comply with the harmonised measures provided for in Article 54a(4), which shall ensure that they are equally efficient in identifying, authenticating, tracing and preventing tampering with medicinal products, and that they are equally technically difficult to duplicate.

**Justification**

This compromise amendment covers AM 30 (Matias), 234 (Weisgerber/Ulmer), 235 (Merkies), 236 (Ayuso), 277 (Chatzimarkakis)

**Amendment 56**

**Proposal for a directive – amending act**
**Article 1 - point 9**
Directive 2001/83/EC
Article 54a - paragraph 2 – point c

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(c) <strong>The replacement of the safety feature is subject to supervision by the competent authority.</strong></td>
<td>(c) <strong>The manufacturing authorisation holder shall be responsible for all the activities involved in the acts described in paragraph 2.</strong></td>
</tr>
</tbody>
</table>

**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 57**

**Proposal for a directive – amending act**
**Article 1 - point 9**
Directive 2001/83/EC
Article 54a – paragraph 2 - point c a (new)
Text proposed by the Commission  

Amendment  

(ca) The safety features referred to in point (o) of Article 54 shall be applied without discrimination between distribution channels.  

Justification  

If certain medicinal products have been identified to be in need of additional safety protection, this protection should be applied irrespective of its distribution channel as to avoid unnecessary confusion.  

Amendment 58  

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

Text proposed by the Commission  

Amendment  

(3) Manufacturing authorisation holders referred to in paragraph 2 shall be considered to be producers in accordance with Council Directive 85/374/EEC. They shall be liable for damage suffered by the original manufacturer, the holder of the marketing authorisation and consumers, resulting from changes that they have made to medicinal products, irrespective of whether the product is falsified or genuine.  

Justification  

Clarification is required to ensure that manufacturing authorisation holders, which repackage products, will be strictly liable for all their activities, including where falsified medicines enter into the supply chain. Repackagers should be liable for damages resulting from all changes that they make with respect to pharmaceutical products, irrespective of whether the product is falsified or genuine.  

Amendment 59
Proposal for a directive – amending act
Article 1 - point 9
Directive 2001/83/EC
Article 54a – paragraph 4 – subparagraph 1

Text proposed by the Commission

4. The Commission shall adopt the measures necessary for the implementation of point (o) of Article 54 and of paragraphs (1) and (2) of this Article.

Amendment

4. The Commission shall adopt, **by means of delegated acts in accordance with Article 121a and subject to the conditions of Articles 121b and 121c**, the measures necessary for the implementation of point (o) of Article 54 and of paragraphs (1) and (2) of this Article. **Before specific measures are proposed in accordance with point (o) of Article 54, and in order to choose the option that best matches citizens' needs, the Commission shall carry out a public impact assessment of the costs and benefits of existing safety features, as well as a consultation with the parties involved in the implementation and use of such safety features, so as to demonstrate the effectiveness of the specific measures compared with existing national arrangements.**

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 60

Proposal for a directive – amending act
Article 1 - point 9
Directive 2001/83/EC
Article 54a – paragraph 4 – subparagraph 2

Text proposed by the Commission

**Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 121(2a).**

Amendment

deleted
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 61

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>When adopting those measures, the Commission shall consider the risk related to products or categories of products and at least all of the following:</td>
<td>When adopting those measures, the Commission shall consider the risk related to prescription products or categories of products and at least all of the following:</td>
</tr>
</tbody>
</table>

Justification

The risk-based assessment in the Commission proposal will enhance patient safety and will help to focus the fight against counterfeiting on precisely those medicines that are affected. Therefore, guaranteeing that all medicines are included and the correct criteria are well established is essential. Moreover, the criteria employed must guarantee that the true drivers of counterfeiting will be pinpointed and deny room for counterfeiters to develop new initiatives. Price and past incidents within the EU represent the most appropriate criteria.

Amendment 62

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(aa) the complexity of the supply chain;</td>
<td></td>
</tr>
</tbody>
</table>

Justification

The assessment to determine which drugs are most at risk of counterfeiting should take into account the complexity of the distribution chain of a product. Certain products (for example immunoglobulins) are delivered directly by the manufacturer to the hospital or other healthcare setting. There are clearly fewer opportunities for counterfeits to enter that very short supply chain.
Amendment 63

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

(b) The number of incidences of falsifications in third countries and within the Community;

Amendment

(b) The number and frequency of past incidences of reported cases of falsified medicinal products within the Union and the evolution of those incidences in the past;

Justification

The risk-based assessment in the Commission proposal will enhance patient safety and will help to focus the fight against counterfeiting on precisely those medicines that are affected. Therefore, guaranteeing that all medicines are included and the correct criteria are well established is essential. Moreover, the criteria employed must guarantee that the true drivers of counterfeiting will be pinpointed and deny room for counterfeiters to develop new initiatives. Price and past incidents within the EU represent the most appropriate criteria.

Amendment 64

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

Text proposed by the Commission

(d) the specific characteristics of the products concerned;

Amendment

deleted

Justification

The risk-based assessment in the Commission proposal will enhance patient safety and will help to focus the fight against counterfeiting on precisely those medicines that are affected. Therefore, guaranteeing that all medicines are included and the correct criteria are well established is essential. Moreover, the criteria employed must guarantee that the true drivers of counterfeiting will be pinpointed and deny room for counterfeiters to develop new initiatives. Price and past incidents within the EU represent the most appropriate criteria.
Amendment 65

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

Text proposed by the Commission  
Amendment

e) the severity of the conditions intended to be treated.
deleted

Justification

The risk-based assessment in the Commission proposal will enhance patient safety and will help to focus the fight against counterfeiting on precisely those medicines that are affected. Therefore, guaranteeing that all medicines are included and the correct criteria are well established is essential. Moreover, the criteria employed must guarantee that the true drivers of counterfeiting will be pinpointed and deny room for counterfeiters to develop new initiatives. Price and past incidents within the EU represent the most appropriate criteria.

Amendment 66

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

Text proposed by the Commission  
Amendment

e(a) the risk to public health.

Justification

Public health protection is essential.

Amendment 67

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

Text proposed by the Commission  
Amendment

(eb) whether the product is delivered directly, without the involvement of third
parties, such as wholesale distributors, traders or brokers, to a healthcare setting in which the product is administered directly to the patient.

Amendment 68

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>On the basis of these criteria, the requirements referred to in points (a) and (b) of paragraph (1) of this Article may be waived for certain products or product categories.</td>
<td>On the basis of these criteria, the requirements referred to in points (a) and (b) of paragraph 1 of this Article may be waived for certain products or product categories, including generic medicinal products.</td>
</tr>
</tbody>
</table>

Justification

This compromise amendment covers AM 32 (Matias), 271 (Perello Rodríguez), 272 (Parnova/Yannakoudakis/Sonik), 273 (Liese), 274 (Krahmer)

Amendment 69

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>The safety features may be used voluntarily for all medicinal products irrespective of their prescription status and the marketing authorisation holders may employ the safety features on their products.</td>
<td></td>
</tr>
</tbody>
</table>

Justification

As pharmaceutical companies have the most expertise on their products and are therefore suited best to assess the level of risk they should be able to employ the safety feature as a
Amendment 70

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

Text proposed by the Commission

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.

Amendment

The measures referred to in this paragraph shall comply with the relevant provisions of Union law with regard to the protection of personal data and shall take due account of at least all the following:

(a) the cost-effectiveness of the system, in order to guarantee that any measure that is applied is based on a cost-benefit analysis;

(b) the ownership and confidentiality of the data generated by the use of the safety feature to identify, to authenticate and to trace medicinal products;

(c) the legitimate interests to protect information of a commercially confidential nature.

Member States shall ensure that no collection or commercial processing of data takes place that would enable a link to be made between the medicinal products provided and the corresponding patients and shall ensure that the confidentiality of data generated by the use of safety features to authenticate medicinal products is safeguarded.

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...
safety features should comply with the following three principles:

a) Cost effectiveness of the system

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

c) Guaranteed independence of the system, the protection of information of a commercially confidential nature of industrial and commercial property rights, and of confidential patient information.

Amendment 71

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>The measures referred to in this paragraph shall be updated every year on the basis of the Commission report pursuant to Article 46(1a).</td>
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</tbody>
</table>

Justification

The use of safety features to authenticate medicines generates data that may be personally sensitive. Information about personal medicine consumption should be subject to relevant data protection laws.

The issue of falsification is different from the protection of industrial and commercial property rights.

It is important to update the requirements on the application of the safety feature based on the annual report.

Amendment 72

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
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<tbody>
<tr>
<td>4a. Member States having already</td>
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introduced safety features for medicinal products shall adapt their systems accordingly. For those Member States, a transitional period of maximum 4 years from entry into force of this Directive shall apply.

Amendment 73

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

4b. 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 purposes referred to in paragraph 2.

Justification

Even after the Directive comes into force, it is unlikely that any concrete measures will actually be in place for some years. As a result, interim measures should continue until the full measures can be put into place. These 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 74

Proposal for a directive – amending act
Article 1 – point 10 a (new)
Directive 2001/83/EC
Article 63 – paragraph 1

Text proposed by the Commission

In Article 63, paragraph 1 is replaced by the following:
1. The particulars for labelling listed in Articles 54, 55, 59 and 62 shall appear in the official language or languages of the Member State where the product is placed on the market.

The first subparagraph shall not prevent these particulars from being indicated in several languages, provided that the same particulars appear in all the languages used.

In the case of certain orphan medicinal products, the particulars listed in Article 54 may, on reasoned request, appear in only one of the official languages of the Union.

Justification

Adding Article 55 ensures that the name of the marketing authorisation holder, the expiry date, the batch number and the method of administration are displayed in the official language(s) of the Member State where the product is placed on the market. An adjustment of the labelled information may be necessary in the case of parallel trade requiring the overlabelling of the blister with a sticker as it is already done by some parallel traders (for example for an adjustment of product names to the authorised name in the national market and special dosage instruction (e.g. weekdays)).

Amendment 75

Proposal for a directive – amending act
Article 1 – point 11
Directive 2001/83/EC
Title VII – Heading

Text proposed by the Commission
Wholesale distribution and trading of medicinal products’;

Amendment
Wholesale distribution, trading and brokering of medicinal products’;

Justification

The heading of Title VII needs to be modified to clarify that brokers are also covered by the provisions thereunder.

Amendment 76
(11a) In Article 76, paragraph 3 is replaced by the following:
3. Any distributor, not being the marketing authorisation holder, who imports a product from another Member State shall notify the marketing authorisation holder and the competent authority in the Member State to which the product will be imported of his intention to import it. In the case of products which have not been granted an authorisation pursuant to Regulation (EC) No 726/2004, the notification to the competent authority shall be without prejudice to additional procedures provided for in the legislation of that Member State, including fees payable to the competent authorities for the examination of the notification.

(11b) In Article 76, the following paragraph is added:
3a. In the case of products which have been granted an authorisation pursuant to Regulation (EC) No 726/2004, the distributor shall submit the notification in accordance with paragraph 3 to the marketing authorisation holder and the Agency. The notification shall be accompanied by a fee payable to the Agency for checking that the conditions
Amendment 78
Proposal for a directive – amending act
Article 1 – point 11 c (new)
Directive 2001/83/EC
Article 77 – paragraph 1

Text proposed by the Commission

(11c) In Article 77, paragraph 1 is replaced by the following:

1. Member States shall take all appropriate measures to ensure that the wholesale distribution, trade and brokering of medicinal products is subject to the possession of an authorization to engage in activity as a wholesaler, trader or broker in medicinal products, stating the place for which it is valid.

Justification

It is essential to address all participants in the distribution chain. Member States should have in place procedures for authorizing ‘traders’ and ‘brokers’ who are active on their territory in the same manner as those authorization procedures which are in place for authorization manufacturers and wholesale distributors. If the legislation does not address the activity of trading and brokering in medicinal products, certain participants may remain outside the scope of the legislation.

Amendment 79
Proposal for a directive – amending act
Article 1 – point 12 a (new)
Directive 2001/83/EC
Article 77 – paragraph 5

Text proposed by the Commission

(12a) In Article 77, paragraph 5 is replaced by the following:

5. Checks on the persons authorized to
engage in the activity of wholesaling, trading or brokering in medicinal products and the inspection of their premises, as applicable, shall be carried out under the responsibility of the Member State which granted the authorization.

Justification

In several Member States a large number of wholesale distribution authorizations are currently inactive, resulting in a lack of transparency with regard to their status. This situation is potentially open to abuse particularly where an inactive license may be used by unscrupulous persons attempting to introduce counterfeit medicines into the legal distribution chain. Therefore, authorization control should be tightened, whereby an inactive license would be deemed to be revoked or suspended after 3 years of inactivity.

Amendment 80

Proposal for a directive – amending act
Article 1 – point 12 b (new)
Directive 2001/83/EC
Article 77 – paragraph 6

Text proposed by the Commission

(12b) In Article 77, paragraph 6 is replaced by the following:

6. The Member State which granted the authorisation referred to in paragraph 1 shall suspend or revoke that authorisation, after having notified the holder thereof, if the conditions of authorisation cease to be met or if the authorisation has not been used for more than three years, except in cases where the authorisation was not used on account of the time reasonably necessary to comply with the obligations under this Directive, and shall forthwith inform the other Member States and the Commission thereof.

Justification

In many Member States, wholesale distribution authorisations have been issued but are not currently in use. This situation artificially increases the number of stakeholders and
unnecessarily complicates the market and, thereby, the system of controls. It is important to ensure, however, that such authorisations are not suspended or revoked in cases where they are not being used on account of the time reasonably necessary to comply with the obligations under the Directive. The authorisation holder therefore needs to be notified beforehand, so as to avoid any unwarranted suspensions.

Amendment 81

Proposal for a directive – amending act
Article 1 – point 12 c (new)
Directive 2001/83/EC
Article 78

Text proposed by the Commission

(12c) Article 78 is replaced by the following:

Member States shall ensure that the time taken for the procedure for examining the application for the distribution, trading or brokering authorization does not exceed 90 days from the day on which the competent authority of the Member State concerned receives the application.

The competent authority may, if need be, require the applicant to supply all necessary information concerning the conditions of authorization. Where the authority exercises this option, the period laid down in the first paragraph shall be suspended until the requisite additional data have been supplied.

Justification

Member States should have in place procedures for authorizing ‘traders’ and ‘brokers’ which are active on their territory in the same manner as those authorization procedures which are in place for manufacturers and wholesale distributors. The timeframe for examining the applications for trading and brokerage authorization should be the same as for wholesale distributors and therefore the authorization of ‘traders’ and ‘brokers’ should be added in this provision.

Amendment 82
Proposal for a directive – amending act
Article 1 – point 12 d (new)
Directive 2001/83/EC
Article 79 a (new)

Text proposed by the Commission

(12d) The following Article is inserted:

‘Article 79a

The Commission shall, in cooperation with the Agency and Member State authorities, lay down rules and criteria for obtaining trading and brokering authorisations.

Applicants must fulfil the following minimum requirements:

(a) they must have a permanent address or contact details, so as to ensure accurate identification and location of their official place of business;

(b) they must undertake to ensure that they conduct their activities only with those persons or entities that are able to fulfil their obligations under the terms of Article 80.’

Justification

There should not only be requirements on distribution for wholesalers but for all traders and brokers.

Amendment 83

Proposal for a directive – amending act
Article 1 – point 13 - point -a (new)
Directive 2001/83/EC
Article 80 – introductory sentence

Text proposed by the Commission

(-a) The introductory sentence is replaced by the following:

‘Holders of the authorisation for distributing, trading or brokering medicinal products must fulfil the
following minimum requirements:

Justification

To ensure the safety of pharmaceutical products, due account needs to be taken of all those working in the sector— not just wholesale distributors – all of whom need to be subject to a rigorous accreditation, verification and good practice system.

Amendment 84

Proposal for a directive – amending act
Article 1 – point 13 - point -a a (new)
Directive 2001/83/EC
Article 80 – point c a (new)

Text proposed by the Commission

(-a a) The following point (ca) is added:
'(ca) they must randomly verify that the medicinal products they have purchased are not falsified by checking the safety feature on the outer packaging, as referred to in point (o) of Article 54;'

Justification

Medicinal products contain numerous overt and covert safety features the majority of which cannot be authenticated by pharmaceutical wholesalers unless information about such has been communicated to them by the manufacturer. However, wholesalers are able to randomly check the identity of individual packs which contains on their outer packaging a carrier (safety feature) comprising an individual number in a machine readable format and provided they have access to the database containing this information.

Amendment 85

Proposal for a directive – amending act
Article 1 – point 13 – point a
Directive 2001/83/EC
Article 80 – point e

Text proposed by the Commission

(e) they must keep records either in the form of purchase/sales invoices or on computer, or in any other form, giving for any transaction in medicinal products

Amendment

(e) they must keep records either in the form of purchase/sales invoices or on computer, or in any other form, giving for any transaction in medicinal products
received, dispatched or traded at least the following information:
- date,
- name of the medicinal product,
- quantity received, supplied or traded,
- name and address of the supplier or consignee, as appropriate;

- national identification number, where appropriate,

Justification

To ensure the safety of pharmaceutical products, due account needs to be taken of all those working in the sector – not just wholesale distributors – all of whom need to be subject to a rigorous accreditation, verification and good practice system.

In most EU Member States a national identification number is used for all transactions (ordering and reimbursement).

Amendment 86

Proposal for a directive – amending act
Article 1 – point 13 – point a a (new)
Directive 2001/83/EC
Article 80 – point g

Text proposed by the Commission

Amendment

(aa) Point (g) is replaced by the following:
'(g) they must comply with the principles and guidelines of good distribution, trading and brokering practices for medicinal products as laid down in Article 84.'

Amendment 87

Proposal for a directive – amending act
Article 1 – point 13 – point b
Directive 2001/83/EC
Article 80 – point i – paragraph 1
(i) they must inform the competent authority of products they receive, trade or broker which they identify as infringing, or they suspect of infringing, either of the following:

Justification

To ensure the safety of pharmaceutical products, due account needs to be taken of all those working in the sector – not just wholesale distributors – all of whom need to be subject to a rigorous accreditation, verification and good practice system.

Amendment 88

Proposal for a directive – amending act
Article 1 – point 13 – point b
Directive 2001/83/EC
Article 80 – point i – paragraph 2

Text proposed by the Commission

Moreover, in cases where these infringements or suspected infringements relate to a falsified medicinal product, the holder of the marketing authorisation or of the trademark that has been falsified shall be informed.

Amendment

Moreover, in cases where these falsified representations or suspected falsified representations relate to a falsified medicinal product, the holders of both the manufacturing authorisation and the marketing authorisation shall be informed.

In the same way, the holder of a marketing or manufacturing authorisation shall inform both the competent authorities as well as other supply chain operators in cases where falsified products are suspected of having infiltrated the legal supply chain.

Justification

This Directive tackles the issue of falsification of medicinal products in its health aspects and not counterfeiting from an Intellectual Property Rights standpoint. Any mention of trademark should therefore be deleted to avoid confusion.

In addition an information obligation imposed on all actors involved in the legal supply chain will help in attaining the maximum level of transparency and traceability.
Amendment 89

Proposal for a directive – amending act
Article 1 – point 13 – point c
Directive 2001/83/EC
Article 80 – subparagraphs 1 a and 1 b

Text proposed by the Commission

For the purpose of point (b), in the case where the product is obtained from another wholesale distributor, holders of the wholesale distribution authorisation must verify compliance with good distribution practices of the supplying wholesale distributor either by themselves or through a body accredited for that purpose by the competent authority of a Member State.

Where the product is obtained from the manufacturer or importer, holders of the wholesale distribution authorisation must verify that the manufacturer or importer holds a manufacturing authorization.

Amendment

For the purpose of point (b), in the case where the product is obtained from another wholesale distributor, holders of the wholesale distribution authorisation must verify compliance with good distribution practices of the supplying wholesale distributor either by themselves or through a body accredited for that purpose by the competent authority of a Member State, including checking that the latter is an authorised wholesale distributor through the Community database, as referred to in Article 111(6).

Where the product is obtained from the manufacturer or importer, holders of the wholesale distribution authorisation must verify that the manufacturer or importer holds a manufacturing authorization through the Community database, as referred to in Article 111(6).

When products are obtained through trading or brokering, the holders of the wholesale distribution, trading or brokering authorisation must verify that the persons or entities involved hold the necessary authorisations through the Community database, as referred to in Article 111(6).

Justification

All actors must be equally responsible and fulfil at least minimum requirements. Therefore, the provision must be extended to cover the activities of persons or entities engaged in the trade and brokerage of medicinal products. Furthermore, in order to ensure that all supply chain participants are licensed and in compliance with their respective guidelines, each supply chain participant should verify compliance of partners through the Central database.
established and maintained by European Medicines Agency. Accredited bodies to verify compliance should only be used to complement inspections of national competent authorities.

**Amendment 90**

Proposal for a directive – amending act
Article 1 – point 13 a (new)
Directive 2001/83/EC
Article 84

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td><em>(13a)</em> Article 84 is replaced by the following:</td>
<td></td>
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<tr>
<td>‘Article 84’</td>
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<tr>
<td>The Commission shall publish guidelines on good distribution, trading and brokering practices for medicinal products. To this end, it shall consult the Committee for <em>Proprietary Medicinal Products</em> and the Pharmaceutical Committee established by Council Decision 75/320/EEC.</td>
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<td><em>[1]</em></td>
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*Justification*

Currently manufacturers must comply with guidelines on Good Manufacturing Practices (GMP) and wholesale distributors must comply with guidelines on Good Distribution Practices (GDP) however traders and brokers currently do not have to comply with any equivalent practices related to their specific field of activity, namely the trade or brokerage of medicinal products. Therefore, guidelines on good trade practice and guidelines on good brokerage practice should be set-up.

**Amendment 91**

Proposal for a directive – amending act
Article 1 – point 13 b (new)
Directive 2001/83/EC
Article 84 a (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td><em>(13b)</em> The following Article 84a is inserted:</td>
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Article 84a

The Commission shall publish guidelines on specific good manufacturing practices for active pharmaceutical ingredients and specific good manufacturing practices for excipients. To this end, it shall consult the Committee for Proprietary Medicinal Products established under Council Directive 75/319/EEC and the Pharmaceutical Committee established by Council Decision 75/320/EEC, taking into account the GMP equivalent systems in force such as HACCP and ISO9001/ISO22000 and the voluntary rules such as the EFfCI GMP and the IPEC PQG Guide for pharmaceutical excipients.

Justification

Both excipients and API should be subject to relevant good manufacturing practices developed at the European level. The Commission is called to develop specific GMP for API and specific GMPs for excipients. Concerning the excipients, the Commission should take into account in GMPs equivalent systems in accordance to the EC regulation on HACCP (Hazard analysis and Critical Control Points), the EFfCI (European Federation for Cosmetics Ingredients) GMP Guides for cosmetic ingredients (2005). These rules can also be used in the pharmaceutical industry.

Amendment 92

Proposal for a directive – amending act

Article 1 - point 14
Directive 2001/83/EC
Article 85a

Text proposed by the Commission
In the case of wholesale distribution to third countries Article 76, Article 80(c) and (i), and Articles 81 and 82 shall not apply. Moreover, Article 80(b) shall not apply where a product is directly received from a third country.

Amendment
Member States shall take all appropriate actions to ensure that no falsified medicinal products are distributed or exported from their territory to third countries. This Directive is without prejudice to provisions of the Convention relating to temporary admission (Istanbul Convention) as regards the supply of medicinal products to third countries in the case of emergency situations.
For all supplies of medicinal products to a person authorised or entitled to supply medicinal products to the public in a third country, the authorised wholesaler shall keep records either in the form of purchase/sales invoices, electronically or in any other form, providing for each transaction in medicinal products received or dispatched at least the following information:

— date,
— name of the medicinal product,
— quantity received or supplied,
— name and address of the supplier or consignee, as appropriate;

The authorised wholesaler shall keep those records available to the competent authorities, for inspection purposes, for a period of five years.

Justification

The directive should also seek to reduce wholesale distribution of falsified medicines to third countries. Applying weaker rules for exports or transits to third countries would harm the credibility of the Community in its attempts to strengthen international cooperation in the fight against falsified medicines. For this reason exemptions are not allowed. Nevertheless the Istanbul Convention provisions should be applied to the medicinal products forwarded to third countries for humanitarian purposes as aid to those affected by natural disasters or similar catastrophes.

Amendment 93

Proposal for a directive – amending act
Article 1 – point 14
Directive 2001/83/EC
Article 85b

Text proposed by the Commission

Persons trading medicinal products shall ensure that the traded medicinal products are covered by a marketing authorization granted pursuant to Regulation (EC) No 726/2004 or by the competent authorities of a Member State in accordance with this Directive. In addition, the requirements

Amendment

Persons trading or brokering medicinal products shall ensure that the traded or brokered medicinal products are covered by a marketing authorisation granted pursuant to Regulation (EC) No 726/2004 or by the competent authorities of a Member State in accordance with this
set out in Article 80(d) to (h) shall apply. They shall notify their activity to the competent authority of the Member State where they are established.

Justification

Persons or entities trading or brokering medicinal products should be obliged to verify that products traded or brokered are covered by a valid marketing authorization. The national notification procedure should be strengthened by a Community database similar to the requirements for the holders of wholesale distribution authorization in order to make all participants transparent.

Amendment 94

Proposal for a directive – amending act
Article 1 – point 14 a (new)

Text proposed by the Commission

Amendment

(14a) The following Title VIIa and Article 85c are inserted after Article 85b:

TITLE VIIa

INTERNET SALES

Article 85 c

1. Internet pharmacies shall, in Member States in which they are allowed to operate, require a special authorisation by the competent authority.

2. The Commission shall adopt an EU logo for the front page of internet pharmacy sites, helping the public to identify whether a website offering to sell medicinal products is connected to an authorised pharmacy. The logo shall be linked to a central website at Member State level, to be established by the Member State, that allows the visitor to check the authenticity of the logo and that provides background information on the risks related to buying medicinal products.
on the internet.

3. Member States shall take the appropriate measures to ensure that all authorised pharmacy internet sites linked to pharmacies within their territory display the EU logo referred to in paragraph 1 and to prevent non-authorised pharmacy internet sites from using the logo and linking to the central website referred to in paragraph 1.

4. The Commission shall list the internet pharmacies that are authorised in one or more of the Member States in an EU database, to which the central website at Member State level shall be linked.

5. In order to implement paragraphs 2, 3 and 4 the Commission shall adopt, by means of delegated acts in accordance with Article 121a, and subject to the conditions of Articles 121b and 121c, a Directive laying down:

- the minimum requirements preventing the entry of falsified medicinal products into the supply chain to be applied by the Member States if they authorise such internet pharmacies. Such requirements shall also prevent the reimbursement of medicinal products from unauthorised internet sources,

- the model of the EU logo,

- the type of minimum background information on the risks related to buying medicinal products on the internet, and

- specific control procedures for the authorisation of internet pharmacies.

6. Member States shall ensure that the internet is continuously monitored with regard to the selling of medicinal products and shall take legal actions in the event of non-compliance with this Directive.

7. The provisions of this Directive shall be without prejudice to the right of the Member States to restrict or prohibit trading in prescription medicinal products.
over the internet.

8. By ..., the Commission shall, in cooperation with the Agency and the Member State authorities, produce a qualitative and quantitative study of internet sales of falsified medicinal products in the EU.

* OJ: 12 months after the date of publication of this Directive

Justification

This compromise amendment covers AM 39, 41 (Matias), 167 (Chatzimarkakis/Leinen), 168 (Rapti), 330 (Roth-Behrendt), 331 (Chatzimarkakis), 332 (Matias), 333 (Yannakoudakis), 334 (Rossi), 339 (Tremopoulos, Rivasi), 370 (Bartolozzi), 373 (Ulmer), 374 (Rivellini), 2\textsuperscript{nd} part of 338 (Chatzimarkakis)

Amendment 95

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

Text proposed by the Commission

Amendment

(14b) The following Article 85d is inserted:

Article 85d

Member States shall ensure that all legitimate mail-order pharmacies operating in the internal market adhere to professional standards and guidance for internet pharmacy services, including a specific code of ethics. All mail-order pharmacies are obliged to clearly display the code of conduct on their websites and display contact details for complaints.

Justification

The EAMSP should develop a code of ethics, having already developed a set of standards based on those of the Royal Pharmaceutical Society of Great Britain. They are, since 2003, the national standard in Germany (11a ApoG, 17 ApoBetrO). Designated monitoring bodies
must liaise with internet service providers to prevent illegitimate websites. Severe punitive measures involving fines and prison sentencing must be outlined in the Directive. The paragraph should be extended to elaborate on them.

**Amendment 96**

**Proposal for a directive – amending act**

**Article 1 – point 14 c (new)**

**Directive 2001/83/EC**

**Article 85 e (new)**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tr>
<td>(14c) The following Article 85e is inserted:</td>
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</table>

**Article 85e**

1. The Commission shall, in cooperation with the Agency and Member State authorities, launch an information campaign aimed at the general public on the dangers of falsified medicinal products. 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.

2. The Commission shall, by means of delegated acts in accordance with Article 121a and subject to the conditions of Article 121b and 121c, adopt measures to increase awareness among the general public on the risks related to purchasing medicinal products on the internet, which may include:

- warnings appearing on top of the internet page in search engines in the event of a search for medicinal products on the internet;

- general information campaigns, in cooperation with the Member States;

- advice on how to check the authenticity of websites;
- easily accessible lists of accredited e-pharmacies.

Those measures shall provide a balanced and realistic description of the risks concerned.

Justification

This compromise amendment covers 329 (Bartolozzi), 335 (Chatzimarkakis), 336 (Matias), 333 (Yannakoudakis), 334 (Rossi), 337 (Yannakoudakis)

Amendment 97

Proposal for a directive – amending act
Article 1 – point 14 d (new)
Directive 2001/83/EC
Article 97 – paragraph 5 a (new)

Text proposed by the Commission

(14b) In Article 97, the following paragraph 5a is added:

"5a. The Commission shall ensure, in cooperation with the Agency and national authorities, that manufacturers, importers, wholesale distributors, traders and brokers, either collectively or individually, promote public information campaigns in the various media (press, television, radio, internet) to raise awareness of the risks connected with the purchase of falsified medicinal products on the internet."

Justification

The public needs to be made aware of the risks attached to purchases of medicinal products over the internet and given information on how to distinguish between authorised on-line pharmacies and illicit distributors. Given the financial resources available to manufacturers, importers, wholesale distributors, traders and brokers and given that it is in their best interest to protect their consumers and their reputation, information campaigns should be industry-led with the Commission having a supervisory role to ensure that campaigns are carried out.

Amendment 98
Proposal for a directive – amending act
Article 1 – point 15 – point -a (new)
Directive 2001/83/EC
Article 111 – paragraph 1

Text proposed by the Commission

Amendment

(-a) Paragraph 1 is replaced by the following:

'1. The competent authorities of the Member State concerned shall, under the Agency's coordination, ensure by means of repeated, and where necessary unannounced, inspections, that the legal requirements governing medicinal products are complied with, and shall, where appropriate, commission an official medicinal product test laboratory, or another laboratory designated for that purpose, to carry out sampling tests. Such inspections shall be carried out by officials representing the competent authority who shall be empowered to:

(a) inspect manufacturing or commercial establishments and any laboratories entrusted by the holder of the manufacturing authorization with the task of carrying out checks pursuant to Article 20;

(b) take samples;

(c) examine any documents which relate to the object of the inspection, subject to the provisions in force in the Member States on 21 May 1975, and which place restrictions on these powers with regard to the descriptions of the method of preparation.'

Justification

To ensure the safety of pharmaceutical products, the inspection arrangements need to be fleshed out and applied across the board.

Amendment 99
Proposal for a directive – amending act
Article 1 – point 15 – point a a (new)
Directive 2001/83/EC
Article 111 – paragraph 1 - subparagraph 2

Text proposed by the Commission

(aa) In Article 111(1), subparagraph 2 is replaced by the following:

The competent authorities shall, under the Agency's coordination, also carry out repeated, and where necessary unannounced, inspections of the premises of manufacturers, distributors or importers of active substances used as starting materials, at the premises of marketing authorisation holders whenever it considers that there are grounds for suspecting non-compliance with the principles and guidelines of good manufacturing practices referred to in Article 47. Such inspections shall also be carried out if so requested by a Member State, the Commission or the Agency.

In the case of justified concerns, the competent authorities shall also carry out unannounced inspections at the premises of manufacturers of active substances used as starting materials and of excipients based in third countries.

Justification

This compromise amendment covers AM 42, 344 (Matias), 342 (Gutierrez-Cortines, Sartori, Grossetête, Ulmer), 343 (Gutiérrez-Cortines/Sartori/Grossetête/Ulmer), 345 (Tremopoulos/Rivasi), 346 (Perello Rodriguez), 355 (Roth-Behrendt)

Amendment 100

Proposal for a directive – amending act
Article 1 – point 15 – point b
Directive 2001/83/EC
Article 111 – paragraph 3
3. After every inspection as referred to in paragraph 1, the competent authority shall report on whether the manufacturer, importer, or wholesale distributor complies with the principles and guidelines of good manufacturing practice and good distribution practices referred to in Articles 47 and 84 or on whether the marketing authorization holder complies with the requirements laid down in Title IX.

The competent authority which carried out the inspection shall communicate the content of those reports to the manufacturer, importer, marketing authorization holder, or to the wholesale distributor who has undergone the inspection.

Before adopting the report, the competent authority shall give the manufacturer, importer, marketing authorization holder, or wholesale distributor concerned the opportunity to submit their comments.

Justification

Currently manufacturers must comply with Good Manufacturing Practices (GMP), wholesale distributors must comply with Good Distribution Practices (GDP) however traders and brokers do not have to comply with any standard good practices. Therefore, to further address the “weakest link” in the distribution chain it is important that traders and brokers comply with guidelines such as ‘Good Trade Practices (GTP) and ‘Good Brokerage Practices” (GBP), which are specifically established for persons or entities involved in the trading and brokering of medicinal products.

Amendment 101

Proposal for a directive – amending act
Article 1 – point 15 – point c
Directive 2001/83/EC
Article 111 – paragraph 5 – subparagraph 1
5. Within 90 days of an inspection as referred to in paragraph 1, a certificate of good manufacturing practice or good distribution practice shall be issued to the manufacturer, importer, or wholesale distributor if the outcome of the inspection shows that the person complies with the principles and guidelines of good manufacturing practice or good distribution practice as provided for by Community legislation.

Justification

Currently manufacturers must comply with Good Manufacturing Practices (GMP), wholesale distributors must comply with Good Distribution Practices (GDP) however traders and brokers do not have to comply with any standard good practices. Therefore, to further address the “weakest link” in the distribution chain it is important that traders and brokers comply with guidelines such as “Good Trade Practices (GTP) and “Good Brokerage Practices” (GBP), which are specifically established for persons or entities involved in the trading and brokering of medicinal products.

Amendment 102

Proposal for a directive – amending act
Article 1 – point 15 – point c
Directive 2001/83/EC
Article 111 – paragraph 6

Text proposed by the Commission

(6) Member States shall enter the certificates of good manufacturing practice and good distribution practice which they issue in a Community database managed by the Agency on behalf of the Community.

Amendment

(6) Member States shall enter the certificates of good manufacturing practices, good distribution practices, good trading practices and good brokering practices which they issue in a Union database managed by the Agency on behalf of the Union.
**Justification**

*In order to ensure that all supply chain participants are licensed, each supply chain participant should verify compliance of their supply chain partners through the Central database established and maintained by the Agency (EMA).*

**Amendment 103**

**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**

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.

**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, good distribution practices, good trading practices or good brokering practices as provided for by Union legislation, the information shall be entered in the Union database referred to in paragraph 6 and the manufacturing and distribution processes shall cease forthwith. Such information shall specify the principles, guidelines and rules not complied with. Cases where falsified medicinal products have been discovered on the Union market shall also be reported to this database.

**Amendment 104**

**Proposal for a directive – amending act**

**Article 1 – point 16**

Directive 2001/83/EC

Article 111a

**Text proposed by the Commission**

The Commission shall adopt detailed guidelines laying down the principles for inspections referred to in Article 111.

**Amendment**

The Commission shall adopt detailed guidelines laying down the principles for inspections referred to in Article 111 and, in particular, the Union or national
bodies responsible for carrying out inspections.

Justification

The Commission is proposing that the first inspection be carried out within three years of the third country being entered on the Article 111b list. It should instead be carried out prior to that country's inclusion on the list, not least because under Article 51(2) the qualified persons within EU firms are not required to carry out checks on products from countries with which the Community has concluded agreements guaranteeing that the products are of the required standard.

Amendment 105

Proposal for a directive – amending act
Article 1 – point 16
Directive 2001/83/EC
Article 111b – paragraph 1 – point b

Text proposed by the Commission
(b) the regularity of inspections of good manufacturing practices;

Amendment
(b) the regularity of repeated and unannounced inspections of good manufacturing practices;

Justification

Clarification.

Amendment 106

Proposal for a directive – amending act
Article 1 – point 16
Directive 2001/83/EC
Article 111b - paragraph 2

Text proposed by the Commission
(2) The Commission, in accordance with the procedure set out in Article 121(2), shall adopt guidelines defining in detail the requirements set out in points (a) to (d) of paragraph 1.

Amendment
(2) The Commission shall, by means of delegated acts in accordance with Article 121a and subject to the conditions of Articles 121b and 121c, adopt criteria defining in detail the requirements set out in points (a) to (d) of paragraph 1, performing by means of the appropriate instruments, and possibly also by taking
extraordinary measures, the verification and subsequent monitoring of the quality of the principles and safety.

Amendment 107
Proposal for a directive – amending act
Article 1 - point 16 a (new)
Directive 2001/83/EC
Article 116 - paragraph 2

Text proposed by the Commission

Amendment

(16a) In Article 116, paragraph 2 is replaced by the following:

An authorisation shall also be suspended, revoked, withdrawn or varied where the particulars supporting the application as provided for in Article 8 or Articles 10, 10a, 10b, 10c and 11 are incorrect or have not been amended in accordance with Article 23, or when the inspections referred to in Article 111 demonstrate lack of compliance with good manufacturing practices or good distribution practices, or where the controls referred to in Article 112 have not been carried out.

Justification

The aim of having the competent authority carrying out inspections is to remedy the situation when something is not working according to plan; it is thus relevant to mention explicitly that when an inspection unveils irregularities the holder of the authorization will have to bear the consequences until the situation is reversed. In certain cases this will mean losing the authorization.

Amendment 108
Proposal for a directive – amending act
Article 1 – point 17
Directive 2001/83/EC
Article 118a

Text proposed by the Commission

Amendment

The competent authorities shall issue the

The competent authorities shall issue the
accreditation referred to in Articles 46(f) and 80(b) if the applicant can demonstrate that he is competent to carry out verification of compliance with good manufacturing practices or, in the case of wholesale distributors, good distribution practices.

accreditation referred to in Articles 46(f) and 80(b) if the applicant can demonstrate that he is competent to carry out verification of compliance with good manufacturing practices or, in the case of wholesale distributors, good distribution practices or, in the case of traders, good trading practices or, in the case of brokers, good brokering practices.

Justification

Currently manufacturers must comply with Good Manufacturing Practices (GMP), wholesale distributors must comply with Good Distribution Practices (GDP) however traders and brokers do not have to comply with any equivalent practices or guidelines. Therefore, to further address the “weakest link” in the distribution chain it is important that traders comply with guidelines such as “Good Trade Practices” and brokers with “Good Brokerage Practices” specifically established for persons or entities involved in the trading or brokering of medicinal products.

Amendment 109

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

Text proposed by the Commission

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.

Amendment

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 posed by the falsification of medicinal products. The penalties provided for shall be, effective, proportionate and dissuasive and equivalent, 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 [6 months after the date of publication of this Directive] 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 110

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

Text proposed by the Commission

Amendment

Article 118ba
The penalties referred to in Article 118b should be equivalent to those typically applied for illegal acts related to narcotics and should be equivalent in all Member States in accordance with the draft Convention of the Council of Europe on the counterfeiting of medical products and similar crimes involving threats to public health.

Justification

Replaces Amendment 44 in draft report.

Amendment 111

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

Text proposed by the Commission

Amendment

Article 118bb

The Commission shall establish a network between the Commission, the Agency and the competent authorities in the Member States and involve patients' and consumers' organisations to ensure the exchange of information on the measures taken to combat the falsification of medicinal products, including on the penalties systems in place. This network shall aim at defining best practices and shall contribute to increased cooperation in the area of prevention and enforcement. The Commission, the Agency and the competent authorities in the Member States shall report annually to this network on the actions they have undertaken.

Justification

Exchange of information and best practices will help improve enforcement and create a somewhat uniform sanctions regime throughout the EU.
Amendment 112

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

Text proposed by the Commission

Member States, in applying this Directive, shall take the necessary measures to ensure cooperation between competent authorities for medicinal products and customs authorities.

Amendment

1. Member States, in applying this Directive, shall take the necessary measures to ensure cooperation between competent authorities for medicinal products and customs authorities. In that connection, Member States, working in coordination with healthcare professionals, and the pharmaceuticals industry, shall take the necessary measures to encourage training for customs officers to help them deal with the phenomenon of falsified medicinal products.

That coordination shall be strengthened by international cooperation programmes conducted by the Commission.

2. Member States shall take the necessary measures to ensure that customs officers are provided with the resources they need and shall supply, in particular, the technology essential to the work of detecting falsified medicinal products.

3. The Commission shall draw up a report by ...* on the relevant action taken.

* OJ: 36 months after the date of publication of this Directive

Justification

Training for customs officers is an effective tool to combat the falsification of medicinal products. Steps must therefore be taken to ensure that customs professionals receive appropriate training. In addition, customs officers must be provided with the equipment they need to carry out their task as effectively as possible.

Amendment 113
Proposal for a directive – amending act
Article 1 – point 17
Directive 2001/83/EC
Article 118c a (new)

Text proposed by the Commission

 Amendment

Article 118ca

The Commission, working closely with the Member States, shall take concerted measures with the competent authorities of third countries which have transit areas in which medicinal products are stored.

The Commission shall take the necessary measures to ensure that seizures of suspect products do not serve to hamper trade in legal generic medicinal products.

In the context of international cooperation, the Commission shall authorise the impounding of suspect products so that the necessary checks can be carried out.

Justification

Particularly close attention must be paid to the surveillance of transit areas, on the basis of cooperation with the competent authorities of the third countries concerned. Action must primarily be based on public health considerations which reflect the risks associated with the distribution of falsified medicinal products, in a spirit of cooperation with local authorities and in order to protect patients.

Amendment 114

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

Text proposed by the Commission

 Amendment

Article 118cb

The Commission and the Member States shall cooperate closely with the Council of Europe on the establishment of a
European Convention on the suppression of the falsification of medicinal products and trafficking in falsified medicinal products. The Convention covers the civil and criminal law aspects of falsification and trafficking of falsified medicinal products.

The Commission, working with the Member States, shall support the drafting, under the auspices of the United Nations, of an international convention on the combating of the falsification of medicinal products, with a view to ensuring that stiffer penalties are imposed on those guilty of such falsification.

Justification

It has been noticed that the falsification of medicinal products has become an activity led by international criminal networks and it is not possible to tackle this public health issue only inside EU borders. Therefore, the European Union and Member States should support the signature and ratification of the new International Convention of the Council of Europe.

Amendment 115

Proposal for a directive – amending act
Article 1 – point 17 a (new)
Directive 2001/83/EC
Article 121a

Text proposed by the Commission

(17a) The following Article 121a is inserted:

Article 121a

Exercise of the delegation

(1) The power to adopt the delegated acts referred to in Articles 46(f), 47(3), 52b(2), 54a(4), 85c(5), 85e(2) and 111b(2) shall be conferred on the Commission for an indeterminate period of time.

(2) As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European
Parliament and to the Council.

(3) The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in Articles 121b and 121c.

Amendment 116

Proposal for a directive – amending act
Article 1 – point 17 a (new)
Directive 2001/83/EC
Article 121b

Text proposed by the Commission

(17a) The following Article 121b is inserted:

Article 121b

Revocation of the delegation

1. The delegation of power referred to in Articles 46(f), 47(3), 52b(2), 54a(4), 85c(5), 85e(2) and 111b(2) may be revoked at any time by the European Parliament or by the Council.

2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated power which could be subject to revocation and possible reasons for a revocation.

3. The decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the Official Journal of the European Union.

Amendment 117
Proposal for a directive – amending act
Article 1 – point 17 a (new)
Directive 2001/83/EC
Article 121c

Text proposed by the Commission

(17a) The following Article 121c is inserted:

Article 121c
Objections to delegated acts

1. The European Parliament or the Council may object to a delegated act within a period of two months from the date of notification. At the initiative of the European Parliament or the Council this period shall be extended by two months.

2. If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the Official Journal of the European Union and enter into force at the date stated therein.

The delegated act may be published in the Official Journal of the European Union and enter into force before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.

3. If the European Parliament or the Council objects to a delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.
Amendment 118

Proposal for a directive – amending act
Article 2

Text proposed by the Commission

1) Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [insert concrete date 18 months after publication] at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from [insert concrete date 18 months after publication + one day].

However, the Member States shall apply:

(a) the provisions necessary to comply with Article 1(4) in so far as it relates to Articles 46b(2)(b) and 46b(3) of Directive 2001/83/EC as amended by this Directive from [insert concrete date 24 months after publication];

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

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2) Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Amendment

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [insert concrete date 12 months after publication] at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from [insert concrete date 12 months after publication + one day].

However, the Member States shall apply:

(a) the provisions necessary to comply with Article 1(4) in so far as it relates to Articles 46b(2)(b) and 46b(3) of Directive 2001/83/EC as amended by this Directive from [insert concrete date 12 months after publication],

(b) the provisions necessary to comply with Article 1(6),(8) and (9) from [insert concrete date 24 months after publication].

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Justification

For reasons of public health protection and in the interest of patients, pharmacists and...
manufactures, it is essential to keep the deadlines as short as possible.

Amendment 119

Proposal for a directive – amending act
Article 2 – paragraph 2 a (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td>2a. No later than four years following the entry into force of this Directive, the Commission shall 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 medicinal products in the legal supply chain in the EU. The report shall assess in particular the advisability of extending the safety features to other categories of medicinal products, including medicinal products not subject to medical prescription as defined in Title VI of Directive 2001/83/EC. If appropriate, the Commission shall present proposals to the European Parliament and the Council.</td>
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Justification

This compromise amendment covers AM 50 (Matias), 372 (Grossetête)
EXPLANATORY STATEMENT

The Commission's proposal on the prevention of falsified medicines entering the supply chain highlights a concern which is getting higher and higher on the agenda of the European citizens: the quality and safety of the medicinal products they are consuming. Therefore the Rapporteur welcomes the Commission proposal to combat falsified medicines as a necessary step to respond to this rising health threat and to better ensure patients’ safety.

The problem
The impact assessment by the Commission (SEC(2008)2674) mentions inter alia the following very alarming observations:

- A sharp increase in seizures of falsified medicines by customs (2.7 million medicinal products at EU custom borders in 2006 and 2.5 million in 2007; an increase of 384% compared to 2005)
- A trend from the falsification of 'lifestyle' medicines to life-saving medicines, including medicines to treat cancer and heart disease, psychiatric disorders and infections. Treatment with such falsified medicines can have fatal consequences.
- A trend towards targeting the classical supply chain. Besides the internet, the licensed distribution chain is increasingly targeted. Out of 13 Member States who had data, seven reported incidences of counterfeit medicinal products in the legal supply chain.

It needs to be emphasised that, according to the expert group of the WHO, many countries in Africa, parts of Asia and Latin America have areas where more than 30% of the medicines on sale can be falsified. Policies to prevent falsified medicines on the European market should also have positive impacts in other regions of the world where the problem is even more prominent.

Patients need to be absolutely sure that the medicines they consume are really the medicines they expect it to be. The use of falsified medicines can result in therapeutic failure and can put lives at risk. Your Rapporteur therefore believes that the protection of public health against falsified medicines should be the main focus of the directive. This focus should not be troubled by other additional objectives.

The directive should not concern intellectual property and patent rights, which are already covered by other specific legislative frameworks.

Double legal basis
Your Rapporteur chooses to have a double legal basis for this directive. Falsifying of medicinal products is a criminal act that denies patients the necessary medical treatment and is harmful to their health, sometimes even leading to their death. Therefore the first and most important objective of the directive should be the protection of public health. This should be reflected in the legal basis on the directive. This is in line with the draft Convention of the Council of Europe which puts the focus on public health.

Definitions and responsibilities
To be able to better safeguard the distribution network for medicinal products it is crucial to have clear definitions on not only the scope, but also on the different actors in the supply
What is a falsified medicinal product? What is an active ingredient or an excipient? The Commission proposal does not provide the required clarity. The same applies for the definitions of the different actors in the chain of supply, clarifying their roles and responsibilities. It is essential to make a distinction between those actors who are already formally recognized - and which role is considered liable - and those who are outside that category, although being relevant to the liability of the distribution chain. Therefore it is important to make the distinction between traders and brokers, as well as to clarify their roles and responsibilities. The same applies for other actors, such as transporters or parallel traders. The directive should prevent confusion and should not allow any room for 'grey' areas. It should clearly identify which actors and under which conditions are able to operate in this domain. Clearer definitions will result in simpler implementation.

Sanctions
The falsification of medicinal products is not a minor offence. It is an organised criminal activity that puts human lives at risk. Sanctions against falsification should reflect this and should be equivalent to those typically applied for illegal acts related to narcotics. It is crucial to strengthen the relevant provisions on sanctions in the Commission's proposal.

Safety features
Member States make the distinction between prescription and non prescription medicines since prescription medicines result in higher risks for the patient either when falsified or when unduly taken. Therefore safety features must be mandatory for prescription medicines. It needs however to be recognised that medicines will only be falsified if there are economic reasons for doing so. Because of the low costs of generic medicinal products it is less profitable to falsify this group of medicines. Therefore your Rapporteur is of the opinion that, only if this is in accordance with the conclusions of a risk assessment, the performance criteria for the safety features can be waived for certain generic medicinal products or product categories. Your Rapporteur furthermore proposes to assess within five years after the entry info force of this directive whether safety features should also be mandatory for the so called over the counter medicines.

Excipients
When patients take medicinal products they do not only consume the active ingredients, but also the excipients. The consequences of the use of falsified excipients are well documented. Examples of severe consequences include the death of 89 people in 1995, and of, at least, 59 children in 1996 in Haiti, or the death of 30 children in India, in 1998. The Rapporteur therefore included the excipients in the draft report. The quality and authenticity of the falsified medicines should be verified.

Internet sales
The Commission proposal does not address internet sales, considering it as part of the illegal chain of supply. This does not reflect the fact that in some Member States internet sales are legalized. It is well known that internet represents one of the main routes for falsified medicinal products to enter the European market. Your Rapporteur chooses to include provisions in the draft report to deal with this important route. The first priority is to increase public awareness of the risks of buying medicinal products through the internet. Educational programmes to increase consumer awareness about the existence of falsified products and the risk of buying medicines from unauthorised channels should be put in place. The second
priority is to ensure that patients can recognise those sites which are in compliance with the relevant legislation. A directive aiming at fighting the falsification of medicines, without dealing with internet, the most important route, is not explainable to the public. Addressing this route is one of the key issues in the draft report.

**Information and Reporting**
The creation of a network between the Commission, the European Medicines Agency and the competent authorities in Member States would help to have more data and a better understanding of the phenomenon so as to better tackle it. The Commission, European Medicines Agency and the competent authorities in the Member States shall report annually to this network on the actions they have undertaken.

**International cooperation**
Coordination between various national and international bodies involved in fighting falsified medicines is necessary. It’s important to improve international collaboration and develop appropriate multilateral mechanisms that will enable importing countries to trigger investigations and identification of the actual source of counterfeit medicines entering their markets.

**Imports inspections**
This Directive focuses on the quality control of the import of medicinal products, since this is one of the key entry doors of falsified medicines to the European market. Therefore your Rapporteur considers it to be crucial to create an inspections system which is mainly based on the Good Manufacturing Practices already defined through international agreements. The already existing international cooperation, together with the experience in the Member States are key anchors for a strengthened efficient detection system of falsifications.

**Exports**
The Commission proposal does not address the control and distribution of falsified medicines to third countries. It is difficult to explain why we have stringent provisions for medicines that enter the European market in order to find the responsible actors if medicines are falsified, but no provisions for medicines which are exported to third countries in Africa, South America or Asia. This significantly weakens the possibility for Europe to insist on stronger international cooperation. The manufacturing and the distribution of medicines from the EU to third countries must obey the same criteria as applied for the import. This would strengthen our contribution to fight the criminal falsification of medicines in several third countries where, according to WHO estimates, the problem is very serious.

**Final remarks**
Within this directive several often contradictory interests are at the stake. For some actors the solution involves the reduction of intermediaries; others would prefer the maintenance of the already existing procedures without taking part in the sharing of responsibilities or costs. Some actors support the principle that this Directive should focus on the risks of the products; some support the focus on the risks of the chain. Your Rapporteur truly believes that the directive should take into account the different interests, but that it should focus on our common interest - patient safety. This is the guiding principle for the amendments in the draft report.
24.3.2010

OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY

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: Amalia Sartori

SHORT JUSTIFICATION

The entry of falsified medicinal products into the legal supply chain is a threat to Europe's entire pharmaceutical system because it undermines public confidence in the quality of the medicinal products available in pharmacies and other legal sales outlets.

The number of falsified medicinal products is rising sharply in all of the Member States. The WHO estimates that 1% of the medicinal products currently sold to the European public through the legal supply chain are falsified. Falsified medicinal products may contain sub-standard or falsified ingredients, or no ingredients or ingredients in the wrong dosage, including active ingredients.

Although the scale of this problem is still relatively small in Europe when compared with other parts of the world, such as Africa, a number of factors point to the need for swift, rigorous action by the European Union.

The first concern is the fact that the risk profile has changed: while in the past most of the medicinal products that were counterfeited were 'lifestyle' drugs, counterfeiting of innovative and life-saving drugs is now increasing sharply.

Second, the problem has already taken on worrying proportions. The Commission puts the number of boxes of falsified medicines sold within the legal supply chain each year in Europe at 1.5 million. The fact that volumes are increasing on average by 10-20% per year is of still greater concern. With a growth rate of 10%, the number of boxes of falsified medicines in the legal supply chain would reach 42 million by 2020. Other, more pessimistic, estimates put the growth rate at 30%, which would increase that number to 192 million.

In our capacity as members of the committee with responsibility for industry and research, we
cannot afford to ignore the serious threat that falsified medicines pose not just to public health but also to one of the leading sectors of the EU economy. The EU's pharmaceutical sector comprises some 3 700 companies, which employ 634 000 people and have a turnover of more than EUR 170 billion. Some 1500 (40%) of those companies are SMEs. The industry invests at total of more than EUR 26 billion per year in research and development (17% of spending for the EU as a whole). It is therefore important to prevent unfair competition from non-Community producers who place active pharmaceutical ingredients on the EU market without it having been properly ascertained whether those producers comply with good manufacturing practice. This will at the same time serve to protect public health.

Although the Commission has, in its proposal, taken over the concerns Parliament voiced in Written Declaration 61/2006 on active pharmaceutical agreements, a number of points still need to be clarified and fleshed out.

First, it is important to have clear and unambiguous definitions of both the subject of the proposal – namely, falsified medicinal products – and all those involved in the distribution chain, such as traders and brokers, who must operate on the basis of authorisations and be required to comply with good practice in the same way as producers and distributors. This must also apply to parallel traders, who must be the subject of clear obligations and stringent checks.

Furthermore, more stringent, systematic inspections need to be carried out at the plants at which pharmaceutical starting materials, including active ingredients, are produced for export, in order to ensure compliance with good manufacturing practice, while public health needs to be protected by means of an effective traceability system.

While the proposal to establish a mutual recognition system with exporting countries that can guarantee production quality standards equivalent to those in the EU is to be welcomed, the Commission proposal needs to be amended to ensure that the first on-site inspection takes place prior to a country's inclusion on the list and not within three years of that inclusion. This will make it possible to ascertain the reliability of the guarantees provided by the third country before it is authorised to place products on the Community market.

The guarantees required of producers not from a country with which the EU has signed a mutual recognition agreement are not demanding enough. Such producers are authorised to export to the EU if the exporting third country provides written confirmation of production quality standards. This procedure clearly fails to provide a proper and sufficient guarantee and, furthermore, will not encourage third countries to conclude mutual recognition agreements with the EU.

Other issues also need to be addressed, such as Internet sales and the possibility of affixing safety features to over-the-counter medicines, where there is good reason to believe that they may be falsified.

Finally, given that the proposal fails to provide for systematic mandatory inspection of production facilities, the time frames for the entry into force of the directive's provisions are excessively long.
AMENDMENTS

The Committee on Industry, Research and Energy 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
Citation 1

Text proposed by the Commission

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Amendment

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 168 thereof,

Justification

The aim of this Directive is not only to establish the functioning of the internal market for medicinal products but to ensure as well a high level of protection of public health in the EU.

Amendment 2

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

Text proposed by the Commission

(3a) Experience shows that, when medicinal products are purchased on the Internet, the consumer cannot be sufficiently sure that the products purchased have been sourced through the legal supply chain and are thus safe. The Commission should, in cooperation with the Agency and Member State authorities, analyse Internet sales and, where appropriate, submit a legislative proposal seeking to protect the health of European citizens.

Amendment

Justification

The increasingly wide availability of medicinal products on the Internet is a matter of considerable concern. However, until a study is carried out with a view to providing a clear picture of the situation, it would be counter-productive to extend the proposal’s scope to cover...
Internet sales. The various institutional stakeholders therefore need to analyse Internet sales and, where appropriate, submit a legislative proposal that will properly address this problem.

Amendment 3
Proposal for a directive – amending act
Recital 4 a (new)

Text proposed by the Commission

(4a) This Directive seeks to prevent falsified medicinal products from entering the legal supply chain and should be without prejudice to intellectual and industrial property legislation.

Justification
The entry of falsified medicinal products into the legal supply chain not only poses a major threat to public health but is also a matter of serious concern to Europe's pharmaceutical sector, in particular the SMEs working within it. Intellectual and industrial property rights therefore need to be safeguarded in order to ensure that the European pharmaceutical industry is able to continue to invest heavily in research and development.

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

Text proposed by the Commission

(4b) The new draft Convention of the Council of Europe on counterfeiting of medicinal products and similar crimes involving threats to public health, which is expected to be open for signature in 2010, should be supported by the Commission and the Member States.

Justification
An international legal instrument is needed, in the form of a convention, designed to introduce new legislation including a new offence relating to pharmaceutical crime, to establish specific penalties for counterfeiting and impairing the quality of medicines and lay down rules governing jurisdiction allowing the interests of victims of pharmaceutical crime to be taken into account.
### Amendment 5

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(4c) A considerable number of medicines purchased over the internet come from sites that conceal their actual physical address. Therefore, a distinction should be made between legitimate mail-order or internet pharmacies and the illegal supply chain through non-controlled internet purchasing. Member States should ensure that the internet sale of medicinal products is continuously monitored by designated bodies.</td>
<td></td>
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</tbody>
</table>

**Justification**

Since some Member States recognise internet sales as part of the legal supply chain, internet sales have to be taken into account. The International Medical Products Anti-Counterfeiting Taskforce (IMPACT) of the World Health Organisation estimated that medicines purchased over the internet from illegal sites that conceal their physical address are falsified in over 50% of cases. This situation should therefore not be ignored and should be part of the directive.

### Amendment 6

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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</thead>
<tbody>
<tr>
<td>(4d) European citizens should be made aware of the danger to their health from 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 related to purchasing</td>
<td></td>
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</table>


medicinal products on the internet. Public awareness campaigns should inform citizens whether their internet pharmacy is officially registered and controlled by public authorities.

**Justification**

Awareness raising is a crucial element in fighting the supply of falsified medicinal products through internet sales. Information initiatives are crucial because a conscious and knowledgeable consumer is able to avoid falsified medicines. Patients and consumers' organisations have the experience to provide relevant, accurate and accessible information for the communities that they know well.

**Amendment 7**

**Proposal for a directive – amending act**

**Recital 4 e (new)**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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</thead>
<tbody>
<tr>
<td>(4e) 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.</td>
<td></td>
</tr>
</tbody>
</table>

**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 8

Proposal for a directive – amending act
Recital 5

Text proposed by the Commission

(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.

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, such as traders and brokers. 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 and brokers. They should be clearly and unambiguously defined, as should their responsibilities, and 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. In particular, such persons should have a valid licence for their business activities, which should be conducted in accordance with the good practice laid down by the Commission, in cooperation with the Agency and the Member State authorities, by analogy with that applying to producers and distributors of medicinal products.

Justification

To ensure the safety of pharmaceutical products, due account needs to be taken of all those working in the sector and not just wholesale distributors. For the system to be able effectively to protect public health, it is essential for the responsibilities of the various stakeholders to be clearly identified and for all stakeholders to be subject to a rigorous accreditation, verification and good-practice system. This must apply to parallel traders as well.
Amendment 9

Proposal for a directive – amending act
Recital 7

Text proposed by the Commission

(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.

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 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, over-the-counter medicines and medicines sold directly by producers, without any brokering, to establishments at which they are provided to patients. 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.

Justification

An effective system for identifying, authenticating and tracing medicinal products on the basis of the risk assessment provided for in Article 54a(4) needs to be developed. When the safety features are laid down, the product's specific characteristics need to be taken into account so as not to generate disproportionately high costs. For example, it would be counter-productive to impose safety features for medicines sold directly by producers, without any brokering, to healthcare facilities at which they are provided to patients.

Amendment 10
### Proposal for a directive – amending act

#### Recital 7 a (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td><em>Text proposed by the Commission</em></td>
<td><em>(7a) Member States, in cooperation with stakeholders, should be permitted to regulate the particular aspects of authentication of medicines in the way which they consider most appropriate for their market in medicinal products, taking account of the safety features established in accordance with this Directive.</em></td>
</tr>
</tbody>
</table>

**Justification**

*It is important to ensure the authenticity both of prescription medicines and of non-prescription medicines.*

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#### Amendment 11

**Proposal for a directive – amending act**

#### Recital 7 b (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tr>
<td><em>(7b) Technologies which make it possible to identify and trace pharmaceuticals at the individual dose level may be a means of combating counterfeiting of medicinal products more effectively and deserve careful analysis by the institutions responsible for safeguarding public health in Europe.</em></td>
<td></td>
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</tbody>
</table>

**Justification**

*It is important to take account of all the available technologies for combating this phenomenon, which is damaging to the health of Europe’s citizens.*

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#### Amendment 12
Proposal for a directive – amending act
Recital 7 c (new)

Text proposed by the Commission

(7c) In order to provide patients with timely protection from the risks arising from falsified medicinal products, a manufacturing authorisation holder who partly or fully removes or covers-up safety features that are applied on a voluntary basis should be required to replace such safety features with equivalent safety features designed to ensure the identification, authentication and traceability of prescription medicinal products as soon as this Directive enters into force.

Amendment

Justification

Even after the Directive comes into force, it is unlikely that any concrete measures will actually be in place for some years. As a result, interim measures should continue until the full measures can be put into place. These measures should require inter alia that manufacturing authorization holders, (including repackers) 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 13

Proposal for a directive – amending act
Recital 8

Text proposed by the Commission

(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.

Amendment

(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 authorisation 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.

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 14

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

Text proposed by the Commission  
(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.

Justification

It is important to ensure the authenticity both of prescription medicines and of non-prescription medicines.

Amendment 15

Proposal for a directive – amending act
Recital 12

Text proposed by the Commission  
(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.

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.

Justification

To ensure that public health is properly protected, the competent authorities of the Member States should inspect production sites, in cooperation with the European Medicines Agency. 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 16

Proposal for a directive – amending act

Recital 13

Text proposed by the Commission

(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.

Amendment

(13) With a view to ensuring a high level of protection for public health, the manufacture of active pharmaceutical ingredients or excipients should be subject to the relevant good manufacturing practices in force within the Union irrespective of whether those ingredients were manufactured in the Union or imported. With regard to the manufacture of active pharmaceutical ingredients in third countries, it should be ensured that good manufacturing practice is complied with, by means of repeated mandatory inspections carried out by the competent Union authorities or the authorities of countries with which mutual recognition agreements covering, inter alia, active pharmaceutical ingredients, are in force.
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. Both excipients and active pharmaceutical ingredients should be subject to relevant good manufacturing practices developed at the European level taking into account their own specificities.

Amendment 17

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

Text proposed by the Commission

(13a) 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.

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.

Amendment 18

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

Text proposed by the Commission

(15a) Member States should ensure public health and safeguard the competitiveness
of European firms by imposing effective, proportionate, dissuasive and equivalent penalties aimed at preventing falsified medicinal products from entering the legal supply chain.

**Justification**

In order effectively to combat the counterfeiting of medicinal products, the Member States need both to adopt a set of effective, proportionate and dissuasive legal provisions and ensure that uniform penalties apply at European level.

**Amendment 19**

**Proposal for a directive – amending act**

**Recital 17 a (new)**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td>(17a) In order to identify each individual package of medicinal products subject to medical prescription other than radiopharmaceuticals, certain product characteristics (i.e. product code, expiry date, lot number) should appear amongst the safety features. This information should be available in a machine-readable format which is harmonised across Europe using an international coding standard.</td>
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</table>

**Justification**

An end-to-end product verification system should allow a systematic control of each pack's serial numbers at the point of dispensing before it reaches the patient. This requires that all prescription-only medicinal products, other than radiopharmaceuticals, carry a serialisation number that identifies the individual package in a harmonised and standardised way across Europe.

**Amendment 20**
Recital 18 a (new)

(18a) The Member States should cooperate to enforce existing restrictions on illegal trading in medicinal products over the Internet, including by means of Europol.

Amendment 21

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

(-1) In Article 1, the following point 3a is inserted:

"3a. Excipient:

Any constituent of a pharmaceutical form apart from the active substance. Excipients include, for example, fillers, disintegrants, lubricants, colouring matters, antioxidants, preservatives, adjuvants, stabilisers, thickeners, emulsifiers, solubilisers, permeation enhancers, flavouring and aromatic substances, as well as the constituents of the outer covering of the medicinal products, for example gelatine capsules."

Justification

A definition on excipients is needed. As an excipient is an essential part of the finished medicinal product The definition is in accordance with the European Medicines Agency CHMP Guidelines on excipients.

Amendment 22
Proposal for a directive – amending act
Article 1 – point -1 a (new)
Directive 2001/83/EC
Article 1 – point 5 a (new)

Text proposed by the Commission

-Amendment

(-1a) In Article 1, the following point 5a is inserted:

'5a. Falsified medicinal product:

Any medicinal product that has been deliberately falsified in relation to its:
(a) identity, including its packaging, labelling, name or composition in terms of both ingredients, including excipients and active ingredients, or the dosage thereof;
and/or

(b) source, including the manufacturer, the country of manufacture, the country of origin or the marketing authorisation holder;
and/or

(c) history, including the registers or documents enabling the distribution chain to be identified.
The Commission shall, in cooperation with the Agency and Member State authorities, adopt acts updating this definition on the basis of technical and scientific progress and 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. This definition is not related to infringements of legislation on intellectual and industrial property rights or patent rights.
This definition does not include manufacturing errors.'
**Justification**

*In order to be able effectively to combat the entry of falsified medicines into the legal supply chain, we need a clear and exhaustive definition of the term 'falsified medicinal product', not least with a view to tightening up penalties. Manufacturing errors should not be included in the definition.*

**Amendment 23**

**Proposal for a directive – amending act**

**Article 1 – point 1**

Directive 2001/83/EC

Article 1 – point 17a

<table>
<thead>
<tr>
<th><strong>Text proposed by the Commission</strong></th>
<th><strong>Amendment</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>‘17a. Trading of medicinal products: All activities consisting of negotiating independently on behalf of another person the sale or the purchase of medicinal products, or billing or brokering medicinal products, apart from supplying medicinal products to the public, and not falling under the definition of wholesale distribution.’</td>
<td>‘17a. Trading of medicinal products: All activities consisting of the sale, purchase or billing of medicinal products, apart from the physical handling and supply of medicinal products to the public, and not falling under the definition of wholesale distribution.’</td>
</tr>
</tbody>
</table>

**Justification**

*Definitions used in the Directive should be easily understood and should not result in any uncertainty as to their meaning. Therefore, definitions must distinguish between trading and brokering, the former includes cases where the trader is owner of the product, the latter not, whereas both take no physical possession of products and therefore do not control their handling.*

**Amendment 24**

**Proposal for a directive – amending act**

**Article 1 - point 1 a (new)**

Directive 2001/83/EC

Article 1 – point 17 b (new)

<table>
<thead>
<tr>
<th><strong>Text proposed by the Commission</strong></th>
<th><strong>Amendment</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1a) In Article 1, the following point 17b is inserted:</td>
<td>'17b. Brokering of medicinal products:'</td>
</tr>
</tbody>
</table>

'17b. Brokering of medicinal products:
All activities not including the possession and/or physical handling of medicinal products and consisting of negotiating independently on behalf of another person the sale or purchase of medicinal products or in billing on behalf of another person or engaging in any form of brokering of medicinal products with the exception of wholesale and retail distribution.'

Justification

In order to be able effectively to combat the entry of falsified medicines into the legal supply chain, we need a clear and exhaustive definition of all those working in the sector – not only producers and wholesale distributors, but also traders and brokers of medicinal products. It is therefore essential for such persons also to be subject to a rigorous accreditation, verification and good-practice system. This must apply to parallel traders as well.

Amendment 25

Proposal for a directive – amending act
Article 1 – point 1 b (new)
Directive 2001/83/EC
Article 1 – point 18 b (new)

Text proposed by the Commission

(1b) In Article 1, the following point 18b is inserted:

"18b. Persons authorised to supply medicinal products:

Persons or entities in the possession of a wholesale distribution authorisation without prejudice to persons or entities exempt from holding an authorisation to supply medicinal products."

Justification

A definition should be included to explain the meaning of “persons authorized to supply medicinal products” as this terms is used in the current Directive without definition. This definition is needed to ensure the adequate and continuous supply of medicines through persons authorized to supply medicinal products to the public. In order to provide effective protection against counterfeit medicines all participants in and around the supply chain should be clearly identified, their activities defined, fully licensed, controlled and inspected.
Amendment 26
Proposal for a directive – amending act
Article 1 – point 2 a (new)
Directive 2001/83/EC
Article 2 – paragraph 3a (new)

Text proposed by the Commission

(2a) In Article 2, the following paragraph 3a is inserted:

'3a. The provisions of this Directive shall be without prejudice to the right of the Member States to restrict or prohibit trading in prescription medicinal products over the Internet.'

Amendment 27
Proposal for a directive – amending act
Article 1 – point 3 – point a
Directive 2001/83/EC
Article 46 – point f – subparagraph 1

Text proposed by the Commission

'(f) to comply with the principles and guidelines of good manufacturing practice for medicinal products and to use as starting materials only active substances, which have been manufactured in accordance with the detailed guidelines on good manufacturing practice for starting materials. To this end, the holder of the manufacturing authorization shall verify compliance of the active substances manufacturer with good manufacturing practices by himself or through a body accredited for this purpose by the competent authority of a Member State.'

Amendment

'(f) to comply with the principles and guidelines of good manufacturing practice for medicinal products and to use as starting materials only active substances, which have been manufactured in accordance with the detailed guidelines on good manufacturing practice for starting materials. To this end, the holder of the manufacturing authorisation shall ensure that production operations are conducted in accordance with the guidelines and standards of good manufacturing practice in force within the Union through the performance of mandatory inspections by the competent Union authorities or the authorities of countries with which mutual recognition agreements covering, inter alia, active pharmaceutical
ingredients, are in force.'

Justification

To ensure that public health is properly protected, the competent authorities of the Member States should inspect production sites, in cooperation with the European Medicines Agency. 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 28

Proposal for a directive – amending act
Article 1 – point 3 - point a
Directive 2001/83/EC
Article 46 – point f – subparagraph 1 a (new)

Text proposed by the Commission

The manufacturing authorisation holder shall ensure that excipients are assessed as being suitable for use in pharmaceutical products following the specific good manufacturing practices as developed by the Commission in accordance with Article 47. The manufacturing authorisation holder shall also ensure that the process by which the assessment is achieved is described in a quality system which is available for inspection by competent authorities.

Justification

Active Pharmaceutical Ingredients (API’s) and excipients have very different supply chain characteristics. Both excipients and active pharmaceutical ingredients should be subject to relevant good manufacturing practices developed at the European level taking into account their own specificities.

Amendment 29

Proposal for a directive – amending act
Article 1 – point 3 - point b
Directive 2001/83/EC
Article 46 – point g
Text proposed by the Commission

'(g) to inform the competent authority of products he gets knowledge of which are or which are suspected to be falsified in relation to the identity, history or source of products manufactured by him.'

Amendment

'(g) to inform the competent authority of products he gets knowledge of which are or which are reliably suspected to be falsified in relation to the identity, history or source of products manufactured by him.'

Amendment 30

Proposal for a directive – amending act
Article 1 – point 3 – point b a (new)
Directive 2001/83/EC
Article 46 – point g a (new)

Text proposed by the Commission

'(ba) The following point (ga) is added:

'(ga) to assume legal liability for the accuracy of the findings of inspections and checks he has carried out or commissioned, without it being possible to delegate that liability.'

Amendment

Justification

Inspections and checks need to be performed to ensure that medicinal products are manufactured in accordance with good manufacturing practice. In this connection, the manufacturing authorisation holder needs to be held liable for both the manufactured products and the starting materials purchased. The manufacturer's liability for inspection findings therefore needs to be established, all the more so if he has the option of having inspections carried out by a body accredited for that purpose.

Amendment 31

Proposal for a directive – amending act
Article 1 – point 3 - point b b (new)
Directive 2001/83/EC
Article 46 – point g b (new)

Text proposed by the Commission

'(bb) The following point (gb) is added:

(bb) The following point (gb) is added:
'(gb) to make the importation of the active principles from third countries subject to specific and stringent monitoring, in order to check whether good manufacturing practices have been adhered to and the intrinsic quality of the active principles.'

**Justification**

It is desirable to make monitoring more stringent, particularly in the case of imports of active principles from third countries, albeit without forgetting the requirement to distinguish monitoring of good manufacturing practice (and lastly of the quality of the active principles) from checking so-called falsity or falsification, which concerns any patent-holders.

**Amendment 32**

**Proposal for a directive – amending act**

**Article 1 – point 4**

Directive 2001/83/EC

Article 46b – paragraph 2

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td>2. Active substances used as starting material <strong>shall</strong> only be imported if:</td>
<td>2. Active substances used as starting material <strong>may</strong> only be imported if:</td>
</tr>
<tr>
<td>(a) they have been manufactured by applying standards of good manufacturing practice at least equivalent to those laid down by the <strong>Community</strong>; and</td>
<td>(a) they have been manufactured by applying standards of good manufacturing practice at least equivalent to those laid down by the <strong>Union</strong>; and</td>
</tr>
<tr>
<td>(b) they are accompanied by a written confirmation from the exporting third country that the standards of good manufacturing practice applicable to the plant manufacturing the exported active substance are at least equivalent to those laid down by the <strong>Community</strong>, and that the plant is subject to control and enforcement ensuring that those good manufacturing practices cannot be circumvented.</td>
<td>(b) they have, in the past three years, successfully passed an inspection specifically covering active pharmaceutical ingredients carried out by a competent Union authority or an authority of a country with which a mutual recognition agreement is in force. The passing of the inspection shall be documented by a certificate issued by a competent authority, attesting compliance with good manufacturing practice.</td>
</tr>
</tbody>
</table>

**Justification**

Written confirmation from the exporting third country that good manufacturing practice has
been complied with by the plant manufacturing the exported active substance is not a proper and sufficient guarantee. To ensure public health and safeguard the competitiveness of European firms, production sites need to be inspected by the competent national authorities. This system will act as an incentive for foreign producers to ask their countries of origin to conclude mutual recognition agreements with the European Union.

Amendment 33

Proposal for a directive – amending act
Article 1 – point 5
Directive 2001/83/EC
Article 47 – paragraph 2 a (new)

Text proposed by the Commission

The principles by which the manufacturing authorisation holder ensures that excipients are suitable for use in manufacturing operations, carried out using risk-based analysis under the principles of good manufacturing practices, shall be adopted in the form of guidelines.

Justification

Appropriate and proportionate guidelines shall be developed for excipients and active substances as their supply chain characteristics are very different. It is proposed that already exiting guidance form the basis of controls to be applied to excipients and augmented by additional appropriate requirements, when necessary. This proposal would be a pragmatic approach which would fulfil the requirements of current legislation and build on effective systems already in place.

Amendment 34

Proposal for a directive – amending act
Article 1 – point 7
Directive 2001/83/EC
Article 52b – paragraph 1

Text proposed by the Commission

1. Notwithstanding Article 2(1), and without prejudice to Title VII, Member States shall ensure that medicinal products not intended to be placed on the market are

Amendment

1. Notwithstanding Article 2(1), and without prejudice to Title VII, Member States shall ensure that medicinal products not intended to be placed on the market are
not introduced into the Community if there are reasons to believe that the products claim a falsified identity, history or source.

Justification

To ensure the safety of the supply chain, Member States need to monitor medicinal products in transit through the EU, even where the products concerned are intended for a foreign market.

Amendment 35

Proposal for a directive – amending act
Article 1 – point 8
Directive 2001/83/EC
Article 54 – point o

Text proposed by the Commission

(o) safety features making it possible to ascertain identification, authenticity and traceability of medicinal products, other than radiopharmaceuticals, subject to medical prescription as defined in Title VI, other than radiopharmaceuticals and medicinal products which due to their specific characteristics are not suitable for distribution through a wholesaler and pharmacy and therefore are sold directly by the producer to a clinical establishment where they are directly administered to the patient; safety features may be applied, on the basis of a case-by-case analysis, to non-prescription medicinal products where the risk related to the product indicates, on the basis of the criteria set out in Article 54a(4), that there are reasonable grounds for considering that the product may be falsified.

Justification

An effective system for identifying, authenticating and tracing medicinal products on the basis of the risk assessment provided for in Article 54a(4) needs to be developed. As far as implementation of safety features are concerned, the product’s specific characteristics need to be taken into account so as not to generate disproportionately high costs. It would be counterproductive to impose safety features for medicines sold directly by producers, without...
any brokering, to clinical establishments at which they are directly administered to patient (facilities providing medical treatment).

Amendment 36
Proposal for a directive – amending act
Article 1 – point 8
Directive 2001/83/EC
Article 54 – point o – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

These safety features shall be applied without discrimination among marketing channels.

Amendment 37
Proposal for a directive – amending act
Article 1 – point 8 a (new)
Directive 2001/83/EC
Article 54 – point o a (new)

Text proposed by the Commission

Amendment

(8a) In Article 54, the following point (oa) is added:

'(oa) with a view to ensuring the traceability of the active ingredient, details of the product's source (country, firm, production site).'

Justification

An effective system for identifying, authenticating and tracing medicinal products on the basis of the risk assessment provided for in Article 54a(4) needs to be developed. When the safety features are laid down, the product's specific characteristics need to be taken into account so as not to generate disproportionately high costs. For example, it would be counter-productive to impose safety features for medicines sold directly by producers, without any brokering, to healthcare facilities at which they are provided to patients.
Amendment 38

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

Text proposed by the Commission

(b) The manufacturing authorisation holder complies with point (o) of Article 54 by replacing the safety feature with a safety feature which is equivalent as regards the possibility to ascertain identification, authenticity and uninterrupted traceability of the medicinal product, and without opening the immediate packaging as defined in Article 1(23);

Amendment

(b) The manufacturing authorisation holder complies with point (o) of Article 54 by replacing the safety features with safety features which are qualitatively and quantitatively equivalent as regards the possibility to ascertain identification, authenticity and uninterrupted traceability of the medicinal product, and without opening the immediate packaging as defined in Article 1(23);

Justification

Opening a medicine pack for repackaging is always a delicate operation, because it provides the ideal opportunity to replace authentic medicines with falsified ones. This is why the person carrying out the operation must be duly authorised to do so and be subject to strict controls. When a product is repackaged, it must be ensured that safety features that are qualitatively and quantitatively equivalent to those affixed by the producer are affixed to the new packaging.

Amendment 39

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

Text proposed by the Commission

Safety features shall be considered equivalent when they offer the same level of efficacy 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,
unless the primary safety feature is a covert one and therefore cannot be recognised;

Justification

To ensure that parallel traders can indeed apply equivalent safety features during the process of re-packaging, this directive has to introduce the different categories of equivalent safety features according to specific criteria, recognising the fact covert safety features cannot be verified without prior information.

Amendment 40

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

Text proposed by the Commission

(ca) 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 41

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

Text proposed by the Commission

(3) Manufacturing authorisation holders shall be liable for damages in accordance with Council Directive 85/374/EEC caused by medicinal products which are falsified in terms of their identity.

Amendment

(3) Manufacturing authorisation holders referred to in paragraph 2 of this Article shall be considered producers under Council Directive 85/374/EEC. They shall be liable for damages caused by medicinal products which are falsified in terms of
their identity to the original manufacturer, to the holder of the marketing authorisation and to consumers.

Justification

Clarification is required to ensure that manufacturing authorisation holders, which repackage products, will be strictly liable for all their activities, including where falsified medicines enter into the supply chain.

Amendment 42

Proposal for a directive – amending act
Article 1 – point 9
Directive 2001/83/EC
Article 54a – paragraph 4 – subparagraphs 1, 2

Text proposed by the Commission

4. The Commission shall adopt the measures necessary for the implementation of point (o) of Article 54 and of paragraphs (1) and (2) of this Article.

Amendment

4. The Commission shall adopt acts containing the measures necessary for the implementation of point (o) of Article 54 and of paragraphs (1) and (2) of this Article. Before formulating a specific proposal as provided for by Article 54(o), the Commission shall perform an impact assessment of the costs and benefits of the anti-counterfeiting systems currently in force and consult interested parties about the implementation and use of such authenticating seals.

Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 121(2a).

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

There are various options for anti-counterfeiting technologies, such as one-dimensional code, data matrices, seals, holograms, RFID, etc. Before choosing a specific anti-counterfeiting seal, the Commission should perform an impact assessment in order to evaluate all the pros and cons of the seals available on the market and should take account of current experience and the results of the pilot projects which have been completed.
Amendment 43

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

Text proposed by the Commission

Text proposed by the Commission

Amendment

(ea) if the product is delivered directly, without the involvement of third parties, such as wholesale distributors, traders or brokers, to a healthcare setting in which the product is administered directly to the patient.

Amendment 44

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

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. ‘

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. **Member States shall ensure that the ownership and confidentiality of the data generated by using technology to combat counterfeiting of pharmaceutical products are respected.**

Justification

_The use of anti-counterfeiting seals to check the authenticity of pharmaceuticals may generate data which might be commercially and personally sensitive. The ownership of such data should be respected. Data on personal consumption of pharmaceuticals should be subject to the relevant data protection legislation and codes of ethics in force at national level._

Amendment 45
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

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 purposes referred to in paragraph 2.

Justification
Even after the Directive comes into force, it is unlikely that any concrete measures will actually be in place for some years. As a result, interim measures should continue until the full measures can be put into place. These 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 46
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

4b. As from [insert date: 36 months after publication] all medicinal products subject to medical prescription other than radiopharmaceuticals must, from the time of the batch release pursuant to Article 51, carry a serialisation number that identifies the individual package unequivocally.

Justification
An end-to-end product verification system should allow a systematic control of each pack’s serial numbers at the point of dispensing before it reaches the patient. This requires that all
prescription-only medicinal products, other than radiopharmaceuticals, carry a serialisation number that identifies the individual package in a harmonised and standardised way across Europe.

Amendment 47

Proposal for a directive – amending act
Article 1 – point 11
Directive 2001/83/EC
Title VII - heading

Text proposed by the Commission
‘Wholesale distribution and trading of medicinal products’;

Amendment
‘Wholesale distribution, brokering and trading of medicinal products’;

Justification
To ensure the safety of pharmaceutical products, due account needs to be taken of all those working in the sector and not just wholesale distributors and traders.

Amendment 48

Proposal for a directive – amending act
Article 1 – point 12
Directive 2001/83/EC
Article 77 – paragraph 4

Text proposed by the Commission
'4. The Member States shall forward to the Agency a copy of the authorization referred to in paragraph 1. The Agency shall enter that information in the Community database referred to in Article 111(6). At the request of the Commission or any Member State, Member States shall supply all appropriate information concerning the individual authorization which they have granted under paragraph 1.'

Amendment
'4. The Member States shall forward to the Agency a copy of the authorization referred to in paragraph 1. The Agency shall enter that information in the Community database referred to in Article 111(6). At the request of the Commission or any Member State, Member States shall supply, within a reasonable period of time, all appropriate information concerning the individual authorization which they have granted under paragraph 1.'
Amendment 49

Proposal for a directive – amending act
Article 1 – point 12 a (new)
Directive 2001/83/EC
Article 77 – paragraph 6

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(12a) In Article 77, paragraph 6 is replaced by the following:</td>
<td></td>
</tr>
<tr>
<td>'6. The Member State which granted the authorisation referred to in paragraph 1 shall suspend or revoke that authorisation, after having notified the holder thereof, if the conditions of authorisation cease to be met or if the authorisation has not been used for more than three years, except in cases where the authorisation was not used on account of the time reasonably necessary to comply with the obligations under this Directive, and shall forthwith inform the other Member States and the Commission thereof.'</td>
<td></td>
</tr>
</tbody>
</table>

Justification

In many Member States, wholesale distribution authorisations have been issued but are not currently in use. This situation artificially increases the number of stakeholders and unnecessarily complicates the market and, thereby, the system of controls. It is important to ensure, however, that such authorisations are not suspended or revoked in cases where they are not being used on account of the time reasonably necessary to comply with the obligations under the Directive. The authorisation holder therefore needs to be notified beforehand, so as to avoid any unwarranted suspensions.

Amendment 50

Proposal for a directive – amending act
Article 1 – point 12 b (new)
Directive 2001/83/EC
Article 79 a (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(12b) The following Article 79a is inserted:</td>
<td></td>
</tr>
</tbody>
</table>

Article 79a

The Commission shall, in cooperation with the Agency and Member State authorities, lay down rules and criteria for obtaining medicinal product trading and brokering licences. Applicants shall, as a minimum requirement:
(a) have a permanent address and supply details enabling their official trading or brokering offices to be clearly and unambiguously identified;
(b) undertake to ensure that their business is conducted solely with persons or bodies meeting the requirements set out in Article 80.'

Justification

To ensure the safety of pharmaceutical products, due account needs to be taken of all those working in the sector – not just wholesale distributors – all of whom need to be subject to a rigorous accreditation, verification and good-practice system. This must apply to parallel traders as well.

Amendment 51

Proposal for a directive – amending act
Article 1 – point 13 – point -a (new)

Directive 2001/83/EC
Article 80 – introductory part

Text proposed by the Commission

(-a) The introductory part is replaced by the following:

'Holders of the distribution authorisation, holders of the trading authorisation and holders of the brokering authorisation for medicinal products must fulfil the following minimum requirements:'

Justification

See previous justification.
Amendment 52

Proposal for a directive – amending act
Article 1 – point 13 – point a
Directive 2001/83/EC
Article 80 – point e

Text proposed by the Commission

(c) they must keep records either in the form of purchase/sales invoices or on computer, or in any other form, giving for any transaction in medicinal products received, dispatched or traded at least the following information:
– date,
– name of the medicinal product,
– quantity received, supplied or traded,
– name and address of the supplier or consignee, as appropriate;

Amendment

(e) they must keep records either in the form of purchase/sales invoices or on computer, or in any other form, giving for any transaction in medicinal products received, dispatched, traded or brokered at least the following information:
– date,
– name of the medicinal product,
– quantity received, supplied, traded or brokered,
– name and address of the supplier or consignee, as appropriate;

Amendment 53

Proposal for a directive – amending act
Article 1 – point 13 – point a a (new)
Directive 2001/83/EC
Article 80 – point g

Text proposed by the Commission

(aa) Point (g) is replaced by the following:
'(g) they must comply with the principles and guidelines of good distribution, trading and brokering practice for medicinal products as laid down in Article 84.'

Amendment

Justification

See above justification.
### Amendment 54

**Proposal for a directive – amending act**  
**Article 1 – point 13 – point b**  
Directive 2001/83/EC  
Article 80 – point i – introductory part

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) they must inform the competent authority of products they receive which they identify as infringing, or they suspect of infringing, either of the following:</td>
<td>(i) they must inform the competent authority of products they receive, <em>trade or broker</em> which they identify as infringing, or they suspect of infringing, either of the following:</td>
</tr>
</tbody>
</table>

**Justification**

*See previous justification.*

### Amendment 55

**Proposal for a directive – amending act**  
**Article 1 – point 13 – point c**  
Directive 2001/83/EC  
Article 80 – subparagraph 2

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>For the purpose of point (b), in the case where the product is obtained from another wholesale distributor, holders of the wholesale distribution authorisation must verify compliance with good distribution practices of the supplying wholesale distributor <em>either by themselves or through a body accredited for that purpose by the competent authority of a Member State.</em></td>
<td>For the purpose of point (b), in the case where the product is obtained from another wholesale distributor, holders of the wholesale distribution authorisation must verify compliance with good distribution practices of the supplying wholesale distributor <em>and check that the latter holds a wholesale distribution authorisation.</em></td>
</tr>
</tbody>
</table>

**Justification**

*Certainty as to the source and quality of active pharmaceutical ingredients is of essential importance. To ensure compliance with good manufacturing practice, everyone involved must be duly authorised to conduct their specific business and must undergo thorough inspections on a regular basis.*
Amendment 56

Proposal for a directive – amending act
Article 1 – point 13 a (new)
Directive 2001/83/EC
Article 84

Text proposed by the Commission

(13a) Article 84 is replaced by the following:

'Article 84

The Commission shall publish guidelines on good distribution, trading and brokering practice for medicinal products. To this end, it shall consult the Committee for Proprietary Medicinal Products and the Pharmaceutical Committee established by Council Decision 75/320/EEC1.

1 OJ L 147, 9.6.1975, p. 23.'

Justification

To ensure the safety of pharmaceutical products, due account needs to be taken of all those working in the sector – not just wholesale distributors – all of whom need to be subject to a rigorous accreditation, verification and good-practice system. This must apply to parallel traders as well.

Amendment 57

Proposal for a directive – amending act
Article 1 – point 13 b (new)
Directive 2001/83/EC
Article 84 a (new)

Text proposed by the Commission

(13b) The following Article 84a is inserted:

"Article 84a

The Commission shall publish guidelines on specific good manufacturing practices
for active pharmaceutical ingredients and specific good manufacturing practices for excipients. To this end, it shall consult the Committee for Proprietary Medicinal Products established by Council Directive 75/319/EEC and the Pharmaceutical Committee established by Council Decision 75/320/EEC."

Justification

Both excipients and active pharmaceutical ingredients should be subject to relevant good manufacturing practices developed at the European level taking into account their own specificities. The European Commission is called to develop specific GMP for APIs and specific GMPs for Excipients taking into account the very characteristics of those two different categories of ingredients and specially the fact that excipients have no therapeutic activity.

Amendment 58

Proposal for a directive – amending act
Article 1 – point 14
Directive 2001/83/EC
Article 85b

Text proposed by the Commission

Persons trading medicinal products shall ensure that the traded medicinal products are covered by a marketing authorization granted pursuant to Regulation (EC) No 726/2004 or by the competent authorities of a Member State in accordance with this Directive. In addition, the requirements set out in Article 80(d) to (h) shall apply.

They shall notify their activity to the competent authority of the Member State where they are established.

Amendment

Persons trading or brokering medicinal products shall ensure that the traded or brokered medicinal products are covered by a marketing authorisation granted pursuant to Regulation (EC) No 726/2004 or by the competent authorities of a Member State in accordance with this Directive.

They shall notify their activity to the competent authority of the Member State where they are established, which shall inform the Agency.

Justification

Persons or entities trading or brokering medicinal products should be obliged to verify that products traded or brokered are covered by a valid marketing authorization. The national notification procedure should be strengthened by a Community database similar to the
requirements for the holders of wholesale distribution authorization in order to make all participants transparent.

Amendment 59

Proposal for a directive – amending act
Article 1 – point 14 a (new)
Directive 2001/83/EC
Article 88 b (new)

Text proposed by the Commission

14a) The following Article 88b is inserted:

"Article 88b
Member States, in cooperation with the Commission and after consultation with representatives of stakeholders, shall devise an information strategy relating to the safety of consignments of medicinal products. The strategy shall take account of the various national legal provisions concerning the supply of medicinal products and the risks associated with certain types of supply of medicinal products and with illegal trading on the Internet."

Justification

The Internet is the main source of illegal medicinal products. Citizens should be advised not to order medicinal products through illegal channels. In particular, public information measures should be promoted in the Member States and throughout Europe.

Amendment 60

Proposal for a directive – amending act
Article 1 – point 14 b (new)
Directive 2001/83/EC
Article 97 – paragraph 5 a (new)

Text proposed by the Commission

(14b) In Article 97, the following paragraph 5a is added:

"5a. The Commission shall ensure, in
cooperation with the Agency and national authorities, that manufacturers, importers, wholesale distributors, traders and brokers, either collectively or individually, promote public information campaigns in the various media (press, television, radio, Internet) to raise awareness of the risks connected with the purchase of falsified medicinal products on the Internet."

Justification
The public needs to be made aware of the risks attached to purchases of medicinal products over the internet and given information on how to distinguish between authorised on-line pharmacies and illicit distributors. Given the financial resources available to manufacturers, importers, wholesale distributors, traders and brokers and given that it is in their best interest to protect their consumers and their reputation, information campaigns should be industry-led with the Commission having a supervisory role to ensure that campaigns are carried out.

Amendment 61

Proposal for a directive – amending act
Article 1 – point 15 – point -a (new)
Directive 2001/83/EC
Article 111 – paragraph 1

Text proposed by the Commission

(-a) Paragraph 1 is replaced by the following:
'1. The competent authorities of the Member State concerned shall, under the Agency's coordination, ensure, by means of repeated, and where necessary unannounced, inspections, that the legal requirements governing medicinal products are complied with, where appropriate commissioning an official medicinal product test laboratory or another laboratory designated for that purpose to carry out sampling tests. Such inspections shall be carried out by officials representing the competent authority who shall be empowered to:
(a) inspect manufacturing or commercial establishments and any
laboratories *entrusted* by the holder of the manufacturing authorisation *with the task of carrying out* checks pursuant to Article 20;
(b) *take samples*;
(c) examine any documents relating to the object of the inspection, subject to the provisions in force in the Member States on 21 May 1975 which place restrictions on these powers with regard to the descriptions of the *method of preparation*.

**Justification**

*To ensure the safety of pharmaceutical products, the inspection arrangements need to be fleshed out and applied across the board.*

**Amendment 62**

**Proposal for a directive – amending act**
**Article 1 – point 15 – point a a (new)**
**Directive 2001/83/EC**
**Article 111 – paragraph 2**

*Text proposed by the Commission*  
(aa) Paragraph 2 is replaced by the following:
'2. The competent authorities may carry out repeated, and where necessary unannounced, inspections of the premises of producers, distributors or importers of active ingredients used as starting materials, the premises of manufacturing authorisation holders, the premises of medicinal product traders and brokers or the premises of excipient producers, importers and distributors where there are sound grounds for suspecting, on the basis of information available to the authorities or of previous cases, that legal obligations and/or the guidelines are not being complied with. Such inspections may also be carried out at the request of a Member State, the Commission or the Agency.'
Justification

See previous justification.

Amendment 63

Proposal for a directive – amending act
Article 1 – point 15 – point b
Directive 2001/83/EC
Article 111 – paragraph 3

Text proposed by the Commission

3. After every inspection as referred to in paragraph 1, the competent authority shall report on whether the manufacturer, importer, or wholesale distributor complies with the principles and guidelines of good manufacturing practice and good distribution practices referred to in Articles 47 and 84 or on whether the marketing authorization holder complies with the requirements laid down in Title IX.

Amendment

3. After every inspection as referred to in paragraph 1, the competent authority shall report on whether the manufacturer, importer, wholesale distributor, trader or broker complies with the principles and guidelines of good manufacturing practice and good distribution, trading and brokering practices referred to in Articles 47 and 84 or on whether the marketing authorization holder complies with the requirements laid down in Title IX.

The competent authority which carried out the inspection shall communicate the content of those reports to the manufacturer, importer, marketing authorization holder, or to the wholesale distributor who has undergone the inspection.

Before adopting the report, the competent authority shall give the manufacturer, importer, marketing authorization holder, or wholesale distributor concerned the opportunity to submit their comments.

Justification

To ensure the safety of pharmaceutical products, due account needs to be taken of all those working in the sector – not just wholesale distributors – all of whom need to be subject to a rigorous accreditation, verification and good-practice system. This must apply to parallel traders as well.
Amendment 64

Proposal for a directive – amending act
Article 1 – point 15 – point c
Directive 2001/83/EC
Article 111 – paragraph 5 – subparagraph 1

Text proposed by the Commission
5. Within 90 days of an inspection as referred to in paragraph 1, a certificate of good manufacturing practice or good distribution practice shall be issued to the manufacturer, importer, or wholesale distributor if the outcome of the inspection shows that the person complies with the principles and guidelines of good manufacturing practice or good distribution practice as provided for by Community legislation.

Amendment
5. Within 90 days of an inspection as referred to in paragraph 1, a certificate of good manufacturing practice, good distribution practice, good trading practice or good brokering practice shall be issued to the manufacturer, importer, or wholesale distributor if the outcome of the inspection shows that the person complies with the principles and guidelines of good manufacturing practice, good distribution practice, good trading practice and good brokering practice as provided for by Union legislation.

Amendment 65

Proposal for a directive – amending act
Article 1 – point 15 – point c
Directive 2001/83/EC
Article 111 – paragraph 6

Text proposed by the Commission
6. Member States shall enter the certificates of good manufacturing practice and good distribution practice which they issue in a Community database managed by the Agency on behalf of the Community.

Amendment
6. Member States shall enter the certificates of good manufacturing practice, good distribution practice, good trading practice and good brokering practice which they issue in a Union database managed by the Agency on behalf of the Union.
Amendment 66
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

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.

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, good distribution practices, good trading practices or good brokering practices as provided for by Union legislation, the information shall be entered in the Union database referred to in paragraph 6 and the manufacturing and distribution processes shall cease forthwith.

Amendment 67
Proposal for a directive – amending act
Article 1 – point 16
Directive 2001/83/EC
Article 111a

Text proposed by the Commission

The Commission shall adopt detailed guidelines laying down the principles for inspections referred to in Article 111.

Amendment

The Commission shall adopt detailed guidelines laying down the principles for inspections referred to in Article 111 and, in particular, the Union and/or national bodies responsible for carrying out inspections.

Justification

The Commission is proposing that the first inspection be carried out within three years of the third country being entered on the Article 111b list. It should instead be carried out prior to that country's inclusion on the list, not least because under Article 51(2) the qualified persons within EU firms are not required to carry out checks on products from countries with which the Community has concluded agreements guaranteeing that the products are of the required standard.
Amendment 68

Proposal for a directive – amending act
Article 1 – point 16
Directive 2001/83/EC
Article 111b – paragraph 1 – introductory part

Text proposed by the Commission
1. The Commission shall, following a request from a third country, list that country by way of a Decision if its regulatory framework for active substances exported to the Community and the respective control and enforcement ensure a protection of public health equivalent to that in the Community. Particular account shall be taken of:

Amendment
1. The Commission shall, following a request from a third country and the satisfactory conclusion of the inspection by the body responsible on the basis of Article 111a, list that country by way of a Decision if its regulatory framework for active substances exported to the Union and the respective control and enforcement ensure a protection of public health equivalent to that in the Union. Particular account shall be taken of:

Justification

In view of the exemption provided for in Article 51(2), the fact that the first inspection is scheduled to take place within three years of the third country being entered on the Article 111b list would mean that the products concerned would be placed on the EU market and distributed to the public without having been subjected to any form of checking.

Amendment 69

Proposal for a directive – amending act
Article 1 – point 16
Directive 2001/83/EC
Article 111b – paragraph 2

Text proposed by the Commission
2. The Commission, in accordance with the procedure set out in Article 121(2), shall adopt guidelines defining in detail the requirements set out in points (a) to (d) of paragraph 1.

Amendment
2. The Commission, in accordance with the procedure set out in Article 121(2), shall adopt guidelines defining in detail the requirements set out in points (a) to (d) of paragraph 1, performing by means of the appropriate instruments, and possibly also by means of extraordinary measures, the verification and subsequent monitoring of the quality of the principles and safety.
Justification

It is desirable to make monitoring more stringent, particularly in the case of imports of active principles from third countries, albeit without forgetting the requirement to distinguish monitoring of good manufacturing practices (and lastly of the quality of the active principles) from checking so-called falsity or falsification, which concerns any patent-holders.

Amendment 70

Proposal for a directive – amending act
Article 1 – point 16
Directive 2001/83/EC
Article 111b – paragraph 3

Text proposed by the Commission
3. The Commission, in cooperation with the Agency and competent authorities of the Member States, shall verify regularly whether the conditions set out in paragraph 1 are fulfilled. The first verification shall take place no later than 3 years after the country has been listed in accordance with paragraph 1.

Amendment
3. The Commission, in cooperation with the Agency and competent authorities of the Member States, shall verify regularly whether the conditions set out in paragraph 1 are fulfilled. The first verification shall be conducted with a view to confirming compliance with the criteria set out in paragraph 1 and shall be followed by regular verifications at intervals of no less than three years.

Justification

In view of the exemption provided for in Article 51(2), the fact that the first inspection is scheduled to take place within three years of the third country being entered on the Article 111b list would mean that the products concerned would be placed on the EU market and distributed to the public without having been subjected to any form of checking.

Amendment 71

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

Text proposed by the Commission
The competent authorities shall issue the accreditation referred to in Articles 46(f) and 80(b) if the applicant can demonstrate that he is competent to carry out

Amendment
The competent authorities shall issue the accreditation referred to in Articles 46(f) and 80(b) if the applicant can demonstrate that he is competent to carry out
verification of compliance with good manufacturing practices or, in the case of wholesale distributors, good distribution practices.

verification of compliance with good manufacturing practices or, in the case of wholesale distributors, good distribution practices or, in the case of traders, good trading practices or, in the case of brokers, good brokering practices.

**Justification**

*To ensure the safety of pharmaceutical products, due account needs to be taken of all those working in the sector – not just wholesale distributors – all of whom need to be subject to a rigorous accreditation, verification and good-practice system. This must apply to parallel traders as well.*

**Amendment 72**

**Proposal for a directive – amending act**

**Article 1 – point 17**

Directive 2001/83/EC

Article 118b

**Text proposed by the Commission**

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.

**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, dissuasive and equivalent.

The Member States shall notify those provisions to the Commission by [insert concrete date 6 months after publication] at the latest and shall notify it without delay of any subsequent amendment affecting them.

**Justification**

*In order effectively to combat the counterfeiting of medicinal products, the Member States need both to adopt a set of effective, proportionate and dissuasive legal provisions and ensure that uniform penalties apply at European level. Given the major threat posed both to public health and the bond of trust between patients, pharmacists and producers, the provisions of this Directive need to be implemented extremely rapidly.*
Amendment 73

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

Text proposed by the Commission  
Amendment

Article 118ca

The Commission and the Member States shall cooperate closely with the Council of Europe on the establishment of a European Convention on the suppression of the falsification of medicinal products and trafficking in falsified medicines. The Convention covers the civil and criminal law aspects of falsification and trafficking of falsified medicinal products.

Justification

It has been noticed that the falsification of medicinal products has become an activity led by international criminal networks and it is not possible to tackle this public health issue only inside EU borders. Therefore, the European Union and Member States should support the signature and ratification of the new International Convention of the Council of Europe.

Amendment 74

Proposal for a directive – amending act  
Article 2 – paragraph 1

Text proposed by the Commission  
Amendment

1) Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [insert concrete date 18 months after publication] at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from [insert concrete date 18 months after

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publication + one day].

However, the Member States shall apply:

(a) the provisions necessary to comply with Article 1(4) in so far as it relates to Articles 46b(2)(b) and 46b(3) of Directive 2001/83/EC as amended by this Directive from [insert concrete date 24 months after publication];

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

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

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

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Justification

Even after the Directive comes into force, it is unlikely that any concrete measures will actually be in place for some years. As a result, interim measures should continue until the full measures can be put into place. These 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 75

Proposal for a directive – amending act
Article 2 – paragraph 2 a (new)

Text proposed by the Commission

2a. By ... [insert date: 12 months after publication], the Commission shall, in cooperation with the Agency and the Member State authorities, produce a qualitative and quantitative study of Internet sales of falsified medicinal products in Europe and, where appropriate, submit a legislative proposal seeking to protect the health of European citizens.

Justification

The increasingly wide availability of medicinal products on the Internet is a matter of considerable concern. With a view to protecting public health and before taking any legislative action, data need to be collected on the scale and seriousness of the problem in Europe.
**PROCEDURE**

<table>
<thead>
<tr>
<th>Title</th>
<th>Falsified medicinal products (amendment of Directive 2001/83/EC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Committee responsible</td>
<td>ENVI</td>
</tr>
<tr>
<td>Opinion by</td>
<td>ITRE</td>
</tr>
<tr>
<td>Date announced in plenary</td>
<td>19.10.2009</td>
</tr>
<tr>
<td>Rapporteur</td>
<td>Amalia Sartori</td>
</tr>
<tr>
<td>Date appointed</td>
<td>16.9.2009</td>
</tr>
<tr>
<td>Discussed in committee</td>
<td>15.10.2009, 27.1.2010</td>
</tr>
<tr>
<td>Date adopted</td>
<td>18.3.2010</td>
</tr>
<tr>
<td>Result of final vote</td>
<td>+: 51, -: 0, 0: 0</td>
</tr>
<tr>
<td>Members present for the final vote</td>
<td>Jean-Pierre Audy, Zigmantas Balčytis, Zoltán Balczó, Bentd Bendtsen, Jan Březina, Reinhard Bütkofer, Maria Da Graça Carvalho, Giles Chichester, Pilar del Castillo Vera, Lena Ek, Ioan Enciu, Adam Gierek, Norbert Glante, Fiona Hall, Jacky Hénin, Romana Jordan Cizelj, Sajjad Karim, Arturs Krišjānis Kariņš, Judith A. Merkies, Angelika Niebler, Jaroslav Paška, Herbert Reul, Teresa Riera Madurell, Michèle Rivasi, Paul Rübig, Amalia Sartori, Francisco Sosa Wagner, Britta Thomsen, Patrizia Toia, Evžen Tošenovský, Ioannis A. Tsoukalas, Claude Turmes, Marita Ulvskog, Vladimir Urutchev, Adina Ioana Valean, Kathleen Van Brempt, Alejo Vidal-Quadras, Henri Weber</td>
</tr>
<tr>
<td>Substitute(s) present for the final vote</td>
<td>Lara Comi, António Fernando Correia De Campos, Ilda Figueiredo, Andrzej Grzyb, Jolanta Emilia Hibner, Oriol Junqueras Vies, Ivailo Kalifin, Marian-Jean Marinescu, Vladko Todorov Panayotov, Frédérique Ries, Silvia-Adriana Țicău, Hermann Winkler</td>
</tr>
<tr>
<td>Substitute(s) under Rule 187(2) present for the final vote</td>
<td>Britta Reimers</td>
</tr>
</tbody>
</table>
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

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 substandard 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

(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

(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

(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.

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. 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

(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.

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.
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)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td>(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.</td>
<td></td>
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</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td>(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.</td>
<td></td>
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</tbody>
</table>

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

-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

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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</thead>
<tbody>
<tr>
<td>(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:</td>
<td>(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:</td>
</tr>
</tbody>
</table>

**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)

<table>
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<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tr>
<td>(ba) The manufacturing authorisation holder clearly indicates on the outer packaging when original safety features have been partly or fully removed or covered up;</td>
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</table>

**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**
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

<table>
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<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td>(b) the number of incidences of falsifications in third countries and within the Community;</td>
<td>(b) the number of incidences of falsifications worldwide, particularly within the Union;</td>
</tr>
</tbody>
</table>

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)
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.
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.

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)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td>The measures referred to in this paragraph shall take due account of at least all of the following:</td>
<td></td>
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<tr>
<td>(a) The cost-effectiveness of the system, in order to ensure that any measure that is applied is based on a cost-benefit analysis.</td>
<td></td>
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<tr>
<td>(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.</td>
<td></td>
</tr>
<tr>
<td>(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.</td>
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</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td>(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.</td>
<td>(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.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tbody>
<tr>
<td>The Member States shall lay down the</td>
<td>Without prejudice to the principle of</td>
</tr>
</tbody>
</table>

PE430.883v03-00 152/158 RR\430883EN.doc
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.

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
(-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

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

Amendment

(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

(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].

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

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<tr>
<th><strong>Title</strong></th>
<th>Falsified medicinal products (amendment of Directive 2001/83/EC)</th>
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<tr>
<td><strong>Committee responsible</strong></td>
<td>ENVI</td>
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<tr>
<td><strong>Opinion by</strong></td>
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<tr>
<td>Date announced in plenary</td>
<td>IMCO 19.10.2009</td>
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<tr>
<td><strong>Rapporteur</strong></td>
<td>Regina Bastos</td>
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<tr>
<td>Date appointed</td>
<td>14.9.2009</td>
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<tr>
<td><strong>Discussed in committee</strong></td>
<td>29.9.2009 4.11.2009 27.1.2010</td>
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<tr>
<td>Date adopted</td>
<td>17.3.2010</td>
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| **Result of final vote** | +: 30  
| | -: 0  
| | 0: 2 |
| **Substitute(s) present for the final vote** | Regina Bastos, Cornelis de Jong, Othmar Karas, Sylvana Rapti, Wim van de Camp |
**PROCEDURE**

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<td>ITRE 19.10.2009, IMCO 19.10.2009</td>
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<td>Rapporteur(s)</td>
<td>Marisa Matias 31.8.2009</td>
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<td>Date adopted</td>
<td>27.4.2010</td>
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<td>János Áder, Elena Oana Antonescu, Kriton Arsenis, Paolo Bartolozzi, Sandrine Bélier, Sergio Berlato, Martin Callanan, Nessa Childers, Chris Davies, Esther de Lange, Anne Delvaux, Bas Eickhout, Edite Estrela, Elisabetta Gardini, Julie Girling, Françoise Grossetête, Cristina Gutiérrez-Cortines, Satu Hassi, Dan Jørgensen, Karin Kadenbach, Christa Klaß, Holger Krahmer, Jo Leinen, Peter Liese, Linda McAvan, Radviš Morkūnaitė-Mikulienė, Miroslav Ouzký, Gilles Pargneaux, Antonia Parvanova, Mario Pirillo, Frédérique Ries, Anna Rosbach, Oreste Rossi, Dagmar Roth-Behrendt, Horst Schnellhardt, Richard Seeber, Theodoros Skylakakis, Catherine Soullie, Anja Weisgerber, Glenis Willmott, Sabine Wils, Marina Yannakoudakis</td>
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<td>Matthias Groote, Marisa Matias, Alojz Peterle, Michèle Rivasi, Crescenzio Rivellini</td>
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<td>Substitute(s) under Rule 187(2) present for the final vote</td>
<td>Søren Bo Søndergaard</td>
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