EUROPEAN PARLIAMENT 2009 - 2014

Committee on the Environment, Public Health and Food Safety

2008/0261(COD)

7.1.2010

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

Committee on the Environment, Public Health and Food Safety

Rapporteur: Marisa Matias

PR_COD_1am

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

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

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics.*** In the case of amending acts, passages in an existing provision that the Commission has left unchanged, but that Parliament wishes to amend, are highlighted in **bold**. Any deletions that Parliament wishes to make in passages of this kind are indicated thus: [...]. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). Suggested corrections of this kind are subject to the agreement of the departments concerned.

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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))

(Codecision 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 opinion of the Committee on Legal Affairs on the proposed legal basis,

– having regard to Rules 55 and 37 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 (A6-0000/2009),

1. Approves the Commission proposal as amended;

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. Notes that the wording of certain provisions of the proposed directive concerning the adoption of implementing measures will have to be adapted in the light of Articles 290 and 291 of the Treaty on the Functioning of the EU.

4. Instructs its President to forward its position to the Council and the Commission.

Amendment 1

Proposal for a directive – amending act
Citation 1

Text proposed by the Commission	*Amendment*
Having regard to the Treaty establishing the European Community, and in particular ***Article*** 95 thereof,	Having regard to the Treaty establishing the European Community, and in particular ***Articles*** 95 ***and 152*** thereof,

Or. en

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 2

Text proposed by the Commission	*Amendment*
(2) There is an alarming increase of medicinal products detected in the Community which are falsified in relation to their identity, history or source. These products usually contain sub-standard or falsified ingredients, or no ingredients or ingredients in the wrong dosage, including active ingredients, thus posing an important threat to public health.	(2) There is an alarming increase of medicinal products detected in the Community which are falsified in relation to their identity, history or source. These products usually contain sub-standard or falsified ingredients, or no ingredients or ingredients in the wrong dosage, including active ingredients, thus posing an important threat to public health ***and undermining public trust in medicinal products***.

Or. en

Justification

Falsified medicines can seriously undermine people's confidence in medicinal products.

Amendment 3

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

Text proposed by the Commission	*Amendment*
	(4a) This Directive is without prejudice to provisions concerning intellectual and industrial property rights and aims specifically to prevent falsified medicines from entering the legal distribution chain.

Or. en

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	*Amendment*
	(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.

Or. en

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)

Text proposed by the Commission	*Amendment*
	(4c) Medicines purchased over the internet from sites that conceal their actual physical address are estimated to be falsified in more than 50 % of the cases. 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.

Or. en

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)

Text proposed by the Commission	*Amendment*
	(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 should adopt measures to increase awareness among the general public on the risks related to purchasing medicinal products on the internet. Public awareness campaigns should inform citizens whether their internet pharmacy is officially registered and controlled by public authorities.

Or. en

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.

Amendment 7

Proposal for a directive – amending act
Recital 5

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

Or. en

Justification

Transporters are an important part in the distribution chain. The Commission attempts to put more emphasis on activities such as trading and brokering because these represent a real weakness as they are not yet associated with accountability and liability. It is thus important to explicitly include both traders and brokers.

Amendment 8

Proposal for a directive – amending act
Recital 7

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

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

Or. en

Justification

The impact of the envisaged safety features should be assessed after five years. This should allow for an evaluation of their contribution to the reduction of falsified medicines in the legal supply chain. This evaluation should include the possibility to extend the EU wide

harmonised safety features to non-prescriptive medicines. At this point in time it is reasonable and adequate to limit the application of safety features to prescription medicines. Unnecessary regulatory burden should be avoided, to prevent higher costs for European citizens.

Amendment 9

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

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

Or. en

Justification

To implement a risk-based approach, safety features have to be categorised according to the risk involved in the falsification of the different types of medicinal products. This amendment ensures that this is possible following a technology-neutral stance. Moreover, to ensure original and new safety features used by re-packagers are indeed equivalent, this directive has to introduce the different categories of equivalent features according to specific criteria.

Amendment 10

Proposal for a directive – amending act
Recital 8

Text proposed by the Commission	*Amendment*
(8) Any actor in the supply chain who packages medicinal products has to be a holder of a manufacturing *authorisation*. In order for the safety features to be effective, the manufacturing *authorisation* holder should only be permitted to remove,	(8) Any actor in the supply chain who packages medicinal products, ***or makes changes to the labelling or packaging***, has to be a holder of a manufacturing *authorisation*. In order for the safety features to be effective, the manufacturing

replace or cover these features under strict conditions.	*authorisation* holder should only be permitted to remove, replace or cover these features under strict conditions.

Or. en

Justification

Repackagers should be subject to the same standards of conduct as the original manufacturer and should ensure the same level of product integrity. They should ensure that no falsified medicines enter the supply chain as a result of their intervention. Because of the nature of their activities, repackagers not only have essential duties to patients and health professionals, but also owe a duty of care to the original manufacturer and the marketing authorisation holder whose products they manipulate.

Amendment 11

Proposal for a directive – amending act
Recital 13

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

Or. en

Justification

Falsified excipients also pose an important risk to health and should be included in the scope of this directive. They can cause severe incidents (in Haiti 89 people were reported dead in 1995 and at least 59 children in 1996; in India 30 children died in 1998).

Amendment 12

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

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

Or. en

Justification

While routine inspections usually give a low yield in detected falsified medicinal products, risk-analysis and targeted inspections are much more effective.

Amendment 13

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

Text proposed by the Commission	*Amendment*
	(15a) Member States should impose effective sanctions for acts related to falsified medicines. These sanctions should at least be equivalent to those typically applied for illegal acts related to narcotics. The Commission may issue general guidelines for such an effective criminal sanctions regime. Specific provisions should be included in Directive 2001/83/EC for enforcing the new safety feature requirements.

Or. en

Justification

Enforcement is crucial in this field. Sanctions will be a useful disincentive tool. For this to be efficient, an equivalent sanction regime through the EU is welcome to ensure that criminals do not choose a Member State with a less strict sanctions regime. Extending the scope of

criminal sanctions to include acts relating to falsified medicines and specifying enforcement provisions for the new safety feature requirements would provide patients with more effective protection.

Amendment 14

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

Text proposed by the Commission	*Amendment*
	(15b) The falsification of medicines is a global problem, requiring effective and enhanced international coordination and cooperation in order to ensure that anti-falsification strategies are more effective.

Or. en

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 15

Proposal for a directive – amending act
Recital 18

Text proposed by the Commission	*Amendment*
(18) Since the objective of ensuring the functioning of the internal market for medicinal products, while ensuring a high level of protection of public health against medicinal products which are illegal in view of a falsified identity, history or source, cannot be sufficiently achieved by the Member States, as they cannot adopt individually harmonised measures applicable in the Community and can be better achieved by action at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is	(18) Since the objective of ensuring the functioning of the internal market for medicinal products, while ensuring a high level of protection of public health against medicinal products which are illegal in view of a falsified identity, history or source, cannot be sufficiently achieved by the Member States, as they cannot adopt individually harmonised measures applicable in the Community and can be better achieved by action at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. ***Stricter safety measures already in place in Member States may be maintained.*** In accordance with the

necessary in order to achieve that objective.	principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

Or. en

Justification

Member States must have the possibility to maintain stricter legislation.

Amendment 16

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	*Amendment*
	(-1) In Article 1, the following point 2a is inserted after point 2:
	(2a) Falsified medicinal product:
	Any medicinal product with a false representation of:
	a) its identity, including its packaging and labelling, name, composition in respect of any of its components and strength; and/or
	b) its source, including the manufacturer, country of manufacturing, country of origin, marketing authorisation holder; and/or
	c) its history, including the records and documents relating to distribution channels.
	This definition is not related to infringements of legislation on intellectual and industrial property rights or patent rights.

Or. en

Justification

A definition on falsified medicinal products is needed, as there is currently confusion on what

it entails. 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 17

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

Text proposed by the Commission	*Amendment*
	(-1a) In Article 1, the following point 2b is inserted after point 2a:
	(2b) Active Pharmaceutical Ingredient: 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 other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

Or. en

Justification

A definition on Active Pharmaceutical Ingredients is needed. The definition is in accordance with the Good Manufacturing Practices Guidelines.

Amendment 18

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

Text proposed by the Commission	*Amendment*
	(-1b) In Article 1, the following point 3a is inserted after point 3:
	(3a) Excipient:
	A substance or compound, other than the active pharmaceutical ingredient and packaging materials, that is intended or designated to be used in the manufacture of a medicinal product.

Or. en

Justification

A definition on excipients is needed. An excipient is an essential part of the finished medicinal product which is absorbed by the body, therefore entailing risks for public health if falsified.

Amendment 19

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

Text proposed by the Commission	*Amendment*
‘17a. *Trading **of medicinal products:***	‘17a. *Trading:*
'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.'	'All activities consisting of negotiating independently on behalf of another person the sale or the purchase of medicinal products***, active pharmaceutical ingredients or excipients***, or billing medicinal products***, active pharmaceutical ingredients or excipients,*** apart from supplying ***them*** to the public, and not falling under the definition of wholesale distribution.'

Or. en

Justification

Trading does not apply only to medicinal products but also to APIs and excipients; it is thus important to make an explicit reference in the text.

Amendment 20

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

Text proposed by the Commission	*Amendment*
	(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.

Or. en

Justification

A distinction between trading and brokering is necessary.

Amendment 21

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

Text proposed by the Commission	*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.'	'(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***.'

Or. en

Justification

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

Amendment 22

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	*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 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.'	'(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 ***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 with good manufacturing practices by himself or through a body accredited for this purpose by the competent authority of a Member State. ***Excipients shall be subject to the same conditions of good manufacturing and distribution practices.'***

Or. en

Justification

Excipients can also be falsified and can thus also result in risks for public health. They should therefore also be subject to the same conditions as the active substances.

Amendment 23

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	*Amendment*
	(ba) The following point (ga) is added:
	'(ga) to verify the authenticity and quality of the active substances and the excipients.'

Or. en

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 24

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

Text proposed by the Commission	*Amendment*
(a) they have been manufactured ***by applying*** standards of good manufacturing practice at least equivalent to those laid down by the Community; and	(a) they have been manufactured ***in plants which comply with EU good manufacturing practices or*** standards of good manufacturing practice at least equivalent to those laid down by the Community. ***Compliance with good manufacturing practices should be ascertained by inspections;*** and

Or. en

Justification

Each plant in a third country manufacturing APIs intended for European medicinal products should be inspected.

Amendment 25

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	*Amendment*
(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***.	(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 ***regular*** control and ***efficient*** enforcement ***of good manufacturing practices*** ensuring ***a protection of public health at least equivalent to that in the Community, and that in the event of findings related to non-compliance, this information shall be supplied by the exporting third country to the Community without any delay.***

Or. en

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 26

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

Text proposed by the Commission	*Amendment*
'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.'	'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 shall be adopted in the form of detailed guidelines.'

Or. en

Amendment 27

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

Text proposed by the Commission	*Amendment*
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.	Importers**,** manufacturers ***and distributors*** of active substances used as starting materials ***and excipients*** established in the Community shall notify their address to the competent authority of the Member State where they are established.

Or. en

Amendment 28

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. ***For generic medicines, subject to medicinal prescription as defined in Title VI, safety features are mandatory if the Commission considers this to be necessary on a risk basis approach in accordance with Article 54a(4).***'

Or. en

Justification

*For prescription medicines there should be mandatory safety features. Generics should be included on a risk assessment basis***.**

Amendment 29

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

Or. en

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 30

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

Text proposed by the Commission	*Amendment*
	Safety features shall be considered equivalent when they offer the same level of efficiency for ascertaining identification, authentication, traceability and absence of tampering, as well as the same level of technical difficulty for duplication as the original safety feature.

Or. en

Justification

Repackagers should be subject to the same standards of conduct as the original manufacturer and should ensure the same level of product integrity.

Amendment 31

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*
	(ea) the risk to public health.

Or. en

Justification

Public health protection is essential.

Amendment 32

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

Text proposed by the Commission	*Amendment*
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.	On the basis of these criteria, the requirements referred to in points (a) ***to (c)*** of paragraph (1) of this Article may be waived for certain ***generic medicinal*** products or ***generic*** product categories;

Or. en

Amendment 33

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

Text proposed by the Commission	*Amendment*
The measures referred to in this paragraph shall take due account of the legitimate	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***.	interests to protect information of a commercially confidential nature.

Or. en

Justification

The legislation is not meant to protect the industrial and commercial property rights, but is meant to protect public health. Commercially confidential information should indeed be protected.

Amendment 34

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

Text proposed by the Commission	*Amendment*
	(-a) In Article 80 the following point (ca) is added after point (c):
	(ca) they must check whether the medicinal products they have purchased are not falsified by authenticating the safety feature on the outer packaging;

Or. en

Justification

Every actor involved in the legal supply chain must ascertain the authenticity of the medicinal products they have in their possession; this is the only way to prevent the changing of hands of medicinal products to become a point of entry of falsified medicinal products into the legal supply chain.

Amendment 35

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	*Amendment*
‘(e) they must keep records either in the	‘(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:	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,	– date,
– name of the medicinal product,	– name of the medicinal product,
– quantity received, supplied ***or*** traded,	– quantity received, supplied***,*** traded ***or brokered***,
– name and address of the supplier or consignee, as appropriate***;***	– name and address of the supplier or consignee, as appropriate***,***
	- batch number,
	- registration number of the marketing authorisation;

Or. en

Justification

Brokering should be included as it is even less regulated and unaccountable than trading. This Directive should remedy the current vacuum by including brokering and thus tightening the functioning of the legal supply chain.

Amendment 36

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

Text proposed by the Commission	*Amendment*
(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***:	(i) they must inform the competent authority of products they receive which they identify as infringing, or they suspect of infringing***, Article 6(1) of this Directive;***:
– Article 6(1) of this Directive;	Moreover, in cases where these infringements or suspected infringements relate to a falsified medicinal product, the holder of ***both the manufacturing authorisation and*** the marketing authorisation shall be informed.'
– trademark-holder's rights under Community law, as provided for by	

Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trademark or under the law of the Member State where the product has been received.

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.'

Or. en

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.

Amendment 37

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

Text proposed by the Commission	*Amendment*
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.	
	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 in the Istanbul Convention as regards the supply of medicines 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, or on computer, or in any other form, giving for any 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;

Or. en

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 38

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

Text proposed by the Commission	*Amendment*
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	Persons trading ***or brokering*** medicinal products shall ensure that the traded ***or brokered*** 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

out in ***Article 80(d)*** to (h) shall apply.	Directive. In addition, the requirements set out in ***Article 80(b)*** to (h) shall apply.

Or. en

Justification

Notifications are not enough to ensure that traders and brokers comply with certain safety standards. Moreover, they have to be accountable for their actions and be held responsible in cases of counterfeits; holding such an authorisation would achieve these goals.

Amendment 39

Proposal for a directive – amending act
Article 1 - point 14 a (new)
Directive 2001/83/EC
Title VII a (new) - Article 85 c (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. The Commission shall adopt a Community 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 a registered 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.
	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).
	2. Member States shall take the appropriate measures to ensure that all

registered pharmacy internet sites linked to pharmacies within their territory display the Community logo referred to in paragraph 1 and to prevent non-registered pharmacy internet sites from using the logo and linking to the central website referred to in paragraph 1.

Or. en

Justification

Internet is the largest point of entry of falsified medicinal products into the EU and should thus be included in this Directive.

Amendment 40

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
	1. The Commission shall 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;
	- easily accessible lists of accredited e-pharmacies
	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).

Or. en

Justification

It is important to increase the public awareness on the dangers of falsified medicines.

Amendment 41

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

Text proposed by the Commission	*Amendment*
	(14c) The following Article 85e is inserted::
	Article 85 e
	Member States shall ensure that the internet is continuously monitored by a designated body with regard to the selling of medicinal products and shall take legal actions in the event of non-compliance with this Directive.

Or. en

Justification

It is important to track down unlawful internet pharmacies to dismantle criminal networks falsifying medicinal products.

Amendment 42

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

Text proposed by the Commission	*Amendment*
	(aa) Article 111, paragraph 1, subparagraph 2 is replaced by the following:
	The competent authority *shall* also carry

out *routine or* unannounced inspections at the premises of manufacturers, *distributors or importers* of active substances used as starting materials, at the premises of marketing authorisation holders *and at the premises of manufacturers or importers or distributors of excipients,* whenever it considers that there are grounds for suspecting non-compliance with the principles and guidelines of good manufacturing practice referred to in Article 47. These inspections may also be carried out at the request of a Member State, the Commission or the Agency.

The competent authority 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.

Or. en

Justification

Pooling together resources from the 27 Member States as well as from the United States, Canada and Switzerland under the coordination of EMEA will enable the inspection of every single API manufacturer situated outside the Community and thus effectively combat API falsification.

Amendment 43

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) 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 where the controls referred to in Article 112 have not been carried out, *or when the inspections referred to in Article 111 demonstrate lack of compliance with Good Manufacturing Practices or Good Distribution Practices.*

Or. en

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 44

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.

Or. en

Justification

Enforcement is crucial in this field. Sanctions will be a useful disincentive tool. For this to be efficient an equivalent sanction regime throughout the EU would be welcome to ensure that criminals do not choose a Member State with a less strict sanctions regime.

Amendment 45

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, EMEA and the competent authorities in the Member States 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, EMEA and the competent authorities in the Member States shall report annually to this network on the actions they have undertaken.

Or. en

Justification

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

Amendment 46

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

Text proposed by the Commission	*Amendment*
Member States, in applying this Directive, shall take the necessary measures to ensure cooperation between competent authorities for medicinal products and customs authorities.	Member States, in applying this Directive, shall take the necessary measures to ensure cooperation between competent authorities for medicinal products and customs authorities***; Member States shall also ensure that customs officers receive***

proper training for the identification of falsified medicinal products.

Or. en

Justification

Customs officers' training is an efficient tool to combat the falsification of medicines. Therefore it is important that adapted trainings will be given to customs professionals.

Amendment 47

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, along with the Member States, shall develop concerted actions with the competent authorities of third countries to inspect transit zones where medicinal products are stocked.

Or. en

Justification

A particular attention should be granted to the surveillance of transit zones in cooperation with the competent authorities of the concerned third countries.

Amendment 48

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 medicines, covering the civil and criminal law aspects of the problem.

Or. en

Justification

It has been noticed that the falsification of medicines 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 49

Proposal for a directive – amending act
Article 2

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.	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 ***18*** months after publication + one day].	They shall apply those provisions from [insert concrete date ***12*** months after publication + one day].
However, the Member States shall apply:	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];	(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 ***48*** 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	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.	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.	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.

Or. en

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 50

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

Text proposed by the Commission	*Amendment*
	No later than five years of the date of 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 medicines in the legal supply chain in Europe. The report should include an assessment of the safety features to other categories of medicines, including medicinal products not subject to medical prescription as defined in Title VI of Directive 2001/83/EC. If appropriate the Commission shall present proposals to the European Parliament and the Council.

Or. en

Justification

Certain non-prescription medicinal products are vulnerable to falsification. Therefore the Commission must in the review of this Directive consider the possibility to include them in the scope on a risk basis approach.

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

chain. 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 EMEA 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, EMEA 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.