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Committee on the Environment, Public Health and Food Safety

2008/0261(COD)

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AMENDMENTS
201 - 294

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

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

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

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Amendment 201
Jorgo Chatzimarkakis

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, ***which, because of their particular characteristics, are not suitable for marketing by wholesalers and pharmacies and are therefore supplied by the manufacturer directly to clinics, where they are administered directly to patients*** – subject to medical prescription as defined in Title VI. ***For generic and well-established use medicines, subject to medical prescription as defined in Title VI, safety features are mandatory if the Commission considers this to be necessary on a risk-based approach in accordance with Article 54a(4). The risk-based approach shall be performed with a so-called opt-in procedure.***

Or. en

Justification

Certain products can only be administered in-hospital, rendering the application of safety features of little benefit to the patient, and possibly delaying patient-access to the product. Goods of a low-price segment, rarely counterfeited, could in principal be exempt from the safety feature requirement - unless price or past incidents call for safety labelling. The opt-in procedure disregards the financial burdens of SMEs with few production lines.

Amendment 202
Andres Perello Rodriguez

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 is 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 is possible to ascertain identification ***and*** authenticity and ***make it possible to detect any tampering with the packaging*** of medicinal products other than radiopharmaceuticals ***which are at risk of being falsified or tampered with.*** . ***The decision to require these safety features for medicinal products or categories thereof shall be based on a risk assessment carried out under the provisions of paragraph (4) of Article 54a’.***

Or. es

Justification

There is no justification for automatically limiting safety feature requirements to prescription medicinal products alone. Furthermore, this is not borne out by previously detected cases of falsified medicinal products. Effective public protection requires an approach based on the risk concerning any given type of medicinal product.

Amendment 203
Sylvana Rapti

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	(o) safety features making it possible to

ascertain identification authenticity of medicinal products, other than radiopharmaceuticals***, subject to medical prescription as defined in Title VI***.	ascertain identification authenticity of medicinal products, other than radiopharmaceuticals.

Or. en

Justification

It is important to guarantee the authenticity of all medicines including prescription and non-prescription medicines. All medicines are special products that when counterfeited could have a disastrous effect on human health. Moreover there is a growing trend at national and at European level towards switching medicines from prescription to non-prescription status.

Amendment 204
Michail Tremopoulos, Michèle Rivasi

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, as defined in Title VI.

Or. en

Justification

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

Amendment 205
Paolo Bartolozzi

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.’

Or. it

Justification

It is important to guarantee the authenticity of all categories of pharmaceuticals, whether or not they are subject to prescription. All pharmaceuticals are special products which, if counterfeited, may have a disastrous impact on human health. Moreover, the phenomenon of switching of pharmaceuticals – i.e. prescription medicines becoming OTC medicines – is becoming increasingly widespread in Europe. Nor should it be forgotten that counterfeiting non-prescription medicines can also be very profitable.

Amendment 206
Linda McAvan

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, ***and other products that are subject to a managed distribution chain,*** subject to medical prescription as defined in Title VI.

Or. en

Justification

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

Amendment 207
Thomas Ulmer

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 ***and*** authenticity of medicinal products, other than radiopharmaceuticals, subject to medical prescription as defined in Title VI.’

Or. de

Justification

The issue of whether a specific medicinal product must be traceable through the entire supply chain from manufacturer to pharmacy should be a matter for the Member States to decide each on their own responsibility. Traceability is not required for the detection of falsified medicinal products. Such a function would in addition involve substantial additional expenditure which would give rise to disproportionate costs for many small and medium-sized undertakings, in particular.

Amendment 208
Pilar Ayuso

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 ***unique*** identification, authenticity and traceability of medicinal products, other than radiopharmaceuticals, subject to medical prescription as defined in Title VI.

Or. en

Justification

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

Amendment 209
Peter Liese, Thomas Ulmer

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***, where the Commission decides that there is a risk that a medicinal product will be counterfeited due to the price or past incidences***.

Or. en

Justification

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

Amendment 210
Marina Yannakoudakis

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. ***This point shall apply to all generic medicines subject to medicinal prescription.***

Or. en

Justification

For prescription medicines, there should be mandatory safety features and in order to ensure the safety of patients all generics should be included within the scope of this legislation.

Amendment 211
Françoise Grossetête, Frédérique Ries

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 medicinal prescription as defined in Title VI. ***36 months at the latest after entry into force of this Directive, the traceability procedure for medicinal products should be harmonised at EU level. Hence, each medicinal product should be unequivocally identified by means of a serial number on its individual packaging.’***

Or. fr

Justification

It is important to harmonise traceability procedures for medicinal products.

Amendment 212
Jorgo Chatzimarkakis, Jo Leinen

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. ***Those safety features shall be applied without discrimination through marketing channels.***

Or. en

Amendment 213
Thomas Ulmer

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. ***Homeopathic medicinal products are exempt in accordance with Article 1(5). Where a medicinal product, such as a homeopathic medicinal product, is not subject to medical prescription, the safety features may be applied on a voluntary basis.***

Or. en

Justification

An application to homeopathic medicines would be disproportionate. The Commission reported no cases of falsified non-prescription medicines in the legal supply chain. These products would not be profitable for counterfeiters because they are low price product with in most cases low sales volumes per product.

Amendment 214
Vittorio Prodi

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

Text proposed by the Commission	*Amendment*
	(oa) details of the product source (country, firm, production site) with a view to ensuring the traceability of the active pharmaceutical ingredient and

where the active ingredient is produced outside the European Union, an indication of the country of origin on the medicinal product package.

Or. en

Justification

The traceability is mandatory in the food industry, where the consumer is entitled to know where the chosen product comes from. This choice should be given for medicinal products too, also in order to fight counterfeits and increase transparency in the whole sector, from API production to the pharmacy/consumer.

Amendment 215
Andres Perello Rodriguez

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

Text proposed by the Commission	*Amendment*
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:	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:

Or. es

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 216
Andres Perello Rodriguez

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

Text proposed by the Commission	*Amendment*
a) verify authenticity ***by assessing overt, covert or forensic devices;***	a) verify authenticity;

Or. es

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 217
Françoise Grossetête

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

Text proposed by the Commission	*Amendment*
(a) verify authenticity by assessing overt***, covert, or forensic*** devices;	(a) verify authenticity by assessing overt devices;

Or. fr

Justification

Currently, only the marketing authorisation holder and the enforcement and regulatory authorities are authorised to know of the existence of covert or forensic devices on packaging. For security reasons, it appears essential to ensure that this information is not divulged to anyone other than the above stakeholders.

Amendment 218
Pilar Ayuso

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	*Amendment*
(b) identify individual packs;	(b) identify individual packs ***by means of a unique machine-readable serialisation code***;

Or. en

Justification

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

Amendment 219
Peter Liese

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

Or. en

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 220
Antonyia Parvanova

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

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

Or. en

Justification

In the framework of an optimal security required by all, the medicinal product should not be subject to particular handling. From the moment a medicinal product is packaged by the marketing authorisation holder, it should remain intact till the delivery to the patient following the example of the current requirements in the framework of the European strategy on food safety.

Amendment 221
Oreste Rossi

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

Text proposed by the Commission	*Amendment*
(2) The safety features referred to in point (o) of Article 54 ***shall not be partly or fully removed or covered-up***, unless ***the following conditions are fulfilled:***	*2.* ***Member States shall ensure that the holder of a manufacturing authorisation does not exchange, partly or fully remove, or cover up*** the safety features referred to in point (o) of Article 54, unless ***that holder has a marketing authorisation for the relevant medicinal product in***

accordance with Article 6(1) or has obtained written authorisation from the marketing authorisation holder.

Or. en

Justification

If products are repackaged - other than by the original manufacturer, the MA holder of the original product, other companies within their group or a third party contracted to repack by any of them – the effectiveness of any anti-counterfeit features incorporated into the original packaging is seriously compromised. Repackaging should therefore be prohibited. There is one important exception, which is preserving the ability of a duly authorized sponsor of a clinical trial to repackage medicines in accordance with the clinical study protocol

Amendment 222
Françoise Grossetête

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

Text proposed by the Commission	*Amendment*
2. The safety features referred to in point (o) of Article 54 shall not be ***partly or fully*** removed or covered-up***, unless the following conditions are fulfilled***:	2. The safety features referred to in point (o) of Article 54 shall not be removed or covered-up. ***If*** the following conditions are fulfilled ***and justified for public health reasons, the manufacturing authorisation holder may place the original medicinal product inside another package while preserving intact its original safety feature.***

Or. fr

Justification

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

Amendment 223
Oreste Rossi

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

Text proposed by the Commission	*Amendment*
(a) The manufacturing authorisation holder verifies, prior to partly or fully removing or covering-up the safety feature, the authenticity of the product;	***deleted***

Or. en

Justification

If products are repackaged - other than by the original manufacturer, the MA holder of the original product, other companies within their group or a third party contracted to repack by any of them – the effectiveness of any anti-counterfeit features incorporated into the original packaging is seriously compromised. Repackaging should therefore be prohibited. There is one important exception, which is preserving the ability of a duly authorized sponsor of a clinical trial to repackage medicines in accordance with the clinical study protocol

Amendment 224
Antonyia Parvanova

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

Text proposed by the Commission	*Amendment*
(a) The manufacturing authorisation holder verifies, prior to partly or fully removing or covering-up the safety feature, the authenticity of the product;	***deleted***

Or. en

Justification

In the framework of an optimal security required by all, the medicinal product should not be subject to particular handling. From the moment a medicinal product is packaged by the marketing authorisation holder, it should remain intact till the delivery to the patient following the example of the current requirements in the framework of the European strategy on food safety.

Amendment 225
Françoise Grossetête

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

Text proposed by the Commission	*Amendment*
(a) The manufacturing authorisation holder ***verifies, prior to partly or fully removing or covering-up*** the safety feature, the authenticity of the product;	(a) The manufacturing authorisation holder ***must leave*** the safety feature ***relating to the identification,*** authenticity ***and traceability*** of the product ***visible and usable***;

Or. fr

Justification

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

Amendment 226
Oreste Rossi

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	*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 uninterrupted traceability of the medicinal product, and without opening the immediate packaging as defined in Article 1(23);	***deleted***

Or. en

Justification

If products are repackaged - other than by the original manufacturer, the MA holder of the original product, other companies within their group or a third party contracted to repack by any of them – the effectiveness of any anti-counterfeit features incorporated into the original packaging is seriously compromised. Repackaging should therefore be prohibited. There is one important exception, which is preserving the ability of a duly authorized sponsor of a clinical trial to repackage medicines in accordance with the clinical study protocol.

Amendment 227
Antonyia Parvanova

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	*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 uninterrupted traceability of the medicinal product, and without opening the immediate packaging as defined in Article 1(23);	***deleted***

Or. en

Justification

In the framework of an optimal security required by all, the medicinal product should not be subject to particular handling. From the moment a medicinal product is packaged by the marketing authorisation holder, it should remain intact till the delivery to the patient following the example of the current requirements in the framework of the European strategy on food safety.

Amendment 228
Françoise Grossetête

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	*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 uninterrupted traceability of the medicinal product***, and without opening the immediate packaging as defined in Article 1(23)***;	(b) The manufacturing authorisation holder complies with point (o) of Article 54. ***Under no circumstances may he replace*** the safety feature ***applied to the original container, which enables the*** identification, authenticity and uninterrupted traceability of the ***initial*** medicinal product ***to be ascertained***;

Or. fr

Justification

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

Amendment 229
Andres Perello Rodriguez

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	*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 uninterrupted traceability*** of the medicinal product, and without opening the immediate packaging as defined in Article 1(23);	(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 opening the immediate packaging as defined in Article 1(23);

Or. es

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 230
Thomas Ulmer

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	*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 uninterrupted traceability*** of the medicinal product, and without opening the immediate packaging as defined in Article 1(23);	(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 ***and*** authenticity of the medicinal product, and without opening the immediate packaging as defined in Article 1(23);

Or. de

Justification

The issue of whether a specific medicinal product must be traceable through the entire supply chain from manufacturer to pharmacy should be a matter for the Member States to decide each on their own responsibility. Traceability is not required for the detection of falsified medicinal products. Such a function would in addition involve substantial additional expenditure which would give rise to disproportionate costs for many small and medium-sized undertakings, in particular.

Amendment 231
Dagmar Roth-Behrendt

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	*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 uninterrupted traceability of the medicinal product, and without ***opening*** the immediate packaging as defined in Article 1(23);	(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 ***any changes to*** the immediate packaging as defined in Article 1(23) ***other than for the purposes set out in Article 55***;

Or. en

Justification

Any changes to the immediate packaging shall be forbidden (including the cutting of blisters). Cut-up blisters do not contribute to the trust of the patients in the medicinal product.

Amendment 232
Horst Schnellhardt

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	*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 uninterrupted traceability of the medicinal product, and without opening the immediate packaging as defined in Article 1(23);	(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). ***To this effect, the manufacturing authorisation holder shall produce a new outer carton replicating all relevant product and trademark information and subject to carrying safety features as required by Article 54(o); original cartons shall be destroyed;***

Or. de

Justification

Mandatory reboxing will increase patient safety. The introduction of the possibility of reboxing puts the focus on public health and patient safety rather than on the trademark rights of manufacturers.

Amendment 233
Bogusław Sonik

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	*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 uninterrupted traceability of the medicinal product, and without opening the immediate packaging as defined in Article 1(23);	(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); ***To this effect, the manufacturing authorisation holder shall produce a new outer carton replicating all relevant product and trademark information and subject to carrying safety features as required by Article 54(o); original cartons shall be destroyed;***

Or. en

Justification

Mandatory reboxing will improve patient compliance and confidence. Reboxing involves the disposal and controlled destruction of the original outer packaging, which is replaced by a new outer package designed by the parallel distributor (sourced from a GMP approved packaging material producer). The introduction of the possibility of reboxing puts the focus on public health and patient safety rather than on the trademark rights of manufacturers.

Amendment 234
Anja Weisgerber, Thomas Ulmer

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	*Amendment*
	Safety features shall be considered equivalent where they are equally efficient in identifying, authenticating, tracing and preventing tampering with medicinal product, and where they are equally technical difficult to duplicate. This paragraph shall also apply to the removal, replacement or covering up of new safety features unless the primary safety feature is a covert one and cannot be recognised.

Or. en

Justification

This amendment is an addition to amendment 30 by the rapporteur. To ensure that parallel traders can indeed apply equivalent safety features during the process or 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 235
Judith A. Merkies

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	*Amendment*
	Safety features shall be considered equivalent where they are equally efficient in identifying, authenticating, tracing and preventing tampering with medicinal products, and where they are equally technical difficult to duplicate. This paragraph shall also apply to the removal, replacement or covering up of new safety features.

Or. en

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.

Amendment 236
Pilar Ayuso

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	*Amendment*
	Safety features shall be considered equivalent where they are equally efficient in identifying, authenticating, tracing and preventing tampering with medicinal products, and where they are equally technical difficult to duplicate.

Or. en

Justification

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

Amendment 237
Oreste Rossi

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

Text proposed by the Commission	*Amendment*
(c) The replacement of the safety feature	***deleted***

is subject to supervision by the competent authority.

Or. en

Justification

If products are repackaged - other than by the original manufacturer, the MA holder of the original product, other companies within their group or a third party contracted to repack by any of them – the effectiveness of any anti-counterfeit features incorporated into the original packaging is seriously compromised. Repackaging should therefore be prohibited. There is one important exception, which is preserving the ability of a duly authorized sponsor of a clinical trial to repackage medicines in accordance with the clinical study protocol.

Amendment 238
Antonyia Parvanova

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

Text proposed by the Commission	*Amendment*
(c) The replacement of the safety feature is subject to supervision by the competent authority.	***deleted***

Or. en

Justification

In the framework of an optimal security required by all, the medicinal product should not be subject to particular handling. From the moment a medicinal product is packaged by the marketing authorisation holder, it should remain intact till the delivery to the patient following the example of the current requirements in the framework of the European strategy on food safety.

Amendment 239
Françoise Grossetête

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

Text proposed by the Commission	*Amendment*
(c) ***The replacement of the safety feature is subject to supervision by the competent authority.***	(c) ***The manufacturing authorisation holder is responsible for all the activities involved in the acts described in point 2.***

Or. fr

Justification

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

Amendment 240
Frédérique Ries

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*
	(c a) Manufacturing authorisation holders clearly indicate on the outer packaging where the original safety features have been partly or fully removed or covered up.

Or. en

Justification

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

Amendment 241
Anja Weisgerber, Thomas Ulmer

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

Or. en

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 242
Judith A. Merkies

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

Or. en

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 243
Holger Krahmer

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 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***.	*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***.

Or. en

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 244
Frédérique Ries

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 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.	*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 or consumers*** caused by medicinal products which are falsified in terms of their identity.

Or. en

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 245
Andres Perello Rodriguez

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 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.	(3) Manufacturing authorisation holders ***engaged in the activities referred to in paragraph (2) of Article 54a*** 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.

Or. es

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 246
Theodoros Skylakakis

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	*Amendment*
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.	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. ***Before specific measures are proposed in accordance with point (o) of Article 54, 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.

Or. el

Justification

A number of options exist regarding the safety features which must be used, as well as pilot projects undertaken at national level evaluating the benefits of these features. Before selecting a specific safety feature, the Commission should carry out an impact assessment in order to evaluate the pros and cons of existing safety features, the results of the pilot projects under consideration and the effectiveness of the proposed features compared with existing national arrangements.

Amendment 247
Thomas Ulmer

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	*Amendment*
(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.	*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. ***Before a specific measure is proposed in accordance with point (o) of Article 54, the Commission shall carry out a public impact assessment in order to evaluate the costs and benefits of existing safety features and consult the parties involved in the implementation and use of such safety features.***

Or. en

Justification

There are a number options in respect of safety features to be used to authenticate medicines, such as one dimensional code, data matrix, seals, holograms, RFID etc. There are also pilot projects undertaken at national level evaluating the benefits of those features. Before selecting a specific safety feature, the Commission should carry out an impact assessment in order to evaluate the pros and cons of all safety features currently available on the market, and it should consider existing experiences and results of performed pilot projects.

Amendment 248
Crescenzio Rivellini

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	*Amendment*
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.	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. ***Before formulating a specific proposal, and in order to choose the option that best matches citizens' needs, the Commission shall perform an impact assessment of the costs and benefits of the anti-counterfeiting systems currently in force and seek the views of those involved in the implementation and use of such authenticating seals.***

Or. it

Justification

As things currently stand, there are various options as regards anti-counterfeiting technologies, such as one-dimensional codes, data matrices, seals, holograms and RFID. Pilot projects are currently under way at national level to assess their respective benefits. 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 currently available on the market, and should take account of past experience.

Amendment 249
Marisa Matias

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	*Amendment*
(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.	*4.* The Commission shall adopt***, by means of delegated acts in accordance with Article 121a and subject to the conditions of Articles 212b and 121c,*** the measures necessary for the implementation of point (o) of Article 54 and of paragraphs (1) and (2) of this Article.

Or. en

Justification

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

Amendment 250
Michail Tremopoulos, Michèle Rivasi

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	*Amendment*
(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.	*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. ***Before adopting such measures, the Commission shall commission an independent impact assessment to evaluate the costs and benefits of different safety measures, and undertake a public consultation of all relevant stakeholders, including independent patient and consumer organisations.***

Or. en

Justification

Further increases in the prices of pharmaceutical products would be a significant financial burden for the health insurers and patients. It is therefore important that the cost-effectiveness of the safety features to be used is assessed so as to identify the measure with the highest benefit at the relatively lowest cost. Similarly, a public consultation should take place before any measures are adopted.

Amendment 251
Paolo Bartolozzi

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

Text proposed by the Commission	*Amendment*
	Before formulating a specific proposal, the Commission shall perform an impact assessment of the costs and benefits of the anti-counterfeiting systems currently in force and seek the views of those involved in the implementation and use of such authenticating seals.

Or. it

Justification

There are various options as regards anti-counterfeiting technologies, such as one-dimensional codes, data matrices, seals, holograms and RFID. Pilot projects are currently under way at national level to assess their respective benefits. Before choosing a specific anti-counterfeiting seal, the Commission should perform an impact assessment in order to evaluate the seals currently available on the market, and should take account of past experience and the findings of the pilot projects.

Amendment 252
Marisa Matias

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	*Amendment*
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).	***deleted***

Or. en

Justification

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

Amendment 253
Jorgo Chatzimarkakis, Holger Krahmer

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

Text proposed by the Commission	*Amendment*
	Before the Commission adopts a measure to implement point (o) of Article 54, it shall perform a public impact assessment evaluating the costs and benefits of the existing safety features and consult all parties involved in the implementation and use of such safety features.

Or. en

Justification

There are a series of options regarding safety features: one-dimensional indices, a data matrix, seals, holograms, etc. At national level, pilot projects are conducted in order to assess the various advantages of the safety features. The Commission should assess all the safety features on the market before choosing a particular safety feature.

Amendment 254
Antonyia Parvanova, János Áder, Bogusław Sonik

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

Text proposed by the Commission	*Amendment*
When adopting those measures, the Commission shall consider the risk related to products or categories of products and at least all of the following:	When adopting those measures, the Commission shall consider the risk related to ***prescription*** products and at least all of the following:

Or. en

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 255
Cristian Silviu Buşoi

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

Text proposed by the Commission	*Amendment*
When adopting those measures, the Commission shall consider the risk related to products or categories of products and at least all of the following:	When adopting those measures, the Commission shall consider the risk related to ***all*** products or ***all*** categories of products and at least all of the following:

Or. en

Justification

The cost-effectiveness of the process should be taken into account. Further increases in the prices of pharmaceutical products would be a significant financial burden for the health insurers and patients. Unnecessary regulatory burden should be avoided. The use of safety features to authenticate medicines generates data that may be personally and commercially sensitive. The ownership rights in such data should be respected. The proposal may cover highly sensitive information and should be subject to relevant data protection laws.

Amendment 256
Antonyia Parvanova, János Áder, Bogusław Sonik

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

Text proposed by the Commission	*Amendment*
(a) the price ***and sales volume*** of ***the product***;	a) the price of ***medicinal products****;*

Or. en

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 257
Peter Liese

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

Text proposed by the Commission	*Amendment*
(a) the price ***and sales volume*** of the	(a) the price of the product

product;

Or. en

Justification

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

Amendment 258
Linda McAvan

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

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

Or. en

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 259
Holger Krahmer

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

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

Or. en

Justification

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

Amendment 260
Antonyia Parvanova, János Áder, Bogusław Sonik

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

Text proposed by the Commission	*Amendment*
(b) The number of incidences ***of falsifications in third countries and*** within the ***Community***;	(b) The number ***and frequency*** of ***past*** incidences ***of reported cases of counterfeited medicines*** within the ***Union and the evolution of those incidences in the past***;

Or. en

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 261
Peter Liese

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

Text proposed by the Commission	*Amendment*
(b) the number of incidences ***of falsifications in third countries and*** within the ***Community;***	(b) the number ***and frequency*** of ***past*** incidences ***of reported cases of counterfeited medicines*** within the ***Union and the evolution of those incidences in the past***;

Or. en

Justification

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

Amendment 262
Cristian Silviu Buşoi

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

Text proposed by the Commission	*Amendment*
(b) the number of incidences ***of falsifications*** in third countries and within the ***Community***;	(b) the number ***and frequency*** of ***past*** incidences of ***reported cases of falsified medicines*** in third countries and within the ***Union***;

Or. en

Justification

The cost-effectiveness of the process should be taken into account. Further increases in the prices of pharmaceutical products would be a significant financial burden for the health insurers and patients. Unnecessary regulatory burden should be avoided. The use of safety features to authenticate medicines generates data that may be personally and commercially sensitive. The ownership rights in such data should be respected. The proposal may cover highly sensitive information and should be subject to relevant data protection laws.

Amendment 263
Antonyia Parvanova, János Áder, Bogusław Sonik

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

Text proposed by the Commission	*Amendment*
(c) the evolution of those incidences in the past;	***deleted***

Or. en

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 264
Peter Liese

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

Text proposed by the Commission	*Amendment*
(c) the evolution of those incidences in the	***deleted***

past;

Or. en

Justification

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

Amendment 265
Antonyia Parvanova, János Áder, Bogusław Sonik

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	*Amendment*
(d) the specific characteristics of the products concerned;	***deleted***

Or. en

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 266
Peter Liese

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	*Amendment*
(d) the specific characteristics of the products concerned;	***deleted***

Or. en

Justification

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

Amendment 267
Antonyia Parvanova, János Áder, Bogusław Sonik

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***

Or. en

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 268
Peter Liese

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***

Or. en

Justification

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

Amendment 269
Andres Perello Rodriguez

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) other potential public health hazards.

Or. es

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.

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Amendment 270
Holger Krahmer

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

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

Or. en

Justification

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.

Amendment 271
Andres Perello Rodriguez

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.	***deleted***

Or. es

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.

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Amendment 272
Antonyia Parvanova, János Áder, Bogusław Sonik

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 ***measures referred to in point (o) of Article 54 and the*** requirements referred to in paragraph (1) and (2) of this Article ***shall be applied compulsorily only to those products or product categories found to pose a high risk of falsification, and*** be waived ***or voluntary*** for ***those*** products or product categories ***that do not pose a high risk of falsification such as, generic medicinal products authorised in accordance with Article 10***.

Or. en

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 273
Peter Liese

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 Commission may decide that the security features referred to in point (o) of Article 54 and the requirements in points (a) to (c) of paragraph 1 of this Article shall be applied to certain medicinal products subject to prescription that pose a high risk of being counterfeited***.

Or. en

Justification

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

Amendment 274
Holger Krahmer

Proposal for a directive – amending act
Article 1 - point 9
Directive 2001/83/EC
Article 54 a – 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 ***point (a)*** of paragraph (1) of this Article may be waived for certain products or product categories.

Or. en

Justification

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.

Amendment 275
Peter Liese

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

Text proposed by the Commission	*Amendment*
	The safety features may be used voluntarily for all medicinal products irrespectively of their prescription status and it the marketing authorisation holders may employ the safety features on their products.

Or. en

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 precautionary option.

Amendment 276
Dagmar Roth-Behrendt

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

Text proposed by the Commission	*Amendment*
	4a. By five years after the date of entry into force of the implementing measure of this Article, 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 and their contribution to the reduction of the number of falsified medicines in the legal supply chain in the Union and the potential benefits of alternative

technologies and the possibilities for authentication of individual dosage forms.

Or. en

Justification

The use of technologies that allow the authentication and tracing of medicinal products at the level of individual dosage forms, as a complement to the safety features proposed for the packaging of medicinal products, would 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 277
Jorgo Chatzimarkakis

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

Text proposed by the Commission	*Amendment*
	4a. For a transitional period of three years, safety features shall be regarded as equivalent if they make it equally possible to ascertain the identity, authenticity and uninterrupted traceability of the medicinal product, without its being necessary to open the immediate packaging, or they make it equally difficult to counterfeit the product. If a safety feature is removed, replaced or covered, this point should also be applicable to the new safety feature, provided that the primary safety feature is not hidden and cannot be recognised.

Or. en

Justification

It is important to ensure that in future a uniform safety feature will exist throughout the EU.

Amendment 278
Cristian Silviu Buşoi

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

Text proposed by the Commission	*Amendment*
The measures referred to in this paragraph shall take due account of the legitimate interests to protect information of a commercially confidential nature ***and of the protection of industrial and commercial property rights***.	The measures referred to in this paragraph shall take due account of ***the 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) Member States shall ensure that the ownership and confidentiality of the data generated by the use the safety feature to identify, to authenticate and to trace medical products;
	(c) the legitimate interests to protect information of a commercially confidential nature ***and personal data***.

Or. en

Justification

The cost-effectiveness of the process should be taken into account. Further increases in the prices of pharmaceutical products would be a significant financial burden for the health insurers and patients. Unnecessary regulatory burden should be avoided. The use of safety features to authenticate medicines generates data that may be personally and commercially sensitive. The ownership rights in such data should be respected. The proposal may cover highly sensitive information and should be subject to relevant data protection laws.

Amendment 279
Antonyia Parvanova, Marina Yannakoudakis, Ashley Fox, János Áder, Bogusław Sonik

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	*Amendment*
The measures referred to in this paragraph shall take due account of the legitimate interests to protect information of a commercially confidential nature and of the protection of industrial and commercial property rights.	The measures referred to in this paragraph shall take due account ***at least all*** of ***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 proportional application of costs related to the measures to all participants in the supply chain and the linking of those costs to the price of the medicinal product concerned;
	(c) the independence of the system and the legitimate interests to protect information of commercially confidential nature and the protection of industrial and commercial property rights ***and personal data***.

Or. en

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 280
Thomas Ulmer

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	*Amendment*
The measures referred to in this paragraph shall take due account of the legitimate interests to protect information of a commercially confidential nature and of the protection of industrial and commercial property rights.	The measures referred to in this paragraph shall take due account ***at least all*** of ***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 proportional application of costs related to the measures to all participants in the supply chain and the linking of those costs to the price of the medicinal product concerned;
	(c) the independence of the system and the legitimate interests to protect information of commercially confidential nature and the protection of industrial and commercial property rights ***and personal data***.

Or. en

Justification

Any safety features that are to be implemented should comply with at least the three principles mentioned above.

Amendment 281
Peter Liese

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	*Amendment*
The measures referred to in this paragraph shall take due account of the legitimate interests to protect information of a commercially confidential nature and of the protection of industrial and commercial property rights.	The measures referred to in this paragraph shall take due account of the legitimate interests to protect information of a commercially confidential nature and of the protection of industrial and commercial property rights. ***The safety features shall not be used to transfer data apart from the necessary data to prevent counterfeiting and data related to social security systems. Especially the commercial treatment of data, that makes it possible to connect the pharmaceuticals with the patients, the doctors or the pharmacist has to be prevented.***

Or. en

Justification

The data transmitted should be limited to the purposes of preventing counterfeit and enabling reimbursement. The implementation of the security features should not be exploited for additional commercial interests.

Amendment 282
Michail Tremopoulos, Michèle Rivasi

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	*Amendment*
The measures referred to in this paragraph shall take due account of the legitimate interests to protect information of a	The measures referred to in this paragraph ***shall comply with relevant provisions of Union law with regard to protection of***

commercially confidential nature ***and of the protection of industrial and commercial property rights***.	***personal data and*** shall take due account of the legitimate interests to protect information of a commercially confidential nature.

Or. en

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 283
Thomas Ulmer

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	*Amendment*
The measures referred to in this paragraph shall take due account of the legitimate interests to protect information of a commercially confidential nature and of the protection of industrial and commercial property rights.'	The measures referred to in this paragraph shall take due account of the legitimate interests to protect information of a commercially confidential nature and of the protection of industrial and commercial property rights. ***It has to be ensured 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 or pharmacies.***'

Or. de

Justification

The need for data protection must be taken into account in the development of the safety features. Since this directly concerns the individual patient and the confidential relationship between patient and pharmacy, the sensitive data involved here require particular protection.

Amendment 284
Holger Krahmer

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	*Amendment*
The measures referred to in this paragraph shall take due account of the legitimate interests to protect information of a commercially confidential nature and of the protection of industrial and commercial property rights.'	The measures referred to in this paragraph shall take due account of the legitimate interests to protect information of a commercially confidential nature and of the protection of industrial and commercial property rights. ***Member States shall ensure that the ownership and confidentiality of data generated by the use of safety features to authenticate medical products is respected.***

Or. en

Justification

The use of safety features to authenticate medicines generates data that may be personally and commercially sensitive. The ownership rights in such data should be respected. Data related to personal medicine consumption should be subject to relevant data protection laws and national ethical rules on professional confidentiality.

Amendment 285
Horst Schnellhardt

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	*Amendment*
The measures referred to in this paragraph shall take due account of the legitimate interests to protect information of a commercially confidential nature and of the protection of industrial and commercial property rights.'	The measures referred to in this paragraph shall take due account of the legitimate interests to protect information of a commercially confidential nature and of the protection of industrial and commercial property rights. ***It has to be ensured that no collection or commercial processing of data takes place that would enable a link to be made between the medicinal products supplied and the corresponding patients or pharmacies.'***

Or. de

Justification

The need for data protection must be taken into account in the development of the safety features. Since this directly concerns the individual patient and the confidential relationship between patient and pharmacy, the sensitive data involved here require particular protection.

Amendment 286
Sylvana Rapti

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	*Amendment*
The measures referred to in this paragraph shall take due account of the legitimate interests to protect information of a commercially confidential nature and of the protection of industrial and commercial property rights.	The measures referred to in this paragraph shall take due account of the legitimate interests to protect information of a commercially confidential nature and of the protection of industrial and commercial property rights. ***Member States shall ensure that the ownership and confidentiality of data generated by the use of safety features to authenticate medical products is respected.***

Or. en

Justification

The use of safety features to authenticate medicines generates data that may be personally and commercially sensitive. The ownership rights in such data should be respected. Data related to personal medicine consumption should be subject to relevant data protection laws and national ethical rules on professional confidentiality.

Amendment 287
Crescenzio Rivellini

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

Text proposed by the Commission	*Amendment*
The measures referred to in this paragraph shall take due account of the legitimate interests to protect information of a commercially confidential nature and of the protection of industrial and commercial property rights.'	The measures referred to in this paragraph shall take due account of the legitimate interests to protect information of a commercially confidential nature and of the protection of industrial and commercial property rights. ***Member States shall undertake to ensure that the ownership and confidentiality of the data generated by using technology to combat counterfeiting of pharmaceutical products are respected.***'

Or. it

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 preserved in the interests of individuals. 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 288
Michail Tremopoulos, Michèle Rivasi

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

Text proposed by the Commission	*Amendment*
	The measures referred to in this paragraph shall be updated every year on the basis of the Commission report pursuant to Article 46(h).

Or. en

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 289
Paolo Bartolozzi

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

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

Or. it

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 290
Jorgo Chatzimarkakis

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

Text proposed by the Commission	*Amendment*
	Member States shall ensure that both the ownership and the confidentiality of the data elicited when applying the safety features for the purpose of identifying medicinal products are respected.

Or. en

Justification

There are a series of options regarding safety features: one-dimensional indices, a data matrix, seals, holograms, etc. At national level, pilot projects are conducted in order to assess the various advantages of the safety features. The Commission should assess all the safety features on the market before choosing a particular safety feature.

Amendment 291
Andres Perello Rodriguez

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. Five years from the entry into force of this Directive, the Commission shall

present a report to the European Parliament and the Council concerning the implementation thereof. In this report the Commission shall assess the effectiveness of the provisions adopted further to Article 54 concerning measures to prevent falsified medicinal products entering the legal distribution chain.

Or. es

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 292
Andres Perello Rodriguez

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. Any Member State may extend the scope of the safety features referred to in paragraph (o) of Article 54 to other medicinal products and to other relevant areas of national policy such as reimbursement.

Or. es

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.

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Amendment 293
Michail Tremopoulos, Michèle Rivasi

Proposal for a directive – amending act
Article 1 - point 9 a (new)
Directive 2001/83/EC
Article 55 – paragraph 2

Text proposed by the Commission	*Amendment*
	(9a) In Article 55, paragraph 2 is replaced by the following:
	2. The following particulars at least shall appear on immediate packagings which take the form of blister packs and are placed in an outer packaging that complies with the requirements laid down in Articles 54 and 62.
	- the name of the medicinal product as laid down in point (a) of Article 54,
	- the name of the holder of the authorization for placing the product on the market,
	- the expiry date,
	- the batch number,
	***- the INN name.*"**

Or. en

Justification

The fight against falsified medicinal products relies on rigorous technical controls and inspections of the whole distribution chain. The use of the INN denomination can help to preserve the authenticity the medicinal product. Current legislation should therefore be amended accordingly.

Amendment 294
Cristian Silviu Buşoi

Proposal for a directive – amending act
Article 1 - point 9 a (new)
Directive 2001/83/EC
Article 55 – paragraph 2

Text proposed by the Commission	*Amendment*
	(9a) In Article 55, paragraph 2 is replaced by the following:
	"2. The following particulars at least shall appear on immediate packagings which take the form of blister packs and are placed in an outer packaging that complies with the requirements laid down in Articles 54 and 62.
	- the name of the medicinal product as laid down in point (a) of Article 54,
	- the name of the holder of the authorization for placing the product on the market,
	- the expiry date,
	- the batch number,
	***- the INN name.*"**

Or. en

Justification

The fight against falsified medical products relies on rigorous technical controls and inspections of the whole distribution chain from manufacturing through to commercialisation. The use of the INN denomination can constitute a dissuasive element, a protection, or even a brake against counterfeiting, to preserve and to guarantee the quality of the medical product. Current legislation should therefore be amended (art. 55.2 Dir. 2001/83/EC) by stipulating that each product should be identified through its INN name. This would contribute to strengthening the security of the product user.