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NOTE

From :	General Secretariat of the Council
to :	Permanent Representatives Committee (Part 1)
No. prev. doc:	16870/10 MI 493 SAN 272 ECO 106 ENT 191 CODEC 1370 UD 323
No. Cion prop. :	17504/08 MI 566 SAN 355 ECO 198 ENT 334 CODEC 1889
Subject :	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

Procedure

1. The Commission submitted its proposal[1] to the Council and the European Parliament on 10 December 2008.

2. The European Economic and Social Committee and the Committee of the Regions have delivered their opinions.

[1] 17504/08 MI 566 SAN 355 ECO 198 ENT 334 CODEC 1889

3. The Committee on the Environment, Public Health and Food Safety of the European Parliament (ENVI) voted its report (suggesting 119 amendments to the proposal) on 27 April 2010.

State of play in the Council

4. The Working Party on Pharmaceuticals and Medical devices met on 40 days to examine the proposal during the Czech, Swedish, Spanish and Belgian Presidencies. The latest of the meetings took place on 15 December 2010. At that meeting, there were still a number of reservations, each held by one or a few delegations. These reservations are set out in footnotes to the text in the Annex to this Note.

5. Furthermore, the Maltese delegation has entered a Parliamentary scrutiny reservation.

Contacts with the European Parliament

6. The Czech, Swedish, Spanish and Belgian Presidencies all had informal contacts with the European Parliament with the aim to paving the way for an early agreement. These showed that the European Parliament and the Commission were willing to enter into negotiations with the aim of exploring the possibilities for an agreement at first reading.

7. On 22 September, the Permanent Representatives Committee mandated the Presidency to start negotiations with the other Institutions with the aim of reaching an agreement. This mandate was updated by the Committee on 10 November and on 8 December 2010.

8. Following the meetings of the Permanent Representatives Committee, three informal trialogues and a number of technical meetings were held by the Institutions during September, October and November.

9. On 16 December 2010, representatives of the three Institutions met in an informal trialogue, which resulted in the draft compromise text set out in the Annex to this Note. This text is still subject to scrutiny and final approval by the respective Institution.

Conclusion

The Permanent representatives committee is invited to endorse the draft compromise text set out in the Annex to this Note and mandate the Presidency to inform the Parliament and the Commission accordingly.

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the functioning of the European Union, and in particular Article 114 and paragraph 4 point c of Article 168 thereof,

Having regard to the proposal from the European Commission[2],

Having regard to the opinion of the European Economic and Social Committee[3],

Having regard to the opinion of the Committee of the Regions[4],

Acting in accordance with the ordinary legislative procedure[5],

Whereas:

(1) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[6] lays down the rules for *inter alia* manufacturing, importation, placing on the market, and wholesale distribution of medicinal products in the Union as well as rules relating to active substances.

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2 OJ C , , p. .
3 OJ C , , p. .
4 OJ C , , p. .
5 OJ C , , p. .
6 OJ L 311, 28.11.2001, p. 67.

(2) There is an alarming increase of medicinal products detected in the Union which are falsified in relation to their identity, history or source. These products usually contain sub-standard or falsified ingredients, or no ingredients or ingredients in the wrong dosage, including active substances, thus posing an important threat to public health.

(3) Past experience shows that such medicinal products do not reach patients only through illegal means, but via the legal supply chain as well. This poses a particular threat to human health and may lead to a lack of trust of the patient also in the legal supply chain. Directive 2001/83/EC should be amended in order to respond to this increasing threat.

(4) The threat to public health is also recognised by the World Health Organisation (WHO), who set up the International Medical Products Anti-Counterfeiting Taskforce ("IMPACT"). IMPACT developed Principles and Elements for National Legislation against Counterfeit Medical Products, which were endorsed by the IMPACT General Meeting in Lisbon on 12 December 2007. The Union participated actively in the Taskforce.

(5) A definition of 'falsified medicinal product' should be introduced in order to clearly distinguish falsified medicinal products from other illegal products, as well as from violations of intellectual property rights. Furthermore products with unintended quality defects resulting from manufacturing or distribution errors should not be confused with falsified medicinal products. To ensure uniform application of this Directive, the terms active substance and excipient should also be defined.

(6) Persons procuring, holding, storing, supplying or exporting medicinal products are only entitled to pursue their activities if they meet the requirements for obtaining a wholesale distribution authorisation in accordance with Directive 2001/83/EC. However, today's distribution network for medicinal products is increasingly complex and involves many players which are not necessarily wholesale distributors as defined in that Directive. In order to ensure reliability of the supply chain, legislation in relation to medicinal products should address all actors in the supply chain: this includes not only wholesale distributors (whether or not physically handling the medicinal products[7]), but also brokers who are involved in the sale or purchase of medicinal products without selling or purchasing themselves, and without owning and physically handling the products.

(7) Falsified active substances and active substances that do not comply with applicable requirements pose serious public health risks. These risks should be addressed by strengthening verification requirements for the manufacturer of the medicinal products.

(8) There is a range of different good manufacturing practice that is suitable for the manufacturing of excipients. In order to provide for a high level of protection of public health, the manufacturer of the medicinal product should assess the suitability of excipients on the basis of appropriate good manufacturing practice for excipients.

(9) In order to facilitate enforcement and control of Union rules relating to active substances, the manufacturers, importers or distributors of those substances should notify the respective competent authorities of their activities.

[7] **DELETED**: Add: "without prejudice to public service obligations of the Member State in which the application for wholesale distribution authorisation has been submitted".

(10) Medicinal products may be introduced into the Union while not being intended to be imported, i.e. released for free circulation. If these medicinal products are falsified they present a risk to public health within the EU. In addition, these medicinal products may reach patients in third countries. Member States should take measures to prevent these medicinal products, if introduced into the EU, from entering into circulation. When adopting provisions supplementing this rule the Commission should take account of the administrative resources available and the practical implications, as well as the need to maintain swift trade flows for legitimate medicinal products. These provisions should be without prejudice to customs legislation, the distribution of competences between European and national level and the distribution of responsibilities within Member States.

(11) Safety features for medicinal products should be harmonised in the EU in order to take account of new risk profiles, while ensuring the functioning of the internal market for medicinal products.

These safety features should allow verification of the authenticity and identification of individual packs, and provide evidence of tampering.

The scope of these safety features should take due account of the particularities of certain products or categories of products, such as generic medicinal products. Medicinal products subject to prescription should as a general rule bear the safety feature. However, in view of the risk of products or product categories there should be the possibility to exclude products or product categories of prescription medicinal products from the scope by way of a delegated act, following a risk assessment. Safety features shall not be introduced for medicinal products or product categories not subject to medical prescription unless, by way of exception, an assessment shows the risk of falsification, which leads to serious consequences. These products shall accordingly be listed in a delegated act.

The risk assessments should consider aspects such as the price of the medicinal product and past incidences of falsifications in the Member States and abroad, as well as the consequences of falsifications for public health in view of the specific characteristics of the products concerned or of the severity of the conditions intended to be treated.

The safety features should allow the verification of each[8] supplied pack of the medicinal products, regardless of how they are supplied including through sales at a distance[9].

The unique identifier as well as the corresponding repositories system should apply without prejudice to Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and should retain clear and effective safeguards whenever personal data are processed.

The repositories system of safety features might contain commercially sensitive information. This information must be appropriately protected.

When the obligatory safety features are introduced, due account should be taken of the particular characteristics of the supply chains in Member States.

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8 **DELETED**: add "batch or, if necessary and proportionate, the identification of each".

9 **DELETED**: Scrutiny reservation.

(12) Any actor in the supply chain who packages medicinal products has to be a holder of a manufacturing authorization. In order for the safety features to be effective, a manufacturing authorization holder who is not himself the original manufacturer of the medicinal product should only be permitted to remove, replace or cover these safety features under strict conditions.

In particular, the safety features should be replaced in the case of re-packaging by equivalent safety features. To this end, the meaning of the term 'equivalent' should be clearly specified.

Those strict duties should provide adequate safeguards against falsified products entering the distribution chain, in order to protect patients, as well as the interests of marketing authorisation holders and manufacturers.

(13) Manufacturing authorisation holders who repackage medicinal products should be liable for damages in the cases and under the conditions set out in Council Directive 85/374/EEC

(14) In order to increase reliability in the supply chain, wholesale distributors should verify that their supplying wholesale distributors are authorised.

(15) The provisions applicable to the export of medicinal products from the European Union and those applicable to the introduction of medicinal products into the Union with the sole purpose of exportation need to be clarified. According to Directive 2001/83/EC a person exporting medicinal products is a wholesale distributor. In particular, the rules for wholesale distributors and good distribution practices should be applicable to all these activities whenever they are performed on the European Union territory, including in areas such as free trade zones or free warehouses.

(16) In order to ensure transparency, a list of wholesale distributors for whom it has been established that they comply with applicable Union legislation through inspection by a competent authority of a Member State, should be published in a database at Union level.

(17) The rules for inspections and controls of all actors involved in the manufacturing and supply of medicinal products and their ingredients should be clarified and specifically address different actors. This should not prevent Member States from performing additional inspections, where considered appropriate.

(18) In order to ensure a similar level of protection of human health throughout the Union, and to avoid distortions in the internal market, the harmonised principles and guidelines for inspections of holders of manufacturing and wholesaler authorisations of medicinal products as well as of manufacturers and distributors of active substances should be strengthened. Such principles and guidelines should also help to ensure the functioning of existing mutual recognition agreements with third countries which rely on efficient and comparable inspection and enforcement throughout the Union.

(19) Manufacturing plants of active substances should be subject not only to inspections carried out on the grounds of suspected non-compliance but also on the basis of a risk-analysis.

(20) The manufacture of active substances should be subject to good manufacturing practice regardless of whether those ingredients were manufactured in the Union or imported. With regard to the manufacture of active substances in third countries, it should be ensured that the legislative provisions applicable to manufacture of active substances intended for export to the Union, together with inspection and enforcement, provide for a level of protection of public health equivalent to that provided for by EU law.

(21) The illegal sale of medicinal products to the public via the internet is an important threat to public health as falsified medicinal products may reach the public through these channels. This Directive should address this threat. In doing so, account should be taken of the fact that specific conditions for retail supply of medicinal products to the public have not been harmonised at Union level and therefore, Member States may impose conditions for supplying medicinal products to the public within the limits of the EU Treaties.

(22) When examining the conditions for the retail supply of medicinal products, the Court of justice has recognised the very particular nature of medicinal products, whose therapeutic effects distinguish them substantially from other goods. It has also held that health and life of humans rank foremost among the assets and interests protected by the Treaty and that it is for Member States to determine the level of protection which they wish to afford to public health and the way in which that level has to be achieved. Since such level may vary from one Member State to another, Member States must be allowed discretion as regards the conditions for the supply on their territory of medicinal products to the public..

(23) In particular, in the light of the risks to public health and given the power accorded to Member States to determine the level of protection of public health, the case law of the Court of justice has recognised that Member States may, in principle, restrict the retail sale of medicinal products to pharmacists alone.

(24) [10]Therefore and in the light of the case law of the Court of Justice, Member States should be able to impose conditions justified by the protection of public health for the retail supply of medicinal products offered for sale at a distance by way of information society services. Such conditions should not unduly restrict the functioning of the internal market.

(25) The public should be assisted in identifying websites which are legally offering medicinal products for sale at a distance to the public. A logo should be established, which is recognisable throughout the Union**,** while allowing for the identification of the Member State where the person or body offering medicinal products for sale at a distance is established. The Commission should develop the design for such a logo. Websites offering medicinal products for sale at a distance to the public should be linked to the website of the respective competent authority. The websites of the competent authorities of Member States, as well as that of the Agency, should give an explanation of the use of the logo. All these websites should be linked in order to allow for comprehensive information.

(26) In addition, the Commission should, in cooperation with the Agency and Member States, run awareness campaigns to warn of risks of purchasing medicinal products from illegal sources in the internet.

(27) Member States should impose effective penalties for acts involving falsified medicinal products taking into account the threat to public health posed by these products.

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[10] **DELETED**: Reinstate two sentences at the beginning with an addition (underlined): "Conditions for retail sales supply of medicinal products to the public have not been harmonised at Union level. Given the power accorded to Member States to determine the level of protection of public health and the protection of the financial balance of their social security systems, the conditions for retail supply of medicinal products to the public are regulated by the legislation of the Member State of destination.".

(28) Falsified medicinal products are a global problem, requiring effective and enhanced international coordination and cooperation in order to ensure that anti-falsification strategies are more effective, in particular as regards supply of such products via the internet. To that end, the Commission and the Member States should cooperate closely and support ongoing work in international fora on this subject, such as the Council of Europe, Europol, and the United Nations. In addition, the Commission, working closely with Member States, should cooperate with the competent authorities of third countries with a view to effectively combating the commercialisation of falsified medicinal products on a global level.

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

(30) The Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the functioning of the EU (TFEU) in order to supplement the provisions in Articles 47, 52b, 54(o) and 54a of Directive 2001/83/EC concerning good manufacturing and distribution practices for active substances, detailed rules for medicinal products introduced into the EU without being imported and regarding safety features. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.

The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

(31) The Commission should adopt implementing measures for the assessment of the regulatory framework applying for the manufacturing of active substances exported from third countries to the European Union. Moreover, this Directive provides for a common logo that identifies websites which are legally offering medicinal products for sale at a distance to the public and that should be established by the European Commission through implementing measures. In accordance with Article 291 of the Treaty, rules and general principles concerning mechanisms for the control by Member States of the Commission's exercise of implementing powers shall be laid down in advance by a regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of that new regulation, Council Decision 1999/468/EC of 28 June 1999[11] laying down the procedures for the exercise of implementing powers conferred on the Commission continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable.

(32) The safety features introduced with this Directive require substantial adaptations of manufacturing processes. In order to allow for these adaptations, the time-limits for the application of the rules on the safety features should be sufficiently long and should count as of publication of the delegated acts setting out the details for these safety features. In addition, account should be taken of Member States which have already a national system in place. These Member States should have an additional transitional period for adapting to the harmonised EU system.

(33) Since the objective of ensuring the functioning of the internal market for medicinal products, while ensuring a high level of protection of public health against medicinal products which are illegal in view of a falsified identity, history or source, cannot be sufficiently achieved by the Member States, and can be better achieved Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union (TEU). In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

[11] OJ L184, 17.7.1999, p.21.

(34) It is important that Member States' competent authorities, the Commission and the Agency co-operate to ensure the exchange of information on measures taken to combat the falsification of medicinal products, including on the penalties systems in place. Currently, this takes place through the Working Group of Enforcement Officers.

Member States should ensure that patients' and consumers' organisations are kept informed about enforcement activity as far as is consistent with operational needs.

(35) In accordance with point 34 of the Inter-institutional Agreement on better law-making[12], Member States are encouraged to draw up, for themselves and in the interests of the *Union*, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.

(36) Directive 2001/83/EC was recently amended by Directive [2010/xxxx/EC on Pharmacovigilance]. That Directive *inter alia* amended Article 111 on inspections and Article 116 on suspension and revocation and varying of marketing authorisations under certain circumstances. Furthermore, it introduced provisions on delegated acts in Articles 121a, 121b and 121c. The present Directive requires some further and complementary changes to these articles.

(37) Directive 2001/83/EC should be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

[12] OJ C 321, 31.12.2003, p. 1.

Article 1

Directive 2001/83/EC is hereby amended as follows:

1) Article 1 is amended as follows:

a) The following point*s are* inserted after point 2:

"2a. Falsified medicinal product:

Any medicinal product with a false representation of:

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

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

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

This definition does not include unintentional quality defects and is without prejudice to infringements of legislation on intellectual property rights.

2b. Active substance

Any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or making a medical diagnosis"

b) The following point 3a is inserted after point 3:

"3a. Excipient:
Any constituent of a medicinal product other than the active substance and packaging material."

c) The following point 17a is inserted after point 17:

'17a. Brokering of medicinal products:

All activities in relation to the sale or purchase of medicinal products, except for wholesale distribution as defined in point 17 of this article, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person'[13]

2) Article 2 is amended as follows:

a) Paragraph 3 is replaced by the following:

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

b) The following paragraph 4 is inserted:

'(4). Paragraph 1 is without prejudice to Articles 52b and 85a.'

[13] **DELETED**: Need to cover transporters in this Directive in order to stop falsified products from entering the legal supply chain.

2a) In Article 8, paragraph 3, the following point is added after point h):

‘(ha) A written confirmation that the manufacturer of the medicinal product has verified compliance of the manufacturer of the active substance with principles and guidelines of good manufacturing practice by conducting audits, in accordance with Article 46(f). The written confirmation shall include a reference to the time of the audit and a declaration that the outcome of the audit confirm that the manufacturing complies with the principles and guidelines of good manufacturing practice.’

2b) In Article 40, paragraph 4 is replaced by:

“4. The Member States shall enter the information of the authorisation referred to in paragraph 1 in the EU database referred to in Article 111(6).”

3) Article 46 is amended as follows:

(a) Point (f) is replaced by the following:

‘(f) to comply with the principles and guidelines of good manufacturing practice for medicinal products and to use only active substances, which have been manufactured in accordance with good manufacturing practice for active substances and distributed in accordance with good distribution practices for active substances. To this end, the holder of the manufacturing authorisation shall either by himself or, without prejudice to his responsibility as provided for in this Directive, by an entity contracted by him, verify compliance by the manufacturer and distributors of active substances with good manufacturing practice and good distribution practices by conducting audits at the manufacturing and distribution sites of the manufacturer and distributors of active substances.

The holder of the manufacturing authorisation shall ensure that the excipients are suitable for use in medicinal products by verifying the appropriate good manufacturing practice on the basis of a formalised risk assessment in accordance with the applicable guidelines referred to in the fifth paragraph of Article 47, taking into account other suitable quality system requirements, ensuring that the appropriate good manufacturing practices are applied and document this. In this risk assessment, the holder of the manufacturing authorisation shall take into account the source and intended use of the excipients and previous incidents.’

(b) The following points (g), (h) and (i) are added:

'(g) to inform the competent authority and the marketing authorisation holder immediately if he obtains information that medicinal products which come under the scope of his manufacturing authorisation are, or are suspected of being, falsified irrespective of whether these products were distributed in the legal supply chain or by illegal means, including sold illegally via the Internet.

(h) to verify that the manufacturers, importers or distributors from whom they obtain active substances are registered with the competent authority of the Member State in which they are established.

(i) to verify the authenticity and quality of the active substances and the excipients.'

4) The following Article 46b is inserted after Article 46a:

'Article 46b

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

(2) Active substances shall only be imported if the following conditions are fulfilled[14]:

(a) the active substances have been manufactured in accordance with standards of good manufacturing practice at least equivalent[15] to those laid down by the Union pursuant to Article 47; and

[14] **DELETED**: In general there is no concept exactly corresponding to GMP in third countries. Difficult for organisations in third countries to check whether their rules are compliant with EU rules.

[15] **DELETED**: This concept must be specified. Which organisation verifies that practices are equivalent?

(b) the active substances are accompanied by[16] a written confirmation from the competent authority of the exporting third country that the standards of good manufacturing practice applicable to the plant manufacturing the exported active substance are at least equivalent to those laid down by the Union pursuant to Article 47, and that[17] the plant is subject to regular, strict and transparent control and efficient enforcement of good manufacturing practice including repeated and unannounced inspections, ensuring a protection of public health at least equivalent to that in the Union, and that in the event of findings relating to non-compliance, that information shall be supplied by the exporting third country to the Union without any delay. This written confirmation is without prejudice to the obligations set out in Article 8 and Article 46 point (f).

(3)[18] The requirement set out in point (b) of paragraph 2 shall not apply if the exporting country is included in the list referred to in Article 111b.

(4)[19] For exceptional reasons of availability of medicinal products, when a plant manufacturing an active substance for export has been inspected by a Member State and was found to comply with the principles and guidelines of good manufacturing practice laid down pursuant to Article 47, the requirement set out in point (b) of paragraph 2 may be waived by any Member State for a period not exceeding the validity of the certificate of Good Manufacturing Practice. Member States that make use of this possibility, shall communicate this to the Commission. ’

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16 **DELETED**: Replace " a written confirmation from the exporting third country" by " an authentic written confirmation from the competent authority of a Member State or of a third country".

17 **DELETED**: Replace "and that" by " If the confirmation is issued by the competent authority of the third country it should also declare that".

18 **DELETED**: Reservation on this point.

19 **DELETED**: Member State inspection should always be valid. Article 46a(2)(b) could be amended to this aim. Then this paragraph is not needed.

5) In Article 47, the third and fourth paragraphs are replaced by the following and a fifth paragraph is added:

‘The Commission shall adopt, by means of delegated acts in accordance with Article 121a and subject to the conditions of Articles 121b and 121c, the principles and guidelines of good manufacturing practice for active substances referred to in point (f) of Article 46 and in Article 46b.

The principles of good distribution practices for active substances referred to in point (f) of article 46 shall be adopted by the Commission in the form of guidelines.

Guidelines on the formalised risk assessment for verification of the appropriate good manufacturing practice for excipients referred to in the second paragraph of point (f) of article 46 shall be adopted by the Commission. ”

5a) The following Article 47a is inserted after Article 47:

‘Article 47a

(1) 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:

(a) The manufacturing authorisation holder verifies, prior to partly or fully removing or covering-up the safety features referred to in Article 54(o), that the medicinal product concerned is authentic and that it has not been tampered with;

(b) The manufacturing authorisation holder complies with point (o) of Article 54 by replacing the safety feature**s** with safety feature**s** which **are** equivalent as regards the possibility to ascertain identification, authenticity and tampering evidence of the medicinal product, and without opening the immediate packaging as defined in Article 1(23).

Safety features shall be considered equivalent if the following is fulfilled:

- they comply with the requirements set out in the delegated acts referred to in Article 54a, paragraph 4, and

- they are equally efficient in identifying, authenticating and preventing tampering with medicinal products;

(c) These operations are conducted in accordance with applicable good manufacturing practice for medicinal products; and

(d) The replacement of the safety features is subject to supervision by the competent authority.

(2) Manufacturing authorisation holders, including those performing the activities described in paragraph (1) of this Article, shall be regarded as producers and therefore held liable for damages in the cases and under the conditions set forth in Council Directive 85/374/EEC.

6) In Article 51, paragraph 1, the following subparagraph is added before the last subparagraph:

'The qualified person referred to in Article 48 shall in the case of medicinal products intended to be placed on the market in the Union, ensure that the safety features referred to in point (o) of Article 54 have been affixed on the packaging.'

7) The following Articles 52a and 52b are inserted after Article 52:

'Article 52a[20] [21] [22]

1. Importers, manufacturers and distributors of active substances who are established in the Union shall register their activity with the competent authority of the Member State in which they are established.

2. The registration form shall include, at least, the following information:

- name or corporate name and permanent address;
- the active substance(s) which are to be imported, manufactured or distributed;
- particulars regarding the premises and the technical equipment for his activity.

3. The operators referred to in paragraph 1 shall submit the registration form to the competent authority at least 60 days prior to the intended commencement of their activity.

[20] **DELETED**: Reservation on all time limits in this article.

[21] **DELETED**: scrutiny reservation on this article, holds that importers of active substances should be subject to authorisation.

[22] **DELETED**: Scrutiny reservation on this article.

4. The competent authority may, based on an assessment of risk, decide to carry out an inspection. If the competent authority notifies the applicant within 60 days that an inspection shall be carried out, the activity may not begin before the competent authority has notified the applicant that he may commence the activity. If within 60 days of the receipt of the registration form the competent authority has not notified the applicant that an inspection shall be carried out, the applicant may commence his activity.

5. The operators referred to in paragraph 1 shall communicate annually to the competent authority an inventory of the changes that have taken place regarding the information contained in the registration form. Any changes that may impact on the quality or safety of the active substance(s)[23] that are manufactured, imported or distributed must be notified immediately.

6. Operators referred to in paragraph 1 who had commenced their activity before [insert the date of application of that provision] shall submit the registration form to the competent authority no later than [insert date 60 days[24] after the date of application].

7. Member States shall enter the information of the registrations referred to in paragraph 2 in the EU database referred to in Article 111(6).

8. This article is without prejudice to Article 111.

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[23] **DELETED**: Replace " the change relates to the quality or safety of the active substance(s)" by "changes occur in such information which may impact on the quality and safety of active substance(s)".

[24] **DELETED**: prefers longer period, suggests 6 months. **DELETED**: Support.

Article 52b

(1) Notwithstanding Article 2(1), and without prejudice to Title VII, Member States shall take the necessary measures in order to prevent that medicinal products that are introduced in the European Union but are not intended to be placed on the market of the Union enter into circulation if there are sufficient grounds to suspect that these products are falsified.

(2) In order to establish the necessary measures referred to in paragraph (1), the Commission may adopt measures supplementing the provisions in that paragraph by means of delegated acts in accordance with Article 121a, and subject to the conditions of Articles 121b and 121c, as regards the criteria to be considered and the verifications to be made when assessing the potential falsified character of medicinal products introduced into the EU but not intended to be placed on the market.

8) In Article 54, the following point (o) is added: [25]

'(o) for medicinal products other than radiopharmaceuticals[26] referred to in paragraph 1 of Article 54a, safety features making it possible for wholesale distributors and persons authorised or entitled to supply medicinal products to the public to:

- verify their authenticity and[27]

- identify individual packs

as well as a device allowing verification of whether the outer packaging has been tampered with.

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25 **DELETED**: It should be possible to read the batch number, required under point (m), automatically.

26 **DELETED**: exclude OTCs à priori.

27 **DELETED**: Replace "and" by "or" or delete "identify individual packs".

9) The following Article 54a is added:

'Article 54a[28] [29]

(1) Medicinal products subject to prescription, shall bear the safety features referred to in point (o) of Article 54, unless they have been listed in accordance with the procedure referred to in paragraph 4, point b of this article.

Medicinal products, not subject to prescription shall not bear the safety features referred to in point (o) of Article 54, unless, by way of exception, they have been listed in accordance with the procedure referred to in paragraph 4, point b of this article, after having been assessed to be at risk of falsification.

(1a) The Commission shall adopt measures supplementing the provision in point (o) of Article 54 by means of delegated acts in accordance with Article 121a and subject to the conditions of Articles 121b and 121c with the objective of establishing the detailed rules for the safety features referred to in point (o) of Article 54.

(4) To this end, the delegated acts[30] shall set out:

(a) the characteristics and technical specifications of the unique identifier for[31] the safety features referred to in point (o) of Article 54 allowing to verify the authenticity of medicinal products and identify individual packs[32]; when establishing the safety features due consideration to their cost-effectiveness shall be given;

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28 **DELETED**: exclude OTCs à priori.

29 **DELETED**: proposes adding "homeopathic medicinal products".

30 **DELETED**: scrutiny reservations on use of delegated acts for all points under Article 54a paragraph 4; in particular, some delegations ponder whether point c) d) and e) could be treated through implementing acts under Article 291 TFEU.

31 **DELETED**: delete "the unique identifier for".

32 **DELETED**: delete reference to individual packs.

(b) the lists[33] containing the medicinal products or product categories which, in the case of prescription medicines should not bear and in the case of non-prescription medicines should bear the safety features referred to in point (o) of Article 54, considering the risk of falsification related to products or categories of products based on at least the following criteria:

(i) the price and sales volume of the medicinal product;

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

(iii) the specific characteristics of the medicinal products concerned;

(iv) the severity of the conditions intended to be treated;

(v) other potential risks to public health.

(c) procedures for the notification to the Commission by national competent authorities of medicinal products at risk or deemed not at risk of falsification and a rapid system for evaluation and decision on these notifications for the purpose of the application of the provision of point b) above.

(d) the modalities of verifications of the safety features referred to in point (o) of Article 54 by the manufacturers, wholesalers, pharmacists and persons authorised or entitled to supply medicinal products to the public and by the competent authorities. These provisions shall allow the verification of the authenticity of each supplied pack of the medicinal products[34] referred to in paragraph 1 and determine the extent thereof. When establishing those provisions, the particular characteristics of the supply chains in Member States, and the need to ensure that the impact of verification measures on particular actors in the supply chains is proportionate, shall be taken into account.

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33 **DELETED**: Reservation on the use of two separate lists with different meaning.

34 **DELETED**: suggests a system that allows verification at least at batch level.

(e) provisions on the establishment, management and accessibility of the repositories system in which information on the safety features, necessary to identify and verify authenticity of medicinal products , as provided for in Article 54(o) shall be contained. The costs for the repositories system shall be borne by the manufacturing authorisation holders of medicinal products that bear the safety features.

(4a) The measures referred to in paragraph 4 shall take due account of at least all the following:

(i) the protection of personal data as provided for in Union law;

(ii) the legitimate interests to protect information of a commercially confidential nature ;

(iii) the ownership and confidentiality of the data generated by the use the safety features;

(iv) the cost-effectiveness of the system.

(4b) The national competent authorities shall notify the Commission about non prescription medicinal products which they judge are at risk of falsification and may inform about medicinal products which they deem are not at risk according to the criteria set out in paragraph 4, point (b) of this Article.

(4c) A Member State may extend the scope of the unique identifier referred to in point (o) of Article 54 to all medicinal products subject to prescription or subject to reimbursement for the purposes of reimbursement or pharmacovigilance.

A Member State may use the information contained in the repositories system referred to point (e) of paragraph 4 in article 54a for the purposes of reimbursement, pharmacovigilance or pharmaco-epidemiology.

A Member State may extend the scope of the anti-tampering device referred to in point (o) of article 54 to other medicinal products for the purpose of patient safety.'

10) The fourth indent of the first paragraph of Article 57 is replaced by the following:

'- identification and authenticity in accordance with Article 54a(4c).'

11) The heading of title VII is replaced by the following:

'Wholesale distribution and brokering of medicinal products';

11a) Article 76 is amended as follows:

a) paragraph 3 is replaced by the following:

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

b) the following paragraph is added:

'4. In the case of products which have been granted an authorisation pursuant to Regulation (EC) No 726/2004, the distributor shall submit the notification in accordance with paragraph 3 to the marketing authorisation holder and the Agency. The notification shall be accompanied by a fee payable to the Agency for checking that the conditions laid down in Union legislation are complied with.'

12) Article 77 is amended as follows:

a) paragraph 1 is replaced by the following:

‘(1) Member States shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to the possession of an authorization to engage in activity as a wholesaler in medicinal products, stating the premises within their territory for which it is valid.’

b) paragraphs 4 and 5 are replaced by the following:

‘(4) The Member States shall enter the information of the authorization referred to in paragraph 1 in the EU database referred to in Article 111(6). At the request of the Commission or any Member State, Member States shall supply all appropriate information concerning the individual authorization which they have granted under paragraph 1.

(5) Checks on the persons authorized to engage in the activity of wholesaler in medicinal products and the inspection of their premises, shall be carried out under the responsibility of the Member State which granted the authorization for premises located on their territory.’

13) Article 80 is amended as follows:

(a0) The following point (ca) is added:

'(ca) they must verify that the medicinal products they have purchased are not falsified by checking the safety features on the outer packaging; in accordance with what is laid down in the delegated acts referred to in Article 54a(1a)'

(a) Point (e) is replaced by the following:

‘(e) they must keep records either in the form of purchase/sales invoices or on computer, or in any other form, giving for any transaction in medicinal products received, dispatched or brokered at least the following information:

– date,

– name of the medicinal product,

– quantity received, supplied or brokered,

– name and address of the supplier or consignee, as appropriate;

– batch number of the medicinal product at least for products subject to the safety features as set out in Article 54(o)[35];’

[36]

(b) The following points (h) and (i) are added:

‘(h) they must maintain a quality system setting out responsibilities, processes and risk management in relation to their activities;

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[35] **DELETED**: Scrutiny reservation.

[36] **DELETED**: Add indents on "details on the manufacturer" and "expiry dates of batches". **DELETED**: add indent: "details of the authority of the supplier or consignee to supply, or be supplied, as appropriate "(guidelines required).

(i) they must immediately inform the competent authority and, where applicable, the holder of the marketing authorisation of medicinal products they receive or are offered which they identify as falsified or suspect to be falsified medicinal products.

(c) The following subparagraphs are added:

'For the purpose of point (b), where the product is obtained from another wholesale distributor, holders of the wholesale distribution authorisation must verify compliance with the principles and guidelines of good distribution practices of the supplying wholesale distributor which includes verifying whether the supplying wholesale distributor holds a wholesale distribution authorisation..

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

When products are obtained through brokering, the holders of the wholesale distribution, and the brokers of medicinal products must verify that the operators involved fulfil the requirements set out in this Directive.'

13a) In Article 82 the following indent is added:

'- batch number of the medicinal product at least for products subject to the safety features as set out in Article 54a; '

14) The following Articles are inserted after Article 85:

'Article 85a[37]

In the case of wholesale distribution to third countries, Article 76 and Article 80(c) shall not apply. Moreover, Article 80(b) shall not apply where a product is directly received from a third country. The requirements of Article 82 shall apply to the supply of medicinal products to persons in third countries authorised or entitled to supply medicinal products to the public.

Article 85b

1. Persons brokering medicinal products shall ensure that the brokered medicinal products are covered by a marketing authorization granted pursuant to Regulation (EC) No 726/2004 or by the competent authorities of a Member State in accordance with this Directive[38].

They must have a permanent address and contact details in the Union, so as to ensure accurate identification, location, communication and surveillance of their activities by competent authorities.

The requirements set out in Article 80(d) to (i) shall apply with a view to the brokering of medicinal products. [39]

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37 **DELETED**: Suggests the following changes 1) keep the reference to " of medicinal products introduced in the European Union but not intended to be placed on the market", 2) add a reference to Article 80(ca), 3) keep the reference to Article 81, 4) require that Article 82 shall apply to any supply of medicinal products.

38 **DELETED**: What about authorisation requirements for trading of intermediate products, bulk or investigational products?

39 **DELETED**: Questions that all requirements listed should apply to brokers.

2. Persons may only broker medicinal products if they are registered with the competent authority of the Member State of the permanent address referred to in paragraph (1). They shall register, at least, their name and corporate name and permanent address. They shall without unnecessary delay notify the competent authority of any changes thereof.

Persons brokering medicinal products who had commenced their activity before [insert the date of application of this Article] shall register with the competent authority no later than [insert date 60 days after the date of application].

The competent authority shall enter information concerning the person brokering medicinal products in a registry that shall be publicly accessible.

3. The guidelines referred to in Article 84 shall include specific provisions for brokering.

4. This Article is without prejudice to Article 111. Inspections referred to in that Article shall be carried out under the responsibility of the Member State where the person brokering medicinal products is registered.

If a person brokering medicinal products does not comply with the requirements set out in this article, the competent authority may decide that that person shall be taken off the registry referred to in paragraph 2. The competent authority shall notify that person thereof.

14a) The following Title VIIa is inserted before Title VIII

'Title VIIa – Sales at a distance to the public

Article 85c

1. Without prejudice to national legislation prohibiting the offer for sale at a distance of prescription medicinal products to the public by way of information society services, Member States shall ensure that medicinal products are offered for sale at a distance by way of information society services as defined in Directive 98/34/EC[40] under the following conditions:

a) the natural or legal person or the body provided for by national law offering medicinal products for sale at a distance is authorized or entitled to supply medicinal products to the public, also at a distance, according to national legislation where that person or body is established;

b) the person or body referred to under the first indent has notified the Member State where that person or body is established of at least the following:

- name or corporate name and permanent address of the place of activity from where the medicinal products are supplied;

- the starting date of the activity of offering medicinal products for sale at a distance by way of information society services,

[40] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 1aying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services; (OJ L 24, 21.7.1998, p. 37)

- the address of the website used for that purpose and all relevant information necessary to identify that website,

- if applicable, the classification in accordance with Title VI of the medicinal products offered for sale at a distance by way of information society services,

Where appropriate, this information shall be updated;

c) the medicinal products offered for sale at a distance by way of information society services comply with the national legislation of the Member State of destination in accordance with Article 6(1);

d) deleted.[41]

e) without prejudice to the information requirements set out in Directive 2000/31/EC, the website offering medicinal products for sale at a distance by way of information society services contains at least:

- the contact details of the competent authority or the authority designated for that purpose referred to in point b),

- a link to the website referred to in paragraph 3 of the Member State of establishment,

- the common logo referred to in paragraph 2 clearly displayed on every page of the website that relates to the offer for sale at a distance of medicinal products. The common logo shall be linked to the entry of the notified person or body in the list referred to in the third indent of paragraph 3.

[41] **DELETED**: Scrutiny reservation on deletion of " the conditions for retail supply of medicinal products for sale at a distance by way of information society services, comply with the national legislation of the Member State of destination;"

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1a. Member States may impose conditions justified by public health protection for the retail supply on their territory of medicinal products for sale at a distance by way of information society services.[42]

2. A common logo shall be established that is recognisable throughout the Union, while allowing for the identification of the Member State where the person or body offering medicinal products for sale at a distance is established. This logo shall be clearly displayed on websites offering medicinal products for sale at a distance in accordance with paragraph 1 point e.

In order to harmonise the functioning of this common logo for websites offering medicinal products for sale at a distance, the Commission shall adopt implementing measures regarding:

- the technical, electronic and cryptographic requirements to allow assessing the authenticity of the common logo;

- the design of the common logo;

Those measures shall, where necessary, be revised to take account of technical and scientific progress. Those measures shall be adopted in accordance with the regulatory procedure referred to in Article 121(2).

[42] **DELETED**: Scrutiny reservation.

3. Member States shall set up a website providing at least the following elements:

- information on the national legislation for offering medicinal products for sale at a distance by way of information society services, including information on the fact that there may be differences between Member States regarding classification of medicinal products and the conditions for their supply.

- information on the purpose of the common logo;

- the list of notified persons or bodies offering medicinal products for sale at a distance by way of information society services in accordance with paragraph 1 and their website addresses;

- background information on the risks related to medicinal products supplied illegally to the public via Internet;

This website shall contain a link to the website referred to in paragraph 4.

4. The Agency shall set up a website providing the information referred to in paragraph 3, indents 2 and 4, information on the EU legislation on falsified medicinal products as well as links to Member States' websites. The Agency website shall explicitly mention that the national websites contain information on persons or bodies authorised or entitled to supply medicinal products to the public and entitled to offer them for sale at a distance by way of information society services in the respective Member State.

5. Without prejudice to Directive 2000/31/EC and the requirements set out in this Title, Member States shall also take the necessary measures to ensure that other persons or bodies than those referred to in paragraph 1 offering for sale at a distance medicinal products to the public and operating in their Member State are subject to effective, proportionate and dissuasive penalties.

Article 85d

Without prejudice to Member State competencies, the Commission shall, in cooperation with the Agency and Member State authorities, conduct or promote information campaigns aimed at the general public on the dangers of falsified medicinal products. These campaigns shall raise consumer awareness of the risks related to medicinal products supplied illegally to the public via Internet and the function of the common logo, the national websites and the Agency website.'

15) Article 111 is amended as follows:

(a) Paragraph 1 is replaced by the following:

"1. The competent authority of the Member State concerned shall, in cooperation with the Agency, ensure that the legal requirements governing medicinal products are complied with, by means of inspections, if necessary unannounced, and, where appropriate, by asking an Official Medicines Control Laboratory or a laboratory designated for that purpose to carry out tests on samples. This cooperation shall consist in sharing information with the Agency on both inspections that are planned and that have been conducted. Member States and the Agency shall cooperate in the co-ordination of inspections in third countries. The inspections will include but not be limited to the ones mentioned in paragraphs 1a to 1f.

1a. Manufacturers, located in the European Union or in third countries, and wholesale distributors of medicinal products shall be subject to repeated inspections

1b[43]. The competent authority shall have a system of supervision including by inspections at an appropriate frequency based on risk, at the premises of the manufacturers, importers, or distributors of active substances, located on their territory, and effective follow up thereof.

Whenever it considers that there are grounds for suspecting non-compliance with the legal requirements of this directive , including the principles and guidelines of good manufacturing practice referred to in Articles 46(f) and 47, the competent authority may carry out inspections at the premises of:

(a) manufacturers or distributors of active substances located in third countries

(b) manufacturers or importers of excipients

[43] **DELETED**: Reservation on this paragraph.

1c. Inspections referred to in paragraphs 1a and 1b may also be carried out in the European Union and in third countries at the request of a Member State, the Commission or the Agency."

1d. Inspections may also take place at the premises of marketing authorisation holders, and brokers of medicinal products."

1e. In order to verify whether the data submitted in order to obtain a conformity certificate comply with the monographs of the European Pharmacopoeia, the standardisation body of the nomenclatures and the quality norms within the meaning of the Convention relating to the elaboration of the European Pharmacopoeia (European Directorate for the quality of Medicinal Products) may ask the Commission or the Agency to request such an inspection when the starting material concerned is the subject of a European Pharmacopoeia monograph.

1f. The competent authority of the Member State concerned may carry out inspections of starting material manufacturers at the specific request of the manufacturer himself.

1g. Inspections shall be carried out by officials representing the competent authority who shall be empowered to:

(a) inspect the manufacturing or commercial establishments of manufacturers of medicinal products, of active substances or excipients, and any laboratories employed by the holder of the manufacturing authorisation to carry out checks pursuant to Article 20;

(b) take samples including with a view to independent tests being carried out by an Official Medicines Control Laboratory or a laboratory designated for that purpose by a Member State;

(c) examine any documents relating to the object of the inspection, subject to the provisions in force in the Member States on 21 May 1975 placing restrictions on these powers with regard to the description of the manufacturing method;

(d) inspect the premises, records, documents and pharmacovigilance system master file of the marketing authorisation holder or any firms employed by the marketing authorisation holder to perform the activities described in Title IX.

1h. Inspections shall be carried out in accordance with the guidelines referred to in Article 111a.'

(b) Paragraph 3 is replaced by the following:

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

The competent authority which carried out the inspection shall communicate the content of those reports to the inspected entity.

Before adopting the report, the competent authority shall give the inspected entity concerned the opportunity to submit comments'[44]

(c) Paragraphs 4, 5 and 6 are replaced by the following:

'(4) Without prejudice to any arrangements which may have been concluded between the European Union and third countries, a Member State, the Commission or the Agency may require a manufacturer established in a third country to submit to an inspection as referred to in this article.

[44] **DELETED**: suggests to use standard Community procedure for inspections.

(5) Within 90 days of an inspection as referred to in paragraph 1, a certificate of good manufacturing practice or good distribution practices shall, when applicable, be issued to the inspected entity if the outcome of the inspection shows that it complies with the principles and guidelines of good manufacturing practice or good distribution practices as provided for by Union legislation.

If inspections are performed as part of the certification procedure for the monographs of the European Pharmacopoeia, a certificate shall be drawn up.

(6) Member States shall enter the certificates of good manufacturing practice and good distribution practices which they issue in a Union database managed by the Agency on behalf of the Union. Pursuant to Article 52a(7) Member States shall also enter information in this database regarding the registration of importers, manufacturers and distributors of active substances.. This database shall be publicly accessible.

(c1) In paragraph 7, the words "paragraph 1" are replaced by the words "paragraph 1g" and the words “used as starting materials” are deleted.

(c2) In paragraph 8, the words "paragraph 1" are replaced by "paragraph 1g".

16) The following Articles 111a and 111b are inserted after Article 111:

‘Article 111a

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

Member States shall, in cooperation with the Agency, establish the form and content of the authorisation referred to in articles 40(1) and 77 (1), of the reports referred to in article 111(3), of the certificates of good manufacturing practice and of the certificates of good distribution practices referred to in article 111(5).

Article 111b[45] [46]

(1) At the request of a third country, the Commission shall assess whether its regulatory framework for active substances exported to the European Union and the respective control and enforcement ensure a level of protection of public health equivalent to that in the European Union. This assessment shall take the form of a review of relevant documentation and, unless there are arrangements referred to in Article 51(2) of this Directive in place that cover this area of activity, it must also include confirmation by on-site review of the third country's regulatory system and, if necessary, observed inspection of one or more of the third country's manufacturing sites for active substances. If the assessment confirms this, the Commission shall include the third country in a list, by a way of decision. In this assessment, particular account shall be taken of:

(a) the country’s rules for good manufacturing practice;

(b) the regularity of inspections of good manufacturing practice;

(c) the efficacy of enforcement of good manufacturing practice;

(d) the regularity and rapidity of information provided by the third country relating to non-compliant producers of active ingredients.

[45] **DELETED**: reservation on the establishment of the list of third countries.
[46] **DELETED**: suggests mandatory inspection as pre-requisite for import.

(2) The Commission, shall adopt the necessary implementing measures to apply the requirements set out in points (a) to (d) of paragraph 1. Those measures shall be adopted in accordance with the regulatory procedure referred to in Article 121(2).

(3) The Commission, shall verify regularly whether the conditions laid down in paragraph 1 are fulfilled. The first verification shall take place no later than 3 years after the country has been included in the list referred to in paragraph 1. [47]

(4) The Commission shall perform the assessment and verification referred to in paragraphs 1 and 3 in cooperation with the Agency and competent authorities of the Member States. ’

16a) The following third paragraph is added to Article 116:

‘The second paragraph of this article applies also in case where manufacture of the medicinal product is not carried out in compliance with the particulars supplied pursuant to Article 8(3)(d), or controls are not carried out in compliance with the control methods described pursuant to Article 8(3)(h).’

[47] **DELETED**: reservation. Proposes first verification prior to Commission Decision.

16b) The following Article 117a is inserted after Article 117:

'Article 117a[48]

Member States shall have a system in place which aims at preventing medicinal products that are suspected to be dangerous from reaching the patient.

To this aim the system shall cover the receipt and handling of notifications of suspected falsified medicinal products as well as of suspected quality defects of medicinal products and cover recalls by marketing authorisation holders or ordered by national competent authorities from all relevant actors in the supply chain both during and outside normal working hours. The system shall also allow recalls from patients, who received them, where necessary with the assistance of health professionals.

If the medicinal product in question is suspected to present a serious risk to public health, the competent authority of the Member State in which the product was first identified, shall without any delay transmit a rapid alert notification to all Member States and all actors in the supply chain in that Member State. In the case where such medicinal products are deemed to have reached patients, urgent public announcements shall be issued within 24 hours in order to recall the medicinal products from the patients. These announcements shall contain sufficient information on the suspected quality defect or falsification and the risks involved.

Member States shall within two years after the entry into force of this Directive notify the Commission of the details of their respective national systems mentioned in this Article.'

[48] **DELETED**: Scrutiny reservation.

17) The following Articles 118b, 118ba and 118c are inserted after Article 118:

Article 118b[49]

The Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all necessary measures to ensure that these penalties are implemented. The penalties must be effective, proportionate and dissuasive.

These penalties shall not be inferior to those applicable to infringements of national law of similar nature and importance.

They shall address, inter alia, the following:

(1) the manufacturing, distribution, brokering, import and export of falsified medicinal products, including the supply of falsified medicinal products on the internet;

(2) non-compliance with the rules laid down in this Directive on manufacturing, distribution, import and export of active substances;

(3) non-compliance with the rules laid down in this Directive on the use of excipients.

Where relevant, the penalties shall take into account the threat to public health presented by falsification of medicinal products.

The Member States shall notify the national provisions adopted pursuant to this Directive to the Commission by [insert concrete date 18 months after publication] at the latest and shall notify any subsequent amendment affecting these provisions without delay. [50]

Within 5 years of the date referred to in the previous subparagraph, the Commission shall submit a report to the European Parliament and to the Council containing an overview of the transposition measures of Member States as regards this Article, together with an appraisal of the effectiveness of those measures.

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[49] **DELETED**: Scrutiny reserve on this article.

[50] **DELETED**: reservation on notification without delay.

Article 118ba

Member States shall organise meetings involving patients' and consumers' organisations and, as necessary, Member State enforcement officers, in order to communicate public information about the actions undertaken in the area of prevention and enforcement to combat the falsification of medicinal products.

Article 118c

Member States, in applying this Directive, shall take the necessary measures[51] to ensure cooperation between competent authorities for medicinal products and customs authorities.'

18) In Paragraph 1 of Article 121a, the words "Article 22b" are replaced by "Articles 22b, 47, 52b and 54a".

19) In Paragraph 1 of Article 121b, the words "Article 22b" are replaced by "Articles 22b, 47, 52b and 54a".

Article 2[52] [53]

1) Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [insert concrete date 18 months after publication] at the latest. They shall forthwith inform the Commission thereof.

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

[51] **DELETED**: Replace "the necessary measures" by "all relevant legal measures".

[52] **DELETED**: suggests extension of all dates by 6 months. **DELETED**: scrutiny reservation on dates.

[53] **DELETED**: need for transitional period of ten years for 'safety feature' systems already in place in some Member States.

However, the Member States shall apply:

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

(b) the provisions necessary to comply with Article 1(5a), 1(6),(8) and (9) from [insert concrete date 36 months after the publication of the delegated act referred to in Article 54a(1a)].

Notwithstanding the above, Member States who have systems in place for the purpose referred to in Article 1(8) of this Directive shall apply the provisions necessary to comply with Article 1(5a), 1(6), (8) and (9) at the latest from [insert date 6 years after the date referred to in the first subparagraph of Article 2(1)(b)].

(c) the provisions necessary to comply with article 1(14a) in so far as it relates to Article 85c of Directive 2001/83/EC as amended by this Directive 12 months after the publication of the implementing acts referred to in Article 85c(2).

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such references shall be laid down by Member States.

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

Article 2a

Within 5 years of [the date referred to in Article 2(1)(b) (Date of application of rules on safety feature)], the Commission shall submit a report to the European Parliament and to the Council containing the following:

- a description, where possible quantified, of the trends in the falsification of medicinal products in terms of categories of medicinal products affected, distribution channels including sales at the distance via Internet, Member States concerned, the nature of the falsifications, and the regions of provenance of these products; and

- an evaluation of the contribution of the measures provided in this Directive regarding the prevention of the entry of falsified medicinal products in the legal supply chain. This evaluation shall in particular assess the provisions contained in Articles 54(o) and 54a of Directive 2001/83/EC.

Article 2b

In order to establish the delegated acts referred to in Article 54a(1a), the Commission shall perform a study assessing at least the following aspects:

- the technical options for the unique identifier for the safety features referred to in Article 54(o);
- the options for the extent and the modalities of verification of the authenticity of the product bearing safety features. This assessment shall take into account the particular characteristics of the supply chains in the Member States;
- the technical options for the establishing and managing of the repositories system, referred to in Article 54a(4)(e).

The study shall for each of the options assess benefits, costs and cost-effectiveness.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*