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Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (Text with EEA relevance)

DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 8 June 2011

amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products

(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 point (c) of Article 168(4), thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Having regard to the opinion of the Committee of the Regions[(2)],

Acting in accordance with the ordinary legislative procedure[(3)],

Whereas:

(1) Directive 2001/83/EC of the European Parliament and of the Council[(4)] lays down the rules for, inter alia, manufacturing, importing, placing on the market, and the wholesale distribution of medicinal products in the Union as well as rules relating to active substances.

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

(3) Past experience shows that such falsified 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), which set up the International Medical Products Anti-Counterfeiting Taskforce (‘IMPACT’). IMPACT developed Principles and Elements for National Legislation

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against Counterfeit Medical Products, which were endorsed by the IMPACT General Meeting in Lisbon on 12 December 2007. The Union participated actively in IMPACT.

(5) A definition of 'falsified medicinal product' should be introduced in order to clearly distinguish falsified medicinal products from other illegal medicinal products, as well as from products infringing intellectual property rights. Furthermore, medicinal products with unintentional 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 who are not necessarily wholesale distributors as referred to in that Directive. In order to ensure the 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 they physically handle the medicinal products, but also brokers who are involved in the sale or purchase of medicinal products without selling or purchasing those products themselves, and without owning and physically handling the medicinal products.

(7) Falsified active substances and active substances that do not comply with applicable requirements of Directive 2001/83/EC pose serious risks to public health. Those risks should be addressed by strengthening the verification requirements applicable to the manufacturer of the medicinal product.

(8) There is a range of different good manufacturing practices that are suitable for being applied to 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 practices for excipients.

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

(10) Medicinal products may be introduced into the Union while not being intended to be imported, i.e. not intended to be released for free circulation. If those medicinal products are falsified they present a risk to public health within the Union. In addition, those falsified medicinal products may reach patients in third countries. Member States should take measures to prevent these falsified medicinal products, if introduced into the Union, from entering into circulation. When adopting provisions supplementing this obligation on Member States to take those measures, 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. Those provisions should be without prejudice to customs legislation, to the distribution of competences between the Union and the Member States and to the distribution of responsibilities within Member States.

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(11) Safety features for medicinal products should be harmonised within the Union in order to take account of new risk profiles, while ensuring the functioning of the internal market for medicinal products. Those 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 medicinal products or categories of medicinal products, such as generic medicinal products. Medicinal products subject to prescription should as a general rule bear the safety features. However, in view of the risk of falsification and the risk arising from falsification of medicinal products or categories of medicinal products there should be the possibility to exclude certain medicinal products or categories of medicinal products subject to prescription from the requirement to bear the safety features by way of a delegated act, following a risk assessment. Safety features should not be introduced for medicinal products or categories of medicinal products not subject to prescription unless, by way of exception, an assessment shows the risk of falsification, which leads to serious consequences. Those medicinal products should accordingly be listed in a delegated act.

The risk assessments should consider aspects such as the price of the medicinal product; previous cases of falsified medicinal products being reported in the Union and in third countries; the implications of a falsification for public health, taking into account the specific characteristics of the products concerned; and the severity of the conditions intended to be treated. The safety features should allow the verification of each supplied pack of the medicinal products, regardless of how they are supplied including through sale at a distance. 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[(5)] and should retain clear and effective safeguards whenever personal data is processed. The repositories system containing information on safety features might include commercially sensitive information. This information must be appropriately protected. When introducing the obligatory safety features, due account should be taken of the particular characteristics of the supply chains in Member States.

(12) Any actor in the supply chain who packages medicinal products has to be a holder of a manufacturing authorisation. In order for the safety features to be effective, a manufacturing authorisation holder who is not himself the original manufacturer of the medicinal product should only be permitted to remove, replace or cover those safety features under strict conditions. In particular, the safety features should be replaced in the case of repackaging by equivalent safety features. To this end, the meaning of the term ‘equivalent’ should be clearly specified. Those strict conditions should provide adequate safeguards against falsified medicinal products entering the supply 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 of 25 July 1985 on the approximation of the laws, regulations and

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administrative provisions of the Member States concerning liability for defective products[6].

(14) In order to increase reliability in the supply chain, wholesale distributors should verify that their supplying wholesale distributors are holders of a wholesale distribution authorisation.

(15) The provisions applicable to the export of medicinal products from the Union and those applicable to the introduction of medicinal products into the Union with the sole purpose of exporting them need to be clarified. Under Directive 2001/83/EC a person exporting medicinal products is a wholesale distributor. The provisions applicable to wholesale distributors as well as good distribution practices should apply to all those activities whenever they are performed on 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 by means of an inspection by a competent authority of a Member State, should be published in a database that should be established at Union level.

(17) The provisions on inspections and controls of all actors involved in the manufacturing and supply of medicinal products and their ingredients should be clarified and specific provisions should apply to different types of 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 manufacturers and wholesale distributors of medicinal products as well as of active substances should be strengthened. Such harmonised principles and guidelines should also help to ensure the functioning of existing mutual recognition agreements with third countries whose application depends 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 active substances are 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 the manufacturing of active substances intended for export to the Union, as well as inspections of facilities and enforcement of the applicable provisions, provide for a level of protection of public health equivalent to that provided for by Union 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 in this way. It is necessary to 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 Treaty on the Functioning of the European Union (TFEU).

(22) When examining the compatibility with Union law of the conditions for the retail supply of medicinal products, the Court of Justice of the European Union ('the Court of Justice') has recognised the very particular nature of medicinal products, whose therapeutic effects distinguish them substantially from other goods. The Court of Justice has also held that health and life of humans rank foremost among the assets and interests protected by the TFEU 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 that level may vary from one Member State to another, Member States must be allowed discretion[(7)] 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[(8)].

(24) 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 upon the retail supply of medicinal products offered for sale at a distance by means 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 common logo should be established, which is recognisable throughout the Union, while allowing for the identification of the Member State where the person 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 competent authority concerned. The websites of the competent authorities of Member States, as well as that of the European Medicines Agency ('the Agency'), should give an explanation of the use of the logo. All those websites should be linked in order to provide comprehensive information to the public.

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

(28) The falsification of medicinal products is a global problem, requiring effective and enhanced international coordination and cooperation in order to ensure that anti-falsification strategies are more effective, in particular as regards sale 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,

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working closely with Member States, should cooperate with the competent authorities of third countries with a view to effectively combating the trade in falsified medicinal products at a global level.

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

(30) The Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in order to supplement the provisions of Directive 2001/83/EC, as amended by this Directive, concerning good manufacturing and distribution practices for active substances, concerning detailed rules for medicinal products introduced into the Union without being imported and concerning 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) In order to ensure uniform conditions for implementation, implementing powers should be conferred on the Commission as regards the adoption of measures for the assessment of the regulatory framework applicable to the manufacturing of active substances exported from third countries to the Union and as regards a common logo that identifies websites which are legally offering medicinal products for sale at a distance to the public. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers[(9)].

(32) The safety features for medicinal products introduced under this Directive require substantial adaptations to manufacturing processes. In order to enable manufacturers to make those adaptations, the time limits for the application of the provisions on the safety features should be sufficiently long and should be calculated as from the date of publication in the *Official Journal of the European Union* of the delegated acts setting out detailed rules in relation to those safety features. It should also be taken into account that some Member States already have a national system in place. Those Member States should be granted an additional transitional period for adapting to the harmonised Union system.

(33) Since the objective of this Directive, namely to safeguard the functioning of the internal market for medicinal products, whilst ensuring a high level of protection of public health against falsified medicinal products, cannot be sufficiently achieved by the Member States, and can, by reason of the scale of the measure, be better achieved at 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. 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.

(34) It is important that the competent authorities of the Member States, the Commission and the Agency cooperate to ensure the exchange of information on measures taken to

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combat the falsification of medicinal products and on the penalties systems that are in place. Currently, such exchange takes place through the Working Group of Enforcement Officers. Member States should ensure that patients' and consumers' organisations are kept informed about enforcement activities to the extent that this is compatible with operational needs.

(35) In accordance with point 34 of the Interinstitutional Agreement on better law-making[(10)], 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 2010/84/EU[(11)] as regards pharmacovigilance. That Directive, inter alia, amended Article 111 with regard to inspections and Article 116 with regard to the suspension and revocation and variation of marketing authorisations under certain circumstances. Furthermore, it inserted provisions on delegated acts in Articles 121a, 121b and 121c of Directive 2001/83/EC. This Directive requires some further and complementary changes to those Articles of Directive 2001/83/EC.

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

HAVE ADOPTED THIS DIRECTIVE:

Article 1

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

(1) Article 1 is amended as follows:

(a) the following points are inserted:

3a. 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 to make a medical diagnosis.

3b. Excipient:

Any constituent of a medicinal product other than the active substance and the packaging material.;

(b) the following point is inserted:

17a. Brokering of medicinal products:

All activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person.;

(c) the following point is added:

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33. Falsified medicinal product:

Any medicinal product with a false representation of:

(a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;

(b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; 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 intellectual property rights.;

(2) in Article 2, paragraph 3 is replaced by the following:

3. Notwithstanding paragraph 1 of this Article 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.

4 Paragraph 1 shall be without prejudice to Articles 52b and 85a.;

(3) in Article 8(3), the following point is inserted:

(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 point (f) of Article 46. The written confirmation shall contain a reference to the date of the audit and a declaration that the outcome of the audit confirms that the manufacturing complies with the principles and guidelines of good manufacturing practice.;

(4) in Article 40, paragraph 4 is replaced by the following:

4. Member States shall enter the information relating to the authorisation referred to in paragraph 1 of this Article in the Union database referred to in Article 111(6).;

(5) in Article 46, 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 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 verify such compliance either by himself or, without prejudice to his responsibility as provided for in this Directive, through an entity acting on his behalf under a contract.

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The holder of the manufacturing authorisation shall ensure that the excipients are suitable for use in medicinal products by ascertaining what the appropriate good manufacturing practice is. This shall be ascertained on the basis of a formalised risk assessment in accordance with the applicable guidelines referred to in the fifth paragraph of Article 47. Such risk assessment shall take into account requirements under other appropriate quality systems as well as the source and intended use of the excipients and previous instances of quality defects. The holder of the manufacturing authorisation shall ensure that the appropriate good manufacturing practice so ascertained, is applied. The holder of the manufacturing authorisation shall document the measures taken under this paragraph;

(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 those medicinal products were distributed within the legal supply chain or by illegal means, including illegal sale by means of information society services;

(h) to verify that the manufacturers, importers or distributors from whom he obtains 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.;

(6) the following Article is inserted:

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:

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

b the active substances are accompanied by a written confirmation from the competent authority of the exporting third country of the following:

(i) 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 the third paragraph of Article 47;

(ii) the manufacturing plant concerned is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the Union; and

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(iii) in the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country to the Union without any delay.

This written confirmation shall be without prejudice to the obligations set out in Article 8 and in point (f) of Article 46.

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

4 Exceptionally and where necessary to ensure the 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 the third paragraph of Article 47, the requirement set out in point (b) of paragraph 2 of this Article 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 the possibility of such waiver, shall communicate this to the Commission.;

(7) in Article 47, the third and fourth paragraphs are replaced by the following:

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

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

The Commission shall adopt guidelines on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients referred to in the second paragraph of point (f) of Article 46.;

(8) the following Article is inserted:

Article 47a

1 The safety features referred to in point (o) of Article 54 shall not be removed or covered, either fully or partially, unless the following conditions are fulfilled:

a the manufacturing authorisation holder verifies, prior to partly or fully removing or covering those safety features, 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 those safety features with safety features which are equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering of the medicinal product. Such replacement shall be conducted without opening the immediate packaging as defined in point 23 of Article 1.

Safety features shall be considered equivalent if they:

(i) comply with the requirements set out in the delegated acts adopted pursuant to Article 54a(2); and

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(ii) are equally effective in enabling the verification of authenticity and identification of medicinal products and in providing evidence of tampering with medicinal products;

c the replacement of the safety features is 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 referred to 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 Directive 85/374/EEC.;

(9) in Article 51(1), the following subparagraph is inserted before the second 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.;

(10) the following Articles are inserted:

Article 52a

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:

(i) name or corporate name and permanent address;

(ii) the active substances which are to be imported, manufactured or distributed;

(iii) particulars regarding the premises and the technical equipment for their activity.

3 The persons 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.

4 The competent authority may, based on a risk assessment, decide to carry out an inspection. If the competent authority notifies the applicant within 60 days of the receipt of the registration form that an inspection will be carried out, the activity shall 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 will be carried out, the applicant may commence the activity.

5 The persons referred to in paragraph 1 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in the registration form. Any changes that may have an impact on the quality or safety of the active substances that are manufactured, imported or distributed must be notified immediately.

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6 Persons referred to in paragraph 1 who had commenced their activity before 2 January 2013 shall submit the registration form to the competent authority by 2 March 2013.

7 Member States shall enter the information provided in accordance with paragraph 2 of this Article in the Union database referred to in Article 111(6).

8 This Article shall be without prejudice to Article 111.

Article 52b

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

2 In order to establish what the necessary measures referred to in paragraph 1 of this Article are, the Commission may adopt, by means of delegated acts in accordance with Article 121a, and subject to the conditions laid down in Articles 121b and 121c, measures supplementing paragraph 1 of this Article 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 Union but not intended to be placed on the market.;

(11) in Article 54, the following point is added:

(o) for medicinal products other than radiopharmaceuticals referred to in Article 54a(1), safety features enabling wholesale distributors and persons authorised or entitled to supply medicinal products to the public to:

— verify the authenticity of the medicinal product, and

— identify individual packs,

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

(12) the following Article is inserted:

Article 54a

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 pursuant to point (b) of paragraph 2 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 pursuant to point (b) of paragraph 2 of this Article, after having been assessed to be at risk of falsification.

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

Those delegated acts shall set out:

a the characteristics and technical specifications of the unique identifier of the safety features referred to in point (o) of Article 54 that enables the authenticity of medicinal products to be verified and individual packs to be

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identified. When establishing the safety features due consideration shall be given to their cost-effectiveness;

b the lists containing the medicinal products or product categories which, in the case of medicinal products subject to prescription shall not bear the safety features, and in the case of medicinal products not subject to prescription shall bear the safety features referred to in point (o) of Article 54. Those lists shall be established considering the risk of and the risk arising from falsification relating to medicinal products or categories of medicinal products. To this end, at least the following criteria shall be applied:

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

(ii) the number and frequency of previous cases of falsified medicinal products being reported within the Union and in third countries and the evolution of the number and frequency of such cases to date;

(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 the procedures for the notification to the Commission provided for in paragraph 4 and a rapid system for evaluating and deciding on such notification for the purpose of applying point (b);

d the modalities for the verification 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. Those modalities shall allow the verification of the authenticity of each supplied pack of the medicinal products bearing the safety features referred to in point (o) of Article 54 and determine the extent of such verification. When establishing those modalities, 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;

e provisions on the establishment, management and accessibility of the repositories system in which information on the safety features, enabling the verification of the authenticity and identification of medicinal products, as provided for in point (o) of Article 54, shall be contained. The costs of the repositories system shall be borne by the manufacturing authorisation holders of medicinal products bearing the safety features.

3 When adopting the measures referred to in paragraph 2, the Commission shall take due account of at least the following:

a the protection of personal data as provided for in Union law;

b the legitimate interests to protect information of a commercially confidential nature;

c the ownership and confidentiality of the data generated by the use of the safety features; and

d the cost-effectiveness of the measures.

4 The national competent authorities shall notify the Commission of non-prescription medicinal products which they judge to be at risk of falsification and may inform the Commission of medicinal products which they deem not to be at risk according to the criteria set out in point (b) of paragraph 2 of this Article.

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5 Member States may, for the purposes of reimbursement or pharmacovigilance, extend the scope of application of the unique identifier referred to in point (o) of Article 54 to any medicinal product subject to prescription or subject to reimbursement.

Member States may, for the purposes of reimbursement, pharmacovigilance or pharmacoepidemiology, use the information contained in the repositories system referred to in point (e) of paragraph 2 of this Article.

Member States may, for the purposes of patient safety, extend the scope of application of the anti-tampering device referred to in point (o) of Article 54 to any medicinal product.;

(13) in Article 57, the fourth indent of the first paragraph is replaced by the following:

— authenticity and identification in accordance with Article 54a(5).;

(14) the heading of title VII is replaced by the following:

Wholesale distribution and brokering of medicinal products;

(15) in Article 76, paragraph 3 is replaced by the following:

3. Any distributor, not being the marketing authorisation holder, who imports a medicinal product from another Member State shall notify the marketing authorisation holder and the competent authority in the Member State to which the medicinal product will be imported of his intention to import that product. In the case of medicinal 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 and to fees payable to the competent authority for examining the notification.

4 In the case of medicinal 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 of this Article to the marketing authorisation holder and the Agency. A fee shall be payable to the Agency for checking that the conditions laid down in Union legislation on medicinal products and in the marketing authorisations are observed.;

(16) 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 authorisation to engage in activity as a wholesaler in medicinal products, stating the premises located on their territory for which it is valid.;

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

4. Member States shall enter the information relating to the authorisations referred to in paragraph 1 of this Article in the Union database referred to in Article 111(6). At the request of the Commission or any Member State, Member States shall provide all appropriate information concerning the individual authorisations which they have granted under paragraph 1 of this Article.

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5 Checks on the persons authorised to engage in activity as a wholesaler in medicinal products, and the inspection of their premises, shall be carried out under the responsibility of the Member State which granted the authorisation for premises located on its territory.;

(17) Article 80 is amended as follows:

(a) the following point is inserted:

(ca) they must verify that the medicinal products received are not falsified by checking the safety features on the outer packaging, in accordance with the requirements laid down in the delegated acts referred to in Article 54a(2);;

(b) 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 products at least for products bearing the safety features referred to in point (o) of Article 54;;

(c) the following points are added:

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

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

(d) the following paragraphs are added:

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

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

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Where the medicinal product is obtained through brokering, the wholesale distribution authorisation holders must verify that the broker involved fulfils the requirements set out in this Directive.;

(18) in the first paragraph of Article 82, the following indent is added:

— batch number of the medicinal products at least for products bearing the safety features referred to in point (o) of Article 54;;

(19) the following Articles are inserted:

Article 85a

In the case of wholesale distribution of medicinal products to third countries, Article 76 and point (c) of Article 80 shall not apply. Moreover, points (b) and (ca) of Article 80 shall not apply where a product is directly received from a third country but not imported. The requirements set out in 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 authorisation granted pursuant to Regulation (EC) No 726/2004 or by the competent authorities of a Member State in accordance with this Directive.

Persons brokering medicinal products shall have a permanent address and contact details in the Union, so as to ensure accurate identification, location, communication and supervision of their activities by competent authorities.

The requirements set out in points (d) to (i) of Article 80 shall apply *mutatis mutandis* to the brokering of medicinal products.

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

Persons brokering medicinal products who had commenced their activity before 2 January 2013 shall register with the competent authority by 2 March 2013.

The competent authority shall enter the information referred to in the first subparagraph in a register that shall be publicly accessible.

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

4 This Article shall be without prejudice to Article 111. Inspections referred to in Article 111 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 to remove that person from the register referred to in paragraph 2. The competent authority shall notify that person thereof.;

(20) the following Title is inserted before Title VIII:

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TITLE VIIA

SALE 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 means of information society services, Member States shall ensure that medicinal products are offered for sale at a distance to the public by means of information society services as defined in Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services[(12)] under the following conditions:

a the natural or legal person offering the medicinal products is authorised or entitled to supply medicinal products to the public, also at a distance, in accordance with national legislation of the Member State in which that person is established;

b the person referred to in point (a) has notified the Member State in which that person is established of at least the following information:

(i) name or corporate name and permanent address of the place of activity from where those medicinal products are supplied;

(ii) the starting date of the activity of offering medicinal products for sale at a distance to the public by means of information society services;

(iii) the address of the website used for that purpose and all relevant information necessary to identify that website;

(iv) if applicable, the classification in accordance with Title VI of the medicinal products offered for sale at a distance to the public by means of information society services.

Where appropriate, that information shall be updated;

c the medicinal products comply with the national legislation of the Member State of destination in accordance with Article 6(1);

d without prejudice to the information requirements set out in Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce)[(13)], the website offering the medicinal products contains at least:

(i) the contact details of the competent authority or the authority notified pursuant to point (b);

(ii) a hyperlink to the website referred to in paragraph 4 of the Member State of establishment;

(iii) the common logo referred to in paragraph 3 clearly displayed on every page of the website that relates to the offer for sale at a distance to the public of medicinal products. The common logo shall contain

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a hyperlink to the entry of the person in the list referred to in point (c) of paragraph 4.

2 Member States may impose conditions, justified on grounds of public health protection, for the retail supply on their territory of medicinal products for sale at a distance to the public by means of information society services.

3 A common logo shall be established that is recognisable throughout the Union, while enabling the identification of the Member State where the person offering medicinal products for sale at a distance to the public is established. That logo shall be clearly displayed on websites offering medicinal products for sale at a distance to the public in accordance with point (d) of paragraph 1.

In order to harmonise the functioning of the common logo, the Commission shall adopt implementing acts regarding:

a the technical, electronic and cryptographic requirements for verification of the authenticity of the common logo;

b the design of the common logo.

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

4 Each Member State shall set up a website providing at least the following:

a information on the national legislation applicable to the offering of medicinal products for sale at a distance to the public by means 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;

b information on the purpose of the common logo;

c the list of persons offering the medicinal products for sale at a distance to the public by means of information society services in accordance with paragraph 1 as well as their website addresses;

d background information on the risks related to medicinal products supplied illegally to the public by means of information society services.

This website shall contain a hyperlink to the website referred to in paragraph 5.

5 The Agency shall set up a website providing the information referred to in points (b) and (d) of paragraph 4, information on the Union legislation applicable to falsified medicinal products as well as hyperlinks to the Member States' websites referred to in paragraph 4. The Agency's website shall explicitly mention that the Member States' websites contain information on persons authorised or entitled to supply medicinal products at a distance to the public by means of information society services in the Member State concerned.

6 Without prejudice to Directive 2000/31/EC and the requirements set out in this Title, Member States shall take the necessary measures to ensure that other persons than those referred to in paragraph 1 that offer medicinal products for sale at a distance to the public by means of information society services and that operate on their territory are subject to effective, proportionate and dissuasive penalties.

Article 85d

Without prejudice to the competences of the Member States, the Commission shall, in cooperation with the Agency and Member State authorities, conduct or promote

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information campaigns aimed at the general public on the dangers of falsified medicinal products. Those campaigns shall raise consumer awareness of the risks related to medicinal products supplied illegally at a distance to the public by means of information society services and of the functioning of the common logo, the Member States' websites and the Agency's website.;

(21) 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 coordination of inspections in third countries. The inspections shall include but not be limited to the ones mentioned in paragraphs 1a to 1f.

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

1b The competent authority of the Member State concerned 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 its territory, and effective follow-up thereof.

Whenever it considers that there are grounds for suspecting non-compliance with the legal requirements laid down in this Directive, including the principles and guidelines of good manufacturing practice and good distribution practices referred to in point (f) of Article 46 and in Article 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.

1c Inspections referred to in paragraphs 1a and 1b may also be carried out in the 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 of 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 (the European Directorate for the Quality of Medicines and Healthcare) 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.

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

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 of 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) paragraphs 3 to 6 are 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 authorisation 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.

4 Without prejudice to any arrangements which may have been concluded between the 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.

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.

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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 that database regarding the registration of importers, manufacturers and distributors of active substances. The database shall be publicly accessible.;

(c) paragraph 7 is amended as follows:

(i) the words ‘paragraph 1’ are replaced by the words ‘paragraph 1g’;

(ii) the words ‘used as starting materials’ are deleted;

(d) in the first subparagraph of paragraph 8, the words ‘paragraph 1(d)’ are replaced by the words ‘point (d) of paragraph 1g’;

(22) the following Articles are inserted:

Article 111a

The Commission shall adopt detailed guidelines laying down the principles applicable to 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

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

a the country’s rules for good manufacturing practice;

b the regularity of inspections to verify compliance with good manufacturing practice;

c the effectiveness 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 substances.

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

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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.

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

(23) in Article 116, the following paragraph is added:

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

(24) the following Article is inserted:

Article 117a

1 Member States shall have a system in place which aims at preventing medicinal products that are suspected to present a danger to health from reaching the patient.

2 The system referred to in paragraph 1 shall cover the receipt and handling of notifications of suspected falsified medicinal products as well as of suspected quality defects of medicinal products. The system shall also cover recalls of medicinal products by marketing authorisation holders or withdrawals of medicinal products from the market ordered by national competent authorities from all relevant actors in the supply chain both during and outside normal working hours. The system shall also make it possible to recall, where necessary with the assistance of health professionals, medicinal products from patients who received such products.

3 If the medicinal product in question is suspected of presenting a serious risk to public health, the competent authority of the Member State in which that 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 event of such medicinal products being deemed to have reached patients, urgent public announcements shall be issued within 24 hours in order to recall those medicinal products from the patients. Those announcements shall contain sufficient information on the suspected quality defect or falsification and the risks involved.

4 Member States shall by 22 July 2013 notify the Commission of the details of their respective national systems referred to in this Article.;

(25) the following Articles are inserted:

Article 118a

1 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 those penalties are implemented. The penalties must be effective, proportionate and dissuasive.

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

2 The rules referred to in paragraph 1 shall address, inter alia, the following:

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a the manufacturing, distribution, brokering, import and export of falsified medicinal products, as well as the sale of falsified medicinal products at a distance to the public by means of information society services;

b non-compliance with the provisions laid down in this Directive on manufacturing, distribution, import and export of active substances;

c non-compliance with the provisions laid down in this Directive on the use of excipients.

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

3 The Member States shall notify the national provisions adopted pursuant to this Article to the Commission by 2 January 2013 and shall notify any subsequent amendment of those provisions without delay.

By 2 January 2018, the Commission shall submit a report to the European Parliament and to the Council giving an overview of the transposition measures of Member States as regards this Article, together with an evaluation of the effectiveness of those measures.

Article 118b

Member States shall organise meetings involving patients "and consumers" organisations and, as necessary, Member States' 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 to ensure cooperation between competent authorities for medicinal products and customs authorities.;

(26) in Article 121a(1), the words 'Article 22b' are replaced by the words 'Articles 22b, 47, 52b and 54a';

(27) in Article 121b(1), the words 'Article 22b' are replaced by the words 'Articles 22b, 47, 52b and 54a';

Article 2

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 2 January 2013. They shall forthwith inform the Commission thereof.

2 Member States shall apply those measures from 2 January 2013.

However, the Member States shall apply:

a the provisions necessary to comply with point 6 of Article 1 of this Directive in so far as it relates to Article 46b(2)(b) and Article 46b(3) and (4) of Directive 2001/83/EC as inserted by this Directive from 2 July 2013;

b the provisions necessary to comply with points 8, 9, 11 and 12 of Article 1 of this Directive from 3 years after the date of publication of the delegated acts referred to in point 12 of Article 1 of this Directive.

Nevertheless, Member States which, on 21 July 2011, have systems in place for the purpose referred to in point 11 of Article 1 of this Directive shall apply the provisions necessary to comply with points 8, 9, 11 and 12 of Article 1 of this Directive at the

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latest from 6 years after the date of application of the delegated acts referred to in point 12 of Article 1 of this Directive;

c the provisions necessary to comply with point 20 of Article 1 of this Directive in so far as it relates to Article 85c of Directive 2001/83/EC as inserted by this Directive at the latest from 1 year after the date of publication of the implementing acts referred to in Article 85c(3) as inserted by this Directive.

3 When Member States adopt the measures referred to in paragraph 1, 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.

4 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 3

At the latest 5 years after the date of application of the delegated acts referred to in Article 54a(2) of Directive 2001/83/EC as inserted by this Directive, the Commission shall submit a report to the European Parliament and to the Council containing the following:

(a) a description, where possible including quantitative data, of the trends in the falsification of medicinal products in terms of: categories of medicinal products affected, distribution channels including sale at a distance to the public by means of information society services, the Member States concerned, the nature of the falsifications, and the regions of provenance of these products; and

(b) an evaluation of the contribution of the measures provided for in this Directive regarding the prevention of the entry of falsified medicinal products in the legal supply chain. That evaluation shall in particular assess point (o) of Article 54 and Article 54a of Directive 2001/83/EC as inserted by this Directive.

Article 4

In order to adopt the delegated acts referred to in Article 54a(2) of Directive 2001/83/EC as inserted by this Directive, the Commission shall perform a study assessing at least the following aspects:

(a) the technical options for the unique identifier of the safety features referred to in point (o) of Article 54 of Directive 2001/83/EC as inserted by this Directive;

(b) the options for the extent and the modalities of verification of the authenticity of the medicinal product bearing the safety features. This assessment shall take into account the particular characteristics of the supply chains in the Member States;

(c) the technical options for establishing and managing the repositories system, referred to in point (e) of Article 54a(2) of Directive 2001/83/EC as inserted by this Directive.

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

Article 5

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

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Article 6

This Directive is addressed to the Member States.

Done at Strasbourg, 8 June 2011.

For the European Parliament

The President

J. BUZEK

For the Council

The President

GYŐRI E.

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(**1**) OJ C 317, 23.12.2009, p. 62.

(**2**) OJ C 79, 27.3.2010, p. 50.

(**3**) Position of the European Parliament of 16 February 2011 (not yet published in the Official Journal) and decision of the Council of 27 May 2011.

(**4**) OJ L 311, 28.11.2001, p. 67.

(**5**) OJ L 281, 23.11.1995, p. 31.

(**6**) OJ L 210, 7.8.1985, p. 29.

(**7**) Judgment of the Court of 19 May 2009 in Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others* v *Saarland* ECR [2009] I-4171, paragraphs 19 and 31.

(**8**) Judgment of the Court of 19 May 2009 in Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes and Others* v *Saarland* ECR [2009] I-4171, paragraphs 34 and 35.

(**9**) OJ L 55, 28.2.2011, p. 13.

(**10**) OJ C 321, 31.12.2003, p. 1.

(**11**) OJ L 348, 31.12.2010, p. 74.

(**12**) OJ L 204, 21.7.1998, p. 37.

(**13**) OJ L 178, 17.7.2000, p. 1.’;