Annex

Transposition note for Directive 2011/62/EU 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

Article	Provision which Implements
Article 1(1)(a) Inserts point 3a into article 1 of the Directive providing the meaning of 'active substance'. Inserts point 3b into article 1 of the Directive providing the meaning of 'excipient'.	Regulation 3(a)(i) inserts the definition of "active substance" into regulation 8 (general interpretation) of the principal Regulations. Regulation 3(a)(iv) inserts the definition of "excipient" into regulation 8 of the principal Regulations.
Article 1(1)(b) Inserts point 17a into article 1of the Directive providing the meaning of 'brokering of medicinal products'.	Regulation 3(a)(iii) inserts the definition of "brokering" into regulation 8 of the principal Regulations.
Article 1(1)(c) Inserts point 33 into article 1 of the Directive providing the meaning of 'falsified medicinal product'.	Regulation 3(a)(vi) inserts definition of falsified medicinal product into regulation 8 of the principal Regulations.
Article 1(2) Substitutes new paragraphs 3 and 4 into article 2 concerning the scope of the Directive and to ensure that provisions on manufacture and importation apply to the manufacture of medicinal products intended only for export and to intermediate products, active substances and excipients.	Regulation 16 inserts new regulation 45O(5) into the principal Regulations to provide this requirement in relation to active substances.
Article 1(3) This inserts point (ha) into Article 8(3) of the Directive to provide a requirement on the manufacturer of the medicinal product to take certain action in relation to the manufacturer of an active substance to ensure compliance with good manufacturing practice.	Regulation 34 inserts paragraph 9A into Schedule 8 of the principal Regulations to provide this requirement.
Article 1(4) This substitutes paragraph 4 of article 40 of the Directive providing a requirement on Member States to enter the information relating to manufacturing authorisations in the relevant	N/A

Article	Provision which Implements
EU database.	
Article 1(5) This replaces point (f) in Article 46 of the Directive (obligations of manufacturing authorisation holders) with the following points. Point (f) (first paragraph) provides that the authorization holder has to comply with the principles and guidelines of good manufacturing practice for medicinal products and to use only active substances which have been manufactured and distributed in accordance with good manufacturing practice or good distribution practice for active substances. The holder is to carry out certain compliance activities in this regard. Point (f), second paragraph imposes further obligations on the manufacturing authorization holder in relation to the suitability of excipients for use in medicinal products.	Regulation 11 substitutes new regulation 37 into the principal Regulations. The requirements of first paragraph of point (f) are met by paragraphs (3) and (4) of regulation 37. The requirements of second paragraph of point (f) are met by paragraph (5) of regulation 37.
Article 1(5) Inserts new point (g) into article 46 to provide that a manufacturing authorization holder has to inform the competent authority if he obtains information about falsified medicinal products which come within the scope his authorisation.	Regulation 11 substitutes new regulation 37 into the principal Regulations. Paragraph (11) of regulation 37 implements point (g).
Article 1(5) New point (h) is inserted into article 46 to provide that a manufacturing authorization holder is obliged 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.	Regulation 11 substitutes new regulation 37 into the principal Regulations. Paragraph (4)(b) of regulation 37 implements point (h).
Article 1(5) Inserts new point (i) into article 46 to provide that a manufacturing authorization holder is obliged to verify the authenticity and quality of the active substances and the excipients.	Regulation 11 substitutes new regulation 37 into the principal Regulations. Paragraph (4)(c) and (5)(d) of regulation 37 implements this point.
Article 1(6) This inserts new article 46b into the Directive relating to active substances.	N/A

Article	Provision which Implements
Article 46b, paragraph 1, imposes a duty on Member States to take appropriate measures to ensure that the manufacture, import and distribution of, including for export, of active substances complies with good manufacturing practice and good distribution practice.	
Article 46b, paragraph 2 provides that active substances shall only be imported if certain conditions are fulfilled.	Regulation 16 inserts regulation 45O(3) into the principal Regulations to provide these requirements.
Condition at point (a) is that 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.	Regulation 45O(3)(b).
Condition at point (b) is that the active substances are accompanied by a written confirmation from the competent authority of the exporting third country giving the following information:	Regulation 45O(3)(c).
(i) about the standards of good manufacturing practice relevant to the exported active substance;	Regulation 45O(3)(c)(i).
(ii) that the manufacturing plant is subject to certain controls and enforcement measures to ensure protection of public health is at least equivalent to that in the EU; and	Regulation 45O(3)(c)(ii).
(iii) that 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.	Regulation 45O(3)(c)(iii).
This written confirmation shall be without prejudice to the obligations set out in Article 8 and in point (f) of Article 46.	Regulation 45O(3).
Article 46b, paragraph 3 provides that 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.	Regulation 45O(4)(a)

Article	Provision which Implements
Article 46b, paragraph 4 provides for circumstances 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. Where a waiver is used there is a notification requirement to the Commission.	Regulation 45O(4)(b).
Article 1(7) This replaces the third and fourth paragraphs of article 47 with 3 new paragraphs. New paragraph 3 provides for the Commission to adopt the principles and guidelines of good manufacturing practice for active substances by means of delegated acts. New paragraph 4 for the principles of good distribution practices for active substances to be adopted by the Commission in the form of guidelines. New paragraph 5 provides for the Commission to adopt guidelines on the formalised risk assessment for ascertaining the appropriate good manufacturing practice for excipients.	N/A
Article 1(8) This inserts new article 47a into the Directive Paragraph 1 of article 47a provides that the safety features referred to in point (o) of Article 54 shall not be removed or covered, either fully or partially, unless the certain conditions are fulfilled. Paragraph 2 of article 47a provides that 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.	N/A N/A N/A.
Article 1(9) This inserts a subparagraph into Article 51(1) to provide that the qualified person referred to	N/A

Article	Provision which Implements
in Article 48 shall, in relation to 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.	
Article 1(10) This inserts articles 52a and 52b into the Directive.	
Article 52a provides for new provisions for importers, manufacturers and distributors of active substances.	Regulation 16 inserts new regulations 45M to 45V into the principal Regulations.
Paragraph 1 of article 52a provides a registration requirement for such activity.	Regulation 45N(1)
Paragraph 2 of article 52a provides for certain details to be included on the registration form.	Regulation 45N(5)(b) and Schedule 7A.
Paragraph 3 of article 52a provides for the registration form to be submitted to the competent authority at least 60 days prior to the intended commencement of their activity.	Regulation 45M(1) and 45N(1).
Paragraph 4 of article 52a provides for the competent authority, on the basis of a risk assessment, to carry out an inspection. The applicant is permitted to commence the activity if he has not been notified of an inspection within 60 days of the competent authority having received the registration form.	Regulation 45N(1)(a) to (c).
Paragraph 5 of article 52a provides for the registered person to notify any changes to the registration details on an annual basis. Any changes having an impact on the quality or safety of active substances imported, manufactured or distributed must be notified immediately.	Regulation 45N(2) and (3). Regulation 45N(3) is necessary so that where changes to the registration details are accepted, registration can continue.
Paragraph 6 of article 52a provides that persons requiring registration who had commenced their activity before 2 January	Regulation 45N(6).

Article	Provision which Implements
2013 shall submit the registration form to the competent authority by 2 March 2013. Paragraph 7 of article 52a requires Member States to enter the information provided under paragraph 2, in the Union database referred to in Article 111(6). Paragraph 8 provides that article 52a is without prejudice to Article 111. Article 52b provides that Member States shall take the necessary measures to prevent such products from entering into circulation if there are sufficient grounds to suspect that those products are falsified. The necessary measures are to be adopted by the Commission.	N/A N/A N/A
Article 1(11) This inserts point (o) into article 54 for the provision of safety features that would enable wholesale distributors and persons authorised to supply medicinal products to the public to authenticate, identify or otherwise establish if a medicinal product has been tampered with.	N/A
Article 1(12) This inserts article 54a into the Directive providing further provisions in relation to safety features of medicinal products and the delegated acts to be adopted by the Commission.	N/A
Article 1(13) This amends article 57 so that Member States may require the use of certain forms of labelling including to ascertain the authenticity and identity of a medicinal product.	None adopted.
Article 1(14) Substitutes a new heading for Title VII of the Directive.	N/A

Article	Provision which Implements
Article 1(15) The replaces paragraph 3 in article 76 of the Directive with two new paragraphs. New paragraphs 3 and 4 provide that any distributor, not being the marketing authorisation holder, who imports a medicinal product from another Member State shall have to comply with certain notification requirements.	Regulation 14 substitutes regulation 43 of the principal Regulations. The relevant provision is provided at paragraph (8)(a) and (b) of regulation 43.
Article 1(16) This amends article 77 of the Directive. Point (a) replaces paragraph 1 of article 77 to provide that the wholesale dealers license has to state the premises for which it is valid. Point (b) replaces paragraphs 4 and 5 of article 77. Paragraph 4 imposes a requirement for Member States to enter information in the Union database and to provide information about individual authorisations if requested to do so by the Commission or any Member State. Paragraph 5 provides that checks and inspections of wholesalers shall be carried out by the Member State.	Regulation 5 substitutes regulation 18 of the principal Regulations. The implementing provision is in paragraph (3) of regulation 18. N/A N/A
Article 1(17) This amends article 80 of the Directive which requires holders of a distribution authorization to fulfil certain requirements. Point (a) inserts point (ca) into article 80 requiring licence holders to verify that the medicinal products received are not falsified by checking the safety features on the outer packaging as laid down by the Commission in the delegated acts.	Regulation 14 substitutes regulation 43 of the principal Regulations. The implementing provision is in paragraph (11) of regulation 43.

Article	Provision which Implements
Point (b) replaces point (e) of article 80 to provide that the license holder must keep certain records about transactions in medicinal products.	Regulation 43(7)(c).
Point (c) inserts points (h) and (i) into article 80	
Inserted point (h) requires the license holder to maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities.	Regulation 43(12).
Inserted point (i) requires the license holder to 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.	Regulation 43(13)
Point (d) inserts 3 new paragraphs after point (i) in article 80.	Regulation 15 substitutes regulation 44 of the principal Regulations.
The first paragraph provides that where products are obtained from another wholesale distributor certain verification must be carried out to ensure that the supplier complies with the principles and guidelines of good distribution practices and that he holds a wholesale distribution authorisation.	Regulation 44(1), (2)(a) and (b) and (3)(a).
The second paragraph provides that where the product is obtained from the manufacturer or importer, wholesale distribution authorisation holders must verify that the manufacturer or importer holds a manufacturing authorisation.	Regulation 44(1)(a) and (b), (2)(a) and (b) and (3)(b)
The third paragraph provides that 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 the Directive.	Regulation 43(14).

Article	Provision which Implements
Article 1(18) This amends article 82 of the Directive to provide a new requirement that where a wholesaler supplies a medicinal product to a person authorised to sell medicinal products to the public, they must enclose a document giving the batch number – at least for products required to bear the safety features under the Directive.	Regulation 15 substitutes regulation 44 of the principal Regulations. The implementing provision is at regulation 44(6)(e).
Article 1(19) This inserts article 85a and 85b into the Directive. Article 85a applies to the trade in medicines with third countries. In the case of wholesale distribution of medicinal products to third countries, Article 76 (only products with a marketing authorization can be distributed) and point (c) of Article 80 (the recipient of such products must hold a distribution authorisation or be entitled to supply products to the public) shall not apply. Moreover, restrictions on who they obtain their supplies from (article 80 point (b)) and the requirement verify the products are not falsified by checking the safety features provided for in the Directive (article 80 point (ca)) do not apply where a product is 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 applies to brokered medicinal products. The first sub-paragraph of paragraph 1 of article 85b provides the brokers shall ensure that brokered products have a marketing authorization issued by a Member State or by	Regulation 5 substitutes regulation 18 of the principal Regulations. Regulation 15 substitutes regulation 44 of the principal Regulations. The implementing provisions are at regulations 18(6) and 44(4) and (5) Regulation 43(11) and 44(1). Regulation 44(4) and (5). Regulation 16 inserts the brokering provisions (regulations 45A to 45L into the principal Regulations. Regulation 45A(1)(a).

Article	Provision which Implements
the EC pursuant to Regulation (EC) No 726/2004.	
The second sub-paragraph of paragraph 1 provides that brokers to have a permanent address and contact details in the Union to enable the Regulators to carry out certain supervisory functions.	Regulation 45B(2)(c).
The third sub-paragraph of paragraph 1 provides that the requirements set out in points (d) to (i) of Article 80 shall apply as appropriate to the brokering of medicinal products.	Regulations 45A(1)(b)(iii), 45E(3).
The first sub-paragraph of paragraph 2 provides that persons may only broker medicinal products if they are registered with the competent authority of the Member State of their permanent address.	Regulation 45A(1)(b)(i).
Brokers shall submit, at least, their name, corporate name and permanent address in order to register.	Regulation 45B(2)(a) to (c).
Brokers shall notify the competent authority of any changes thereafter without unnecessary delay.	Regulation 45F(4).
The second sub-paragraph of paragraph 2 requires brokers who commenced their activity before 2 January 2013 to register with the competent authority by 2 March 2013.	Regulation 45A(3).
The third sub-paragraph of paragraph 2 provides that the competent authority shall enter the information referred to in the first sub-paragraph in a register that shall be publicly accessible.	Regulation 45D(3) and (4).
Paragraph 3 provides that the guidelines referred to in Article 84 shall include specific provisions for brokering.	N/A

Article	Provision which Implements
The first sub-paragraph of paragraph 4 provides that article 85b shall be without prejudice to the Directive provisions (article 111) concerning inspections. The competent authority where the broker is registered shall carry out any inspection. The second sub-paragraph of paragraph 4 provides that If a broker does not comply with the requirements set out in this Article, the competent authority may remove that person from the register and notify him accordingly.	Regulation 45E(7). Regulation 45G.
Article 1(20) This inserts Title V11A (sale at a distance to the public) provisions (articles 85c and 85d) into the Directive. Article 85c Paragraph 1 of article 85c provides that without prejudice to national legislation prohibiting the sale of prescription medicinal products to the public by means of information society services (as defined in European legislation), Member States shall ensure the medicinal products are only offered for sale to the public under certain conditions. The condition at point (a) of paragraph 1 is that 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; The condition at point (b) is that the person referred to in point (a) has notified the Member State in which that person is established of certain information. Where appropriate, that information is required to be updated.	Regulation 28 inserts Part 12A into the principal regulations. Regulations 256A to 256N include the relevant provisions. Regulation 256A provides the definition of "information society services". The obligation is in regulation 256B(1). Regulation 256B(4). Regulation 256C(2)(b) and 256F(2).

Article	Provision which Implements
The condition at point (c) is that the medicinal products comply with the national legislation of the Member State of destination in accordance with provisions on marketing authorisations.	Regulation 256B(3).
The condition at point (d) provides that without prejudice to certain European law aspects of information society services, in particular electronic commerce, in the Internal Market, the website offering the medicinal products contains at least- (i) the contact details of the relevant competent authority ; (ii) a hyperlink to the website of the Member State of establishment; (iii) the common logo referred to in paragraph 3 clearly displayed on every page of the website with a hyperlink from the logo to the entry of the person in the list referred to in point (c) of paragraph 4.	Regulation 256H(3) and (4)
Paragraph 2 of article 85c provides that Member States may impose conditions on grounds of public health protection, for the retail supply on their territory of medicinal products for sale at a distance.	None adopted.
The first sub-paragraph of paragraph 3 provides the requirements for a common logo shall be established that is recognisable throughout the Union. That logo is to be displayed on websites offering products for sale at a distance.	Regulation 256H(4).
The second sub-paragraph of paragraph 3 provides for the Commission to adopt certain implementing acts, including in relation to it's design, regarding the logo.	N/A.
The third sub-paragraph of paragraph 3 provides for the implementing acts in sub-paragraph 2 to the take account of technical and scientific progress and for certain	N/A.

Article	Provision which Implements
procedural requirements.	
The first sub-paragraph of paragraph 4 of article 85c requires Member States to set up a website providing at least the information in points (a) to (d).	256A - see definition of the relevant website of the Member State.
Point (a) requires information about relevant national legislation on the sale of medicinal products at a distance and information that there may be differences between classifications of products and the conditions for their supply between Member States.	256A - see definition of the relevant website of the Member State at sub-paragraphs (a) and (b).
Point (b) requires information on the purpose of the common logo.	256A - see definition of the relevant website of the Member State at sub-paragraph (c).
Point (c) requires publication of the list of persons offering the medicinal products for sale at a distance including their website addresses.	256A - see definition of the relevant website of the Member State at sub-paragraph (d).
Point (d) requires publication of background information on the risks related to medicinal products supplied illegally to the public by means of information society services.	256A - see definition of the “relevant website of the Member State” at sub-paragraph (e).
The second sub-paragraph of paragraph 4 provides that the website of the Member State to contain a hyperlink to the website referred to in paragraph 5.	256A - see definition of the “relevant website of the Member State” at sub-paragraph (f).
Paragraph 5 of article 85c provides the requirements for the website of the European Medicines Agency.	N/A
Paragraph 6 of article 85c requires Member States to provide effective, proportionate and dissuasive penalties for persons selling medicinal products at a distance when they don’t satisfy the conditions under paragraph 1.	Regulations 256M and 256N provide the offences and penalties.

Article	Provision which Implements
Article 85d This provides for cooperation between the Commission, European Medicines Agency and Member States to promote public information campaigns on the dangers of falsified medicinal products, and raise consumer awareness on the logo and other related matters.	N/A
Article 1(21) This amends article 111 of the Directive. Point (a) replaces paragraph 1 of the Directive dealing with the compliance action to be taken through inspections in cooperation with the European Medicines Agency and on the powers and duties of officials representing the competent authority. Point (b) replaces paragraphs 3 to 6 of article 111 New paragraphs 3 and 4 make no significant changes to the existing text. New sub-paragraph one of paragraph 5 provides that 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 they are compliant with Union legislation. Sub-paragraph two of paragraph 5 provides that if inspections are performed as part of the certification procedure for the monographs of the European Pharmacopoeia, a certificate shall be drawn up. New paragraph 6 provides that Member States shall enter details about the certificates of good manufacturing practice and good distribution practices and information regarding the registration of importers, manufacturers and distributors of active substances on the	Regulations 29 and 30 update regulations 327 and 330 of the principal Regulations where necessary to reflect the new requirements. Transposition not required.

Article	Provision which Implements
publicly accessible Union database. Point (c) makes two consequential amendments to paragraph 7 of article 111.	Transposition not required.
Article 1(22) inserts article 111a and 111b into the Directive. Article 111a Article 111a provides that the Commission shall adopt detailed guidelines laying down the principles applicable to inspections referred to in Article 111. It also provides for cooperation between Member States and the European Medicines Agency to establish the form and content of the authorisations, reports, certificates of good manufacturing practice and of certificates of good distribution practices. Article 111b This sets out provisions for the Commission to perform certain regulatory and implementing Acts in relation to the practices adopted by Member States.	N/A N/A
Article 1(23) This amends article 116 of the Directive by inserting a third paragraph. The inserted paragraph means that a marketing authorisation can also be suspended, revoked or varied where the manufacture of the medicinal product is not carried out in accordance with the description of the manufacturing method or, where the control methods are not in compliance with the description of those methods adopted by the manufacturer.	N/A
Article 1(24) This inserts article 117a into the Directive. This provides for Member States to have in	N/A .

Article	Provision which Implements
place a system which aims to prevent medicinal products that are suspected to present a danger to health from reaching the patient. The system shall cover falsified medicinal products, quality defects, processes for recalls and withdrawals of medicinal products from the market and also from patients. The system shall also incorporate rapid alert and urgent public announcement elements.	
Article 1(25) This inserts articles 118a, 118b and 118c into the Directive. Article 118a provides for Member States to lay down the rules on effective, proportionate and dissuasive penalties to deal with infringements of the provisions in the Directive that are at least equivalent to those in national provisions. Paragraphs 2 and 3 of article 118a provide further details of the requirements, for national provisions to be notified to the Commission and, in due course, for a report to be provided by the Commission to the European Parliament giving an overview of the transposition measures. Article 118b provides that 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 provides for Member States to take the necessary measures to ensure cooperation between competent authorities for medicinal products and customs authorities in applying the Directive.	Regulations 16 and 28 provide in new regulations 45K, 45L, 45U, 45V, 256M and 256N, new rules on offences and penalties in relation brokering, active substances and sale at a distance provisions. Penalties are already provided for in HM Regulations for the other regulated activities. N/A N/A
Articles 2 to 6 These provide commencement, administrative and procedural requirements in relation to the	Regulation 1(1) commences the provisions in domestic legislation. Most of these provisions

Article	Provision which Implements
implementation of Directive 2011/62/EU.	do not require further transposition..