



**PHARMACEUTICAL COMMITTEE
28 March 2012**

**Subject: Directive on Falsified medicines
Transposition and implementation, state of play**

Agenda item 2b)

The 'Falsified Medicines Directive' 2011/62/EU has been adopted in June 2011 and published on 1 July 2011.

Directive 2011/62/EU requires not only transposition measures by Member States (1), but also various implementing measures by the Commission (2) and the European Medicines Agency ('the Agency') (3). Moreover, in the context of the transposition and implementation, various questions have been put forward to the Commission (4).

1. Transposition by Member States

Directive 2011/62/EU has to be transposed by the Member States by 2 January 2013. Subject to exceptions, the rules of the Directive, and the respective transposing national laws, apply as of 2 January 2013.¹

The transposing laws, regulations, and administrative provisions have to be communicated to the Commission.² The Commission is going to carefully assess the correct transposition of Directive 2011/62/EU in the interest of public health protection, and in order to ensure the functioning of the internal market.

Moreover, regarding national provisions adopted pursuant to Article 118a of Directive 2001/83/EC, the Member States shall notify to the Commission any subsequent amendment to those provisions without delay.³

¹ Article 2(2) of Directive 2011/62/EU.

² Article 2(1) of Directive 2011/62/EU.

³ Article 118a(3) of Directive 2001/83/EC.

Finally, the Council has committed to encourage the Member States to draw up, for themselves and in the interests of the Community, their own tables which will, as far as possible, illustrate the correlation between the directives and the transposition measures and to make them public.⁴

2. Implementation measures by the Commission

Directive 2011/62/EU establishes 14 specific formal measures to be taken by the European Commission. An overview of these measures is contained in Annex 1.

The following measures of the Commission are highlighted here:

- a. Implementing act on the requirements for the assessment of the regulatory framework applicable to the manufacturing of active substances of medicinal products for human use: A public consultation has been launched⁵ and closed on 23 March 2012. The draft final legal act has to undergo a favourable opinion of the Standing Committee prior to adoption by the Commission. Adoption is scheduled for 2013.

In the context of this consultation, the Commission has held a 1-day workshop with representatives of the main exporters of active substances. The meeting served as occasion to establish contacts at an operational level, and to give third countries the opportunity to ask for clarifications.

A draft template for the 'written confirmation' accompanying imports of active substances is going to be published by the Commission in the next weeks for comments.

- b. Delegated act on the introduction of medicines: The Commission is currently preparing a public consultation paper. In order to discuss the file with Member States, a 'joint expert group' is being put up, comprising one expert from the medicinal products authority, and one expert from the customs authority, per Member State. The first meeting is tentatively scheduled for 18 July 2012. A definite invitation is going to be sent out in early June 2012.
- c. Delegated act on the detailed rules for a unique identifier for medicinal products for human use, and its verification: A public consultation has been launched⁶ and closes on 27 April 2012. The Commission has set up the Expert Group 'Delegated act on safety features for medicinal products for human use'.⁷ The first meeting was held on 19 December 2011, and followed by a stakeholder workshop on the 20 December 2011. The next meeting of the expert group is scheduled for autumn 2012. Adoption of the act is planned in 2014.
- d. Delegated act on the principles and guidelines of good manufacturing practice for active substances in medicinal products for human use: A public consultation has been launched⁸ which closes on 20 April 2012.

⁴ Point 34 of the Interinstitutional Agreement of better law-making of 2003 (OJ C 321, 31.12.2003, p. 1).

⁵ http://ec.europa.eu/health/files/counterf_par_trade/api_import.pdf.

⁶ http://ec.europa.eu/health/files/counterf_par_trade/safety_2011-11.pdf.

⁷ <http://ec.europa.eu/transparency/regexpert/detailGroup.cfm?groupID=2719>

⁸ http://ec.europa.eu/health/files/gmp/2012_01_20_gmp_cp_en.pdf.

The file is going to be discussed at the first meeting of the expert group referred to under point 2b).

- e. Implementing act on the design of a common logo identifying legally online pharmacies and the technical detail for the verification of the authenticity of this logo: A public consultation is expected to be launched later in 2012 and the adoption of the act is foreseen in 2013.

In addition, where appropriate the Commission is going to profit from all relevant expert bodies to gather additional expertise, such as the GMP/GDP Inspectors working group ('GMDP IWG') and the Working Group of Enforcement Officers ('WGEO') of the Heads of Medicines Agencies ('HMA').

3. Implementation measures by the Agency

The key responsibility for the Agency in terms of implementation of Directive 2001/83/EC is setting up an additional module in the existing EudraGMP database in order to allow for entering and publishing information referred to in Articles 77(4) and 111(6) of Directive 2001/83/EC. The GMDP IWG is working on various templates in this context.

According to the information provided for by the Agency, this implementation is work is on track.

4. Questions put forward to the Commission

The Commission has been contacted on various interpretation/implementation issues in relation to Directive 2011/62/EU. For the purpose of transparency, and in order to ensure a coherent interpretation, transposition, and application of Directive 2011/62/EU, Annex 2 sets out some of these questions and their answers.

Annex 1: Specific implementation measures of the Commission in the context of Directive 2011/62/EC amending Directive 2001/83/EC on falsified medicines

	Article in Dir. 2001/83/EC	Type of Commission measure	Topic	Target date for adoption/publication	Involvement of Member States/experts from Member States Other comments
1.	47	Delegated act	Good manufacturing practice for active substances	2013	Member States expert group; first meeting tentatively scheduled for 18 July 2012.
2.	52b	Delegated act	Criteria to be considered and verifications to be made when assessing the potential falsified character of medicinal products introduced into the EU but not intended to be placed on the market	2013	Member States expert group; first meeting tentatively scheduled for 18 July 2012.
3.	111b	Implementing act	Implementing measure on the requirements for the assessment of a third country in terms of API manufacturing	2013	Vote in Standing Committee.
4.	111b	Decisions ('Autonomous Decisions') (at the request of a third country)	Inclusion of a third country on a list	-	Depends on request from third country.
5.	47	Guidelines	Principles of good distribution practices for active substances	2013	Strong collaboration with GMDP IWG.
6.	47	Guideline	Formalised risk assessment for verification of the appropriate good manufacturing practice for excipients	2013	Strong collaboration with GMDP IWG.
7.	85b	Guideline	Specific provisions for brokering in the guidelines on good distribution practices	2012	GMDP IWG are currently assessing comments. Consultation of CHMP and Pharmaceutical Committee (Article 84 of Directive 2001/83/EC).
8.	111a	Guideline	Principles for inspections	-	GMDP IWG.
9.	54a(4) 2b (Dir.	Delegated act	(a) the characteristics and technical specifications of the SF	2014	Member States Expert group. First meeting took place on 19 December 2011.

	Article in Dir. 2001/83/EC	Type of Commission measure	Topic	Target date for adoption/publication	Involvement of Member States/experts from Member States Other comments
	2011/62/EU)		(b) the lists of prescription medicines that should not bear the SF and the list of non-prescription medicines that should bear the SF (c) procedures for the notification of medicinal products at risk of falsification and a rapid system for evaluation and decision on these notifications (d) the modalities of verifications of the SF by the manufacturers, wholesalers, pharmacists (e) provisions on the establishment, management and accessibility of the repositories system		
10.	85c(2)	Implementing act	Design of the common logo for legally-operating online-websites, including the technical, electronic, cryptographic requirements	2013	Vote in Standing Committee.
11.	85c	Information campaign	The dangers of falsified medicinal products	Continuously ongoing	http://ec.europa.eu/health/human-use/videos/index_en.htm
12.	118a	Report to the Council and the European Parliament	Overview of transposition measures on the rules on penalties applicable to infringements of the national provisions adopted pursuant to the Directive	By 2 January 2018	-
13.	3 (Dir. 2011/62/EU)	Report to the Council and the European Parliament	Trends of falsifications	See Article 3 of Directive 2011/62/EU.	-
14.	121a	Report	In respect of the delegated powers conferred to the Commission	By June 2015.	Covers all delegated powers given in Directive 2001/83/EC.

Annex 2: Questions relating to interpretation of the falsified medicines directive.

A. Safety feature

- 1. When do the rules on the anti-tampering device (Article 54(o) of Directive 2001/83/EC) apply?**

Answer: The rules for the transposition/application of the provisions on the anti-tampering device are those for the unique identifier. The application date is set out in Article 2(2)(b) of Directive 2011/62/EU.

B. Wholesale distribution, brokering

- 1. Does a wholesale distribution authorisation include implicit brokering?**

Answer: No, see Article 1(17a) of Directive 2001/83/EC.

- 2. Is a person labelling medicinal products a wholesale distributor**

Answer: No. That person is a manufacturer, see Article 40(2) of Directive 2001/83/EC.

- 3. If that person is responsible for the labelling, but outsources the actual operation: can that person be a wholesale distributor?**

Answer: No. That person is a manufacturer, see Article 40(2) of Directive 2001/83/EC.

- 4. Does a finished product manufacturer who imports active substances require a registration in accordance with Article 52a of Directive 2001/83/EC?**

Answer: Yes, see Article 52a of Directive 2001/83/EC.

- 5. Does a manufacturer have to comply with good distribution practices?**

Answer: Yes. Article 77(3) of Directive 2001/83/EC lays down that possession of a manufacturing authorisation shall include authorisation to distribute by wholesale the medicinal products covered by that authorisation. Article 80 of Directive 2001/83/EC lists the minimum requirements for holders of the distribution authorization. These requirements include the compliance with the principles and guidelines of good distribution practices.