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

Overview (rev.1) (March 2013)

	Article in Directive 2001/83/EC	Type of Commission measure	Topic	Target date for adoption/ publication	Stakeholder consultation, Involvement of Member States/experts from Member States, Other comments
1.	47	**Delegated act**	**Good manufacturing practice for active substances**	2013	Public stakeholder consultation closed. Member States expert group.[1]
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		Public stakeholder consultation closed. Member States expert group. Following consultation by Commission with stakeholders and Member States, adoption is not going to be pursued for the time being (NB: adoption is not mandatory - "may provision").
3.	111b	**Implementing act**	Implementing measure on the **requirements for the assessment of a third country in terms of API manufacturing**	2013	Adopted and published (OJ L 21, 24.1.2013, p. 36): http://ec.europa.eu/health/files/eudralex/vol-1/dec_2013_51/dec_2013_51_en.pdf
4.	111b	**Decisions ('Autonomous Decisions')** (at the request of a third country)	Inclusion of a **third country on a list**	Ongoing	Adopted and published (OJ L 325, 23.11.2012, p. 15): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:325:0015:0016:EN:PDF Ongoing assessments: http://ec.europa.eu/health/human-use/quality/index_en.htm#ias
5.	47	**Guidelines**	Principles of **good distribution practices for active substances**	2013	Public consultation launched: http://ec.europa.eu/health/files/gmp/2013-02_gdp_for_api_cons.pdf Strong collaboration with Good Distribution and Manufacturing Practices Inspector's Working Group[2] (GMDP IWG).

[1] http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2752

[2] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000161.jsp&mid=WC0b01ac05800296c9&jsenabled=true

	Article in Directive 2001/83/EC	Type of Commission measure	Topic	Target date for adoption/ publication	Stakeholder consultation, Involvement of Member States/experts from Member States, Other comments
6.	47	**Guideline**	Formalised risk assessment for verification of the appropriate **good manufacturing practice for excipients**	2013	Public consultation launched: http://ec.europa.eu/health/files/gmp/2013-02_guidelines_excipients_cons.pdf Strong collaboration with GMDP IWG.
7.	85b	**Guideline**	Specific provisions for **brokering** in the **guidelines** on good distribution practices	2013	Adopted and published (OJ C68, 8.3.2013, p. 1): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:068:0001:0014:EN:PDF
8.	111a	**Guideline**	**Principles for inspections**	-	GMDP IWG.
9.	54a(4) of Directive 2001/83/EC and Article 2b of Directive 2011/62/EU	**Delegated act**	(a) the **characteristics and technical specifications** of the safety features (SF) (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	2014	Public stakeholder consultation closed . Member States Expert group.[3]
10	85c(2)	**Implementing act**	**Design of the common logo for legally-operating online-websites, including the technical, electronic, cryptographic requirements**	2013	Public stakeholder consultation closed. Vote in Standing Committee.
11	85d	**Awareness raising**	Conducting or promoting information campaigns on the dangers of falsified medicinal products	Continuously ongoing	In cooperation with the European Medicines Agency and Member States 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	-

[3] http://ec.europa.eu/transparency/regexpert/detailGroup.cfm?groupID=2719

	Article in Directive 2001/83/EC	Type of Commission measure	Topic	Target date for adoption/ publication	Stakeholder consultation, Involvement of Member States/experts from Member States, Other comments
13	3 of Directive 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.