EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Medical products – quality, safety and innovation

Implementation measures by the Commission in the context of Directive 2011/62/EU – overview and state of play

	Article in Directive 2001/83/EC	Type of Commission measure	Topic	Target date for adoption/ publication	State of play Involvement of Member States/experts from Member States, Other comments
1	47	**Delegated act**	**Good manufacturing practice for active substances**		**Adopted and published** (OJ L 337, 25.11.2014, p. 1) http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_337_R_0001&from=EN
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 consulted once. 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**		**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**	Continuously 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 Finalised and 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**		**Adopted and published** (OJ C 95, 21.3.2015, p. 1–9): http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2015.095.01.0001.01.ENG

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6	47	**Guideline**	Formalised risk assessment for verification of the appropriate **good manufacturing practice for excipients**		**Adopted and published** (OJ C 95, 21.3.2015, p. 10–13): http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2015.095.01.0010.01.ENG
7	85b	**Guideline**	Specific provisions for **brokering** in the **guidelines** on good distribution practices		**Adopted and published** (OJ C343, 23.11.2013, p1) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:343:0001:0014:EN:PDF
8	111a	**Guideline**	**Principles for inspections**		Compilation of Community Procedures on Inspections and Exchange of Information exists: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf
9	54a(4) of Directive 2001/83/EC and Article 2b of Directive 2011/62/EU	**Delegated act**	Detailed rules for the **safety features** appearing on the packaging of medicinal products for human use In particular: (a) the **characteristics and technical specifications** of the safety features (SF) (b) the **modalities of verifications** of the SF by the manufacturers, wholesalers, pharmacists (c) provisions on the **establishment, management and accessibility of the repositories** system (d) the **lists** of **prescription medicines that should not bear** the SF and the list of **non-prescription medicines that should bear the SF** (e) **procedures for the notification** of medicinal products at risk of falsification and **a rapid system for evaluation** and decision on these notifications		**Adopted and published** (OJ L 32, 9.2.2016, p. 1-27) http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2016_032_R_0001&from=EN All linguistic versions: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.032.01.0001.01.ENG
10	85c(2)	**Implementing act**	**Design of the common logo for legally-operating online-websites, including the technical, electronic, cryptographic requirements**		**Adopted and published** (OJ L185, 25.6.2014, p.5): http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2014_184_R_0004&from=EN Applies as of 1 July 2015

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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	-
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		**Adopted** (30 March 2015) **and communicated to the EP and the Council** http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2015:138:FIN