(April 2012)

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

## Overview

| | 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 launched: http://ec.europa.eu/health/files/gmp/2012_01_20_gmp_cp_en.pdf Member States expert group. |
| 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. |
| 3. | 111b | **Implementing act** | Implementing measure on the **requirements for the assessment of a third country in terms of API manufacturing** | 2013 | Public stakeholder consultation launched: http://ec.europa.eu/health/files/counterf_par_trade/api_import.pdf Vote in Standing Committee[1]. |
| 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 Good Distribution and Manufacturing Practices Inspector's Working Group[2] (GMDP IWG). |
| 6. | 47 | **Guideline** | Formalised risk assessment for verification of the appropriate **good manufacturing practice for excipients** | 2013 | Strong collaboration with GMDP IWG. |

1 http://ec.europa.eu/transparency/regcomitology/index.cfm

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

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| 7. | 85b | **Guideline** | Specific provisions for **brokering** in the **guidelines** on good distribution practices | 2012 | Public stakeholder consultation launched: http://ec.europa.eu/health/files/eudralex/vol-4/2011-07_gdpguidline_publicconsultation.pdf<br>GMDP IWG are currently assessing comments.<br><br>Consultation of CHMP[3] and Pharmaceutical Committee[4] (Article 84 of Directive 2001/83/EC). |
| 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)<br>(b) the **lists** of **prescription medicines that should not bear** the SF and the list of **non-prescription medicines that should bear the SF**<br>(c) **procedures for the notification** of medicinal products at risk of falsification and **a rapid system for evaluation** and decision on these notifications<br>(d) the **modalities of verifications** of the SF by the manufacturers, wholesalers, pharmacists<br>(e) provisions on the **establishment, management and accessibility of the repositories** system | 2014 | Public stakeholder consultation launched: http://ec.europa.eu/health/files/counterf_par_trade/safety_2011-11.pdf<br>Member States Expert group.[5] |
| 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 | 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://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000094.jsp

4 http://ec.europa.eu/health/documents/pharmaceutical-committee/index_en.htm

5 http://ec.europa.eu/transparency/regexpert/detailGroup.cfm?groupID=2719

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|---|---|---|---|---|---|
| | | Parliament | | | |
| 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. |