EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – quality, safety and efficacy

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Template for the 'written confirmation' for active substances exported to the European Union for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Version 2.0 (January 2013)

1. Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 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 (OJ L 174, 1.7.2011, p. 74) introduces EU-wide rules for the importation of active substances: According to Article 46b(2) of Directive 2001/83/EC, active substances shall only be imported if, *inter alia*, the active substances are accompanied by a **written confirmation** from the competent authority of the exporting third country which, as regards the plant manufacturing the exported active substance, confirms that the standards of good manufacturing practice and control of the plant are equivalent to those in the Union.

2. The template for this written confirmation is set out in annex.

Document history:	
Date of submission of draft to the Pharmaceutical Committee:[1]	16 January 2013
Date of publication:	See above
Date of entry into force:	N/A[2]
Supersedes:	Version 1.0 of July 2012[2]
Changes compared to superseded version 1.0:	- Clarification that EU-GMP are those of WHO/ICH Q7 - Indication of inspection authority if different from that issuing the written confirmation - Reminder of general principle of manufacturer's responsibility

[1] http://ec.europa.eu/health/documents/pharmaceutical-committee/index_en.htm

[2] Written confirmations based on the previous version of the template remain valid.

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Annex:

Letterhead of the issuing regulatory authority

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Confirmation no. (given by the issuing regulatory authority):

……

1. Name and address of site (including building number, where applicable):

……

2. Manufacturer's licence number(s):[3]

……

REGARDING THE MANUFACTURING PLANT UNDER (1) OF THE FOLLOWING ACTIVE SUBSTANCE(S) EXPORTED TO THE EU FOR MEDICINAL PRODUCTS FOR HUMAN USE

Active substance(s):[4]	Activity(ies):[5]

THE ISSUING REGULATORY AUTHORITY HEREBY CONFIRMS THAT:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.[6]

Date of inspection of the plant under (1). Name of inspecting authority if different from the issuing regulatory authority:

……

This written confirmation remains valid until

……

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

……..

Name and function of responsible person:

……

E-mail, Telephone no., and Fax no.:

……

Signature *Stamp of the authority and date*

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3 Where the regulatory authority issues a licence for the site. Record 'not applicable' in case where there is no legal framework for issuing of a licence.

4 Identification of the specific active substances through an internationally-agreed terminology (preferably international nonproprietary name).

5 For example, 'Chemical synthesis', 'Extraction from natural sources', 'Biological processes', 'Finishing steps'.

6 qdefect@ema.europa.eu.