EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

Brussels, 16/04/2012
SANCO/D6/(2012)ddg1.d6.517666

DRAFT TEMPLATE FOR THE WRITTEN CONFIRMATION FOR ACTIVE SUBSTANCES IMPORTED INTO THE EUROPEAN UNION FOR MEDICINAL PRODUCTS FOR HUMAN USE

PUBLIC CONSULTATION

1. On 1 July 2011, 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 was published.1 This Directive amends Directive 2001/83/EC on the Community Code relating to medicinal products for human use.[2]

2. Directive 2011/62/EU introduces EU-wide rules for the importation of active substances:[3] 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.

3. The requirement of a written confirmation is waived for third countries listed by the Commission in accordance with Article 111b of Directive 2001/83/EC.

4. A draft template for this written confirmation is annexed. **The draft template is based on, and in conformity with, the Model Certificate of Good Manufacturing Practices of the World Health Organisation (WHO).**[4]

Stakeholders are invited to comment on this consultation paper, and especially on the draft template, by **1 June 2012** at the latest. Responses should be sent preferably by e-mail to sanco-pharmaceuticals-d6@ec.europa.eu, or by post to Unit SANCO/D/6, DM24 02/34, BE-1049 Brussels.

When sending your comments and responses, you should state whether you are a stakeholder association or a private individual. If you represent an association, please indicate clearly what type of association this is (patient, API manufacturer, medicinal products manufacturer, API importer, medicinal products importer etc.). If you represent a company, please state whether it falls within the EU definition of a small and medium-sized enterprise (i.e. less than €50 million annual turnover and fewer than 250 employees).

All comments and responses will be made publicly available on the 'Europa website' on pharmaceuticals once the consultation period is over. If you do not wish your contribution to be made public please indicate this clearly and specifically in the documentation you send us (i.e. not just in the covering letter or e-mail). In this case, only an indication of the contributor will be disclosed.

Professional organisations are invited to register in the Union's Register for Interest Representatives (http://ec.europa.eu/transparency/regrin/) set up as part of the European Transparency Initiative to provide the Commission and the public at large with information about the objectives, funding and structures of interest representatives.

5. This draft is submitted for public consultation with a view to finalising the template and publishing it by the European Commission.

6. Publication of the final version of the template is scheduled for 2012.

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1 OJ L 174, 1.7.2011, p. 74

2 OJ L311, 28.11.2001, p. 67. A consolidated version of Directive 2001/83/EC including the amendments by Directive 2011/62/EU is here: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001L0083:20110721:EN:PDF

3 For the definition of active substance, see Article 1(3a) of Directive 2001/83/EC.

4 Annex 5 of the WHO Technical Report Series, No. 908, 2003.

Annex:

Letterhead of the issuing regulatory authority

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use
In accordance with Article 46b(2)(b) of Directive 2001/83/EC[1]

Confirmation no. (given by the issuing regulatory authority):
……..
1. Name and address of site:
……..
……..
……..

2. Manufacturer's licence number:[2]
……..

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):	Category(ies):	Activity(ies):[3]

THE ISSUING REGULATORY AUTHORITY HEREBY CONFIRMS THAT:

The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU;

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.

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

Address of the issuing regulatory authority:
……..

Name and function of responsible person:
……..

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

Signature (handwritten) *Stamp of the authority (original) and date*

……..

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1 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:02001L0083-20110721:EN:NOT

2 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.

3 For examples, see 'Example 2' of the Model Certificate of Good Manufacturing Practices of the World Health Organisation (WHO), Annex 5 of the WHO Technical Report Series, No. 908, 2003.