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European Commission

New rules on importing active pharmaceutical ingredients into the European Union

The European Union (EU) has reformed the rules for importing into the EU active substances for medicinal products for human use.

As of 2 January 2013, all imported active substances must have been manufactured in compliance with standards of good manufacturing practices (GMP) at least equivalent to the GMP of the EU. The manufacturing standards in the EU for active substances are those of the 'International Conference for Harmonisation' – ICH Q7.

As of 2 July 2013, this compliance must be confirmed in writing by the competent authority of the exporting country. This document must also confirm that the plant where the active substance was manufactured is subject to control and enforcement of good manufacturing practices at least equivalent to that in the EU.

The template for such written confirmation can be found overleaf. This must accompany the active substance being imported into the EU.

More information is available here:
http://ec.europa.eu/health/human-use/quality/index_en.htm

...Who issues the written confirmation?
Written confirmation is issued by the regulatory authority of the country where the manufacturing site is located. You need to request it from that authority.

...Does written confirmation need to be issued for each batch/consignment'?
No. Written confirmation is issued per manufacturing plant and for each active substance(s) manufactured on that site.

...Does each imported consignment have to be accompanied by written confirmation?
Yes. However, it may be a copy of the written confirmation issued by the regulatory authority.

...Are there exceptions from the written confirmation requirement?
The Commission publishes a list of countries which, following their request, have been assessed and are considered as having equivalent rules for good manufacturing practices to those in the EU. Active substances manufactured in such countries do not require a written confirmation.

...Do I need written confirmation, even though my manufacturing site has recently been inspected by an EU Member State or by the European Directorate for the Quality of Medicines (EDQM) of the Council of Europe?
Yes. The process of written confirmation is independent of such inspection activities. However, exceptionally and where necessary to ensure the availability of medicinal products, following inspections by an EU Member State, a Member State may decide to waive the need for a written confirmation for a period not exceeding the validity of the GMP certificate.

...Is written confirmation also required where there is a 'mutual recognition agreement' between my country and the EU?
Yes. The process of written confirmation is independent of the existence of 'mutual recognition agreements'.

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Health and Consumers

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.