aqpa
Austrian Qualified Person Association

API-Import aus Drittstaaten

Georg Göstl

Baxter AG

25. Juni 2013

API-Import aus Drittstaaten

- Questions and Answers (4.1) der EMA:

http://ec.europa.eu/health/files/gmp/2013_04_12_qa_en.pdf

- Liste der anerkannten Drittländer:

http://ec.europa.eu/health/human-use/quality/index_en.htm

API-Import aus Drittstaaten

Aktueller Stand:

Country	**Date of request**	**Status, Date of publication in the *Official Journal of the European Union***
Switzerland	4 April 2012	Adopted, Commission implementing Decision (OJ L 325, 23.11.2012)
Israel	9 May 2012	Contacts ongoing.
Australia	18 September 2012	Adopted, Commission implementing Decision (OJ L 113, 25.4.2013)
Singapore	17 September 2012	No listing for the moment (the relevant Singapore legislation provides for a non-mandatory GMP certification scheme). Contacts ongoing. In the meantime, Singapore issues written confirmation.
Brazil	4 October 2012	Equivalence assessment ongoing
Japan	6 December 2012	Adopted, Commission implementing Decision (OJ L 152/52, 5.6.2013)
United States	17 January 2013	Equivalence assessment ongoing

21. Juni 2013 **USA ebenfalls ein „listed country“ !**

API-Import aus Drittstaaten

aqpa Austrian Qualified Person Association

European Commission, Pharmaceutical Committee, 27 March 2013:

Annex 1:

New rules on API quality in the EU; Preparation with regard to exporting third countries – state of play (top 18 API exporters to the EU, plus South Africa and Ukraine)[1]

Third country	Number of API manufacturing sites supplying EU[2]	Option 1 (written confirmation) or option 2 (listing)	State of play
India	496	Option 1	**Good progress, but more work needed – in particular by industry stakeholders.** IND government has announced that the 'Drug Controller General' (i.e. central agency) is going to issue 'written confirmation'. Implementation guidelines have been published.[3]
China	438	Option 1	**Good progress, but more work needed – in particular by industry stakeholders.** CHN has announced[4] that it will issue written confirmation. A 'notice'[5] has previously been published. However, SFDA has already informed COM that it would not issue 'written confirmation' for manufacturing sites which are not under SFDA's supervision. This concerns about 30 sites. EMA is coordinating the inspections of these sites (option 3).
U.S.	186	Option 2	**Situation under control.** On-site audit visit by COM in mid-May 2013. The US FDA has issued a supportive public statement.[6]
Japan	108	Option 2	**Situation under control.** On-site audit visit by COM in mid-April 2013.
Switzerland	67	Option 2	**Situation under control.** Listed.
Korea	37	Option 1	**Situation under control.** Korea has issued written confirmation.
Israel	36	Option 1; then 2	**Situation under control.** Listing had to be refused for the time being. Israel has issued written confirmation.
Mexico	35	Option 1, then 2	**Situation under control.** MEX has confirmed in writing that it would issue written confirmation and later apply for listing.
Brazil	23	Option 1, then 2	**Situation under control.** BRA has applied for listing. However, documentation has not been received yet. As soon as COM receives the information, COM starts the 'equivalence assessment'. In the interim, BRA will have to issue written confirmation.
Canada	17	Option 1	**Situation under control.** CAN has informed COM in writing that it would issue written confirmation.
Taiwan	16	Option 1	**Situation under control.** TWN has sent informally a copy of the written confirmation it intends to issue.

1 These 20 countries account for 97% of all non-EU API manufacturing sites supplying the EU.

2 Survey of the 'Heads of Medicines Agencies' amongst medicines manufacturers in the EU. Duplicates have been removed by MHRA. However, this figure does not take account of the possibility of manufacturers to substitute one API source by another one.

3 http://www.cdsco.nic.in/api%20wc2013.htm

4 Translation: *SFDA Will Issue Written Confirmation for Enterprises Exporting APIs to the EU, Published on 20 Feb 2013 at 17:15 by CCCMHPIE. On 20 February 2013, chaired by Mr. LI Guoqing (Director General, Department of Drug Safety & Inspection, SFDA) , SFDA held the Seminar on Issuing Written Confirmation for Enterprises Exporting APIs to the EU in Beijing. SFDA Deputy Commissioner Mr. WU Zhen attended the Seminar and made important instruction. Vice present of CCCMHPIE Mr. XU Ming also attended the meeting and reported to the Seminar the problems that Chinese APIs exporting enterprises are facing and presented the operational suggestions of issuing Written Confirmation. Representatives from MoFCOM (Department for Foreign Trade, Department for European Affairs), other relevant SFDA departments, local food and drug administrations, and enterprises also attended the meeting. The seminar made it clear that SFDA will issue Written Confirmation for Enterprises exporting APIs to the EU. Relevant notice and detailed implement ru s will be published soon. Mr. CAO Gang and Mrs HE Chunhong from CCCMHPIE also attended the Seminar.*

5 Translation: *Notice on SFDA's intention to carry out thorough investigation on the basic information of Chinese APIs exporters - According to the EU Directive 2011/62/EU, the Department of Drug Safety & Inspection of SFDA hereby publish the notice on the initiative of carry out thorough investigation on the basic information of Chinese APIs exporters (Reference No.:[2013] No. 14) in order to investigate thoroughly the basic information of APIs producers and to improve the bilingual (EN/CN) SFDA database of APIs. The investigation form can be downloaded from here: [form attached]. 18 January 2013. Department of Drug Safety & Inspection SFDA.*

6 http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ImportsandExportsCompliance/ucm336570.htm

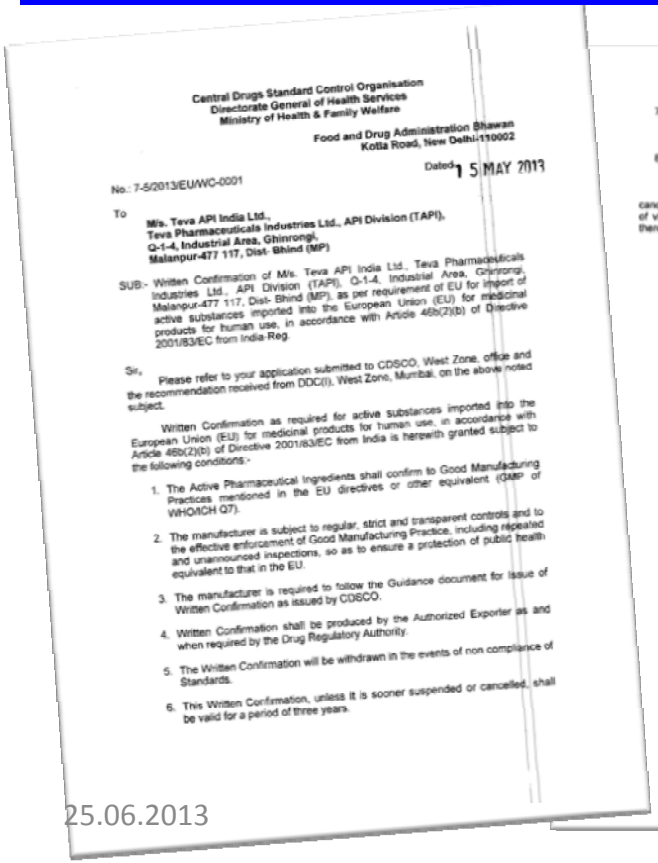
API-Import aus Drittstaaten

Argentina	12	Option 1	**More work needed – in particular by industry stakeholders.** In addition, COM is in contact with ARG authorities.
Turkey	12	Option 1	**Situation under control.** TUR has informed COM that it would issue written confirmation.
Malaysia	7	Option 1	**More work needed – in particular by industry stakeholders.** In addition, COM is in contact with MYS authorities.
Singapore	7	Option 1, then 2	**Situation under control.** Listing had to be refused for the time being. SGP has confirmed in writing that it would issue written confirmation until issue is solved.
Thailand	6		**More work needed – in particular by industry stakeholders.** In addition, COM is in contact with THA authorities.
Australia	5	Option 2	**Situation under control.** The equivalence assessment for AUS is almost concluded.
Russia	5	Option 1	**More work needed – in particular by industry stakeholders.** RUS has informed COM in a meeting that they are going to issue written confirmation.
Ukraine	4	Option 1	**Situation under control.** UKR has issued written confirmation.
South Africa	2	Option 1	**Situation under control.** ZAF has issued written confirmation.

API-Import aus Drittstaaten

1. Beispiel: Indien

http://www.cdsco.nic.in/W



Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002

No.: 7-5/2013/EU/WC-0001

Dated 15 MAY 2013

To

M/s. Teva API India Ltd.,
Teva Pharmaceuticals Industries Ltd., API Division (TAPI),
Q-1-4, Industrial Area, Ghinrongi,
Malanpur-477 117, Dist- Bhind (MP)

SUB:- Written Confirmation of M/s. Teva API India Ltd., Teva Pharmaceuticals Industries Ltd., API Division (TAPI), Q-1-4, Industrial Area, Ghinrongi, Malanpur-477 117, Dist- Bhind (MP), as per requirement of EU for import of 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 from India-Reg.

Sir,

Please refer to your application submitted to CDSCO, West Zone, office and the recommendation received from DDC(I), West Zone, Mumbai, on the above noted subject.

Written Confirmation as required 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 from India is herewith granted subject to the following conditions:-

1. The Active Pharmaceutical Ingredients shall confirm to Good Manufacturing Practices mentioned in the EU directives or other equivalent (GMP of WHO/ICH Q7).
2. The manufacturer 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 equivalent to that in the EU.
3. The manufacturer is required to follow the Guidance document for issue of Written Confirmation as issued by CDSCO.
4. Written Confirmation shall be produced by the Authorized Exporter as and when required by the Drug Regulatory Authority.
5. The Written Confirmation will be withdrawn in the events of non compliance of Standards.
6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.

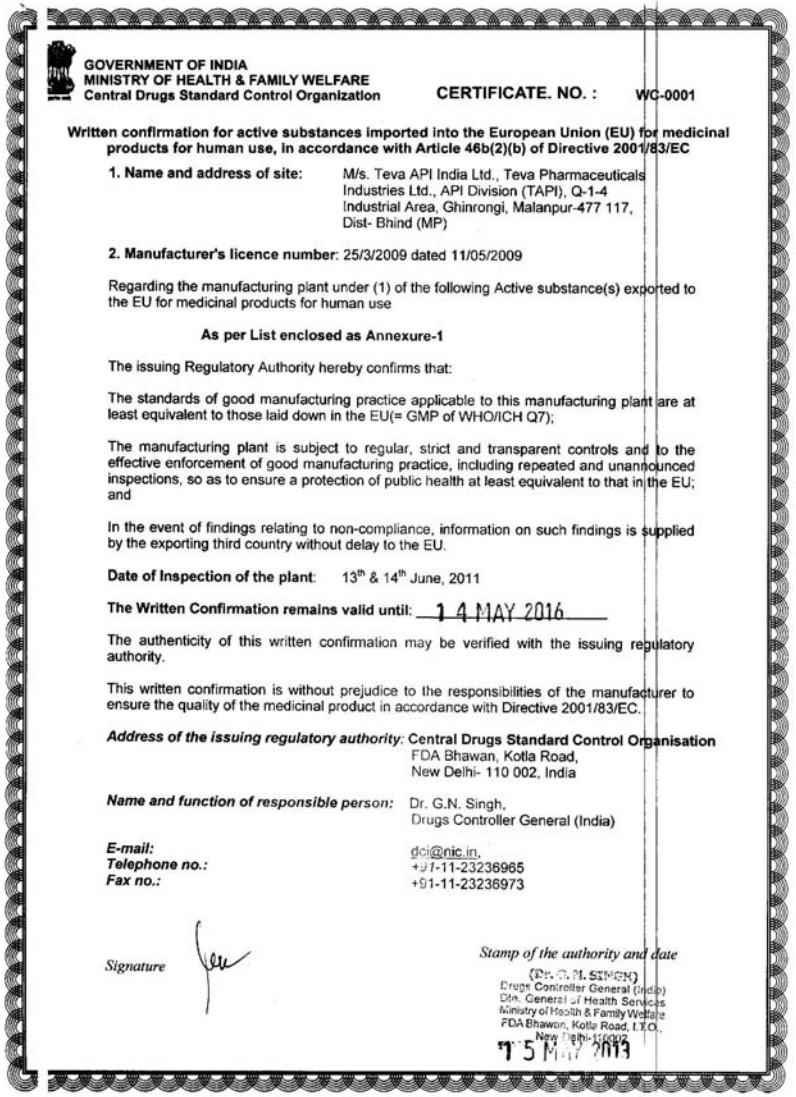
7. In the event of any Non Compliance observed during inspections by Local or International Drug Authorities, the same shall be forwarded office within 7 days of receipt of report.
8. In the event of any drug found not of standard quality, the same reported to this office within 7 days of receipt of report.

Please note that Written Confirmation issued is liable to be suspended cancelled, if any of the conditions stipulated above are not complied with of violation of the provisions of the Drugs & Cosmetics Act, 1940 and thereunder as the case may be.

Please acknowledge the receipt.

Yours

(Dr. G.
Drugs Controller Gene



GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE. NO. : WC-0001

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. Name and address of site: M/s. Teva API India Ltd., Teva Pharmaceuticals Industries Ltd., API Division (TAPI), Q-1-4 Industrial Area, Ghinrongi, Malanpur-477 117, Dist- Bhind (MP)

2. Manufacturer's licence number: 25/3/2009 dated 11/05/2009

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

As per List enclosed as Annexure-1

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(= 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.

Date of Inspection of the plant: 13th & 14th June, 2011

The Written Confirmation remains valid until: 14 MAY 2016

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: **Central Drugs Standard Control Organisation**
FDA Bhawan, Kotla Road,
New Delhi- 110 002, India

Name and function of responsible person: Dr. G.N. Singh,
Drugs Controller General (India)

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

Signature

Stamp of the authority and date
(Dr. G. N. SINGH)
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health & Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi-110002
15 MAY 2013

API-Import aus Drittstaaten

2. Beispiel: China

http://eng.sfda.gov.cn/WS03/CL0757/80514.html

CFDA specifies relevant issues on written confirmation for active substances exported to EU

2013-05-13

China Food and Drug Administration (CFDA) recently issued a notice on relevant issues on written confirmation for active substances exported to EU, which specifies the issuer, the issuance method, and the format of the written confirmation for active substances exported to EU. The notice also specifies the scope of active substances which can apply the written confirmation, and the application and issuance procedures for the written confirmation.