DECISION

No. 7/09.03.2007

on the approval of the content of the manufacturer's batch certificate for a medicinal product exported to countries under the scope of a Mutual Recognition Agreement (MRA)

The Scientific Council of the National Medicines Agency,
set up based on Minister of Public Health Order no. 485/09.05.2005, as amended through Minister of Public Health Order no. 159/22.02.2006, no. 1599/12.12.2006 and no. 395/27.02.2007, reunited on summons of the National Medicines Agency President in the ordinary meeting of 09.03.2007, in accord with Article 10 of Government Ordinance no. 125/1998 related to the set up, organisation and functioning of the National Medicines Agency, approved as amended through Law no. 594/2002, as further amended, agrees on the following

DECISION

Single article. – The content of the batch certificate of a medicinal product exported by a manufacturer in a contry, based on a Mutual Recognition Agreement, is approved, according to the Annex which is integral part of this Decision.

PRESIDENT
of the Scientific Council
of the National Medicines Agency

Acad. Prof. Dr. Victor Voicu

ANNEX

Content of the manufacturer's batch certificate for a medicinal product exported to countries under the scope of a Mutual Recognition Agreement (MRA)

Explanatory note: Mutual Recognition Agreements imply a certification scheme of the medicinal product batch according to the internationally harmonised requirements.

The importer of the batch is to receive and maintain the batch certificate issued by the manufacturer. Upon request, it has to be readily available to the staff of the Regulatory Authority of the importing country. This certification by the manufacturer on the conformity of each batch is essential to exempt the importer from re-control (re-analysis).

Each batch transferred between countries having an MRA in force, must be accompanied by a batch certificate issued by the manufacturer in the exporting country.

This certificate will be issued further to a full qualitative and quantitative analysis of all active and other relevant constituents to ensure that the quality of the products complies with the requirements of the Marketing Authorisation of the importing country.

This certificate will attest that the batch meets the specifications and has been manufactured in accordance with the Marketing Authorisation of the importing country, detailing the specifications of the product, the analytical methods referenced, the analytical results obtained, and containing a statement that the batch processing and packaging quality control records were reviewed and found in conformity with GMP. The batch certificate will be signed by the person responsible for certifying that the batch is suitable for release for sale or export at the manufacturing site.

These harmonised requirements have been agreed by the Regulatory Authorities of the following parties/countries: Australia, Canada, European Community, Switzerland and New Zealand.

CONTENT OF THE MANUFACTURER'S BATCH CERTIFICATE FOR A MEDICINAL PRODUCT EXPORTED TO COUNTRIES UNDER THE SCOPE OF A MUTUAL RECOGNITION AGREEMENT (MRA)

[Letter head of exporting manufacturer]

1. Name of product.
Trade name in the importing country.

2. Importing Country.

3. Marketing authorisation number.
The marketing authorisation number of the product in the importing country should be provided.

4. Strength/Potency.
Identity (name) and amount per unit dose required for all active ingredients/constituents.

5. Dosage form (pharmaceutical form).

6. Package size (contents of container) and **type** (e.g. vials, bottles, blisters).

7. Lot/batch number.
For each product.

8. Date of manufacturing.

According to the national (local) requirements.

9. Expiry date.

10. Name and address of fabricator(s)/manufacturer(s) - manufacturing site(s).

All sites involved in the manufacture including packaging and quality control of the batch should be listed with name and address. The name and address must correspond to the information provided on the Manufacturing Authorisation.

11. Number of Manufacturing Authorisation/Licence or Certificate of GMP Compliance of a manufacturer.

Number should be given for each site listed under item 10.

12. Results of analysis.

Should include the authorised specifications, all results obtained and refer to the methods used (may refer to a separate certificate of analysis which must be dated, signed and attached).

13. Comments/remarks.

Any additional information that can be of value to the importer and/or inspector verifying the compliance of the batch certificate (e.g. specific storage or transportation conditions).

14. Certification statement.

This statement should cover the fabrication/manufacturing, including packaging and quality control. The following text should be used: ”I hereby certify that the above information is authentic and accurate. This batch of product has been fabricated/manufactured, including packaging and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP”.

15. Name and position/title of person authorising the batch release.

Including its company/site name and address, if more than one company is mentioned under item 10.

16. Signature of person authorising the batch release.

17. Date of signature.

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