MINISTERIO DE SANIDAD, POLÍTICA SOCIAL E IGUALDAD

agencia española de medicamentos y productos sanitarios

Information Note

Agencia Española de Medicamentos y Productos Sanitarios
AEMPS

PROCEDURE FOR SUBMISSION OF TRANSLATIONS OF SPCs, LABELLING AND PILs FOR NEW AUTHORISATIONS AND MODIFICATIONS OF MEDICINAL PRODUCTS BY DECENTRALIZED AND MUTUAL RECOGNITION PROCEDURES

Date of publication: 16th August 2011

Category: AEMPS, HUMAN MEDICINAL PRODUCTS, INDUSTRY.
Reference: SGMUH, 15_vi /2011

The Spanish Agency for Medicines and Health Products (AEMPS) one year ago published an information note[1] on the procedure for submission of translations of Summaries of Product Characteristics (SPCs) and Patient Information Leaflets (PILs) of medicinal products authorised by European procedures, so as to resolve the accumulated translation burden at that time.

This procedure pursued the dual objective of improving the quality of translations and providing the AEMPS with greater ease in the issuing of marketing authorizations. Throughout this year the vast majority of authorisations that were pending have been issued.

The goal now is to extend the same criteria and apply them to any procedure (new or modification of marketing authorisation) issued by the reference Member State which involves the presentation of the Spanish language versions of the SPC and/or PIL. The document also includes the necessary steps when there are several simultaneous changes affecting texts that are evaluated by different divisions within the AEMPS in order to reduce the time needed for its resolution.

General Guidelines

To promote the quality of the translations submitted to the AEMPS, it is recommended that the marketing authorization holder (MAH) implements

CORREO ELECTRÓNICO
smhaem@aemps.es

www.aemps.gob.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 50 73
FAX: 91 822 51 61

an internal Standard Operating Procedure for ensuring double checking of the texts. This verification should only be performed by qualified personnel with expertise in both the terminology used in drafting the SPC and PIL and in the correct use of the Spanish language. This standard procedure should also define the roles and responsibilities of the persons who prepare the translation.

Thus, the MAH may state, in accordance with the provisions in this document, that the texts submitted were written after the application of the aforementioned Standard Operating Procedure, which will in turn contribute to the simplification of procedures and substantially improve the period of time needed for the issuing of authorisations by the AEMPS, without prejudice to the verifications considered necessary and any responsibilities that may eventually arise from non fulfilment of stipulated obligations in the legislation currently in force. In any case, the MAH or its representative must submit a declaration confirming the accuracy of the translation with each new version of the texts they submit.

Procedure

1. Following finalisation of the European phase, the MAH will have five days[2] in the case of new registries or revalidations, or seven days[3] in the case of a type II variation with changes in the medicinal product information (SmPC, PIL and/or labelling), to submit the Spanish language versions of texts that are part of the national authorization and the mock-ups to the AEMPS through the usual electronic submission procedures. In the case of type IA or IB variations with text changes and which therefore fall within the scope of this press release, the MAH must submit the declaration confirming the accuracy of the translation with the application through a NEES 9000 sequence, without interfering in the validation procedure by the Member State.

2. The MAH shall attach to these texts a commitment signed by a qualified person to certify that the texts submitted were reviewed by the company according to a standard operating procedure and that they meet the quality criteria for the authorization procedure.

3. The MAH shall inform the AEMPS about the existence of any ongoing modification that has finished the European phase but is still pending of national authorisation, always consolidating the last text approved in each case.

4. The AEMPS shall evaluate the documents and mock-ups received in the following 20 days, verifying how many aspects are deemed necessary to

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grant the national authorization, without prejudice to the responsibilities derived in the case of non fulfilment of obligations in the legislation currently in force.

5. The AEMPS will complete the evaluation of texts 30 days after finalisation of the European phase of the procedure, this being communicated to the MAH when applicable and the texts being updated in RAEFAR in the following two months.

6. Failure on the part of the MAH to submit any documents without justification within the established period after finalisation of the European phase of the procedure, as well as presentation of documentation not fulfilling the requirements set out in the General Guidelines will trigger a non acceptance proposal that shall be notified to the MAH.

7. In the case of discrepancies between the AEMPS and the MAH which are not resolved during the national evaluation of the texts, the AEMPS shall issue a resolution after the assessment period authorising the procedure with the version proposed by the Agency.

References

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2. Co-ordination Group for Mutual Recognition and Decentralised Procedures- Human (CMDh). "*Best Practice Guide for Decentralised and Mutual Recognition Procedures*". *Section National implementation.* Doc. Ref.: CMDh/068/1996/Rev7. March 2010. Internet: http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Application_for_MA/CMDh_068_1996_Rev7-clean_March_2010.pdf
3. Co-ordination Group for Mutual Recognition and Decentralised Procedures- Human (CMDh). "*CMDh Best Practice Guides for the submission and processing of Variations in the Mutual Recognition Procedure*". Chapter 5, Section 8 Outcome. Doc. Ref.: CMDh/094/2003/Rev13. April 2011. Internet: http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Variations/CMDh_094_2003_Rev13-Clean_2011_04.pdf

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