Circular Informativa

N.º 124/CD/100.20.200

Date: 25/09/2017

Subject: **Validation and refusal of variations to the terms of marketing authorisations**

To: Marketing Authorisation Holders

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After the implementation of the Variation Regulation[1] and having assessed the main issues that affect the fast conclusion of variations, the optimization of such procedures is paramount, thus allowing for a more efficient use of the resources available on the changes with greater impact on the safety and quality of medicinal products.

The assurance of correct submission of all relevant documents and information is a responsibility of the applicant, in compliance with the established requirements for the implementation of variations with minimal impact. In this way, and in line with what has been established by other Member States of the EU, the variation requests that do not meet the mandatory requirements laid down on the Guideline[2] will be **directly refused** without any opportunity to supply the missing information. Particularly, the following situations will be included:

- Incorrect category;
- Non-fulfilment of the applicable conditions for the category;
- Missing mandatory documentation or submission of invalid or incorrectly filled documents (example: QP declarations with no valid audit date, copy of the relevant page of the Guideline without ticking the correct conditions or set as not applicable (*N/A*) without justification).

The submission of non-acceptable grouped variations will also be subject to invalidation due to the impossibility to assess the submitted group or whenever the proposed changes are not equally applicable to all strengths and/or dosage forms included in the variation request.

[1] Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products.

[2] Guideline on the details of the various categories of variations, on the operation of the procedures and on the documentation to be submitted pursuant to those procedures

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Further situations of mistakes in the filling of the variation requests or in the supporting documentation, although not sufficient to justify refusal, have a great impact in the quality of the submission and hinder efficient management. Below are the most common examples to which applicants must pay **special attention** to, regardless of the variation category, when submitting the request:

- Wrong procedure number in the Application Form and/or SMUH-ALTER platform;
- Implementation date not defined or incoherent with the nature of the request;
- Lack of information on the submission to CMS, in case of MRP submissions (dispatch list);
- Missing Power of Attorney for submissions filled by an applicant other than the MAH;
- Absent/incorrect working documents of the proposed product information.

All applicants are requested to thoroughly check the correction of these elements in all applicable cases, in order to avoid burdening the regulatory assessment of the submitted variations.

Bear in mind that no refunding of fees is possible in case a variation is refused.

This procedural optimization will have a transitional period of 90 calendar days after the publication of this Circular Informativa.

The Management Board

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