HARMONISATION OF SmPCS

ARTICLE 29(4) REFERRALS

SUSPENSION OF MARKETING AUTHORISATION FOLLOWING A REFERRAL ACCORDING TO ART. 29(4) OF DIRECTIVE 2001/83/EC
HARMONISATION OF SmPCS

Question 1

**Following an Article 30 or 31(1) referral procedure involving medicinal products authorised nationally in more than one MS, should the Mutual Recognition Procedure be used to maintain the harmonisation achieved?**

**Answer:** All applications for variations and renewals following an Article 30 or 31(1) referral have to be submitted according to the Mutual Recognition Procedure.

The MAH must choose a Reference Member State for the Procedure if there is none already in place. The CMDh strongly recommends to choose the same RMS for all strengths and pharmaceutical forms of a product, where possible.

The product information after finalisation of referrals is published on EMA website.

Question 2

**How to proceed if following an Article 30 or 31(1) referral the chosen RMS has not authorised all the strengths, pharmaceutical forms and/or duplicates?**

**Answer:** In this situation different RMSs will be needed to cover the entire range of strengths and pharmaceutical forms.

MAH are advised to obtain MAs for all strengths, pharmaceutical forms and duplicates of the product in one of the RMSs, by repeat-use procedures using the MAs in the other RMSs. The latter RMSs should then transfer the role of the RMS to the chosen, sole, RMS.

**Guidance Documents:**

- Recommendation for implementation of Commission Decisions or CMDh agreements following Union Referral Procedures where the Marketing Authorisation is maintained or varied
- CMDh recommendation on implementation of article 30 decisions cf. directive 2001/83/EC, as amended for generic/hybrid/biosimilar medicinal products approved through MRP/DCP

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Question 3

**In case an application for marketing authorisation is referred to the CHMP, according to Article 29(4) of Directive 2001/83/EC, as amended and the CHMP opinion is that the valid summary of product characteristics, labelling and package leaflet are the final versions achieved during the CMDh procedure, when shall the national translations for the product information be submitted?**

**Answer:** The CMDh has agreed that in order for Member States to be able to comply with the Commission Decision within 30 days following its notification, in accordance with Article 34(3) of Directive 2001/83/EC, as amended, high quality translations of the summary of product characteristics, package leaflet and labelling as achieved during the CMDh referral procedure should be submitted at the latest 7 calendar days after the Commission Decision. However these may be required earlier in the procedure by some National Competent Authorities.
Translations of the summary of product characteristics, package leaflet and labelling achieved during the CMDh referral procedure only need to be submitted to the Reference Member State and Concerned Member States in the procedure.

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**Question 4**

*If as a result of a referral according to Article 29(4) of Directive 2001/83/EC, as amended, the Marketing Authorisation was suspended based on a Decision by the European Commission, who will be responsible to lift the suspension?*

**Answer:** If not otherwise stated in the Decision, this will be the responsibility of the Member States under the lead of the RMS.

**Question 5**

*What is the process for lifting the suspension?*

**Answer:** The outstanding documents/studies as addressed in the Annex of the Decision, have to be submitted to the RMS and, if applicable, to the CMS in line with the procedure outlined in the Commission Regulation (EC) 1234/2008. Normally this will be by a Type II Variation.

**Question 6**

*How can I get a Marketing Authorisation in the Member States which as a result of the Commission Decision, have refused the application?*

**Answer:** A new application is required in the Member State(s) who refused the application. The normal route of a repeat-use MRP has to be followed, after the suspension is lifted in the RMS and, if applicable, existing CMS(s) in the procedure.