The European Agency for the Evaluation of Medicinal Products

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Practical guidance on the extension of Commission Decision Annexes in the new Accession Country languages

This Guidance outlines practical considerations concerning the phasing in of Commission Decisions concerning CAPs in new Member States (MSs). It builds on the conclusions of the "*PERF III Acquis Group Reflection Paper on Organisational Aspects of Phasing In of Commission Decisions Concerning Centrally Authorised Products (CAPs) in new Member States*". (*see*: http://perf.eudra.org/perf3/PDFs/acquis/000304en.pdf).

Marketing Authorisation Holders are legally obliged to provide translations in the new official languages as of the date of accession**.** In order to facilitate the phasing-in of Commission Decisions related to the EU centralised procedure, a voluntary pre-accession checking procedure for Annex I and III[1] has been set up in cooperation with the National Competent Authorities (NCA) of the new MSs (*see*: http://www.emea.eu.int/euenlargement.htm#).

Following the publication of Council Regulation No 930/2004 on temporary derogation measures relating to the drafting in Maltese of EU acts, it is no longer required to provide Maltese translations of SPC, Annex II, Labelling and Package Leaflet texts for Centrally Authorised Medicinal Products, nor to prepare printed packaging materials in Maltese until 1st May 2007.

This Guidance document provides further details on the inclusion of the new languages and new specimens into the operational aspects of the centralised procedure. For general guidance on the handling of new applications and post-authorisation procedures and more practical aspects of the submission requirements of Annexes, please refer to the respective Pre-Submission and Post-Authorisation Guidance Documents published on the EMEA Website.

Applicants/MAHs are advised to systematically discuss the best approach for their product(s) with their Product Team Leader/Project Manager, especially for Regulatory Procedures which will finalise before or around enlargement.

Provision of new language versions of the Commission Decision Annexes

It is considered that 3 possibilities emerge as described below (see also tabulated summary in Appendix 1):

i) CAPs with ongoing regulatory activity, with opinion before May 2004 (*i.e. Commission Decision expected in or after May 2004)*

Commission Decisions issued as of 1st May 2004 will legally be required to be addressed to all MSs of the EU including the 10 Accession Countries (AC). This will have direct consequences for both new applications for a centralised MA as well as for any post-authorisation application for existing CAPs. Applicants/MAHs are advised that they will be requested to provide translated annexes in all 19 official languages of the EU for all CxMP Opinions which will be issued in January/February–April 2004 so as to allow the Commission to address a Decision to all Member States as of 1st May 2004.

[1] No specific checking procedure is foreseen for Annex A and Annex II

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For both new and ongoing applications a post-opinion linguistic check will be conducted in cooperation with the NCAs of the new MSs, as part of the usual post-opinion procedures.

The following requirements will apply for the different types of applications:

a. **New applications and extension applications** will follow the PIPIT procedure (http://www.emea.eu.int/pdfs/human/regaffair/554202en.pdf), which will now include 19 languages (+ IS/NO).

For **new product applications**, applicants are required as of **January 2004** to provide translations in all languages (incl. AC languages) of Annex I, II and III as provided by the QRD Product Information templates[2], after adoption of the Opinion. The current post-opinion procedures will apply.

After adoption of an **Extension** Opinion as of **February 2004**, MAHs are required to provide translations in all languages (incl. AC languages) of the complete set of annexes. A 'complete set of Annexes' includes Annex, I, II, IIIA and IIIB *i.e.* all SPC, labelling and PL texts for all strengths and pharmaceutical forms of the product concerned, as well as Annex II.
MAHs should highlight the differences of the Extension versus the current EU authorised presentations in order to facilitate the linguistic review. MAHs should complete the list of Local Representatives for the AC in the PL in all language versions of all product presentations as part of the extension application. If such change was however not initially covered in the application, the EMEA will allow that such change is introduced before finalisation of the Opinion / Decision concerned.

MAHs should include a reference in the cover letter to the status of the voluntary pre-accession linguistic check *i.e.* date of completion/submission and procedure numbers of text versions agreed. If other changes have occurred in the AC translations of the existing presentations since the pre-accession check, such changes should also be highlighted in the relevant Annexes in these languages. In addition, a reference to the latest procedure number reflected in the updated translations compared to the versions agreed during the pre-accession linguistic check must be included.
Where such pre-accession check has not taken place, MAHs must be aware that the existing post-opinion linguistic checking procedures may not be sufficient for the new MSs to review the complete product information within the available timeframes. It must therefore be envisaged that for products without pre-accession check, delays in the post-opinion transmission phase to the EC could occur pending finalisation of the translations check.

b. For **Type II variations**, for which an CxMP Opinion will be adopted as of **February 2004**, the following requirements will apply. At submission (variations with a 30-day TT) or after adoption of a Type II Opinion (variations with a 60 or 90-day TT), MAHs are required to provide translations in all languages (incl. AC languages) of the complete set of annexes. A 'complete set of Annexes' includes Annex, I, II, IIIA and IIIB *i.e.* all SPC, labelling and PL texts for all strengths and pharmaceutical forms of the product concerned, as well as Annex II. MAHs should highlight the changes introduced during the variation procedure in order to facilitate the linguistic review.
MAHs should complete the list of Local Representatives for the AC in the PL in all language versions as part of the variation procedure. If such change was however not initially covered in the 'scope' of the variation concerned, the EMEA will allow that such change is introduced in the PL before finalisation of the Opinion / Decision concerned.

[2] Updated QRD Product Information templates including Annex I, II and III and reflecting the full list of local representatives are available on the EMEA Website.

MAHs should include a reference in the cover letter to the status of the voluntary pre-accession linguistic check *i.e.* date of completion and procedure numbers of text versions agreed. If other changes have occurred in the AC translations of the existing presentations since the pre-accession check, such changes should also be highlighted in the relevant Annexes in these languages. In addition, a reference to the latest procedure number reflected in the updated translations compared to the versions agreed during the pre-accession linguistic check must be included.

Where such pre-accession check has not taken place, MAHs must be aware that the existing post-opinion linguistic checking procedures may not be sufficient for the new MSs to review the complete product information in addition to the amended text parts related to the application concerned within the available timeframes. It must therefore be envisaged that for products without pre-accession check, delays in the post-opinion transmission phase to the EC could occur pending finalisation of the translations check.

c. For **Type IA/IB variations**, the new Variation Regulation does not provide for an updating of the Commission Decision following each Type IA/IB procedure, but rather on a 6-monthly basis. In absence of any other procedure, MAHs are allowed to use the 6-montly updating point if this were to occur in **April or May 2004.** In such case, the MAH provides the complete set of Annexes in all languages (incl. AC languages) to the EMEA. A 'complete set of Annexes' includes Annex, I, II, IIIA and IIIB *i.e.* all SPC, labelling and PL texts for all strengths and pharmaceutical forms of the product concerned, as well as Annex II. These Annexes will then be part of the Commission Decision on such Type IA/IB variation(s).

MAHs should complete the list of Local Representatives for the AC in the PL in all language versions as part of this procedure. The EMEA will allow that such change is introduced in the PL before finalisation of the Decision concerned.

MAHs should include in the cover letter a reference to the status of the voluntary pre-accession linguistic check *i.e.* date of completion and procedure numbers of text versions agreed.

Where such pre-accession check has not taken place, MAHs must be aware that delays in the transmission of the documents to the EC could occur pending finalisation of the translations check.

MAHs are also advised that as of **April 2004** the complete set of annexes should include the 9 additional AC language versions for Type IA and Type IB Notifications affecting the product information (see also '*EMEA Post-Authorisation Guidance'*). In addition, the list of Local Representatives in the PL should be completed for the ACs.

d. Renewals: at submission of renewal applications as of **February 2004**, MAHs are required to provide translations in all languages (incl. AC languages) of the complete set of annexes. A 'complete set of Annexes' includes Annex, I, II, IIIA and IIIB *i.e.* all SPC, labelling and PL texts for all strengths and pharmaceutical forms of the product concerned, as well as Annex II.

MAHs should highlight the changes introduced during the renewal procedure in order to facilitate the linguistic review.

MAHs should complete the list of Local Representatives for the AC in the PL in all language versions as part of the renewal procedure. If such change was not initially included in the renewal submission, the EMEA will allow that such change is introduced in the PL before finalisation of the Opinion / Decision concerned.

MAHs should include a reference in the cover letter to the status of the voluntary pre-accession linguistic check *i.e.* date of completion and procedure numbers of text versions agreed. If other changes have occurred in the AC translations of the existing presentations since the pre-accession check, such changes should also be highlighted in the relevant Annexes in these languages. In addition, a reference to the latest procedure number reflected in the updated translations compared to the versions agreed during the pre-accession linguistic check must be included.

Where such pre-accession check has not taken place, MAHs can exceptionally use the renewal procedure to provide for a linguistic pre-accession check. EMEA and NCAs of the new MSs will aim at ensuring finalisation of the linguistic check within the normal renewal procedural timeframes. MAHs intending to use this possibility should discuss this well in advance with the EMEA.

For **Annual Re-Assessment** procedures, MAHs are advised to contact the EMEA Product Team Leader in order to discuss the best approach for the product concerned, in view of possible other ongoing/imminent regulatory procedures where the provision of AC translations could be addressed.

e. **Transfer** procedures:at submission of transfer applications as of **February 2004**, MAHs are required to provide translations in all languages (incl. AC languages) of the complete set of annexes. A 'complete set of Annexes' includes Annex, I, II, IIIA and IIIB *i.e.* all SPC, labelling and PL texts for all strengths and pharmaceutical forms of the product concerned, as well as Annex II.
MAHs should highlight the changes introduced during the transfer procedure.
MAHs should complete the list of Local Representatives for the AC in the PL in all language versions as part of the transfer procedure.
MAHs should include a reference in the cover letter to the status of the voluntary pre-accession linguistic check *i.e.* date of completion and procedure numbers of text versions agreed. If other changes have occurred in the AC translations of the existing presentations since the pre-accession check, such changes should also be highlighted in the relevant Annexes in these languages. In addition, a reference to the latest procedure number reflected in the updated translations compared to the versions agreed during the pre-accession linguistic check must be included.
Where such pre-accession check has not taken place, MAHs must be aware that delays in the transmission of the documents to the EC could occur pending finalisation of the translations check.

ii) CAP with ongoing/imminent regulatory activity (CXMP Opinions) after May 1st 2004

In principle once accession occurs any further regulatory action on CAPs e.g. renewals, variations, line extensions, annual reassessments etc. are legally required to be addressed to all Member States. This implies that **any** final CxMP **opinions after May 1st 2004** which are addressed to the Member States as well as EMEA Notifications need to include relevant annexes in all Community languages. Unless such obligation is fulfilled further regulatory action on such products will be blocked/delayed.

In support of this process the MAH would be asked to supply similar elements as outlined in (i) above upon adoption of the opinion or finalisation of the procedure. These would then be processed as per the normal Decision Making Process and the product could be released on the market once the Commission Decision has been made.

iii) CAP with no ongoing regulatory activity

It is likely that there will be MAHs who are currently marketing CAPs under a national license in the New Member State who wish to introduce the product switchover as quickly as possible in order to maintain supply continuity. Alternatively there may be MAHs who would wish to launch their product in the New Member States for the first time as soon as possible upon accession. In order to facilitate this access an Article 61(3) type Notification can be submitted to the EMEA[3]. The official scope of such a Notification could be "inclusion of additional local representatives of the MAH for all new MSs". This would affect all language versions of the PL, including the new languages.

[3] For Veterinary products the EMEA would send an appropriate notification to the Commission

However, a notification according to Art. 61(3) only covers labelling and/or PL. In order to allow the provision of a complete set of up-to-date product information in all languages for such a notification procedure, it has been agreed to exceptionally allow the inclusion of all SPC, Annex II and labelling texts as part of the Notification (*see also below*). However, no changes should be introduced to the SPC and Annex II.

In addition, MAHs should take this Notification as an opportunity to update the new language versions (which have been subject to the voluntary pre-accession linguistic check) in line with the latest EN approved text versions. This will ensure that all language versions included with the Notification will reflect the same reference EN text.

For such Notification procedure, MAHs are required to provide translations in all languages (incl. AC languages) of the complete set of annexes. A 'complete set of Annexes' includes Annex, I, II, IIIA and IIIB *i.e.* all SPC, labelling and PL texts for all strengths and pharmaceutical forms of the product concerned, as well as Annex II. A declaration should be provided that no changes have been introduced in the SPC, Annex II (and labelling, where appropriate).
MAHs should include in the cover letter a reference to the status of the voluntary pre-accession linguistic check *i.e.* date of completion and procedure numbers of text versions agreed. If other changes have occurred in the AC translations of the existing presentations since the pre-accession check, such changes should also be highlighted in the relevant Annexes in these languages. In addition, a reference to the latest procedure number reflected in the updated translations compared to the versions agreed during the pre-accession linguistic check must be included.

Upon receipt of the above elements EMEA would organise or confirm the status of the linguistic check and issue a Notification. The EMEA Notification will be sent to the Commission for information only. The changes to the Annexes introduced via the Art 61(3) notifications will be reflected in a Commission Decision in the framework of the next Regulatory procedure relating to the Marketing Authorisation concerned.

Art 61(3) Notifications may be processed within 90 days of receipt and depending on complexity significantly shorter review times e.g. 60 days or 30 days could be envisaged. Where a pre-accession linguistic check has been finalised and no additional changes have been introduced, such notifications could exceptionally be submitted prior to the actual accession date e.g. as of February 2004 to allow formal EMEA "sign-off" on 1st May 2004 thereby removing any administrative delays to the switchover process. Where such pre-accession check has not taken place, MAHs must be aware that delays in the issuance of the EMEA Notification could occur pending finalisation of the translations check.

In the **absence of any regulatory activity** within 24 months of the Accession, an Article 61(3) type Notification will have to be finalised for all such products to provide these translations to the EMEA. It is in the public interest to address this situation for all CAPs after the Accession in view of the public information sources (EPARs/Community Register) and potential to access such products through other regulatory routes notwithstanding the legal obligation of the MAH to provide such translations as of the Accession.

Provision of specimens for the Accession Countries to the EMEA

In line with the requirements for EU countries, specimens of the final outer and inner packaging and of the package leaflet must be submitted to the EMEA before launch in the new Accession Countries.

When sending specimens to the EMEA, MAHs must clearly indicate in which AC(s) the specimens are intended to be launched, as well as the latest procedure number reflected in the printed materials (e.g. Type II/25). In addition, MAHs must provide a declaration stating that:

- the overall design, lay-out, format etc. is identical to the agreed packs for the current MSs,
- the relevant official language(s) are included on the printed material for the MS(s) concerned,
- the checked translation text(s) for the new MS(s) concerned is correctly implemented in the printed materials,
- the Blue Box is in line with the relevant national requirements, as outlined in the Guideline on Packaging Information. The local representative, when printed in the Blue-Box, is identical to the one mentioned in the Package Leaflet.

Overview of translation requirements for the phasing-in process of the new Accession Countries languages *Appendix 1*

Requirement to submit a 'complete set of Annexes' in all languages (incl. AC languages)	**New Application**	**Extension**	**Type II Variation**	**Type IA/IB** (incl. 6-monthly)	**Renewal**	**Art. 61(3) Notification**	**Transfer**
▪ Submission at time of application			√ (30-day TT) As of Feb 04	√ As of April 04	√ As of Feb 04	√	√ As of Feb 04
▪ Submission after Opinion	√ As of Jan 04	√ As of Feb 04	√ (60/90-day TT) As of Feb 04				
▪ Declaration that no changes have been introduced in the SPC, Annex II (and labelling, where the notification only concerns PL)						√	
▪ Changes due to the actual application/procedure concerned must be highlighted in the text		√	√		√		√
▪ Full list of local representatives must be included in the PL (where such list is provided)	√	√	√	√	√	√	√
▪ Details on status of the voluntary pre-accession check	√	√	√	√	√	√	√
▪ Changes introduced in the new languages since the pre-accession check must be highlighted in the text[4]	√	√	√	√	√	√	√

[4] *i.e.* changes from any finalised procedures which were not yet provided and checked for the AC language versions as part of the pre-accession linguistic check.

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