Q&A - Product Information / Information on Medicinal Products

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1. Languages to be used for Applications for Marketing Authorisation in the Decentralised or Mutual Recognition Procedure

1.1. Is it possible to submit text proposals for the SmPC, Package Leaflet and Labelling for applications for marketing authorisation via the Mutual Recognition or the Decentralised Procedure in English only?

Yes. Member States have agreed to accept text proposals for the SmPC, PL and labelling in English with the submission of the application. However, sample mock-ups in an official language of the EU should also be submitted for the application to be considered valid.

It will not be essential to undertake user testing on leaflets drawn up in more than one language and the testing may be done on leaflets prepared in any official language of the EU which may not necessarily be the language of the RMS. Results of such tests should be presented in English to permit the assessment of the test to be undertaken by RMS and CMS as necessary.

High quality translations of the agreed SmPC, PL and labelling should be submitted at the latest 5 days after the end of the procedure; however, these may be required earlier in the procedure by some Competent Authorities.

2. Languages to be used for Applications for variations and renewals to Marketing Authorisations granted via the Decentralised or Mutual Recognition Procedure

2.1. Is it possible to submit text proposals for the SmPC, PL and Labelling for applications for variations and renewals to marketing authorisation granted via the Mutual Recognition or the Decentralised Procedure in English only?

Member States have agreed to accept text proposals for the SmPC, PL and labelling in English with the submission of type II variation and renewal applications, provided that translations of the agreed SmPC, PL and labelling were submitted after the end of the Mutual Recognition or Decentralised Procedure for the initial marketing authorisation. Sample mock-ups in an official language of the EU should also be submitted (where appropriate) for the application to be considered valid. High quality translations of the agreed SmPC, PL and labelling should be submitted at the latest 5 days after the end of the type II variation or renewal procedure; however, these may be required earlier in the procedure by some Competent Authorities. For type IA/IB variation applications, text proposals for the SmPC, PL and labelling in the respective national language(s) should be submitted together with the application.
2.2. Question 3 deleted in October 2012

2.3. Question 4 deleted in October 2012

3. Consultation with target patient groups for the package leaflet

3.1. Is it possible to justify that a Package Leaflet complies with the requirement of Article 59 by referring to results of consultation with target patient groups on other package leaflets?

The absence of test results from consultation with target patient groups could be justified by referring to another tested package leaflet (the reference PL) provided that the key messages for safe use have been adequately addressed. The package leaflet and the reference PL have to be similar in content, and the design and layout should be considered. The applicant should submit an adequate justification which critically appraises the similarities/differences between the submitted PL and the reference PL and addresses the relevance of test results with the reference PL. In addition, a critical comparison of the design and layout of both PLs should be included.

Justification for absence of consultation with target patient groups by referring to other tested PLs is applicable in all situations (e.g. new applications, renewals, variations) where patient consultation may be required.

3.2. What is the timing in a Mutual Recognition or Decentralised Procedure for the submission to the Competent Authorities of the results of consultation with target patient groups for the Package Leaflet, in accordance with Articles 59(3) and 61(1) of Directive 2001/83/EC?

Applicants are advised to consider the need for ‘user consultation’ in advance of the submission of applications for marketing authorisation via the Mutual Recognition or Decentralised Procedure and undertake initial testing as necessary and/or consider the timing of consultation within the procedural timeframe. Applicants should present the results of the user consultation or justification for their absence in Module 1.3.4 of the application, in accordance with the Guideline on the Readability of the Labelling and Package Leaflet of Medicinal Products for Human Use, available on the European Commission website.


There are further opportunities within the procedural timeframes, such as during the clock stop of a DCP, to submit the results of user consultation. The objective is to have reached agreement on a harmonised label and package leaflet at the completion of the procedure.

For further information on the timing of user consultation, submission and assessment within the evaluation procedure in the Decentralised or Mutual Recognition Procedure, please refer, respectively, to the Decentralised procedure – Member States SOP and to the Best Practice Guide for the Mutual Recognition Procedure, available on the CMDh website.
3.3. **What should be the procedure to harmonise the Labelling and Package Leaflet of a MR medicinal product where the repeat-use procedure is to be used after 30 October 2005?**

Harmonisation of the labelling and package leaflet of a medicinal product should be achieved using a Type II variation before the start of the repeat-use MRP.

There is also the possibility to make use of an Article 61(3) notification procedure where minor changes only to the labelling and package leaflet are required, but Marketing Authorisation Holders are advised to discuss this with the Reference Member State ahead of submission (CMS involvement may also be necessary).

3.4. **Question 8 deleted in October 2012**

3.5. **Question 9 deleted in October 2012**

3.6. **Question 10 deleted in October 2012**

3.7. **Could the requirement in Art. 59(3) of Directive 2001/83/EC, concerning the package leaflet and consultations with target patient groups, be considered fulfilled if the Public Assessment Report (PAR) or European Public Assessment Report (EPAR) of another product containing the same active substance but with a different Marketing Authorisation Holder, reflects that the package leaflet has been subject to an acceptable "user test"?**

Yes, provided that the package leaflet of the product applied for follows the same wording as the tested package leaflet. The applicant needs to submit a bridging report in Module 1.3.4 containing:

- a justification including name and procedure number of the product that has already been subject to an acceptable user test;
- evidence of a successful user test (e.g. a copy of the relevant PAR/EPAR)
- proof that the package leaflets follow the same wording (e.g. comparison of the package leaflets);
- a bridging report regarding the design and layout of the package leaflet applied for.

3.8. **Question 12 deleted in October 2012**

4. Braille

4.1. **What should be considered as the name of the medicinal product for the purpose of complying with Article 56a of Directive 2001/83/EC?**

The name of the medicinal product, as mentioned in Article 1(20) of Directive 2001/83/EC “the name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the Marketing Authorisation Holder”, followed by its strength.

For medicinal products authorised only in a single strength, it is acceptable that only the invented name is expressed in Braille format on the packaging.
Please note that this interpretation does not prevent Companies from expressing further information (strength and pharmaceutical form and, if appropriate, whether the medicinal product is intended for babies, children or adults) in Braille. In addition, the inclusion of the expiry date in Braille is welcome.

5. Public Assessment Reports

5.1. In accordance with Article 21(4) of Directive 2001/83/EC, the Competent Authorities shall make publicly accessible without any delay, the assessment report together with the reasons for their opinion, after deletion of any commercially confidential information. Will the assessment report for Mutual Recognition and Decentralised Procedures be publicly available? If so, where will assessment reports be published?

MSs have agreed to actively publish the public assessment reports for medicinal products submitted via the Mutual Recognition or Decentralised Procedure and completed after 30 October 2005.

The public assessment report (PAR) will be available in English on the MRI-Product Index, Heads of Agencies website http://mri.medagencies.org/Human/ 60 days after the conclusion of the MR or DC Procedure.

The publication of the PAR in the national languages is the decision and responsibility of national competent authorities.

PARs for nationally authorised medicinal products will be made publicly accessible and the respective national competent authority should be contacted in this regard.

6. Information on marketing of Medicinal Products

6.1. Will the requirement set out in Article 23a of Directive 2001/83/EC, to inform the Competent Authority of the authorising Member State of the marketing date of the medicinal product in that MS and of the interruption in the placing on the market be applicable to all authorised medicinal products, regardless of the date of authorisation?

The requirement to inform the Competent Authority of the date of actual marketing of the medicinal product in that Member State and of any temporary or permanent interruption of such marketing applies to all medicinal products.

Marketing Authorisation Holders will therefore have to inform the Competent Authority of the marketing status of all presentations of the medicinal product in that Member State in accordance with national arrangements.

Marketing Authorisation Holders of existing medicinal products shall also notify the Competent Authority of any temporary or permanent interruption of such marketing in accordance with national arrangements.
7. List of Mutual Recognition Products

7.1. Are medicinal products authorised by MRP or DCP listed?

Yes they are listed in the MRI Product Index, available in the Heads of Agencies website at the following web address: http://mri.medagencies.org/Human/

7.2. Are pending applications for MRPs or DCPs listed?

No, they are not listed because the information is confidential.

7.3. Are CMS where applications have been withdrawn, listed?

No, they are not listed because this information is confidential.