



European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

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**QUALITY REVIEW OF DOCUMENTS GROUP
(QRD)**

**PRODUCT INFORMATION TEMPLATES
*Human Medicinal Products***

DISCUSSION AT EMEA & QRD	Nov 2004 - Feb 2005
RELEASE FOR CONSULTATION	21 March 2005
DEADLINE FOR COMMENTS	20 May 2005
DISCUSSION OF COMMENTS AND ADOPTION AT QRD	29 June 2005
ENTRY INTO FORCE	See Below

The EMEA and the Quality Review of Documents Group have updated the Human Product Information Templates in line with Directive 2001/83/EC, as amended by Directive 2004/27/EC. In addition, the updated templates reflect the revised SPC Guideline and recommendations from the EMEA/CHMP Working Group with Patients Organisations.

Three documents are provided:

- A "[Clean Annotated QRD template](#)";
- "[QRD templates](#)" in all EEA languages;
- A "[Highlighted Annotated QRD template](#)", presenting all changes made to the previous template v.6.1.

Implementation of the new QRD templates

1. Ongoing new marketing authorisation applications with Commission Decision expected after 20 November 2005 (i.e. with CHMP opinion as of September 2005)

Product information Annexes to Commission Decisions on new marketing authorisation applications will have to comply with the new legislation as of 20 November 2005. Consequently, the updated QRD templates will apply to the SPC, Annex II, labelling and package leaflet of new marketing authorisation applications for which a CHMP opinion will be adopted as of **September 2005**.

Applicants will therefore have to amend their draft product information to reflect the new QRD templates in time for opinions to be adopted in September and October 2005. For all other ongoing applications, applicants will have to amend their draft product information at Day 121 (if the assessment procedure is before Day 120) or at the latest at Day 181.

2. New marketing authorisation applications submitted around November 2005

Applicants submitting a new marketing authorisation application **as of 20 November 2005** should follow the updated QRD templates for SPC, Annex II, labelling and package leaflet.

For applications submitted before that date, see section 1.

3. Existing marketing authorisations granted by the Centralised Procedure

Product Information of authorised medicinal products will have to be amended to reflect the new legislation and updated QRD templates, at the occasion of a variation affecting the Annexes or extension procedure, **within 2 years** of the application of the new legislation (i.e. by November 2007), unless the marketing authorisation is renewed earlier, in which case the renewal procedure should be used for the update.

This means that product information for **renewal** opinions adopted as of **September 2005** should comply with the updated QRD templates.

For products which have no regulatory activity during these 2 years, the update should be performed at the occasion of the renewal, even if it takes place later.

The update should be clearly included in the scope of the corresponding procedure. Article 61(3) notifications or 6-monthly Type I variation updating procedures should not be used for this purpose.

For **extension applications** for which an opinion will be adopted in September or October 2005, MAHs may apply the new QRD templates to the extension Annexes only. In such a case, the already existing presentations will have to be updated as described in the previous paragraphs.

Applicants/MAHs are advised to discuss the consequences for their product(s) with their Product Team Leader, especially for regulatory procedures which will finalise around September - November 2005.