The European Agency for the Evaluation of Medicinal Products
Technical Co-ordination Unit

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Report on the Activities of the Working Group on Quality Review of Documents in 1998

General

The Working Group on Quality Review of Documents ("QRD") was established in June 1996 and is composed of representatives of the Member States, the Commission, the Luxembourg Translation Centre and the EMEA. The main task of QRD is to ensure consistency and accuracy of translations of the product information attached to the scientific opinions of CXMP.

1998 saw a major change in the functioning of QRD. As from August, QRD started to meet on a bimonthly (rather than monthly) basis. At the same time, the review of product information began to be performed using an electronic procedure rather than discussing the documents during QRD meetings. Early indications of the feasibility of this new way of working are very promising; the procedure has been well received by most delegates and the initial technical problems can apparently soon be resolved, if not already. In light of the fact that the frequency of meetings has now been halved, it is important that meeting time has been freed from the discussion of specific product information in order to continue the good progress already made in resolving generic problems and formulating policies on relevant issues. The results of QRD discussions will continue to be converted into practical advice for applicants, e.g. published compilations of QRD decisions and revised Templates with accompanying guidance.

Working electronically with product information has the advantage of cost savings in relation to employee time needed to prepare mailings and in relation to the actual costs of photocopying and mailing (usually express) documents. More significantly, it allows the work of QRD to be performed satisfactorily on the basis of six meetings per year (with a resulting saving in the cost of five meetings). The electronic procedure is also more efficient than the system of performing reviews during meetings, since there are no delays in waiting for a meeting date before review takes place. However, electronic review would not have been appropriate until around this time, as QRD needed to gain considerable experience in round-table review and discussion of documents in order to identify the issues commonly arising and to reach agreed positions on these with input from all members. Only now that members have acquired this experience and policies have been adopted can much of the reviewing be done outside of the meetings. New or difficult issues will be addressed by members of QRD on an *ad hoc* basis or raised at meetings.

Updating of QRD Templates

Much of the work of QRD between January and July focussed on agreeing an updated version of Template No 1 (CPMP positive opinion full application) and the "human" product information template (SPC, labelling and package leaflet (PL)), including work on a comprehensive set of explanatory notes for applicants. A number of important issues were discussed and resolved in the context of these discussions so that guidance on common problem areas could be included in the explanatory notes. These included expression of the name and strength of the medicinal product, the issues of combined or

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separate SPCs/PLs for different strengths and pharmaceutical forms and mentioning of different pack sizes in the SPC/PL and numerous issues of terminology.

Considerable effort was invested in working together with DGIII to harmonise the texts of the Commission's draft Readability Guideline and the updated template for labelling and package leaflet, with the result that two consistent documents have now been adopted. There was also co-ordination with the CPMP's Ad Hoc Working Group on SPCs to ensure consistency between their guidance being developed and the updated template.

Once adopted, the new version of Template No 1 was published on the EMEA website, together with supplementary guidance for applicants (e.g. compilations of QRD decisions on stylistic matters and on the use of terms) and links to other relevant documents. A number of other Templates (No 2, 4, 4a, 13, 13a and 21) have since been updated to reflect the changes made to Template No 1, and two new Templates (No 7 (line extensions) and No 3 (CPMP negative opinion)) have been adopted in line with Template No 1.

In the October and December meetings, QRD worked on agreeing a new version of Template No 14 (CVMP positive opinion full application) and the "veterinary" product information template (SPC, labelling and package insert), reflecting the updated Template No 1. The new version was adopted at the end of the December meeting and will be discussed in the January 1999 CVMP meeting. Linguistic versions are currently being prepared.

Product Information Reviewed

During 1998, QRD has reviewed the product information for 51 marketing authorisation applications (47 medicinal products for human use and 4 veterinary medicinal products). Of these, 24 were reviewed using the new electronic procedure.