CDR Submission Guidelines for Manufacturers Updated

The Common Drug Review Submission Guidelines for Manufacturers have been updated and posted on the CDR section of CCOHTA’s web site. The new version is dated July 25, 2005 and becomes effective for all submissions filed on or after August 15, 2005.

Changes to the Submission Guidelines include:

1. An additional requirement that manufacturers disclose all unpublished Phase 2, 3 and 4 studies known to the manufacturer (section 1.2.1, item 7)

In the review of drug submissions, the CDR Directorate and the Canadian Expert Drug Advisory Committee (CEDAC) require access to existing information, including unpublished information, about a drug’s safety, efficacy and effectiveness so that the drug can be adequately compared to appropriate comparators and so that a cost-effectiveness determination can be made. While the CDR Directorate undertakes a comprehensive literature search, this identifies only published studies. The Directorate is aware that the published studies represent only a portion of all the studies conducted and lack of access to unpublished studies may not allow a comprehensive comparison with existing therapies. The effect of publication bias is well known and has been described in the medical literature. In order to have a more complete picture of the studies that have been undertaken on the drug under review, the Submission Guidelines have been revised to request a listing of all unpublished Phase 2, 3 and 4 clinical trials known to the manufacturer with a brief description of each. (Please note that manufacturers should continue to submit unpublished studies in accordance with the requirements of section 1.2.1, item 7b.)

A template table with headings for the required information and a template letter, confirming that all unpublished studies known to the manufacturer have been disclosed, can be found on the CCOHTA website in the CDR Submission Guidelines section.

2. Clarification of the definition of New Information and Resubmission requirements (sections 1.3.2 and 1.3.2)

The type of New Information and the stage of the review process when a manufacturer files a resubmission determine what the manufacturer must include when filing a resubmission. To assist in filing resubmissions, the definition of New Information and the type of information that a manufacturer must provide have been clarified.

3. Description of the process for referring to Confidential Information in the CEDAC Recommendation and Reasons for Recommendation document added to the Confidentiality Guidelines (Appendix 8, section C, item 4)

The CDR reviewers and CEDAC use unpublished data submitted by manufacturers in reviewing submissions and providing a listing recommendation to the participating drug plans. This unpublished data may help to clarify CEDAC Reasons for Recommendation; however, manufacturers usually consider submitted unpublished studies as confidential. The new section in the Confidentiality Guidelines describes the CDR Directorate’s process for obtaining permission from the manufacturer to include unpublished data in the final Reasons for Recommendation (i.e., those released to the public) and it describes how the reference is made to the unpublished data if permission is denied.

4. Clarifications to the Submission Requirements have been made to facilitate the review process.

Manufacturers/consultants filing submissions are asked to:

a. Provide an original signed covering letter (not a photocopy), confirming that all of the required information has been provided in each copy of the Submission. (See 1.2.1 Category 1 Requirements, item 1.)

b. Indicate in the covering letter whether the submission includes Category 1, Category 2 or both Category 1 and 2 requirements. (See 1.2.1 Category 1 Requirements, item 1.)

c. Provide disease prevalence information as a Category 1 requirement as well as including it in the budget impact analyses. (See 1.2.1 Category 1 Requirements, item 8.d.) This information is used by the clinical reviewers early in the review process but the budget impact analyses are often submitted later as Category 2 requirements

Procedure for Common Drug Review Updated

The Procedure for the Common Drug Review has been updated to include the description of the process for referring to confidential information in the CEDAC Recommendation and Reasons for Recommendation. (See
Appendix 2.) This is the only change to this document. The updated *Procedure for the Common Drug Review*, dated July 25, 2005, is posted on the CDR section of CCOHTA’s web site.

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