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 www.ccohta.ca The new version is dated July 2004. The template letters and product profile required in a manufacturer’s submission have also been updated.

Changes to the Submission Guidelines are widespread, but some highlights include:

- clarification of the definition of hospital drugs (section 1.1.2)
- the number of copies to be sent to the CDR Directorate once a submission has been deemed complete has been increased to six (see section 1.1.7d)
- more guidance has been provided on the economic information required (see sections 1.2.1, 1.2.2 and 1.2.3)
- in the pricing information (section 1.2.1, item 9), multiple prices for the same product units are not allowed
- bibliography of studies now requires only a list of submitted published and unpublished studies (section 1.2.1, item 10)
- the letter authorizing unrestricted sharing of information must be signed by the holder of the NOC or NOC/c (section 1.2.1, item 12)
- an Appendix 1b has been added to the Submission Guidelines to help identify where submissions for specialty drugs for cancer and HIV/AIDS are to be sent

Manufacturers are reminded that confidential information included in the submission should be clearly identified as such.

Advance Notice of Upcoming Submissions

Manufacturers are encouraged to advise the CDR Directorate of upcoming submissions by email or phone call in order that the Directorate can plan its workload.

CDR Staffing News

The CDR Directorate is pleased to announce that Sandy Pagotto has taken on the role of Manager, CDR Drug Reviews. Since one of her key responsibilities is the coordination of submissions to CDR, Sandy becomes the industry contact regarding submissions. She can be reached at (613) 226-2553, ext. 479 or sandyp@ccohta.ca

CDR Industry Information Session

In late fall, the CDR Directorate will be hosting an information session for industry to provide updates on the CDR program and submission process. More details will follow in a future CDR Update.