Release of recommendations for drugs considered at June 16, 2004 CEDAC meeting

The Canadian Expert Drug Advisory Committee (CEDAC) met on Wednesday, June 16, 2004 to discuss five drug submissions to the Common Drug Review (CDR):

- norelgestromin/ethinyl estradiol (Evra), Janssen-Ortho, a contraceptive patch (Reconsideration)
- gefitinib (Iressa), AstraZeneca, for non-small cell lung cancer (Reconsideration)
- tenofovir disoproxil fumarate (Viread), Gilead, for HIV infection
- agalsidase beta (Fabrazyme), Genzyme, for Fabry Disease
- agalsidase alfa (Replagal), Transkaryotic Therapies Inc., for Fabry Disease

The final CEDAC recommendations on reconsideration and reasons for recommendation for norelgestromin/ethinyl estradiol (Evra) and gefitinib (Iressa) have been publicly released via CCOHTA’s web site (www.ccohta.ca). They can be found in the CDR section of the site on the CEDAC Recommendations page.

The manufacturer of tenofovir disoproxil fumarate (Viread) has requested reconsideration of the CEDAC recommendation. That request has been granted and the reconsideration placed on the August 18, 2004 CEDAC meeting agenda.

CEDAC deferred making recommendations for agalsidase beta (Fabrazyme) and agalsidase alfa (Replagal), requesting clarification of information by the CDR Directorate, as allowed under the CDR Procedure. Both submissions were deferred to the July 21, 2004 CEDAC meeting.

New Submissions Received

The Common Drug Review has received four drug submissions since the May 31st CDR Update newsletter. Teriparatide (rDNA origin) injection (Fortéo), ciprofloxacin hydrochloride and dexamethasone otic suspension (Ciprodex), butoconazole nitrate (Gynazole.1) and eprosartan mesylate/ hydrochlorothiazide (Teveten Plus). The status of all drugs in the CDR review queue may be viewed via the individual Submission Status forms posted on the Common Drug Review – Submission Status web page.

Additions to CDR Staff

The CDR Directorate has recently welcomed several new employees, bringing the Directorate closer to planned staffing levels – which were based on the anticipated number of drug submissions to the program. The new additions to the CDR team include: Pinggang Liu, Clinical Reviewer; Sandy Pagotto, Pharmacist; Lisa McIntyre, Coordinator CDR; Delara Karkan, Clinical Reviewer and Philip la Fleur, Clinical Reviewer (term).

Stakeholder/Outreach Activities

The CDR Directorate continues its liaison activities with stakeholders, meeting with Rx&D representatives on June 28, 2004 and other pharmaceutical manufacturers on an individual basis.

The Directorate will also be delivering presentations at the Regulatory Affairs Professional Society Conference in Toronto July 26th, the IMS Health PRA Breakfast Briefings in Toronto September 23 and Montreal September 28, the National Oncology Pharmacy Symposium in Toronto October 23, and the Drug Information Association Conference in Ottawa November 9.