the DBL report

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An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

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Highlights of New Products Added

■ **CRESTOR** (rosuvastatin calcium) (AZC) – is a new lipid-lowering agent. The Committee indicated that **CRESTOR** appeared to be at least as efficacious as other presently accepted therapies on the *AHWDBL*, and may be cost saving when compared to select agents. Hence, the Committee recommended that **CRESTOR** be listed as it may offer a cost and/or therapeutic advantage.

■ **BIPREL** (perindopril erbumine/indapamide) (SEV) – is indicated in the treatment of mild to moderate essential hypertension in patients for whom combination therapy is appropriate. The Committee noted that the price of **BIPREL** is equivalent to the price of each of its components and there is the potential to realize incremental savings of one dispensing fee (i.e., if patients receive one prescription for **BIPREL** versus individual prescriptions for each component). In addition, the Committee indicated that the availability of such a fixed-dose combination product may offer a therapeutic advantage by improving patient compliance. Accordingly, the Committee recommended that **BIPREL** be listed as it offers a cost and/or therapeutic advantage.

■ **ESTRADOT** (estradiol-17β) (NOV) – This 25 mcg/day transdermal patch is a lower dose formulation of the **ESTRADOT** line of products already listed on the *AHWDBL*. Although the addition of this product represents the addition of another estrogen product to the *AHWDBL*, the Committee has expressed their concern regarding the emerging safety issues associated with the use of estrogen-containing products. Accordingly, the Committee indicated that it is their opinion that clinicians should carefully weigh the risks and benefits when prescribing estrogen-containing products.

■ **ARIXTRA** (fondaparinux sodium) (OSS) – is indicated for the prophylaxis of venous thromboembolic events (VTE) in patients undergoing orthopedic surgeries of the lower limbs such as hip fracture, knee surgery or hip replacement surgery. **ARIXTRA** was deferred from the October 2002 meeting pending the receipt and review of additional information from the manufacturer. After reviewing additional materials, the Committee recommended **ARIXTRA** be listed. Accordingly, **ARIXTRA** will be added to the *AHWDBL* effective **June 1, 2003**.

■ **PMS-ATENOLOL** (atenolol) (PMS) – The 25 mg tablet is a line extension of the Pharmascience atenolol product line. The Committee recognized that the practice of splitting of tablets may be an issue for patients requiring low doses of this agent. The Committee concluded that, in this instance, the availability of a lower strength of atenolol may offer a therapeutic advantage by facilitating dosing in a population that may require lower doses (e.g., geriatric patients). Accordingly, the Committee recommended that this product be added to the *AHWDBL*.

Products Designated as Interchangeable

APO-LITHIUM CARBONATE (lithium carbonate) (APX) – Following a review of information demonstrating the bioequivalence of **APO-LITHIUM CARBONATE** and Lithane, the Expert Committee recommended that **APO-LITHIUM CARBONATE** be deemed interchangeable with Lithane. The Committee noted that **APO-LITHIUM CARBONATE** and Carbolith had been designated as interchangeable previously; however, no evidence has been provided to indicate whether Carbolith and Lithane are interchangeable. Accordingly, the Committee recommended that two separate interchangeable categories for Lithane and Carbolith should be created within the *AHWDBL* with **APO-LITHIUM CARBONATE** designated as interchangeable with both Carbolith and Lithane.

Alberta Post-Marketing Study for Enbrel and Remicade

In recommending the coverage of Enbrel and Remicade for patients with severely active Rheumatoid Arthritis, and Remicade for severe, active and fistulizing Crohn's Disease, the Expert Committee expressed concern about the lack of data on long term safety and effectiveness for these new agents. As a result of these concerns and in consultation with specialists in the respective areas, a study is being launched, supported by Amgen and Schering, to monitor and measure the long-term effects of these drugs. Patients and their physicians are therefore required to provide consent to participate in this study, as a condition for receiving coverage.

Highlights of Additional Strengths and Formulations of Products Available via Special Authorization

■ **ACTONEL** (risedronate sodium) (PGA) – The Committee recommended that **ACTONEL 35 mg**, a once-weekly dosing formulation, be added via special authorization with criteria for coverage at parity with that of ACTONEL 5 mg tablets as it offers both a cost and therapeutic advantage. In addition, it should be noted that those patients with current special authorization approval for ACTONEL for the treatment of osteoporosis will not be required to submit new special authorization requests to receive coverage of **ACTONEL 35 mg** (i.e., such patients may switch to **ACTONEL 35 mg**, depending on the patient or physician preference of dosing regimen).

■ **ANDRODERM** (testosterone) (PAL) – The 5 mg/day strength is a line extension of ANDRODERM 2.5 mg/day transdermal delivery system currently available via special authorization on the *AHWDBL*. As the recommended dosage of ANDRODERM is 5 mg/day, the Committee noted that the use of **ANDRODERM 5 mg/day** may be more convenient than the use of ANDRODERM 2.5 mg/day (i.e., the use of one patch instead of two) and therefore, may offer a therapeutic advantage. Accordingly, this product has been added subject to the same special authorization criteria as ANDRODERM 2.5 mg/day: "For the treatment of congenital and acquired primary and secondary hypogonadism. Coverage cannot be considered when used for the treatment of androgen decline in the aging male (ADAM). Special authorization may be granted for 12 months."

■ **EXELON** (rivastigmine hydrogen tartrate) (NOV) – The 2 mg/mL oral solution is a line extension of the EXELON capsules, indicated for the symptomatic treatment of patients with mild to moderate dementia of the Alzheimer's type. The Committee felt that the availability of an oral solution may offer a therapeutic advantage in a small population of patients. Accordingly, **EXELON 2 mg/mL oral solution** has been added to the *AHWDBL* subject to the same special authorization criteria as EXELON 1.5 mg, 3 mg, 4.5 mg and 6 mg capsules.

Highlights of Deferred Products

■ **KINERET** (anakinra) (AMG) – is a recombinant, non-glycosylated antagonist of the human interleukin-1 (IL-1) receptor, indicated to reduce the signs and symptoms of active rheumatoid arthritis (RA) in patients 18 years of age or older. The review of **KINERET** has been deferred pending the receipt and review of information generated by an external consultation process.

Highlights of Products Not Added

■ **BEXTRA** (valdecoxib) (PFI) – was not recommended for addition as the Expert Committee concluded that it does not offer a cost and/or therapeutic advantage vis-à-vis other presently accepted therapies on the *AHWDBL*. The Committee indicated that the clinical information in the submission did not provide convincing evidence that this product offered a therapeutic advantage over other COX-II inhibitors currently listed on the *AHWDBL*. In addition, the Committee voiced concern that the addition of BEXTRA may serve to grow the COX-II inhibitor market inappropriately.