

Our Reference: 04-104259-111

## NOTICE

### HPFB TO PUBLISH 'SUMMARY BASIS OF DECISION' DOCUMENTS

Further to messages conveyed at the November 2003 Drug Information Association (DIA) First Canadian Annual Meeting in Ottawa, Ontario, Health Canada wishes to inform you of its intent to publish Summary Basis of Decisions (SBD) related to drug submissions and medical device applications. The SBD will outline the scientific and benefit/risk-based reasons for Health Canada's decision to grant market authorization for a product.

Transparency is a fundamental good regulatory practice and a clear expectation of the Canadian public. Health Canada has committed to enhancing the transparency of the regulatory review process for drugs and medical devices and accordingly is developing Canadian SBD documents that will provide appropriate information to Canadians about the benefits and risks of therapeutic products. As a result, Canadian healthcare professionals and consumers will have more information at their disposal to make informed treatment choices.

Once an SBD template is developed, Health Canada proposes a phased implementation strategy to support the SBD initiative. Initially, the documents would be publicly disclosed for market authorizations related to New Drug Submissions (NDSs) for New Active Substances (NASs) and a subset of Class IV medical device applications. The second and third phases of implementation would encompass additional drug submission and medical device application types, including supplemental new drug submissions and an expanded set of Class IV device applications, respectively.

The Health Products and Food Branch (HPFB) will be hosting a spring consultative workshop for interested parties, including patient and consumer groups, to provide input into the proposed content, format and publication of the SBD document.

Any comments regarding the proposed document or consultations should be directed to Tara Bower, Policy Bureau, Therapeutic Products Directorate, within thirty (30) days, at the coordinates below.

**By Mail**

1600 Scott Street,  
Holland Cross, Tower 'B',  
2nd Floor, Address Locator 3102C5,  
Ottawa, Ontario, K1A 1B6,

By fax to 613-941-6458

By email to [tara\\_bower@hc-sc.gc.ca](mailto:tara_bower@hc-sc.gc.ca)