SUMMARY BASIS OF DECISION INITIATIVE

FREQUENTLY ASKED QUESTIONS

1. What is a Summary Basis of Decision?

A Summary Basis of Decision (SBD) is a document that outlines the scientific and benefit/risk based considerations that factor into Health Canada's decision to grant market authorization for a drug or medical device. The document includes regulatory, safety, efficacy and quality (chemistry and manufacturing) considerations.

2. What is a Notice of Decision?

A Notice of Decision (ND) is a one-page summary outlining the authorization received and general information related to the drug or medical device. NDs will be published independently within approximately two weeks of Notice of Compliance or medical device licence issuance. When the SBD is published, the ND will be incorporated into the SBD as Section 2. NDs will be published for the same scope of submissions as SBDs.

3. Why was the SBD initiative undertaken?

The SBD initiative was undertaken in response to Health Canada's commitment to enhance the transparency of the drug and medical device review process. Canadian health professionals frequently rely on foreign approval packages/basis for information about decisions as there is no similar information disseminated in Canada at this time. These approval packages may be inconsistent with the regulatory decisions made in Canada and may not provide information appropriate to the Canadian context.

4. Will SBDs be drafted for all authorized products?

No. SBDs will be implemented in a phased approach beginning with novel drug therapies (New Active Substances) and a subset of Class IV medical device licence applications in January 2005. Once Health Canada have appropriately evaluated the outcomes of Phase I, implementation of Phase II will begin. Phase II will include the drafting of SBDs for an expanded set of drug submissions, including supplements and generic submissions, as well as additional medical device licence applications.

5. Will SBDs be drafted for therapeutic products already on the market?

No. As there are thousands of products authorized for sale in Canada, it is not feasible to draft SBDs for each. Interested parties can seek information related to a previously authorized drug submission or medical device licence application by making a request under the *Access to Information Act*.

6. Will SBDs be available for veterinary and natural health products in addition to drugs and medical devices?

No. While SBDs may eventually prove to be a useful tool to provide consumers information relating to veterinary products and natural health products, these areas have not been included in the scope for SBDs at this time. The scope of SBDs has maintained consistency with the emphasis in the 2002 Speech from the Throne on drug approvals with an extension to include medical devices.

7. How soon after a drug or device is approved can I find the corresponding SBD?

Health Canada aims to publish SBDs within 4 months of Notice of Compliance (NOC)/licence issuance.

8. Where can I find SBDs?

SBDs will be publicly available on the Health Canada website under the Therapeutic Products Directorate (TPD) and Biologic and Genetic Therapies Directorate (BGTD) webpage links. They will accompany posting of related product-specific information concerning issuance of market authorization on the NOC database (drugs) and the Medical Device Application Line Listings (MDALL) database (devices).

9. Who prepares the SBDs?

Technical editors draft the SBDs directly from the Health Canada review reports, vetting all information for accuracy with the responsible review authority.

10. Will I understand the SBD? Who is the intended audience?

SBDs are written for all Canadians interested in the reasons why Health Canada has taken product-specific decisions for drugs and medical devices. The documents are drafted in technical language and although an accompanying Readers' Guide and background documentation is provided as support, the reader may wish to consult their health care provider or alternative source for clarification of some of the technical terminology. The SBD is intended to complement information written in lay terminology and directed to the general public including operator's manuals (devices), package inserts and Section 3 of the Product Monograph: "Information for the Public" (drugs).

11. What is industry's involvement in terms of the content of the SBDs?

The development of the SBDs is independent of industry. Industry will be provided a draft of the completed document with an opportunity to comment on the proprietary nature of any material therein as well as any perceived inaccuracies in data. Health Canada will then review all comments received and make revisions as appropriate and necessary.

12. Will Health Canada update the SBDs to include post-market information or new uses as they are approved?

No. The SBDs will be frozen to reflect the information that supported the original decision to authorize the product. Subsequent submissions reviewed for additional uses (Supplemental Drug Submissions or Application for a Medical Device Licence Amendment) will not be captured under Phase I of the SBD implementation strategy, but will be captured under Phase II. Readers seeking post-market information should also consult the Marketed Health Products Directorate website.

13. Of what benefit is the SBD to consumers, patient groups and health professionals?

SBDs will provide Canadian healthcare professionals, consumers and patients with additional information on the benefits and risks of authorized therapeutic products to support informed treatment choices.

14. Will Health Canada disclose SBDs for negative decisions?

The confidentiality of drug submissions is anchored in Canadian common law, several federal statutes and international trade obligations. Generally speaking, case law in relation to the *Access to Information Act* has determined what parts of a Clinical Trial Application or a drug submission may be lawfully disclosed. Therefore, submissions/applications withdrawn by the product sponsor or negative decisions issued by Health Canada will not be summarized in an SBD at this time.

The Department will explore means to provide additional information through redefining legislative boundaries and carefully reviewing changes in international approaches in an effort to disclose SBDs for these submission types in Phase III of implementation.

15. If Canada does not publish SBDs for negative decisions, how will consumers be informed should Health Canada not approve a drug for a new use due to safety concerns?

The SBD is intended to reflect the information available to the regulator at the time of authorization. It is not intended to be a vehicle for communicating all important up-to-date safety information on a product. Such information is communicated through the issuance of a Dear Health Professional Letter and Public Advisories as appropriate.

16. Will the SBDs contain comparisons of the drug to other available therapies for the same use?

The SBDs may on occasion provide comparative information between available therapies if the clinical trials submitted in the application were so designed. If the sponsor has made a claim of superiority over other available therapies, the SBD would include Health Canada's review of the supporting data.

17. Is Canada the only country to publish SBDs?

The European Medicines Agency (EMEA) publishes European Public Assessment Reports (EPARs) for all products approved through the centralized procedure, thereby providing a similar level of information to the SBD. The US Food and Drug Administration (FDA) does not provide summary information; instead, the FDA publishes lengthy reviews for all approved products, redacted for all proprietary information.

18. Why doesn't Health Canada adopt the US approach of publishing drug reviews?

Concerns related to the readability of lengthy technical review reports for Canadians have been expressed through extensive stakeholder consultations. The majority of stakeholders attending SBD focussed consultations supported the development of a document containing concise summary information. Additional information concerning a drug submission or medical device application is available to interested parties through requests made via the *Access to Information Act*.

19. Where can I find more information on the SBD initiative?

Additional information is available on the Health Canada website. Alternatively, you may contact policy_bureau_enquiries@hc-sc.gc.ca.