Health Canada Santé Canada

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HEALTH PRODUCTS AND FOOD BRANCH (HPFB)

SUMMARY BASIS OF DECISION (SBD) EXTERNAL CONSULTATION

June 10-11, 2004

On June 10 and 11, 2004, Health Canada hosted a multi-stakeholder consultative workshop on a key transparency initiative entitled Summary Basis of Decision (SBD). The workshop engaged interested parties, including patient and consumer groups, to provide input into the direction of the SBD initiative as well as the proposed content, format and publication of SBD documents. As proposed, SBDs would be targeted to the "informed public" (i.e., use technical language), and would outline the scientific and benefit/risk based decisions that factor into Health Canada's decisions to grant market authorization for a drug or medical device. A phased implementation strategy is proposed. The consultative workshop included presentations, table discussions, breakouts and plenary reporting.

PARTICIPANT FEEDBACK – KEY MESSAGES AND ADVICE

Cascading approach to information

The SBD should provide linkages to other documents and sources in order to facilitate the "drilling down" to additional information by individual users to meet their needs. Such information might include the product monograph, pre-clinical and clinical studies, expertise of reviewers, data from other jurisdictions, adverse reaction reports, post marketing information, Health Canada Advisories and other studies and reports.

SBD content – full disclosure yet not duplicating other sources

The SBD should aim to provide a full accounting of the rationale for approval, thereby providing accountability for regulatory decisions, yet remain respectful of proprietary information. The SBD should complement, not duplicate, information available through other sources.

Internet accessibility

The preferred method of distribution is the Internet through a user-friendly website, with the option of mail-outs/faxes as required. Internet publication would also provide the means to include links to other sources.

Reconsider the target audience of "informed public"

The SBD should be focused on meeting consumer needs by providing meaningful and relevant information. The target audience of "informed public" was seen by some participants to be too narrow. These participants suggested that the target audience could be expanded by use of lay language and inclusion of a glossary of terms and definitions, explanations of the regulatory process, and other reader aides.

Timing of Publication of SBD

There was support for publishing the SBD at the time of Notice of Compliance (NOC) issuance, rather than at time of marketing, as the SBD is related to the approval of a product and should not be associated with its marketing. There was also support for issuing the SBD at the time of market notification as not all products receiving approval are subsequently marketed for reasons related to competition, confidentiality and unseen delays. It was further suggested that if the SBD is not published at the time of NOC issuance, a one-page summary or fact sheet should be issued. The SBD should follow within an appropriate time frame.

Adequate resources essential

The production of the SBD should not impact the timelines of the review process or efforts to reduce the backlog of submissions. Resources, including internal capacity for SBD production, must be sustainable over the long term.

Publish SBDs for denied and withdrawn submissions

SBDs for denied and withdrawn submissions/applications and non-approved uses (for claims submitted) should be published. This would include information about non-approved off-label drug use, approved uses in other jurisdictions, failed clinical studies, etc. Publication of reasons for a negative decision are particularly important in cases where the same drug or device is available in another jurisdiction.

Stakeholder satisfaction

There was acknowledgement that it will likely not be possible to create a document that satisfies all needs of all stakeholders. Instead, the SBD could be designed as a "tiered document" with varying levels of scientific detail related to the decision. The provision of links to other sources of further information, such as post-market information, data from other jurisdictions, adverse drug reaction reports, etc., would also help satisfy varying stakeholder needs.

CLOSING REMARKS

Dr. Robert Peterson
Director General, Therapeutic Products Directorate

Dr. Peterson noted that, from Health Canada's perspective, the expectations of the consultation had been fully met. Participants have a better understanding of the SBD, both its potential and limitations, and its overall objective to increase transparency by placing relevant decision-making information in the public domain.

He emphasized that Health Canada is committed to ongoing stakeholder consultation and to achieving a collegial and cooperative approach that respects the commercial interests of sponsors. Health Canada will continue to receive and respond to comments on how the SBD can best meet these goals and the needs of Canadians.