Health Canada Santé Canada

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Frequently Asked Questions: Summary Basis of Decision (SBD) Project: Phase II

1. What is a Summary Basis of Decision document?

A Summary Basis of Decision (SBD) document 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 summarizes Health Canada's risk/benefit analysis and includes regulatory, safety, efficacy, and quality considerations identified within Health Canada's regulatory review reports. SBDs are intended to be reflective of the decision taken by Health Canada, and are not intended to provide up-to-date information about the product; this information is available through other sources.

2. Why was the Summary Basis of Decision initiative initially undertaken?

The SBD initiative was originally launched in 2005 (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/background-contexte-eng.php) in response to Health Canada's commitment to enhance the transparency of the drug and medical device review processes. The SBDs and associated post-authorization (drugs) or post-licensing (devices) activity tables 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.

3. Who is the intended audience for the Summary Basis of Decision? Will I understand the documents?

SBDs are written for all Canadians interested in the reasons why Health Canada has taken product-specific decisions for drugs and medical devices. The language of the documents grows increasingly technical as the reader progresses through the SBD. Although the documents are supported by Readers' Guides, patients may wish to consult their health care provider for clarification. The SBD is intended to complement information about the product that is written in lay terminology and directed to the general public including operator's manuals (devices), package inserts, and the Product Monograph Part III: Consumer Information (drugs).

4. Will Summary Basis of Decision documents be drafted for all drug submissions and medical device applications?

No. SBDs are drafted for the following subsets of *authorized* drug submissions for pharmaceuticals and biologics:

- New drug submissions for new active substances (with the exception of hard surface disinfectants and new salts of existing products[1]); and
- New drug submissions for subsequent entry biologics.

For medical devices, Health Canada will now target to publish 5-7 SBDs per year for newly licensed Class III and IV devices with novel technology.

SBDs are not drafted for negative decisions at this time, though this may be considered for future phases of the project. Please refer to Question 12 for clarification about information available about negative decisions made for an already approved-product after the SBD is published.

[1] Unless there is a new indication or route of administration associated with the new salt.

5. How can I get information about a product or decision that does not have an SBD?
Interested parties can seek information related to a previously authorized drug submission or medical device licence application by making a request (http://www.hc-sc.gc.ca/contact/ahc-asc/csb-dgsg/atip-aiprp-eng.php) under the *Access to Information Act*.

6. What has changed for Phase II of the SBD Initiative?
After careful consideration of the evaluation of Phase I of the SBD initiative (http://www.hc-sc.gc.ca/dhp-mps/pubs/drug-medic/sbd_er_smd-eng.php) and the results of internal and external consultations (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/sbd_ext_consult_sbd-eng.php), Health Canada is now moving into Phase II of the SBD initiative (link to the launch Notice). The following changes will be made as part of the launch of Phase II:

- Documents will be in question and answer format (see Question 8);
- SBDs will have more information about Health Canada's risk/benefit analysis (see Question 9);
- The Notice of Decision will be eliminated (see Question 10);
- The scope of products eligible for an SBD will change slightly (see Question 11);
- Post-authorization (drugs) and post-licensing (devices) activities will be published (see Question 12);
- Links to other Health Canada information will be improved (see Question 14);
- The time to publish SBDs will be decreased (see Question 15);
- Sponsors and manufacturers are no longer allowed to appeal the publication of an SBD (see Question 18).

7. When will Phase II begin?
Phase II is being launched in June 2012 with the publication of a Notice (link to Notice). All eligible Notices of Compliance (NOCs) and licences issued after September 1, 2012 will be included within the scope of Phase II and will have SBDs drafted in the new format. They will also be accompanied by a post-authorization activity table (PAAT) for drugs or post-licensing activity table (PLAT) for devices, as applicable.

8. How will the format of the documents change with Phase II?
The documents will be web-based, in a question and answer format with increasingly technical language as the reader progresses through the document. Inter-document links will be included to improve the ability to navigate through the documents. The SBD documents will no longer be available in PDF format.

9. Will Phase II SBDs contain the same information as did Phase I SBDs?
Phase II SBDs will be streamlined as compared to Phase I SBDs, but will contain a significantly increased focus on Health Canada's risk/benefit analysis for both drugs and medical devices. Moving into Phase II, the non-clinical information will be streamlined for drugs (pharmaceuticals and biologics), as will the quality (chemistry and manufacturing) information for pharmaceuticals. For devices, Phase II SBDs will be streamlined with respect to preclinical and manufacturing information.

10. What is the Notice of Decision? Will it continue to be published?
A Notice of Decision (ND) is an approximately one-page summary outlining the authorization received and general information related to the drug or medical device. In Phase I, the ND was published independently after product authorization and was subsequently incorporated into the SBD as Section 2. In Phase II, Health Canada will no longer produce NDs, in order that SBDs may be produced in a more timely manner. However, the information formerly provided in the ND will continue to be published as part of the Phase II SBD.

11. Will Phase II SBDs be published for the same scope of products as in Phase I?
The scope of SBD-eligible products will remain largely the same for Phase II. Refer to Question 4 for a list of SBD-eligible submissions and applications. Changes from Phase I include the addition of Subsequent Entry Biologics and the removal of hard surface disinfectants and new salts of existing products (unless there is a new indication or route of administration associated with the new salt). For medical devices, Health Canada will now target to publish 5-7 SBDs per year for newly licensed Class III and IV devices with novel technology.

12. Will post-authorization/post-licensing activity be reflected in the SBD?
The SBD documents are intended to explain the rationale for Health Canada's initial decision to authorize the drug or device. In Phase II, a post-authorization activity table (PAAT) for drugs or post-licensing activity table (PLAT) for devices will be published for SBD-eligible products, and will be linked to the SBD. These tables will provide ongoing information about approved products, consistent with international efforts related to transparency.

The PAATs and PLATs will include brief summaries (normally one paragraph) of activities that impact the safe and effective use of the product. Examples of information included in the PAATs/PLATs include a submission or application filed for a new use of the drug/device, changes to the labelling, as well as regulatory decisions such as the cancellation of the Drug Identification Number (DIN) or licence. Note that submission- and application-related information will be made available only after a final decision has been issued by Health Canada or the sponsor/manufacturer has withdrawn the submission/application during review. Also included will be post-authorization submissions filed to fulfil conditions for drugs authorized under the *Notice of Compliance with Conditions Guidance* and post-licensing applications filed for devices issued a licence with conditions.

13. How will I know when the PAAT or PLAT has been updated?
PAATs and PLATs will be updated regularly. The date of the most recent update to the PAAT or PLAT will be clearly identified above the table.

14. What other information will be provided with SBDs?
Each SBD published will contain links to other available Health Canada information as appropriate, including:

- MedEffect Canada (http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php): contains the advisories, warnings and recalls for marketed health products.
- Notice of Compliance (NOC) database (http://webprod3.hc-sc.gc.ca/noc-ac/index-eng.jsp): contains the Health Canada authorization dates for all drugs that have received an NOC (dating back to 1994).
- Drug Product Database (DPD) (http://webprod3.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp): contains product-specific information on those drugs that have been approved for use in Canada *and* have been market notified (that is, the company has told Health Canada the product is being marketed). The DPD also contains the Product Monograph.
- Medical Device All Licence Listing (MDALL) (http://www.mdall.ca/): contains all licensed Class II, III and IV medical devices in Canada.
- Patent Register (http://webprod3.hc-sc.gc.ca/pr-rdb/index-eng.jsp): an alphabetical listing of medicinal ingredients and their associated patents.
- Notice of Compliance with conditions listing (http://hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/conditions/index-eng.php): contains a list of products for which an NOC was issued under the *Notice of Compliance with Conditions (NOC/c) Guidance* (http://hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/compli-conform/noccg_accd-eng.php). Clicking on a

product name links to (as applicable) the Fact Sheet, Qualifying Notice, and Dear Health Care Professional Letter.

- Register of Innovative (http://hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/regist/reg_innov_dr-eng.php) Drugs: contains the drugs that are eligible for data protection under C.08.004.1 of the *Food and Drug Regulations* (http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/index.html).

15. How soon after NOC or licence issuance will the SBD be available?

As discussed in Question 9, SBD content will be streamlined in Phase II, and (as discussed in Question 10), the ND will be eliminated. In addition, Health Canada is implementing a number of process changes to reduce the time to publish SBDs, these are described in Question 18. As a result of these changes, the target for SBD publication will be 12 weeks (decreased from 20 weeks).

16. Will Phase II changes be applied retroactively?

No. All SBDs published under Phase I (that is, where the NOC or licence was issued prior to September 1, 2012) will remain as they are (including the respective ND as Section 2) and will not be accompanied by a PAAT/PLAT.

17. Why has Phase II been changed from the original plan to significantly expand the scope of SBD-eligible submissions?

The evaluation of Phase I, internal and external consultations and analysis confirmed that the products to be included in Phase II (as described in Question 11) are those of the highest priority and interest. As described in Question 4, while future phases of the project may include drafting SBDs for an expanded scope of products and decisions, at this time Health Canada considers it a priority within the SBD project to make more information available in a timely manner related to products approved for sale on the Canadian market.

18. What is the process for SBD preparation in Phase II? What is the involvement of the drug submission sponsor or medical device manufacturer in the SBD?

The SBDs will continue to be drafted by Health Canada technical writers, based upon Health Canada's regulatory review reports. The SBD draft will be sent to the Health Canada review team for comment and possible revision, in order to ensure that review conclusions are appropriately reflected and contained within the SBD. The completed SBDs will then be sent to the sponsor/manufacturer for review; feedback will be limited to inaccuracies of data and it is expected that only minor revisions, if any, will be made to the document as a result of industry feedback received. In addition, the appeal process available under Phase I will no longer be applied. The SBD will be sent for translation and approvals and will then be posted by the publications team. Note that the SBDs are intended to provide a summary of the information that factored into Health Canada's decision to grant market authorization for the drug or device, and therefore, the information contained within will complement (but not necessarily match exactly) the information contained within the Product Monograph and/or Instructions for User.

19. How does Phase II of the SBD project address the recommendations of the 2011 Fall Report of the Auditor General of Canada, Chapter 4 – Regulating Pharmaceutical Drugs – Health Canada?

Recommendation 4.63 of the Auditor General's Fall Report, Chapter 4 – Regulating Pharmaceutical Drugs (http://www.oag-bvg.gc.ca/internet/English/parl_oag_201111_04_e_35936.html) states:

> *"Health Canada should disclose information related to new drug approvals in a timely manner and improve the transparency of "approvals with conditions", rejections, and withdrawals of new drugs so that Canadians and health care professionals can access information about these drugs."*

The Department agreed, stating it

> *"will improve the transparency of approvals with conditions, rejections, and withdrawals to the Canadian public. The Department will consult with stakeholders in fall 2011 about expanding its public communications on post-approval decisions for marketed health products to include information on approvals with conditions, rejections, and withdrawals, with a view to disclosing additional information by June 2012."*

As described on the Background page of the SBD website (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/background-contexte-eng.php), Health Canada consulted on its proposals for Phase II (http://www.hc-sc.gc.ca/dhp-mps/consultation/drug-medic/consult_sbd_smd_e_consult-eng.php) in the fall of 2011 and published the results of external consultations (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/sbd_ext_consult_sbd-eng.php) in early 2012. As described in Question 12, in Phase II a PAAT/PLAT (for drugs/devices respectively) will be published for SBD-eligible products, in addition to the SBD. These tables will provide the reader with additional updated information related to drugs authorized under the *Notice of Compliance with Conditions Guidance* and devices licensed with conditions. The tables will also include information related to, for example, submissions/applications for a new use of the product whether Health Canada's decision was negative or positive and regulatory decisions such as the cancellation of the DIN or licence. Health Canada is also implementing a number of process changes to reduce the time to publish SBDs, as described in Question 18.

20. Where can I find SBD documents?

Phase I SBDs, along with Phase II SBDs and their associated PAAT/PLATs are available on the Health Canada website (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/index-eng.php). In addition, SBDs for drugs are available within the NOC database (http://webprod3.hc-sc.gc.ca/noc-ac/index-eng.jsp) and SBDs for devices are available within the Medical Devices Active Licence Listing (http://www.mdall.ca/).

21. Where can I find more information on the Summary Basis of Decision initiative?

For more information, consult the SBD section (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/index-eng.php) of the Health Canada website. For questions related to the SBD project including policy objectives, consultations, *et cetera*, please contact Policy_Bureau_Enquiries@hc-sc.gc.ca. For questions related to operational aspects of the SBD project including availability of, or processes related to, specific SBDs and/or PAAT/PLATs, please contact OBT_enquiries@hc-sc.gc.ca.