Date: June 29, 2012

Reader's Guide to the Phase II Summary Basis of Decision - Medical Devices

The Reader's Guide to the Phase II Summary Basis of Decision (SBD) Medical Devices describes the new Phase II question and answer format of the SBD documents. It includes a summary of information found in the response to each question.

For more information related to the SBD Project, please refer to the Frequently Asked Questions: Summary Basis of Decision (SBD) Project: Phase II (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/sbd_qa_smd_fq-eng.php).

Title
The introductory lines of the SBD list the name of the medical device, along with the manufacturer to which the licence was issued. The application number(s) and licence number(s) are also listed.

Introduction
The first paragraph of the SBD describes the licence issued to the manufacturer for the medical device, including whether the application was reviewed as per the *Priority Review of Medical Device Licence Applications Policy* (http://hc-sc.gc.ca/dhp-mps/md-im/applic-demande/pol/device_instrument_pr_pol-eng.php) and whether the licence was issued with conditions.

The second paragraph gives a very high-level description of the data submitted, and links to Questions 2 (Why was <Device Name> approved?) and 7 (What was the scientific rationale for Health Canada's decision?) The approved use is given, as per the device labelling.

Q1. What was approved?
The answer to this question first gives a description of the medical device including its various components, and the approved use and the principles of operation of the device. This is followed by a description of contraindications associated with the device.

This answer will then link to Question 7 (What was the scientific rationale for Health Canada's decision?).

Detailed Device Description
More detailed information on the medical device is provided in this section, including (as applicable) detailed principles of operation, materials used in the device (including whether the device contains biological material), reagent characterization, source of monoclonal or polyclonal antibodies, the medicinal ingredient and requirements if the device contains a drug, etc. Included in this section is a summary of Health Canada's assessment of these items.

Q2. Why was <Device Name> approved?
The answer to this question provides an outline of the benefit/risk assessment that was conducted by Health Canada prior to issuing the licence for the device.

Included in this section is a description of the nature and severity of the disease or condition and its consequences. The analysis of the benefits of the device with respect to this disease or condition includes a description of the efficacy information collected from the pivotal trials and may include information related to specific subpopulations expected to receive particular benefit.

Also included in this answer is a description of the potential risks inherent with the use of the device, including a summary of the most important adverse events, complication rates, and strategies for mitigating the risks.

If the device was reviewed as per the *Priority Review of Medical Device Licence Applications Policy* (http://hc-sc.gc.ca/dhp-mps/md-im/applic-demande/pol/device_instrument_pr_pol-eng.php) or licensed with conditions, the rationale will be discussed.

The next paragraph(s) will consist of an overall conclusion about the balance of benefits and risks associated with the use of the device, which may take into account treatment effects, disease, targeted population and existing therapies. An outline of risk mitigation strategies will be described, which may include specific text in the labelling, a risk management process, etc.

This section will conclude with a reference to the authorization of the device as per the *Medical Devices Regulations* (http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/?showtoc=&instrumentnumber=SOR-98-282), a description of conditions placed on the licence if applicable, and a link to Question 7 (What was the scientific rationale for Health Canada's decision?) for more detailed scientific information.

Q3. What steps led to the approval of <Device Name>?

This answer will describe the application process that led to the licensing of the device. It will include a description of (as applicable) negative decisions issued prior to licence issuance, appeals, and re-filed applications. It will also describe the process Health Canada followed in reviewing this application, including if the application was granted or denied priority review status, whether issues were referred to an external committee for deliberation, whether a foreign review was used in the decision-making process, etc.

A table describing the application milestones is included in this section, along with applicable dates. Included in this table are pre-application activities such as meetings, dates of filing and decision for requests for priority review status, and the date of application filing. Notices issued during the process (for example, requests for additional information) will be described with the associated dates. Significant review milestones will be included as appropriate.

This answer concludes with a link to the *Management of Applications for Medical Device Licences and Investigational Testing Authorizations Guidance* (http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/pol/mdlapp_demhim_pol-eng.php)for more information about the medical devices application process.

Q4. What follow-up measures will the company take?

At a minimum, this answer will include a link to the *Medical Devices Regulations* (http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/?showtoc=&instrumentnumber=SOR-98-282) to describe the post-licensing requirements for the sponsor. In addition, conditions placed on the manufacturer as part of a licence with conditions will be described.

Q5. What post-licensing activity has taken place for <Device Name>?
The answer to this question will include a link to the post-licensing activity table (PLAT) for the device, once one has been made available. The PLAT will include brief summaries (normally one paragraph) of activities that impact the safe and effective use of the device. Examples of information found in the PLAT include an application for a new use of the device (whether Health Canada's decision was positive or negative), changes to the labelling, as well as regulatory decisions such as the cancellation of the device licence. Also included will be post-licensing applications filed for devices issued a licence with conditions. Links will be provided to appropriate regulations and guidance documents so that readers will better understand the terminology used in the PLAT.

Q6. What other information is available about <Device Name>?
The answer to this question includes a link back to the introductory page for the product, which contains links to a number of Health Canada web pages, including:

- Medical Devices Active Licence Listing (MDALL)(http://webprod5.hc-sc.gc.ca/mdll-limh/index-eng.jsp): contains all licensed Class II, III and IV medical devices in Canada;
- MedEffect Canada (http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php): contains the advisories, warnings and recalls for marketed health products.

Q7. What was the scientific rationale for Health Canada's decision?
The answer to this question provides scientific information in support of Health Canada's decision to authorize the product on the basis of the clinical, preclinical, and quality information submitted.

Clinical Basis for Decision

Clinical Effectiveness and Safety
This section includes the total number of studies conducted to support licensing, including the study design and number of subjects. The majority of this section will contain Health Canada's analysis of the results of the studies that figured significantly in Health Canada's decision. This may include a description and analysis of device-related investigations conducted, clinical studies in special populations, patient exposure, adverse events during investigational testing, laboratory findings, etc. The section will conclude with an analysis of the clinical effectiveness and safety of the device, including precautions or contraindications that have been included in the labelling.

If the product was reviewed under the *Priority Review of Medical Device Licence Applications Policy* (http://hc-sc.gc.ca/dhp-mps/md-im/applic-demande/pol/device_instrument_pr_pol-eng.php), the rationale for applicability of the guidance will be discussed as it relates to clinical effectiveness and safety.

If Health Canada used a foreign review in its evaluation of the clinical efficacy (in accordance with the *Draft Guidance Document - The Use of Foreign Reviews by Health Canada*) (http://hc-sc.gc.ca/dhp-mps/consultation/drug-medic/consult_draft_foreign_rev_ebauche_exam_etra-eng.php) this will be discussed.

An outline of risk mitigation strategies will be described, which may include specific text in the labelling, a risk management plan or process, etc.

Post-market safety information from other jurisdictions may be included in this section if it was considered as part of the basis for decision.

Limitations of the data are discussed, along with Health Canada's assessment of the data submitted by the manufacturer to address the concerns. If the licence was issued with conditions, a discussion of the limitations of the effectiveness and/or safety data that required further confirmatory studies is included.

If, throughout the course of the application the indication or use as originally submitted by the company changed, this will be discussed along with the rationale. In addition, if the application was previously rejected, this section will include a discussion of the rationale for the rejection along with how the manufacturer has addressed Health Canada's concerns within the current application.

Preclinical Basis for Decision

This section will include a summary of the results of the preclinical studies and Health Canada's assessment. There may be additional information if there were concerns identified from the preclinical studies, particularly if they could have clinical relevance.

An overall analysis of the preclinical assessment, including any information added to the labelling, is also included.

If Health Canada used a foreign review in its evaluation of the non-clinical studies (in accordance with the *Draft Guidance Document - The Use of Foreign Reviews by Health Canada*) (http://hc-sc.gc.ca/dhp-mps/consultation/drug-medic/consult_draft_foreign_rev_ebauche_exam_etra-eng.php), this will be discussed.

Quality Basis for Decision

This section will include a summary of the tests conducted in support of the manufacturing and quality control of the device, along with Health Canada's assessment. This may include a description of Health Canada's assessment of the quality plan, quality manual and quality system certificate, statement(s) of conformity with relevant standard(s), manufacturing process, etc.

If Health Canada used a foreign review in its evaluation of the quality studies (in accordance with the *Draft Guidance Document - The Use of Foreign Reviews by Health Canada*) (http://hc-sc.gc.ca/dhp-mps/consultation/drug-medic/consult_draft_foreign_rev_ebauche_exam_etra-eng.php), this will be discussed.