Health Canada Santé Canada

Summary Basis of Reconsideration Decision (SBRD) - Reconsideration of a Notice of Non-Compliance Withdrawal

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Health Canada

Our mission is to help the people of Canada maintain and improve their health.

Health Products and Food Branch (HPFB)

HPFB's Mandate is to take an integrated approach to managing the health-related risks and benefits of health products and food by:

- minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and,
- promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health.

Également disponible en français sous le titre : Sommaire des motifs de décision de révision (SMDR) – Révision de retrait suite à un avis de non-conformité

FOREWORD

Health Canada's Summary Basis of Reconsideration Decision (SBRD) documents outline the scientific and regulatory considerations that factored into Health Canada's decision to grant or deny a Request for Reconsideration filed as per the Health Canada *Guidance Document: Reconsideration of Final Decisions Issued for Human Drug Submissions*. The SBRD has been prepared in such a way to inform stakeholders of decisions made, without disclosing potentially confidential information about a submission that may not have received authorization.

This document should be read in conjunction with the relevant sections of other applicable guidance documents.

Summary Basis of Reconsideration Decision

Reconsideration Issue

The sponsor filed a Supplemental New Drug Submission (SNDS) to the Biologics and Genetic Therapies Directorate (BGTD) to extend the indications for a drug used in cancer treatment. A Notice of Noncompliance - Withdrawal (NON-w) was issued on the basis that the data submitted did not provide adequate support for approval of the proposed expansion of indications for the drug.

The sponsor filed a Request for Reconsideration for the NON-w decision under the *Guidance for Industry: Reconsideration of Final Decisions Issued for Human Drug Submissions*. In the request, the sponsor stated its position on the benefit-risk profile of the drug.

Reconsideration Process and Decision

In consultation with the Director General, BGTD, the Request for Reconsideration proceeded as an internal review as outlined in the *Guidance for Industry: Reconsideration of Final Decisions Issued for Human Drug Submissions*. The Request for Reconsideration was reviewed by reviewers from the Marketed Health Products Directorate (MHPD) and the Therapeutic Products Directorate (TPD). The sponsor and the original reviewers from BGTD presented their respective positions on the submission to the Director General, BGTD, and the reconsideration reviewers at a Reconsideration Meeting. Following the meeting, the reconsideration reviewers submitted, to the Director General, an Issue Analysis Summary (IAS) containing their recommendation.

Upon reviewing the Request for Reconsideration, the reviewers concluded that the data from two phase III clinical trials showed a modest improvement in progression free survival (PFS). PFS can be a predictive surrogate for overall survival in the clinical setting however, statistical evidence of improvement in overall survival benefit was not demonstrated. The reconsideration reviewers concluded that the information provided in the SNDS was not sufficient to grant a Notice of Compliance for the expansion of indications for the drug. Thus, the reconsideration reviewers supported the original decision, by Health Canada, that the Notice of Non-Withdrawal (NON-w) be upheld.

Based on the totality of the evidence provided, the Director General, BGTD, issued to the sponsor, the Reconsideration Decision upholding the original NON-w.