Canada's Drug Agency
L'Agence des médicaments du Canada
Drugs. Health Technologies and Systems. Médicaments, technologies de la santé et systèmes.

Guidance on the Briefing Book for Scientific Advice

This guidance document should be used in conjunction with the Briefing Book *template that can be found on the Scientific Advice website at Scientific Advice | CDA-AMC.*

The Briefing Book template and Guidance on the Briefing Book are based, with permission, on those developed for the scientific advice process at the National Institute for Health and Care Excellence (NICE).

1. General Points for Preparing a Briefing Book

- Use the provided template to submit a *Briefing Book* to Scientific Advice in **Microsoft Word format.**
- Applicants may insert their company logos on the cover page.
- Replace information in brackets [ ] with relevant information on your product/company.
- Delete any instructions for filling out the template in your final version.
- The length of the *Briefing Book* should be no more than 50 pages (excluding references and annexes).
- Any essential self-standing documents such as study protocols, reports, etc., should be submitted as separate documents in Word or PDF format.
- The template should be used as a guide and judgment exercised as to which sections are relevant to the product for which advice is being sought.
- Additional sections may be inserted into the *Briefing Book*, when required.
- Where relevant data are missing, this should be explained and an indication given as to when they may become available.
- Questions to Scientific Advice should be followed by the company's explanation of its position. The wording of the questions should be clear and concise.
- It is not necessary to reference all statements in the *Briefing Book*; however, references should be provided if they relate to the methodology being proposed or the questions asked.
- Do not include preclinical data, or pharmacodynamics and pharmacokinetic data, unless specifically relevant to questions for Scientific Advice.
- Results of phase 2 trials are not required if these are not available at the time of the *Briefing Book* submission.

2. Selected Section-Specific Points

2.1 Treatment Options and Relevant Guidelines (Section 3.2 of the *Briefing Book*)

Include the following information in this section:

- current clinical care pathway and variations across Canada
- relevant Canadian or other guidance
- current clinical outcomes
- any products in established use regardless of the licence status
- non-drug treatment/procedure options, if appropriate
- new treatments on the horizon in advanced stages of development, if known.

2.2 Regulatory Scientific Advice (Section 3.4 of the Briefing Book)

Indicate if regulatory scientific advice has been or will be obtained on the product. Whereas the minutes of regulatory advice might be of interest, the company is not required to submit these as part of the *Briefing Book.*

2.3 HTA Scientific Advice/Early Dialogues (Section 3.5 of the *Briefing Book*)

Indicate if scientific advice from another health technology assessment (HTA) agency has been or will be sought on the product.

2.4 Indication and Target Population (Section 4.3 of the *Briefing Book*)

To complete this section, use the following guidelines:

- Specify clearly the intended indication(s).
- Specify product positioning in the treatment pathway (e.g., first-line, second-line, third-line, screening pre-treatment, monitoring during treatment, etc.).
- State if it is combination therapy or monotherapy.
- State the aim of the treatment (preventive, curative, palliative, symptomatic, disease-modifying).
- Specify the target population.

2.5 Summary of Patient Engagement — If Available (Section 4.5 of the *Briefing Book*)

Briefly describe if you have engaged with patients and patient organizations as part of your product development program (i.e., related to the design of clinical trials). Include the nature of the engagement and the country in which the engagement activities were conducted.

Describe the issues and questions you have explored with patients and patient organization groups, and the information you have gathered; e.g., real-world applicability, limitations of the trials, outcomes of importance to patients, mode of administration, clarity of definitions, etc.

If you have not engaged with patients at this stage, please state that this is the case.

2.6 Clinical Data Available to Date (Section 4.6 of the *Briefing Book*)

Describe clinical trials performed to date and provide results, if available.

If the administration of the product is associated with the use of a diagnostic test, a medical device, or a medical procedure, provide relevant information; e.g., describe if:

- additional monitoring is required for the product
- additional resources and training are required
- there were any adverse effects and the management of them.

2.7 Product Value Proposition (Section 5 of the *Briefing Book*)

This section of the *Briefing Book* is mandatory. Describe value propositions for the product and how the trial evidence will be used to support these value propositions.

2.8 Proposed Clinical Development Program (Section 6 of the *Briefing Book*)

For each trial, describe the objective, design (randomization, blinding, etc.), location(s), doses and duration of treatment, comparator(s), number of subjects, description of studied population, and end point(s). Provide a trial diagram, if available. Specifically, describe:

- **patient population** (inclusion and exclusion criteria, patient characteristics); discuss any differences between the licensed population and the population for the analysis

- **stratification factors and subgroups** identified (provide justification)
- selected **comparators** (provide justification)
- **end points** (primary, secondary, other); all scales and scores that will be used for end point measurement should be presented and their validity should be reported
- **study duration and follow-up**
- **crossover design** (if applicable)
- relevant **methodologies and analyses of trial data**
- **data gaps** expected in the evidence at the time of the initial appraisal
- **plans to address these data gaps** at the current time and following licensing.

You may include trial diagrams.

2.9 Proposed Economic Analysis (Section 7 of the *Briefing Book*)

This section is required only if questions on economic evaluation are submitted to Scientific Advice.

If plans for the economic evaluation are provided, these should include, to the extent possible:

- a description of the proposed model (diagram, modelling approach, time horizon, perspective)
- data collection plans to inform the model:
  - evidence synthesis/meta-analysis — sources of evidence
  - comparators — mixed-treatment comparisons and indirect comparisons, and the evidence available
  - trial end points used to derive health outcomes in the model
  - quality of life — source and methods, tools used to measure quality of life
  - incorporation of adverse effects
  - resource use — sources and methods, tools used to measure resource utilization
- methodological approaches:
  - extrapolation — assumptions and data sources
  - continuation rules
  - use of surrogate outcomes
  - planned sensitivity analyses
- evidence gaps and model assumptions should be described.

If you have additional questions about the Briefing Book *template or the* Guidance on the Briefing Book*, please email* scientific.advice@cda-amc.ca.