Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

Budget Impact Analysis **Guidelines**

Guidelines for Conducting Pharmaceutical Budget Impact Analyses for Submission to Public Drug Plans in Canada

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Table of Contents

LIST OF TABLES

1

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2

Conflicts of Interest

i3 Innovus is a global leader in health economics, outcomes research and market informatics to support market access and reimbursement of health care products. Part of i3 Innovus' business involves the development of BIAs on behalf of its clients for eventual submission to Canada's federal, provincial, and territorial drug plans.

Drs. George Torrance, Mike Drummond, and Stuart MacLeod are Principal Consultants for i3 Innovus. In addition, Dr. Torrance is a principal of Health Utilities Inc., a company that provides consulting services to users of the Health Utilities Index (HUI).

3

Executive Summary

3.1 Introduction

For Canada's public drug plans, budget impact analysis (BIA) is a tool used to predict and understand the potential financial impact of introducing a new pharmaceutical into a drug reimbursement system that has finite financial resources. Committees and drug plan managers for each of Canada's federal, provincial and territorial (F/P/T) drug plans use BIAs to help inform decisions regarding drug reimbursement. Although many of Canada's F/P/T drug plans use a common process to aid in their decision-making process, the requirements for each drug plan with respect to BIA drug submissions differ widely. There is currently no standardized method of performing and presenting BIAs for inclusion in drug submissions.

In 2005, a survey of drug plan managers and a review of previously submitted BIAs revealed that the quality of submitted BIAs is often unsatisfactory. Key reasons for this evaluation were a lack of transparency, inaccurate or misapplied assumptions, generalized analysis (non-specific or inaccurate jurisdiction and/or plan), inappropriate comparator selection, and overall quality (predictive accuracy).

In February 2006, i3 Innovus was awarded the commission by the PMPRB to produce a literature review of existing BIA guidance and to subsequently develop guidelines for BIAs submitted to the F/P/T drug plans of Canada. Guidelines from Australia, England and Wales, Poland, the United States were identified as part of the literature review. The International Society of Pharmacoeconomics and Outcomes Research (ISPOR) Principles of Good Practice for Budget Impact Analysis, which were released after the performed literature review, were utilized along with key learnings from the literature review to develop the Canadian guidance document. The Canadian guidance document was developed to provide those responsible for the preparation, submission, and evaluation of BIAs with clear guidance regarding the methodology and reporting methods to be used when submitting BIAs to the individual F/P/T drug plans or to Canada's Common Drug Review (CDR). Existing guidance from the provincial drug plan templates and the individual F/P/T drug plans were also considered during the development of these guidelines to ensure that the BIA guidance reflects the requirements of drug plan managers.

3.2 Recommendations for Analytic Framework

Model Design

To be transparent and accessible, the budget impact model and supporting report should be designed in a manner that meets with the needs of the end users, explicitly state all choices and assumptions, use the simplest possible design structure to answer the budget impact question, and be built using readily available software.

Perspective

The BIA should be performed from a drug plan perspective that includes drug-related costs that are reimbursed by the drug plan. Changes to the drug market that are caused by non-drug related changes in practice patterns should also be represented in the model; however, no costs other than drug costs should be included.

Scenarios to be compared

When evaluating the financial impact of granting formulary listing to a given drug, two scenarios, one for the Reference Scenario and one for the New Drug Scenario, should be compared. All assumptions made to develop each scenario should be explicitly stated and justified using the best available information, such as historical data from other markets, published forecasts or, if necessary, expert opinion.

Population

When establishing the population of interest within a BIA, the population should be defined based on the manufacturer's drug label / monograph, plan eligibility / membership, and any restrictions to drug access intended by the manufacturer. Growth of the market over time should be based on general population growth estimates, with suitable adjustments being made if drug availability is anticipated to affect the size of the market. The main analysis presented in the BIA should not include off-label usage of the new drug.

Time horizon

When reporting data used to forecast the budget impact of a new treatment, four years of data should be presented. Specifically, a one-year baseline period and a three-year forecast should be presented. All forecasted data and results should be for 12-month periods (e.g., April 2007 to March 2008) relative to the intended date of formulary listing.

Calculating Drug Costs

When calculating the cost to a drug plan, BIAs should include the expected reimbursement price of the new drug, all relevant drug comparators, and all relevant concomitant medications reimbursed by the drug plan. Drug costs should consider all mark-ups, inventory allowances, dispensing fees, and patient co-payments as per F/P/T drug plan BIA submission requirements. Premiums and deductibles should be excluded.

Characterizing Uncertainty

Deterministic sensitivity analyses should be provided with submitted BIAs to inform decision makers of the sensitivity of the model to specific assumptions. Reasonable and/or cited information regarding the range of uncertainty associated with each assumption should also be included. When reporting the uncertainty analysis, a summary of sensitivity analyses performed on the following parameters should be provided: price, market share of each treatment being compared, market size.

Discounting and Inflation

Results should be neither discounted nor inflated. The budget impact model should allow decision makers to easily study the effect of changes to these rates, if desired.

Validation

All submitted budget impact models should undergo internal validation.

3.3 Recommendations for Inputs and Data Sources

Estimation of the current size of the market

When estimating the size of the market, analysts may choose to develop their models based on either population data or claims data. The use of population data is preferred for BIAs. Whenever possible, the population data used should represent the number of eligible beneficiaries.

If the analyst elects to use claims data to generate forecasts for a BIA, estimates of the size of the population that would require the forecasted number of claims should be provided to help reviewers assess the reasonableness of the presented results.

Selection of relevant comparators

When developing BIAs, the comparators used in the supporting budget impact model should reflect drug-based treatment strategies used to treat the same indication(s) as the new drug. Treatment strategies may be composed of one or more drugs, as treatment of a specific indication may require that more than one drug be administered as a part of patient treatment. Non-drug treatments should be excluded from the treatment strategies used in budget impact calculations. Identification of the relevant treatment strategies for a budget impact model should involve the use of appropriate clinical input (e.g., published research, expert opinion).

Forecasting of the market under the Reference Scenario

To forecast changes in the Reference Scenario market, analysts should use published forecasts, whenever possible. Forecasts developed by the analyst should take into consideration anticipated changes to the market over the time horizon and should be informed using data from available databases.

When developing Reference Scenario forecasts, analysts should estimate the anticipated growth of the market and the market distribution of the treatment strategies expected to be available. Both of these factors should be estimated for the time horizon of interest and commentary regarding the data supporting these estimates should be provided.

Forecasting of the market under the New Drug Scenario

To forecast changes in the New Drug Scenario market, analysts should use current market intelligence on how the reimbursement of the new drug will affect the market. Markets where the new drug is currently reimbursed should be consulted to inform the forecasting process, whenever possible.

When developing New Drug Scenario forecasts, analysts should estimate the anticipated growth of the market following the listing of the new drug, the expected market share of the new drug following its listing on a given drug formulary, the effect of any restrictions to access to the new drug on market size or market share, and estimation of how the new drug will affect the market share of all relevant treatment strategies. These factors should be considered for the entire time horizon of interest and commentary regarding the data supporting these estimates should be provided.

Estimation of drug prices

To price each treatment strategy, analysts should obtain reimbursement prices from the best available source(s), which may include, but is not limited to: the drug plan formulary, the manufacturer, wholesaler catalogues, or providers of public drug plan data. The cost per day to use the treatment strategy, which may consider therapeutic equivalence and patient time to refill, should be considered. For a BIA prepared for a specific public drug plan, analysts should include mark-ups, inventory allowances, dispensing fees and patient co-payments as per the drug plan's specifications.

Drug prices for currently listed drugs should be estimated based on data from the drug plan formulary, whenever possible. For those drugs that are not currently reimbursed, the best available information should be used to price the drug (e.g., setting the comparator's price equal to that of the new drug). When comparing different treatment strategies, it is important to consider therapeutic equivalencies, which often requires evaluating the number of drug units administered per unit of time.

3.4 Recommendations for Reporting Format

Reports submitted to F/P/T drug plans for evaluation, should contain the following sections: report introduction, technology, objectives, study design and methods, results, limitations and assumptions, sensitivity analyses, conclusion, references and appendices. The information presented should include sufficient detail to allow a third party to replicate the submitted results. The inclusion of supporting tables and figures is recommended to enhance the clarity of the report.

In addition, the BIA Completion Checklist (Appendix D) should be used to verify that the BIA was appropriately completed.

Interactive budget impact model

The interactive budget impact model used to produce the results should accompany BIA reports. The model should be developed using the most current interactive budget impact template provided with the BIA Guidelines, with the analyst making any changes that are deemed necessary to ensure the accuracy and clarity of the BIA.

4

Introduction

Budget impact analysis (BIA) is a tool used to predict and understand the potential financial impact of introducing a new health care intervention into a health care system that has finite financial resources.[1] One of the key questions that can be answered through the use of a BIA is whether a new intervention can be afforded by the system of interest. With this knowledge, a better decision regarding reimbursement of the intervention can be made.[2] This is in contrast to a cost-effectiveness analysis (CEA), which measures the value of a new intervention in terms of monetary units per additional unit of health benefit (e.g., dollars per symptom free day, dollars per quality-adjusted life year gained). Both tools should be employed to make an informed decision regarding the reimbursement of a new intervention at a given price for a specific population.

In some international jurisdictions, BIAs are designed to demonstrate net costs to the overall health care system. These comprehensive BIAs will incorporate not only the cost of the new intervention (e.g., a new drug) and the reduction in use of the intervention's direct comparators, but will also incorporate changes to any other health care resources that could be affected by the new intervention's introduction. Such BIAs allow reviewers to study the health care system globally and assist them as they make decisions that touch all parts of the system. For example, these BIAs can help managers of health care systems justify changes to the size of drug plan budgets, which can, in turn, allow new treatments to become accessible and affordable.

For jurisdictions that use BIAs for decision-making related to the introduction of new drugs to their drug formularies, BIAs may focus exclusively on drug costs. Such pharmaceutical BIAs can assist drug plan managers in determining whether a new drug can be afforded by a given drug plan. This becomes more relevant than a BIA that evaluates all health care costs when the drug plan manager has no control over costs outside his or her given drug budget. By using these BIAs in combination with CEAs, drug plan managers can make informed decisions regarding the addition of new drugs that are both affordable from the perspective of the drug plan and also represent good value for money for the health care system as a whole.

In Canada, federal, provincial, and territorial (F/P/T) drug plans use BIAs to aid in their decision-making processes regarding listing and reimbursement of drugs. As such, BIAs are designed in a manner that focuses on the affordability of the new drug. Questions related to the value of the new drug to the overall health care system, as well as those pertaining to drug safety, efficacy or quality, are better answered through the examination of additional material, such as CEAs.

4

4.1 Use of Budget Impact Analyses in Canada

In Canada, the decision to reimburse a new drug lies with the managers of each F/P/T drug plan. The Common Drug Review (CDR) of the Canadian Agency for Drugs and Technologies in Health (CADTH) ensures that manufacturers submit BIAs to the various drug plans for all new drugs. BIAs for drugs that have already obtained formulary listing from a given F/P/T drug plan and for which expansion of their reimbursement criteria is being sought are sent directly to the F/P/T drug plans.

4.2 Unique Needs of F/P/T Drug Plans

Although many of Canada's F/P/T drug plans use the CDR process to inform their decisions regarding drug reimbursement, the requirements of each drug plan with respect to BIA drug submissions differ widely. These differences include, but are not limited to:

- **Access to drug therapies**

  Some drug plans will not add a new drug to their formularies; instead, they will add them to a list of drugs that require special authorization to allow their use. By keeping such drugs off drug formularies in this manner, drug plans are better able to control the use of these drugs.
- **The population covered by the drug plan**

  Some drug plans cover any registered individual not covered by another drug plan, while others restrict drug plan eligibility to those meeting specific socioeconomic or health care-related criteria. The choice of criteria varies by drug plan.
- **Mark-up, dispensing fee and inventory allowance applied to drug costs**

  The maximum amount that drug plans will pay to cover charges in excess of the manufacturer's price (ex-factory price) for a given drug differs across the country.
- **Premiums, deductibles and patient co-payments**

  Each drug plan sets the amount for premiums, deductibles, and patient co-payments based on the specific needs of the plan.
- **The maximum amount reimbursed for the use of a given drug**

  The amount that a given F/P/T drug plan will reimburse for a given drug depends on the structure of the drug plan itself. In some cases, the ex-factory price is reimbursed while, in other cases, the maximum reimbursable unit price is that of the lowest cost alternative to the drug in question, as defined by the drug plan.

As can be seen from this list, many factors help to define a given drug plan. Although differences exist with respect to the specific needs of each drug plan, it remains possible to develop general rules regarding the preparation of BIAs that can provide decision makers with the information they need to identify new drugs that should be added to their drug formularies.

4.3 Harmonization of BIA Methodology

Currently, in Canada, there is no standardized method of performing and presenting BIAs for submission to F/P/T drug plan managers. Only three jurisdictions (Alberta, Manitoba and Ontario) provide manufacturers with documentation regarding the development and / or presentation of BIAs. Given the use of BIAs in the reimbursement decision-making process, it has been recognized by the National Prescription Drug Utilization Information System (NPDUIS) that this lack of formal, standardized guidance must be addressed.

In September 2001, F/P/T Ministers of Health announced a multi-faceted approach to improve pharmaceutical management. One of the decisions made at that time was to establish NPDUIS, a partnership between the Canadian Institute of Health Information (CIHI) and the Patented Medicine Prices Review Board (PMPRB). NPDUIS is responsible for providing "critical analyses of price, utilization and cost trends so that Canada's health system has more comprehensive, accurate information on how prescription drugs are being used, and sources of cost increases."[3] The development of these guidelines was commissioned by the PMPRB.

Phase 1: Budget Impact Analysis Guidelines: Needs Assessment

In 2005, Phase One of the development of the Guidelines for Conducting Pharmaceutical Budget Impact Analyses for Submission to Public Drug Plans in Canada was completed. During this phase, Panacea Canada Inc. surveyed the members of the NPDUIS Steering Committee, which included representation from Health Canada, CIHI, the PMPRB, and the F/P/T drug plans. The purpose of this survey was to assess existing needs for developing BIA guidelines. In responding to this 12-part survey, Steering Committee members commented on the overall effectiveness and utility of BIAs as they are currently conducted. In addition to this survey, 35 previously submitted BIAs were reviewed to determine the main issues that should be addressed with an analysis.

The findings of the survey and BIA evaluations revealed that drug plan managers often find submitted BIAs to be unsatisfactory. Analysis of the survey responses and the results of the BIA evaluations identified 5 key areas of improvements that needed to be addressed in this guidance on the development of BIAs.[4] These key reasons for dissatisfaction amongst drug plan managers regarding BIA submissions were identified as:

- **Lack of transparency**
- **Inaccurate or misapplied assumptions**
- **Generalized analysis – non-specific or inaccurate jurisdiction and/or plan**
- **Inappropriate choice of comparators; and**
- **Overall quality (i.e., predictive accuracy).**

Based on the findings of Phase One of this process, it was determined that the development of BIA Guidelines for Canada should be pursued.

4

Phase 2: Guideline Development

In February 2006, i3 Innovus was awarded the commission by the PMPRB to complete Phase Two of this project - the creation of guidelines for BIAs submitted to Canada's F/P/T drug plans. The first task for i3 Innovus was to review the existing body of literature regarding BIAs. Publicly available documents from several jurisdictions, including guidance from Australia[5], Canada[6,7,8,9], England and Wales[10], Poland[11,12], and the United States[13] were consulted to understand existing standards of practice for BIAs. Following the submission of this literature review[14], the NPDUIS Advisory Committee was consulted to determine the requirements and expectations for the Canadian Guidelines for the Development of Budget Impact Analyses. The committee suggested using the format of the International Society For Pharmacoeconomics and Outcomes Research (ISPOR) Principles of Good Practice for Budget Impact Analysis[15] as the basis for the Canadian guidance document because this was the most current guidance available.

The ISPOR Principles of Good Practice provide general guidance regarding the development of BIAs. The key recommendations include:

- **The budget impact should be computed from data on the size and characteristics of the population with the condition of interest, the current and new treatment mix, the efficacy and safety of the new and current treatments, and the resource use and costs for the treatment and disease symptoms.**
- **The BIAs should be generated as a series of scenario analyses specific to a particular decision maker's population and information needs.**
- **The primary data sources for estimating the budget impact should be published clinical trial estimates for efficacy and safety of current and new technologies, as well as, where possible, the decision maker's own population for the other parameter estimates.**
- **The disease model used for BIA should compute disease outcomes in the total affected population for each year after the new intervention is introduced into clinical practice. The model should be consistent with that used for the cost-effectiveness analysis with regard to clinical and economic assumptions.**

The ISPOR Principles of Good Practice do not provide developers of budget impact models with specific instruction on how BIAs should be performed (e.g., country- or region-specific data sources that should be used, calculations that should be performed). Further, the guidance provided may not be applicable in all jurisdictions (e.g., the inclusion of non-drug costs, cost-offsets, and / or treatment effectiveness in the estimation of the budget impact).

The Guidelines for Conducting Pharmaceutical Budget Impact Analyses for Submission to Public Drug Plans in Canada have been developed to provide more detailed instruction on how BIAs that are to be submitted to public drug plans in Canada should be performed. Existing guidance from the provincial drug plan templates of Alberta[16], Manitoba[17] and Ontario[18], and the individual F/P/T drug plans have been considered to ensure that the BIA guidance reflects the requirements of F/P/T drug plan managers. As part of the preparation of the Guidelines for Conducting Pharmaceutical Budget Impact Analyses for Submission to Public Drug Plans in Canada, an interactive budget impact model template was developed to facilitate model development. This template, which can be found on the Web site of the Patented Medicine Prices Review Board (www.pmprb-cepmb.gc.ca), was created to provide analysts with interactive guidance on how to construct their models and includes information that complements the guidance provided in these BIA Guidelines. Analysts are encouraged to use the template to build their models.

4.4 Purpose of this Document

The purpose of this document is to provide those who are responsible for the preparation, submission and evaluation of BIAs with clear guidance regarding the methodology and reporting methods to be used when submitting BIAs to the CDR or to a F/P/T drug plan that is currently participating in the Common Drug Review process administered by CADTH. The drug plans currently participating in CADTH that require the submission of a BIA are:

- **British Columbia**
- **Alberta**
- **Saskatchewan**
- **Manitoba**
- **Ontario**
- **New Brunswick**
- **Nova Scotia**
- **Prince Edward Island**
- **Newfoundland and Labrador**

In addition to these plans, the Non-Insured Health Benefits Program (NIHBP) requires that BIAs be prepared and submitted. The following F/P/T drug plans do not require the submission of BIAs through the CDR process:

- **Quebec***
- **Yukon Territory**
- **Northwest Territories**
- **Nunavut Territory**
- **Correctional Service Canada (CSC)**
- **Royal Canadian Mounted Police (RCMP)**
- **Veterans Affairs Canada (VAC)**
- **Department of National Defence (DND)**

Using the instructions provided in this document and the associated template, analysts should be able to prepare BIAs that address the requirements of each of the participating drug plans. In addition to being of significance to those developing and submitting BIAs, this document, and the BIA model template that accompanies it, may also be of interest to those developing BIAs for submission to other non-participating jurisdictions and agencies. The NPDUIS Steering Committee has endorsed these guidelines and template.

The intended audience for these guidelines includes those who develop budget impact models or use them to draft and submit BIAs to F/P/T drug plans participating in the CDR, and drug plan managers who evaluate BIA submissions.

* Quebec does not participate in the Common Drug Review process.

5

Recommendations for Analytic Framework

BIAs are commonly conducted using interactive models. By developing these models, both analysts and decision makers are provided with tools that forecast the future impact of decisions made in the present day. The usefulness of these analyses depends on the design of the model, the data used for forecasting purposes, and whether the uncertainty inherent in the model design and data inputs is demonstrated in a meaningful way. Given these limiting factors, it is important for analysts to develop and utilize models built upon a robust analytic framework if their BIAs are to provide information of value to decision makers.

The following section provides an overview of the model design, analytic perspective, time horizon, population, costing, scenarios to be compared, uncertainty analysis, discounting and validation methods that should be used when preparing a BIA. More specific and detailed guidance regarding BIA data requirements is provided in Section 6: Recommendations for inputs and data sources.

5.1 Model Design

All BIAs should be designed to maximize their transparency for decision makers. This can only be achieved through proper model design. Choices made during the development of the BIA should be fully explained to help decision makers understand how the budget impact model works. When developing a model to perform a BIA, the simplest design that generates accurate results should be selected. In addition, the model should be built using a readily available software application, such as Microsoft Excel.

To be transparent and accessible, the BIA model and supporting report should:

- **Be designed in a manner that meets with the needs of the end users**
- **Explicitly state all choices and assumptions made by the authors of the model**
- **Use the simplest possible design structure to answer the budget impact question**
- **Be built using readily available software**

5.2 Perspective

The perspective used in the BIA should be that of the drug plan. As such, only drug costs affected by adding the new drug to a given drug plan should be included. These costs could include:

- **Drug prices (as reimbursed by the drug plan)**
- **Wholesaler mark-ups**
- **Pharmacy mark-ups**
- **Inventory allowances for pharmacies**
- **Dispensing fees**

In addition to the adjustment of expected drug costs through mark-ups, allowances and dispensing fees, these costs may need to be reduced to reflect any co-payments made by drug plan beneficiaries.

The decision to include any of the above-mentioned costs is determined by each F/P/T drug plan. Appendix A includes a table specifying the costs to be included in BIAs for each drug plan as of October 2006.

The costs associated with a health care system perspective should be excluded from BIAs submitted to F/P/T drug plans. These costs include, but are not limited to:

- **Medical procedures (e.g., surgeries)**
- **Emergency room visits**
- **Physician visits**
- **Diagnostic procedures**
- **Hospitalizations**
- **Reimbursed medical devices**

The use of a drug plan perspective that excludes costs specific to a health care system perspective was established as the relevant perspective for Canadian BIAs based on the results of the Phase One survey of the NPDUIS Steering Committee and the input of the NPDUIS Advisory Committee during Phase Two of this project. Costs specific to the health care system should be excluded from Canadian BIAs because they do not have a direct impact on the budget of the F/P/T drug plans. Instead, health care costs affect the F/P/T health care budget. These costs, which can be referred to as cost-offsets as they offset the cost of new drug, sometimes result in downstream effects that generate significant savings to both drug budgets and the overall health care system. Medical cost-offsets are captured in Canadian economic evaluations (i.e., cost-effectiveness analyses) and the exclusion of these offsets from BIAs is a key reason why F/P/T decision makers are encouraged to consider economic evaluations together with BIAs when making formulary decisions.

Although only the cost of treatments covered by F/P/T drug plans should be included in the analysis, it is important to ensure that all changes to the dynamics of the public plan market caused by external factors such as non-drug treatments or other drug plans (public or private) are reflected in the forecasts used in the BIA. More specifically, the effect of non-drug treatments would be seen in projections of market size and market distribution. For example, if the use of surgery increased for a given market to correct an illness that was typically treated pharmacologically, the number of people receiving pharmacological treatment would decrease, resulting in a reduction in the size of the drug market.

In summary, when specifying the details of the perspective from which the BIA should be performed:

- **Only a drug plan perspective that includes drug-related costs that are reimbursed by the drug plan should be included in the analysis**
- **Changes to the drug market that are caused by non-drug related changes in practice patterns should be represented in the budget impact model**

5.3 Scenarios to be Compared

BIAs are used to forecast the incremental cost or savings that will potentially be realized by F/P/T drug plans if the new drug is added to their respective formularies. To achieve this, it is necessary to model two distinct scenarios. These two scenarios can be referred to as the Reference Scenario and the New Drug Scenario. These scenarios are defined as follows:

Reference Scenario

In the Reference Scenario, the composition of the marketplace is forecasted for the time period of interest assuming that the new drug is not added to the F/P/T drug formulary. The composition of the forecasted market over the time horizon is based on the current market's competitive landscape as well as data and supportable assumptions regarding the discontinuation and/or adoption of new therapeutic options.

All assumptions made regarding the market within the Reference Scenario should be explicitly stated and referenced within the BIA report to ensure that F/P/T drug plan managers can assess the reasonableness of the presented scenario. The information used to inform the BIA should be the best available, which may include historical data from other markets, published forecasts or, if necessary, expert opinion.

New Drug Scenario

Unlike the Reference Scenario, the New Drug Scenario assumes that the new drug becomes listed on the drug formulary of the F/P/T drug plan of interest. In this scenario, the composition of the marketplace is forecasted for the duration of the time period of interest. The composition of the forecasted market over the time horizon is based on the current market's competitive landscape, data and supportable assumptions related to how the introduction of the new drug will change the market, and the discontinuation and/or adoption of new therapeutic options.

As is the case for the Reference Scenario, the New Drug Scenario should explicitly state all assumptions made regarding the impact of the new drug on the market. These assumptions should be referenced within the BIA report to ensure that F/P/T drug plan managers are provided with sufficient information to understand and assess the reasonableness of the presented scenario. The information used to inform the BIA should be the best available, which may include historical data from other markets, published forecasts or, if necessary, expert opinion.

Finally, the budget impact model should allow F/P/T drug plan managers to evaluate the impact of different New Drug Scenario assumptions in a straightforward manner. All assumptions should be made explicitly and inputs within the model that affect these assumptions should be presented in an intuitive fashion.

In summary, when evaluating the impact on F/P/T drug plans of granting a given drug formulary listing:

- **Two scenarios, one for the Reference Scenario and one for the New Drug Scenario, should be compared**
- **All assumptions made to develop a given scenario should be explicitly stated and supporting references provided**

5.4 Population

A key driver of the cost incurred (or savings realized) by a given F/P/T drug plan for a new therapy is the size of the covered population that requires access to the new therapy. It is important to note that the number of beneficiaries and the characteristics of the beneficiaries of interest will vary depending on the drug plan being evaluated. For example, all residents of Manitoba who are registered with Manitoba Health and are not covered by another F/P/T drug plan are eligible for drug plan benefits. As such, it is reasonable to assume that the age, gender, and disease prevalence in this population will mirror that of the general population. In Ontario, those individuals who are eligible for reimbursement by the Ontario Drug Benefit Program (ODB) are seniors aged 65 and over, those on social assistance, residents of long term care facilities or Homes for Special Care, and people receiving professional services under Home Care[19]. It would not be expected that age, gender, and disease prevalence figures of those individuals who are covered by the ODB would be similar to those of the entire population of Ontario. Some subpopulations could be assumed to be similar, however, such as the senior population for Ontario and seniors covered by the ODB. As a result of these important differences between drug plans, it is critically important to ensure that the population data used are drug plan-specific.

All drug plan beneficiaries who are expected to be diagnosed and treated for the condition(s) of interest and who are eligible to use the new drug should be included in the BIA. Eligibility for drug use is defined by the population specified by the manufacturer's drug label / monograph and the population eligible for coverage within the plan. Coverage eligibility is defined by each relevant F/P/T plan.

In some cases, manufacturers may request that the reimbursed population be restricted to patients who have failed to respond to other therapies or who meet specific criteria. When this holds true for a given drug, this restricted access should be reflected in the estimation of those individuals who will receive treatment by reducing the number of relevant drug plan beneficiaries accordingly. For example, if only those patients who have failed to improve following initial treatment (first-line therapy) should be considered for the newly listed drug, the percentage of the population expected to fail the first-line therapy should be factored into the calculation of the population of interest. All restricted access criteria should be explicitly stated within the BIA report.

Estimation of the size of this population will depend on assumptions made regarding how the introduction of the new drug will affect overall market dynamics. For example:

- **Market growth should be based on standard population growth if the availability of the new drug is not anticipated to affect the size of the market**
- **Market growth should be based on both standard population growth and growth due to the new drug if the availability of the new drug is anticipated to affect the size of the market**

When determining the size of the population of interest, data from other markets that are known to be similar to the market of interest should be used to forecast how the market would change over time. (Evidence from markets that are known to be different from the population of interest may also be used; however, this should only be performed in the absence of any other available data.)

If off-label usage is expected due to experience in markets outside the jurisdiction of the F/P/T drug plan, expert opinion, or other sources, this should be clearly noted within the BIA report. Further, these data should be used to perform one or more sensitivity analyses that evaluate the effect of off-label use on the F/P/T drug plan budget. For the main analysis presented in the BIA, predicted off-label usage should not be included, since off-label use cannot be supported by the indications for use in the product monograph. Details regarding how the size of the market can be predicted are provided in Section 6.1.

In summary, when establishing the population of interest within a BIA:

- **The population should be defined based on the manufacturer's drug label / monograph, drug plan eligibility / membership and any restrictions to drug access desired by the manufacturer**
- **If the new drug is not anticipated to increase the size of the market, market growth should be based on forecasted growth of the target population**
- **If the new drug is anticipated to increase the size of the market, market growth should be based on forecasted growth of the target population and growth due to the new drug**
- **The main analysis presented in the BIA should not include off-label usage of the new drug**

5.5 Time Horizon

As part of Phase One of the development of BIA Guidelines, drug plan managers were surveyed to determine their preferences with respect to submitted BIAs.[20] At that time, 83% of respondents indicated that a time horizon of 3 to 5 years was desirable. As a result of this and in consultation with the PMPRB and the NPDUIS Advisory Committee, a time horizon of 3 years is requested for all submitted BIAs.

Results should be disaggregated over time in one-year periods. To remain in line with existing F/P/T BIA templates, all forecasted data and results should be reported in full 12-month periods after the proposed listing date (e.g., if the proposed listing date is April 1, 2007, then the forecasted time period is from April 1, 2007 to March 31, 2010).[21,22,23] Data for the baseline year (the 12 months preceding the proposed listing date) should also be reported (e.g., April 1, 2006 to March 31, 2007).

In summary, when reporting data used to forecast the budget impact of a new treatment:

- **A one-year baseline period should be presented**
- **A three-year time horizon should be presented for the forecast**
- **All forecasted data and results should be for 12-month periods (e.g., April 2007 to March 2008)**

5.6 Calculating Drug Costs

When evaluating the budget impact of reimbursing a new drug, prices for the new drug and its comparators are instrumental in determining the cost to the F/P/T drug plan following the addition of the drug to the formulary. Details relating to the calculation of drug costs are discussed below and in Section 6.5.

Drug prices

When pricing the drugs to be included in a BIA for a given F/P/T drug plan, drug prices specific to the F/P/T drug plan should be used. Each drug price should be clearly presented and should be specific to the chemical and dose of interest. To determine the amount reimbursed by each F/P/T drug plan for a given drug, its price should be obtained from the drug plan formularies, a database that summarizes drug plan data, a wholesaler catalogue or the drug manufacturer.

When the annual cost of reimbursing a given drug is being evaluated for use within the budget impact model, the number of times the drug is taken over the period of one year should also be considered. For drugs that are taken as needed or that are taken periodically throughout the year, an average number of treatments should be calculated and used in the evaluation of the annual cost.

5

Concomitant medications

In some cases, the use of a given drug therapy requires the use of concomitant medications. These concomitant medications may be reimbursed by the F/P/T drug plan. To estimate the impact of concomitant medication use on the budget of a given drug plan, the BIA should calculate the cost of 'treatment strategies' rather than the cost of each individual drug. A 'treatment strategy' is defined as one or more drugs taken together to treat a condition.

When including concomitant drugs in BIAs, only drugs related to the active components of the new drug may be considered (based on existing treatment guidelines, the indication of the new drug and the restricted access criteria set by the manufacturer). Treatment strategies that combine drugs may be intended to provide a strengthened pharmacological effect or allow a patient to undergo treatment without suffering from potential side effects. For example, Angiotensin Converting Enzyme inhibitors (ACE inhibitors) may be taken with a diuretic to provide a more potent treatment effect in patients suffering from hypertension, and Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) may be taken with gastroprotective agents (GPAs) to allow for the management of inflammation in patients at risk of experiencing gastrointestinal side effects. In cases where either of these scenarios exists and the use of the new drug would affect the use of these concomitant medications, the concomitant medications should be combined with the primary treatment to define the 'treatment strategy'. As is the case for standard monotherapies, the most current reimbursement price should be used in all relevant calculations within the BIA.

If evidence exists that indicates a new drug will obtain formulary listing during the time horizon of the model and it is known that this new drug will affect assumptions related to concomitant medication use, the relevant concomitant medications should be included in the BIA and its impact studied through sensitivity analyses.

Premiums and deductibles

When performing BIAs for submission to the F/P/T drug plans, premiums and deductibles should not be factored into the calculation of costs to the drug plan. This is due to the fact that premiums and deductibles should be distributed across all drug therapies taken by a given patient in a given calendar year.

Mark-ups, inventory allowances, dispensing fees and patient co-payments

In addition to drug prices, some drug plans require the inclusion of additional F/P/T drug plan-specific charges in submitted BIAs. The additional charges that may be included in F/P/T BIAs are:

- **Wholesaler mark-up**
- **Pharmacy mark-up**
- **Inventory allowance**
- **Dispensing fee**

The dollar value of these mark-ups, inventory allowances and dispensing fees vary by drug plan. Appendix A specifies the mark-ups, inventory allowances and dispensing fees that were in use by F/P/T drug plans as of October 2006. These values must be confirmed every time a BIA submission is performed to ensure that the most current values are being used. Failure to ensure that all costs and cost adjustments made within the budget impact model are current may result in an underestimation of the impact of reimbursing the new drug.

If the new drug will have a significant impact on the amount reimbursed by the F/P/T drug plans for mark-ups, inventory allowances or dispensing fees (e.g., the introduction of a fixed combination therapy that reduces the number of dispensing fees paid per year), the actual mark-up, inventory allowance and dispensing fee values paid by the drug plans may be included in the BIA. The methods used to calculate mark-ups, inventory allowances and dispensing fees should be consistent with those that are presented on the F/P/T drug plan websites. If several drug plans within a given province are applicable to the drug in question (e.g., Social assistance drug plan, Seniors' drug plan), the mark-ups, inventory allowances and dispensing fees used should represent a weighted average of the mark-ups, inventory allowances and dispensing fees of each relevant plan, unless otherwise specified by the drug plan.

Unlike deductibles, patient co-payments are sometimes included in drug cost calculations for BIAs. In cases where F/P/T drug plans request that manufacturers include patient co-payments in their budget impact models, patient co-payments should be included. Those drug plans that require patient co-payments and request that they be included in BIA calculations are indicated in Table A-1 of Appendix A (based on requirements identified in October 2006).

In summary, when calculating the cost to the F/P/T drug plan, BIAs should:

- **Consider treatment strategies rather than the cost of each individual drug**
- **Include the expected reimbursement price for all treatment strategies**
- **Include the price of the new drug**
- **Include the price of all relevant comparators as reimbursed by the F/P/T drug plan**
- **Include the price of all relevant concomitant medications as reimbursed by the F/P/T drug plan**
- **Adjust all drug costs according to the F/P/T drug plan's requirements for BIA submissions**
- **Determine the most current values to be used for all required mark-ups, inventory allowances, dispensing fees and patient co-payments**
- **Add all required mark-ups, inventory allowances and dispensing fees to drug costs**
- **Subtract patient co-payments from drug costs, when required by the F/P/T drug plan**
- **Exclude premiums and deductibles**

5.7 Characterizing Uncertainty

As the purpose of a BIA is to help its users understand the potential financial impact of introducing a new drug into a system with limited financial resources, it is important for decision makers to be informed of the level of uncertainty inherent in the estimates from the model. Uncertainty occurs when the true value of a parameter is unknown, reflecting the fact that knowledge or measurement is imperfect. To ensure the transparency of the BIA, uncertainty analysis should always be included. Access to uncertainty analyses is essential to effective decision making as it demonstrates the range of reasonable values F/P/T drug plans can expect to pay if they choose to reimburse the new treatment.

To examine uncertainty, deterministic sensitivity analyses (DSAs) should be performed. DSAs may include one-way analyses, multi-way analyses and analyses of extremes.

One-way sensitivity analyses involve testing various values for one parameter at a time. Varying the price of a comparator therapy that is anticipated to be reimbursed by the time the new drug achieves formulary listing would constitute a one-way analysis.

Multi-way sensitivity analyses involve changing several parameters within the model simultaneously. An example of this approach would be changing the market share and market growth assumptions simultaneously to illustrate their combined effect on the drug plan budget. Analysis of extremes represents a special case of multi-way sensitivity analysis, where all of the parameters in a model are tested at their lowest values and their highest values (i.e., studying the most pessimistic and optimistic conditions). These analyses can be used to reveal the range of possible results that can be obtained using the model and reasonable assumptions.

Probabilistic sensitivity analysis (PSA) is another special case of multi-way sensitivity analysis. The key difference between a DSA and a PSA is that to perform a PSA, a probability distribution is assigned to each parameter and a value is randomly drawn from the distribution for each model simulation. This process is then repeated many times. Although PSA may be worthwhile to explore in pilot studies, it is not recommended as a required component for a BIA submission at this time.

Values used in sensitivity analyses should be supported by citable data sources whenever possible. For example, if off-label use of the new drug has been noted in a foreign market, this should be explored within the sensitivity analyses using data from the foreign market to inform the model. In cases where confidence intervals have not been established for a given value, large changes to the value of the parameter should be tested. The value used should be justified in the body of the final report.

At a minimum, the following parameters should be tested in a sensitivity analysis to demonstrate to the F/P/T drug plan managers the impact of the assumptions made during model development, as they represent the three main components of estimating the value of the Reference and New Drug Scenarios (as shown in Appendix B):

- **Changes in the size of the market over the time horizon (including uncertainty regarding the utilized population forecasts and off-label use estimates from relevant sources)**
- **Market share distribution amongst the new drug and its comparators (including the evaluation of the impact of assumptions regarding the future reimbursement of potential comparators and/or concomitant medications)**
- **Price of any comparators and/or concomitant medications for which uncertainty exists (e.g., are not currently reimbursed but are anticipated to be granted reimbursement status between the time of BIA submission and the end of the modeled time horizon)**

Exclusion of any of the above-mentioned sensitivity analyses should be justified within the BIA based on available data. Analysts are encouraged to include additional sensitivity analyses if they will provide a better understanding of the impact of assumptions made during model development. These sensitivity analyses may include, but are not limited to:

- **Testing model assumptions regarding the percentage of eligible participants with the condition of interest who are expected to be diagnosed and treated**
- **Testing of assumptions related to the listing of new comparator treatments over the time horizon of interest**
- **Testing of the variability around time to refill estimates**

In summary, the uncertainty analysis provided with submitted BIAs should:

- **Provide DSAs (i.e., one-way sensitivity analysis, multi-way sensitivity analysis, analysis of extremes) to inform decision makers of the sensitivity of the model to specific assumptions**
- **Provide reasonable and/or cited information regarding the range of uncertainty associated with each assumption**
- **Provide a summary of sensitivity analyses performed on the following parameters: price, market share, and market size**

5.8 Discounting and Inflation

Budget impact analyses, unlike economic evaluations, should not be discounted. This is because F/P/T drug plan managers are concerned with the cost (or savings) their budgets will realize each year rather than the value, in present-day terms, of any costs (or savings) brought about through the reimbursement of a new therapy. Indeed, economic theory suggests that future years would have higher costs, due to inflation, not lower costs. While costs in future years could, in theory, be inflated by a predicted inflation rate, this is not recommended. It is recommended that results presented in the BIA should be neither discounted nor inflated, but should be presented in nominal dollars.

The budget impact model should provide decision makers with the ability to vary the model's discount rate or inflation rate should they choose to do so.

In summary, when developing budget impact models and performing BIAs:

- **Results should not be discounted or inflated (both rates should be set to 0%)**
- **The discount rate and inflation rates of the budget impact model should be user-defined variables**

5.9 Validation

Validation of the model used to generate each BIA report should be performed in accordance with the methodology proposed by Weinstein et al in the article: "Principles of good practice for decision analytic modeling in health-care evaluation: report of the ISPOR Task Force on Good Research Practices—Modeling Studies". The key points discussed in this article that are relevant for validating Canadian BIAs are:

Internal validation

- **The model should be rigorously tested to ensure that it is technically sound. Evidence of this testing should be provided.**
- **The model should be compared to available data, whenever possible, and adjusted programmatically to ensure that results returned by the model match (or are close approximations of) available data.**
- **The programming created by the developer of the budget impact model to perform the analysis (source code) should be made available for review (on the condition that property rights are respected).**

As is also mentioned in the ISPOR report, models should be based on the best available information that can be obtained reasonably. Decisions to obtain additional information to inform models should consider the value of the information (cost versus improved model accuracy) when assessing what information constitutes the best available information. Once the model has been developed and populated using the collected data, developers need not test every data estimate or model assumption, as it is understood that the results generated by the model are only as valid as the assumptions upon which they were based.

In summary, all submitted budget impact models should undergo a validation process that involves:

- **Internal validation**

6

Recommendations for Inputs and Data Sources

When developing a budget impact model that will be used to perform a BIA, the selection of data and assumptions used to inform the model are of paramount importance. This is true because all of the results generated by the developed budget impact model are dependent on the values that have been inputted into the model and the methodology used to calculate the end results. Although the final results of BIAs cannot be assumed to be a precise prediction of events that will occur in the future, they can be expected to represent an accurate reflection of what should be expected given the existing body of knowledge regarding the marketplace.

Data, assumptions, and forecasts are used to develop BIAs, which provide analysts and decision makers with an estimate the incremental costs or savings (budget impact) realized by replacing the Reference Scenario with the New Drug Scenario. The process by which this estimation of the budget impact is performed is shown in Figure B-1 of Appendix B. The following sections describe the recommended inputs and data sources that should be used in a BIA prepared for public drug plans in Canada.

6.1 Estimation of the Current Size of the Market

During Phase One of the development of Guidelines for Conducting Pharmaceutical Budget Impact Analyses for Submission to Public Drug Plans in Canada, a review of 35 BIAs revealed that the current market size for BIAs is typically estimated using one of two alternative approaches.[26] These approaches, which are schematically presented in Figure B-2 of Appendix B, involved either:

- **Designing models that predict the manner in which a given population will respond to the availability of therapeutic options (population data-based model); or**
- **Designing models based on historical drug purchasing behaviour (claims data-based model).**

Use of population data provides an effective means of estimating the number of people who are eligible for coverage by a given drug plan (eligible participants) over time, while claims data-based models are better predictors of the number of eligible participants who file a claim within a given year and receive treatment (active beneficiaries).

When appropriate, the use of the population data approach is preferred for BIA submissions, as this approach can provide F/P/T drug plan managers with an estimate of the number of people in a given jurisdiction who are likely to have the condition(s) of interest, an estimate of the number of people who become active beneficiaries by filing a drug claim for treatment of the condition(s), and the number of active beneficiaries within each specialized drug plan (e.g., social assistance, seniors) who are receiving treatment for the condition(s).

Claims data may be used instead of population data when sufficient data are available to enable analysts to estimate the size of both the diseased and reimbursed patient populations for a given set of assumptions (e.g., the introduction of a new drug is not expected to increase the number of treated individuals). Regardless of the methodology selected, an estimate of both the number of people and the number of claims resulting from the Reference and New Drug Scenarios should be provided for transparency and completeness. Estimated figures should be compared to historical data to verify that the model is accurately predicting the size of the market. Recommended methods for estimating market size using population and claims data are provided below.

Recommendations for Determining the Size of the Market with a Population Data-Based Model

The population data-based approach of forecasting the impact of listing a new drug on a drug formulary is a flexible approach for estimating market size, given that different data sources and assumptions can be used to limit the population to individuals with specific characteristics. In this approach, the number of eligible participants should first be determined. For some drug plans, this information is publicly available, while others have data online that can be used to estimate the size of the patient population. A number of drug plans do not have data related to eligible participants in a "ready-to-use" format. In such cases, it is expected that these data will be obtained from other sources or estimated based on active beneficiary data. Selected data sources should be cited within the submitted report and model. In some extreme cases, data related to the number of eligible participants may not be available; in such cases, data from a neighbouring Canadian jurisdiction with a similar drug plan and available eligible participant data should be used. These data should be adjusted based on the ratio of the general population sizes of the neighbouring jurisdiction and the jurisdiction of interest to obtain estimates for the region of interest.

It is important to note that, although many provinces provide statistics regarding the number of active beneficiaries using their plans, active beneficiaries represent the sickest of those within the plan and, as such, should not be expected to have the same disease prevalence statistics as the general population or the eligible participant population. In the absence of more accurate data, the active beneficiary data may be used; however, the effect of all disease prevalence, diagnosis, and treatment assumptions should be thoroughly tested to demonstrate the effect these assumptions have on the final result.

Table C-1, found in Appendix C, indicates where data pertaining to eligible participants for each drug plan can be obtained. Age-specific details regarding these populations are not provided in all cases. In cases where these data are not available, or where the level of detail supplied is insufficient for the analysis being performed, the age distribution should be estimated. Data regarding active beneficiaries may be considered when estimating the distribution of the eligible participant population in the absence of other available information.

When populating a BIA with estimates of the number of eligible participants for 12-month periods, estimates should represent the size of the population halfway through the period of interest. For example, for the 12-month period beginning January 1, 2007 and ending December 31, 2007, the size of the population should be defined as the size of the population on July 2, 2007.* This methodology should be used to reflect the fact that the population at the beginning of the 12-month period may not be the same as the population at the end of the year, and assumes that changes to the size of the population over a given 12-month period would be linear in nature.

With the number of eligible participants in each drug plan now known, disease prevalence statistics, as well as available statistics regarding the percentage of people who are diagnosed and treated for the disease in question should be used to reduce the number of the eligible participants to those individuals who would receive treatment. These details should be obtained from a published source, a public plan database or, if necessary, expert opinion. When valid details regarding the percentage of people who are diagnosed and treated are not available, reasonable assumptions should be made. In the absence of data, all eligible participants with the disease should be expected to be diagnosed and treated. Assumptions should be appropriately tested using sensitivity analysis to determine their impact on the final results.

Suggested methods for determining the number of eligible participants with the condition(s) of interest, in order of data reliability, are outlined below:

Use of prevalence data for the decision maker's population in combination with population data for the F/P/T drug plan

- **Published prevalence data that are specific to the decision maker's population may be used to determine the number of people covered by the F/P/T drug plan that would have the condition of interest. This type of data is ideally suited to the development of a budget impact model as it provides real-world data pertaining to the population of interest.**

* July 2, 2007 represents the midpoint of the 12-month period, where 182 days precede the 12-month period's midpoint and 182 days follow the 12-month period's midpoint (182 days + 1 day + 182 days = 365 days).

Use of prevalence data for the province, territory, or population of interest (e.g., Aboriginal Canadians, not including Métis) in combination with population data for the F/P/T drug plan

- Statistics related to the size of the decision maker's population and the demographic composition of this population (e.g., age, gender, race, ethnicity) and prevalence data for the related jurisdiction are used to determine the number of people covered by the F/P/T drug plan that would have the condition of interest (e.g., use of prevalence data for Canada's Aboriginal peoples, excluding the Métis population, and eligible participant statistics for the NIHBP). It is assumed that the prevalence of the disease in the population of eligible participants is the same as that of the general population, and so the prevalence statistics are applied to the population of the F/P/T drug plan. This represents the best alternative to using actual prevalence data for the F/P/T drug plan.

Use of prevalence data from a province, territory, or population that is similar to the population of interest in combination with population data for the F/P/T drug plan

- Statistics related to the size of the decision maker's population and the demographic composition of this population (e.g., age, gender, race, ethnicity) and prevalence data for a jurisdiction that is known to be similar to the region of interest are used to determine the number of people covered by the F/P/T drug plan that would have the condition of interest (e.g., use of Nova Scotia prevalence data and population statistics for those eligible for reimbursement under the Prince Edward Island Drug Cost Assistance Programs). It is assumed that the prevalence of the disease in the population of eligible participants (by age, gender, race and ethnicity) is the same as that of the population used as a source of prevalence data, and so the prevalence statistics are applied to the population of the F/P/T drug plan. This represents a less than ideal alternative and should only be used when appropriate data are not available.

Use of national prevalence data in combination with population data for the F/P/T drug plan

- Statistics related to the size of the decision maker's population and the demographic composition of this population (e.g., age, gender, race, ethnicity) and Canadian prevalence data are used to determine the number of people covered by the F/P/T drug plan that would have the condition of interest. It is assumed that the prevalence of the disease in the population of eligible participants (by age, gender, race and ethnicity) is the same as that of the Canadian population, and so the prevalence statistics are applied to the population of the F/P/T drug plan. This represents a less than ideal alternative and should only be used when appropriate data are not available.

Restricted Access

As not all new drug submissions obtain or seek a formulary listing that is without restrictions, it is important to include budget projections that reflect the scenario under which access to the new drug may be restricted by one or more conditions. To accomplish this, the market size should be reduced based on available data. For example, if only seniors who are female and have experienced a fracture should be considered in the analysis, only population data for those with the desired demographic profile (i.e., females over 65 years of age) would be considered, and this subpopulation would be further restricted to include only those patients who had experienced a fracture.

The data sources used to calculate the impact of being granted a restricted listing status are the same sources that would be used to estimate market size and growth.

Recommendations for Determining the Size of the Market with a Claims Data-Based Model

When developing a claims data-based analysis, the number of claims dispensed for a given indication should be determined. Such estimates should be obtained through a database that provides detailed claims-based information for public drug plans.

The number of claims used in the model for the baseline year should reflect the number of claims filed for all relevant comparators. In cases where the new and existing drugs are used for multiple indications, claims-based data should only be used if the distribution of claims between the two or more distinct indications can be made for each comparator. In the event that this is not possible, a population-based model is recommended. This is because the population-based model allows analysts to define their population(s) of interest based on specific criteria.

It is recommended that claims data-based models be used to calculate the number of active beneficiaries. This should be done when performing a claims-based BIA to validate the reasonableness of the claims estimates and to provide drug plans with an idea of the number of beneficiaries that are currently being treated for a given indication. The number of active beneficiaries can be estimated by dividing the annual number of claims for each primary treatment by the average annual number of claims filed per person. As each claim filed is specific to a particular patient, there should be no double-counting of patients when using this method of estimating the number of active beneficiaries.

In addition to the general limitations of using active beneficiaries in BIAs, the estimates calculated using this approach cannot be subdivided by age and/or gender and thus age- and gender-specific prevalence data cannot be used for forecasting purposes.

In summary, when estimating the size of the market, analysts should:

- **Generate estimates using a population data-based approach, when appropriate**
- **Provide reviewers with population estimates when using claims data-based models**

6.2 Selection of Relevant Comparators

The drug comparators to be included in the BIA should be an accurate reflection of the existing therapeutic options for the condition(s) of interest. Comparators should be categorized and studied by indication to provide F/P/T drug plan managers with the overall impact of reimbursing the new drug and the effect of this reimbursement by indication. This approach should be used because the market dynamics may differ between subgroups (e.g., subgroup-specific comparators may exist).

As mentioned earlier, the comparators used within a BIA should represent 'treatment strategies' rather than individual drugs. For example, the use of an NSAID and a GPA should be treated as a treatment strategy and reported as such, rather than calculating the cost of the NSAID and the cost of the GPA separately within the model. Fixed combination drug therapies should also be considered to be treatment strategies and should be costed in that manner. Use of fractional costs to represent the proportion of the fixed combination drug that is a direct comparator is discouraged. Non-drug treatments should be excluded from the list of treatment strategies used in the evaluation of the budget impact.

To determine which pre-existing drugs are likely to be displaced by the new drug, data from other markets should be used (e.g., published studies, market research). In the absence of such data, expert opinion may be used. Information from the manufacturer's marketing department may also be included to support the selection of comparators and relevant indications.

If no comparators exist for the new drug, a population data-based model should be developed, as the development of the new market will need to be explored.

In summary, to select relevant comparators for a budget impact model, analysts should:

- **Group drug comparators by indication**
- **Identify treatment strategies that can be compared to the new drug**
- **Seek adequate input (e.g., published studies, market research, expert opinion) to identify comparators and their use**

6.3 Forecasting of the Market Under the Reference Scenario

With data for the baseline year of the analysis now calculated, the next step is to forecast the data for the model over the time horizon of the model. When using software to generate forecasts that will be used in a BIA submission, only tools included in the basic installation of Microsoft Excel (or the modeling software package being used) should be included. All user-defined macros should be written and presented in a clear and transparent method and fully documented. These conditions should be met to ensure that F/P/T drug plan managers are able to use, understand, and evaluate the model.

Estimation of market growth

Estimation of market growth should be based on market intelligence and should be forecasted for the four years of interest (baseline year plus three-year time horizon). Commentary regarding the data supporting the market growth estimates should be provided. The magnitude of the estimated market growth is the product of two factors: general population growth and disease-specific changes.

When entering population growth statistics for a region or drug plan into the model, it is recommended that published, publicly available forecasts be used. Use of published forecasts ensures transparency and also ensures consistency between different submitted BIAs. If an existing and credible published forecast is available for the population of interest, it should be used and referenced. If existing forecasts cannot be identified, forecasts that are generated for the BIA should be based on a published and / or reliable source (e.g., a database derived from F/P/T drug plan data).

Historical population data and population projections for each province can be obtained from a number of reliable sources. The largest collection of relevant data and forecasts can be found at the Statistics Canada website (www.statcan.ca); however, data are also available directly from several provincial and federal sources. Table C-1 of Appendix C provides a selected list of reports and websites that provide data that can be used when developing BIAs.

To facilitate the estimation of population growth when developing population-based models, the budget impact model template provided with this document has been configured to incorporate population projections from Statistics Canada for each of the provinces of interest as well as for the Aboriginal population of Canada (excluding the Métis population). The most appropriate population growth scenario should be selected for the Reference Scenario. This determination should be made by comparing historical data to the available forecasts. The most aggressive and most conservative population projection estimates should be used within the sensitivity analyses. It has been assumed that the age-specific population growth rates for the general population are identical to those of the eligible participant population of the F/P/T drug plans.

As a result of changes in health care standards, drug benefit plans and other related issues, it remains possible that the number of patients treated for a given disease may change over the time horizon. Such changes should also be reflected in the market growth estimates used within the BIA. Information related to expected changes in the marketplace should be obtained from the drug plan and CADTH websites and publications, published literature, expert opinion, the evaluation of historical data and market intelligence. All references should be provided within the BIA report.

In the absence of such information, the growth rate should be assumed to be 0%.

6

Estimation of market share distribution

Once market projections have been generated, the next step is to estimate the market share distribution of the available treatment strategies over the time horizon. These estimates are needed for both the Reference Scenario where the new drug is not listed on the F/P/T formulary and the New Drug Scenario, where the new drug has obtained reimbursement status.

For the current market, data from a database containing public drug plan data should be used to determine how patients (or claims) are distributed between the available treatments. Year over year trends for each comparator should be calculated and these values should be used to forecast market share changes over the time horizon if deemed appropriate following an evaluation of expected market trends. If there is evidence to support the hypothesis that the market is stable (i.e., not changing), the market share distribution of the comparators may be left constant over the time horizon.

In some cases, one or more of the comparators being evaluated in the BIA will be indicated and used for more than one condition. Depending on the data source, these data may not be separable by indication. In cases where this separation cannot be performed using a specific database, published studies exploring this question should be accessed to help determine the percentage of patients being treated with the comparator that are using it for the indication(s) of interest. If published material is unavailable, expert opinion or internal market intelligence may be used. The selected source or sources should be referenced in the BIA report.

If it is expected that new treatments will become available or that existing treatments will become unavailable over the time horizon (e.g., drug discontinuation, anticipated listing of competitor, availability of generics), these estimates should be included in the BIA. In all cases, historical data from the same market for similar drugs should be used to determine how market disruptions might shift the distribution of available treatments. Alternatively, historical data from a private or foreign market that is similar to the market being modeled could be used to forecast market changes. Available market intelligence can also be used to forecast the market share distribution of the comparators. In the absence of all other information, the following strategies may be used:

Listing of a new competing treatment

- **The market share growth of the new treatment should mirror that of the proposed new drug.**

Treatment discontinuation

- **The market share held by the removed drug should be split amongst the remaining treatments proportional to the size of the market held by each comparator. For example, a treatment that held 80% of the market would be expected to capture 80% of the market share of the treatment that was removed from the marketplace.**

If the data suggest that a new comparator will be listed prior to the listing of the proposed new drug with a high degree of certainty, this should be used in the main analysis presented in the BIA. Sensitivity analysis should be used to evaluate the possibility that listing of the new comparator does not occur.

If the data suggest that a new comparator may be listed, but the likelihood of this event is uncertain, this scenario should be included in sensitivity analyses and the main analysis should be used to evaluate the current market distribution.

In the special case where a new drug is to be listed for which there are no comparators, the market used in the BIA that represents the Reference Scenario should be composed of no drugs, while the New Drug Scenario should be composed of only the new drug. This analysis represents the simplest format of a BIA, one where the budget impact is equal to the total cost of the drug being introduced.

In all cases, sufficient commentary should be provided in the BIA to explain the selection of data for all forecasts and the assumptions made to generate the forecasts.

In summary, to forecast changes in the Reference Scenario market, analysts should:

- **Avoid forecasting data using computer applications other than the application in which the budget impact model was developed**
- **Use published forecasts, whenever possible**
- **Access available databases to determine the current distribution of treatment strategies**
- **Develop forecasts that take into consideration anticipated changes (e.g. listing of a new competing treatment or treatment discontinuation) to the market over the time horizon**

6.4 Forecasting of the Market Under the New Drug Scenario

Following the addition of a new drug to a given F/P/T drug formulary, it is possible that the market dynamics that previously existed will no longer be applicable. Changes in the rate of market growth, the use of the available treatments and even the amount paid per year by the drug plan may occur following this addition to the marketplace. As such, it is important for those developing BIAs to ensure that adequate attention is paid to this issue when generating forecasts of expected market changes following the listing of the new drug.

The new treatment strategy mix used within the BIA should reflect how the market is expected to change due to the introduction of the new drug. In addition, the change in the market share distribution brought about through the introduction of the new drug should be explained. The rate at which the new treatment will capture market share from its comparators should be clearly documented and should be reported in a manner that reflects the market share captured from the preceding year of a given scenario.

It is recommended that BIA submissions include market data for products that have been on the market in other jurisdictions. When available, this information should be included either within the main body of the report or within an appendix. A brief evaluation of whether the presented data and / or data trends are likely to reflect expectations for the F/P/T drug plan markets should be provided. When such data are not available, it is up to the manufacturer to determine the best manner in which to predict the impact of having its new drug added to the F/P/T drug formulary. In the sections that follow, details pertaining to how these forecasts should be conducted are presented.

When generating forecasts, the analyst should first assess the information that is available. If the manufacturer has provided the analyst with market share projections for the new drug, these projections should be used within the model and should be referenced as being based on internal estimates. Use of these estimates is the preferred methodology of providing market share estimates as it is expected that the manufacturer will work towards achieving its market share targets over the time horizon.

If the manufacturer cannot provide market share forecasts, the market share of the new drug should be estimated based on the market share growth of the new drug in foreign markets or private payer markets. Foreign or private payer markets should only be utilized if the market is similar to the F/P/T drug plan market for which the BIA is being prepared or if the relationship between the F/P/T market and the foreign (or private payer) market is well understood.

If the new drug has not been listed on drug formularies in other jurisdictions, an alternative method of estimating its market share over the time horizon is to base projections on the market share of a similar product in a foreign or private payer market. As was noted above, data from these markets should only be used if the manufacturer is confident that the data are reasonable for the F/P/T drug plan for which the BIA is being prepared.

In cases where none of the above-mentioned methods can be used to estimate the market share of the new drug, the rate at which the drug gains market share should be forecasted based on published study data, expert opinion, previous experience and/or any other reliable data sources that provide details related to the anticipated usage of the drug. The factors that should be used to calculate the market share of the new drug may include:

- **Percentage of users of competing treatments who are eligible to use the new drug**
- **Percentage of physicians who are aware of the new drug**
- **Percentage of physicians who are willing to prescribe the new drug**
- **Percentage of users of competing treatments who are aware of the new drug**
- **Percentage of users of competing treatments who are likely to switch to the new drug**
- **Percentage of those who try and fail to respond to the new drug**

Additional criteria may be added to this list, as needed. The product of all the percentages for each year in the model represents the expected annual market share of the new drug.

Estimation of market growth

If the introduction of the new drug is expected to change the number of individuals treated for a given indication, this should be reflected in the forecasts used in the BIA. Estimates regarding such a change should be based on experience in foreign markets or with private payer plans, data from similar drugs that have entered the marketplace and/or expert opinion. Sensitivity analyses should be performed on any data-based estimates of market growth. If data-based high and low estimates cannot be generated, reasonable low and high estimates of the growth rate should be used. The reason behind the selection of a given low or high estimate should also be provided.

In the absence of data from which to extrapolate changes in market growth, market growth caused by the introduction of the new drug should be assumed to be 0%. This assumption should be stated explicitly and tested using sensitivity analyses that study the effect of reasonable annual increases or decreases in the size of the market (e.g., 5% increase). Justification for the use of a specific value for the sensitivity analyses should be given.

If there is strong evidence (or reliable expert opinion) to suggest that no market growth will be realized through the introduction of the new treatment, sensitivity analyses to study changes in market growth should not be performed. Evidence supporting that conclusion should, however, be provided in lieu.

In all cases, projections should be made for the entire time horizon of interest and commentary regarding the data supporting these estimates should be provided.

Market share estimation for new drug

The potential utilization of the new drug within the market will have a significant impact on the results of the BIA. As such, it is important to report all assumptions and calculations related to market share estimation for the new drug as thoroughly as possible. When estimating the market share distribution within the New Drug Scenario, the best source of data to inform the estimation of the market share distribution of the market is the use of historical data for the treatment strategies of interest from foreign markets or Canadian private payers. This method represents the best available method as it reflects observed market changes. The limitation of this approach is that it is difficult to evaluate how similar two different markets may be. As a result, information from one market may not be directly transferable to another.

An alternative approach is to develop a model that forecasts the market share of the new therapy based on inputs such as predicted patient awareness of the new drug, physician awareness of the new drug, probable switching behaviour, and other related factors. Under such a scenario, it is the potential changes in the market that are used in the model to estimate the incremental cost or savings realized by the F/P/T drug plan. Expert opinion should be used to assess the reasonableness of these estimates.

Estimation of displacement of existing therapies by new drug

The rate at which the new drug will capture market share will need to be estimated based on a series of explicitly stated assumptions. These assumptions should make use of all available intelligence to ensure that the generated forecasts represent the most reasonable estimate based on current knowledge and should be fully documented.

When calculating market capture, each forecasted year for the new market should be based on forecasts made for the previous year. For example, if 100% of the market share of a given comparator were assumed to be captured by the new drug in year 1, the amount of market share that would be captured in year 2 by the new drug would be 0%, as the comparator would hold 0% market share in the previous year.

In cases where no data are currently available to improve the quality of the market forecasts for each comparator or where the new drug is expected to increase the size of the market without causing patient switching, it should be assumed that the rate at which a new drug will capture market share from a given comparator is proportional to the market share of the comparator. For example, if Comparator A holds 75% of the market and Comparator B holds 25% of the market, it would be assumed that 75% of the new drug's growth would be derived from Comparator A and 25% of the new drug's growth would be derived from Comparator B.

In summary, to forecast changes in the New Drug Scenario market, analysts should:

- **Apply the general rules detailed for the forecasting of the Reference Scenario**
- **Consult drug-specific data from markets where the new drug is currently reimbursed, whenever possible**
- **Consider and appropriately reference current market intelligence on how the reimbursement of the new drug will affect the market**

6.5 Estimation of Drug Prices

Drug prices are a key component of BIAs and, as such, should be estimated with care. Factors such as the unit price of the drug and price adjustments such as mark-ups, dispensing fees and patient co-payments all play a role in determining the incremental cost or savings realized by granting a new drug reimbursement status. The following sections describe how these factors should be estimated and used within budget impact models.

Unit price for drugs currently reimbursed by F/P/T drug plans

When obtaining pricing information for the drugs included in the BIA, print or online versions of the F/P/T drug formulary price lists should be consulted. The most current version of the price list should be used. It should be noted that, under certain circumstances, the additional charges might already be included in the price shown in the provincial drug lists. As noted in Table A-1 of Appendix A:

- **The 2006 Alberta Health and Wellness Drug Benefit List includes a 7.5% wholesaler mark-up in some of the prices presented in the list. No distinction is made between those drug prices that include the mark-up and those that do not. As no method of distinguishing between those prices with mark-up and those without mark-ups exists, it should be assumed that wholesaler mark-ups have not been included in the price of listed drugs.[27]**
- **The 2006 Saskatchewan Health - Drug Plan Formulary includes a wholesaler mark-up in all prices listed in the formulary.[28]**
- **The 2006 Newfoundland and Labrador Interchangeable Drug Products Formulary includes a 9% inventory adjustment charge in all prices.[29]**

The prices used should be the most appropriate price for each comparator. The most appropriate price may represent the lowest reimbursed price for a specific chemical, the lowest reimbursed price for a type of therapy, the actual price of the drug, or some other price. The F/P/T drug formulary will indicate the price that should be used in most cases.

If it is known that the price reimbursed for a given drug is based on the drug's ex-factory price, the drug price may be obtained from the drug manufacturer. The price of the new drug will typically be obtained in this manner.

If the unit price cannot be obtained from either of these sources, wholesaler drug catalogues or providers of public drug plan data may be used to extract data pertaining to the price reimbursed for the drug in question. It is imperative that the data source be as recent as possible, preferably within the same calendar year as the other prices used within the model. This is because the prices calculated using these data do not represent current F/P/T drug plan costs and, as a result, may introduce error into the model by utilizing a drug price that is lower or higher than the actual price.

In all cases, the price used within the BIA should be derived from sources specific to the F/P/T plan being evaluated. For example, a BIA for the province of Ontario should use Ontario costs and not costs for the province of Alberta. The cost sources used should be clearly documented.

Unit cost estimation for drugs not currently reimbursed by F/P/T drug plans

For unlisted drugs that are expected to obtain listing in the future, the price of the drug should be estimated using the available data. If there are data to suggest that the drug will be launched at a specific price, these data should be used.

If the drug represents a lower dose version of an existing treatment, the price of the existing treatment should be used. This is because of the likelihood that the new treatment will be more expensive than the existing treatment is low. If the new drug represents one of a class of drugs, the lowest priced alternative within the class as defined by the drug plan should be used to set the price of the new comparator.

If the amount of information regarding the price of the unlisted comparator is limited, the price of the comparator should be set to the price of the drug for which the BIA is being submitted. This should be done to minimize bias in the analysis.

Any assumptions made about the price of drug comparators should be reported within the BIA report and tested using DSA.

Estimation of therapeutic equivalencies

When determining the cost per prescription or the patient cost per year within a BIA, it is important to accurately and transparently evaluate therapeutic equivalences. "Therapeutic equivalences" refers here to equivalence in use, not equivalency in therapeutic efficacy. For example, a therapy that is taken once a month and a therapy that is taken once a day cannot be fairly compared by looking at the unit prices alone. Instead, the frequency of drug use should also be factored into the comparison of the two treatments.

In order to allow for the equitable comparison of treatments, the number of units of a given treatment used per day and the number of days used per year should be clearly presented within the BIA. These figures, which are required for all treatments modeled within the BIA, should be derived from a database of public drug plan data. These data would provide a clear indication of the average number of units taken per day for each treatment; however, in some cases, this may not be an accurate reflection of the number of units needed for the budget impact model. An example of this would be if a treatment strategy of more than one drug were being examined. Under this scenario, the number of units taken per day as reported in the database would reflect drug use, irrespective of whether additional drugs were being taken concomitantly.

When estimating therapeutic equivalencies, it is also important to consider the duration over which each treatment is taken. For some treatments, patients will be expected to receive a given number of units per day each day over a 12-month period. The number of drug units taken per year and the number of claims filed per year may, however, vary between treatments. As a result, the days per period of treatment and the number of treatment periods per year should be included in the calculation of annual treatment costs.

In cases where data obtained from a public drug plan database can be argued to be inappropriate, product monographs and / or the Compendium of Pharmaceuticals and Specialties[30] may be used to estimate the number of units of treatment administered per day. Alternatively, expert opinion may be sought to inform this component of the budget impact model. In all cases, an explanation of why the selected data source is valid should be provided.

Inclusion of applicable mark-ups, dispensing fees, inventory allowances and patient co-payments

Each participating F/P/T drug plan has a specific reimbursement formula that it uses to determine the amount it is willing to pay, in excess of the ex-factory drug price, for drug mark-ups, dispensing fees and inventory allowances. In addition, patients are sometimes required to cover a portion of the cost of their prescriptions and the amount of this patient co-payment is also drug-plan specific. These price adjustments can be obtained from the web sites of the F/P/T drug plans. To reflect the amount paid by the drug plans accurately, it is necessary to include these price adjustments in the daily drug costs used within the developed model.

Although exact adherence to the reimbursement formula used by a given F/P/T drug plan will provide an accurate representation of the amount paid by the drug plan on an annual basis, not all drug plans wish to have all fee adjustments included in BIAs for new drugs. Table A-1, found in Appendix A, shows the 2006 wholesaler mark-up, pharmacy mark-up, inventory allowance, dispensing fee, and patient co-payment values identified for use in BIAs. These values must be confirmed by the appropriate F/P/T drug plan prior to their use in a submitted BIA.

In situations where F/P/T drug plans request the inclusion of dispensing fees, the number of times that dispensing fees are paid per year should be determined. This value should be based on the maximum number of days of drug treatment a pharmacy can dispense for a given claim. The maximum number of days of treatment can be obtained from the drug plans or from the annual Guidebook on Government Prescription Drug Reimbursement Plans and Related Programs produced by the Canadian Association for Pharmacy Distribution Management (CAPDM).[31] To calculate the number of claims filed (and the amount paid in dispensing fees), the model should divide the number of days in one year (365 days) by the maximum number of days of treatment obtained with one claim (e.g., 90 days). The reviewer should be able to vary the number of days of treatment obtained with one claim within the model to study its impact.

When a BIA is being conducted for a fixed combination therapy, dispensing fees should be included in the calculation of the impact of the new treatment on the overall drug plan budget. This is because the use of a fixed combination therapy reduces the number of submitted claims and thereby reduces the amount paid by the drug plan to cover dispensing fees. Wholesaler mark-up, pharmacy mark-up and inventory allowance should also be included, if they have a direct impact on the calculation of the dispensing fees covered by the drug plan. Co-payments need only be included in this situation if stipulated by the drug plan in question.

Estimation of Time to Refill (Optional)

In cases where data pertaining to the time between the refilling of patient prescriptions exists for all treatment strategies, this information may be included in the BIA to calculate the number of times dispensing fees are paid for each treatment in a given year. These data may not always be available for all treatment strategies. When evidence for all treatments is available, time to refill estimates may be used instead of the maximum number of days of treatment obtained with one claim provided by the drug plans. If data do not exist for all treatment strategies, time to refill estimates should only be included as sensitivity analyses. In the absence of data, time to refill estimates need not be included.

Time to refill can be estimated using data regarding compliance and persistence to therapy. For example, if patients were typically only 90% compliant when taking their medication, both the cost per day and the units taken per day for their medication would be reduced to 90% of their original values. This would translate into a reduction in the number of claims filled per year and would ultimately affect the annual impact of dispensing fees on the drug budget. Evidence supporting assumptions related to compliance should be documented and drug costs should be reduced accordingly. Data from databases and / or published studies should be used as evidence.

In all cases where time to refill estimates are included in the analysis, the variability around the time to refill estimates should be studied in sensitivity analyses and the degree of uncertainty clearly stated. Variability should be represented using the most appropriate method based on the data available (e.g., minimum and maximum values, 95% confidence intervals, etc.) and these values should be tested within the model.

In summary, to price each treatment strategy, analysts should:

- **Obtain reimbursement prices from the best available source(s), such as drug plan formularies, public drug plan databases and wholesaler catalogues**
- **Estimate the number of days of treatment for each treatment strategy (i.e., consider therapeutic equivalencies)**
- **Include appropriate price adjustments for the F/P/T drug plan for which the BIA is being performed**
- **Consider time to refill data to determine the number of times that dispensing fees are paid for each drug (optional)**

6.6 Calculation of Budget Impact

As shown in Figure B-1 of Appendix B, estimates from the Reference Scenario and the New Drug Scenario should be used to determine the incremental cost (or savings) realized by a drug plan. The value of each scenario is equal to the sum total of the annual cost of each treatment strategy. Estimation of the annual cost of a treatment strategy is dependent on the type of BIA performed by the analyst. If a population data-based model has been used, the annual cost of a treatment strategy is equal to:

> Annual number of patients x Annual market share of treatment strategy x Annual drug cost per patient

In the case where a claims data-based model has been used, the annual cost of a treatment strategy is equal to:

> Annual number of claims x Annual market share of treatment strategy x Drug cost per claim

The budget impact is equal to the difference between the value of the New Drug Scenario and the value of the Reference Scenario (i.e., New Drug Scenario Value minus Reference Scenario). A positive budget impact value indicates that the introduction of the new drug will result in increased expenditures for the drug plan, while a negative value indicates that the drug plan will save money by adopting the new drug.

Incremental prescription drug costs should be calculated for each of the three years of the time horizon. In addition, the cumulative incremental prescription drug costs for the time horizon should be evaluated. Summary calculations for the total direct drug costs in each year (Year 1, Year 2 and Year 3) and for all years (Years 1-3), should be presented by scenario to allow reviewers to understand how the budget impact was calculated.

7

Recommendations for Reporting Format

The recommended reporting format presented here, which has been adapted from the preferred ISPOR structure for BIA reporting, describes the information that should be presented to maximize the transparency of the BIA for each F/P/T drug plan.[32] Choices made during the development of the BIA should be fully documented and clearly described to help decision makers understand the methodology behind the submitted budget impact model.

7.1 Report Contents

Report Introduction

The report introduction should contain a summary of all the relevant epidemiological, clinical and economic information related to the disease indication of interest. The specific information to be included in the introduction is the following:

- **Epidemiology**

  Age- and gender-specific details regarding the prevalence, incidence, and risk factors for the disease in question should be reported in the introduction. A brief description of the pathology, prognosis, and progression of the disease should also be included.

- **Available and Future Treatments**

  As the market dynamics assumed in the model will be driven by assumptions related to both pharmacological and non-pharmacological treatment options, both types of treatments should be summarized in this section. If there are additional therapeutic options that are expected to become available by the end of the BIAs time horizon, these should be included in this description as well.

- **Economic impact**

  Studies that discuss the indication and treatments of interest should be discussed. These studies may include:

  - **Previous BIA studies in the condition of interest for another drug**
  - **Burden of illness studies**
  - **Cost-effectiveness or cost-utility studies.**

7

Technology

In this section, the characteristics of the new drug should be described. The description should include details regarding how the new technology compares to existing treatments. The specific characteristics that should be addressed in this section are:

- **Indication (based on the product monograph)**
- **Formulation**
- **Onset of action**
- **Efficacy**
- **Side effects**
- **Serious adverse events**
- **Intermediate outcomes**
- **Adherence/Compliance**

A brief summary of the clinical trials should also be provided in this section, including information on the design, study population, follow-up period, and clinical outcomes. This summary may be provided in a tabular format, if desired.

Objectives

The objective(s) of the BIA should be clearly stated. These objectives should state the population for which reimbursement is being sought, the time horizon being reported and the perspective used within the report. A clear statement of any limits to this analysis should also be included. For example, if the new drug will not affect current drug utilization patterns (i.e., market share distribution) but will decrease the need for specific health care resources, it should be noted that savings to the health care system have not been included due to the use of a drug plan perspective.

Study Design and Methods

The methods section of the report should provide sufficient detail to allow a third party to replicate the analysis. Each of the following model characteristics should be included:

- **Patient population**

  The patient population of interest should be clearly and succinctly defined within this section of the report. Details regarding restricted access to the new drug following its obtaining formulary listing should be noted.

- **Treatment strategy mix**

  Assumptions made regarding the treatment strategy mix included in the model for the Reference Scenario and the New Drug Scenario should be presented with justification. The selected treatment strategies should represent the treatment patterns and clinical guidelines of the F/P/T region of interest.

- **Perspective, Target audience and Time horizon**

  Unlike BIAs that may be performed in some other jurisdictions, Canadian BIAs focus exclusively on the impact that the listing of a new drug on the F/P/T drug formulary will have on the drug plan budget. Confirmation that the perspective used in the analysis is that of a drug plan should be provided. The specific plan for which the BIA was prepared should also be stated.

The reported time horizon should be three years from the anticipated date of listing for the new treatment.

- **Model description**

  A schematic illustration of the model should be provided, along with a detailed description of the structure of the BIA model.

- **Input data and data sources**

  To allow reviewers to replicate the submitted results, all values used within the BIA to generate results for all developed analyses should be presented within the report. Depending on the structure of the budget impact model, these parameters may include cost, epidemiological, or drug utilization data items.

  Each parameter value or set of parameter values should be described and referenced to allow the reader to assess the validity of the selected data. Selection criteria for studies and databases should be discussed to provide guidance for this assessment process. In addition, an indication should be given of the direction and magnitude of potential bias in the data sources that were used.

- **Data collection**

  The methods and processes employed for any primary data collection (e.g., expert opinion) or data abstraction (e.g., from databases) should be provided. In addition, any data, summary reports, or data collection forms / queries should be included as report appendices.

- **Primary analysis**

  A description of the methods used to calculate the total budget required to introduce the new drug and incremental prescription cost compared to the Reference Scenario should be provided for the main analysis. The description should be of sufficient detail and clarity to allow the reader to perform the same analysis and obtain the same results.

Results

When reporting the model results, both the total budget and the incremental budget impact should be presented for each year of the time horizon. Tables showing aggregated and disaggregated drug costs over time before and after applying costing information (e.g., mark-up, dispensing fees, patient co-payment) should be provided. An explanation of these results should accompany the provided tables.

7

Limitations and Assumptions

The submitted report should contain a clearly identified section that itemizes the known limitations and assumptions made to develop the model and / or report. The reason behind each limitation or assumption should be briefly noted within this section. In addition, a summary table should be included for simplified access to this information. The Limitations and Assumptions section should, at the very least, consist of the following subsections:

- **Limitations and Assumptions: Model Structure**
- **Limitations and Assumptions: Input Data and Data Sources**

Sensitivity Analyses

The results of the sensitivity analyses should be described and the choices made with respect to changes to the inputs used in the Reference Scenario should be justified. A table summarizing the results of the sensitivity analyses should be provided in this section. A graphical representation of the results should also be included (e.g., Tornado chart).

Sensitivity analyses should be presented within the main body of the report. Related sensitivity analyses should be reported together (e.g., sensitivity analyses pertaining to market size should be reported together and the range of the market size sensitivity analyses should be reported explicitly.)

Any limitations or assumptions specific to the sensitivity analyses should be reported as a subsection of this section in a manner similar to that used in the Limitations and Assumptions section.

Conclusion

A conclusion that summarizes the key information presented in the report should be included. The incremental budget impact for each of the three forecasted years as well as the incremental budget impact for the time horizon should be reported in this section.

References and Appendices

References should be provided and appendices are strongly advised to ensure the transparency of submitted BIAs. The inclusion of information related to data inputs used in the model and report will facilitate the assessment of each submission's validity.

7.2 Interactive Model

Submitted BIA models should include detailed descriptions and justification for all calculation steps performed. Models should be presented as a series of clearly defined steps to facilitate model review.

When developing a model to perform a BIA, the simplest design that generates reasonable results should be selected. For example, as BIAs do not consider the clinical impact of treatment, a disease model that employs more complex modeling techniques (e.g., Markov modeling) should not be required. In addition, the designed model should be built using a readily available software application, such as Microsoft Excel.

It is recommended that submitted BIA models be developed from the interactive BIA template provided with these guidelines. Analysts may modify the template to ensure that the final BIA is calculated as accurately as possible based on available data while maintaining overall model transparency.

7.3 Additional Submission Details

Use of Tables and Figures

Inclusion of graphical and / or tabular representations of the model structure, inputs and results will provide drug plan managers with a clearer vision of the structure and function of the budget impact model used to estimate a new drug's future budget impact.

All provided reports should contain the following items:

- **Schematic Representation of Model**

  A diagram that clearly explains the model's function should be provided. Sample formats include influence diagrams and decision tree structures. All schemas should be provided with descriptive text. This diagram may be developed as a drug-specific adaptation of the diagrams provided in Appendix B and the BIA model template.

- **Tables of Inputs and Outputs**

  Listing the model inputs (along with their references) and outputs in tables provides reviewers with an easily accessed summary of the model. These tables should be included in the Input data and data sources section of the report.

- **Table of Limitations and Assumptions**

  Listing the limitations and assumptions of the model improves its overall transparency. This table should be included in the Limitations and Assumptions sections of the report.

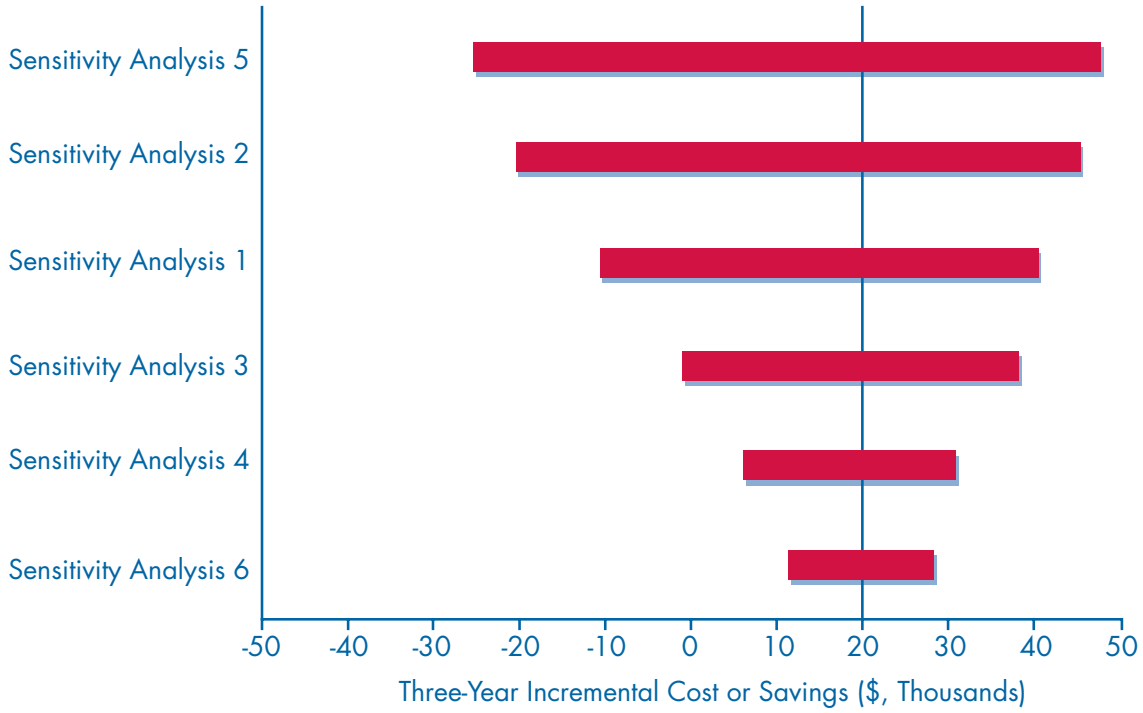
- **Schematic Representation of Uncertainty**

  Analysts are encouraged to use diagrams (such as Tornado diagrams) as an effective means of presenting the variables with the greatest impact on the model's results to BIA reviewers. These diagrams should be included in the Sensitivity Analysis section of the report.

When using diagrams to demonstrate the uncertainty inherent in a given model, summary results of the net impact to the budget for the three-year period (i.e., Years 1-3) following formulary listing should be presented. The net impact for individual years (i.e., Year 1, Year 2, Year 3) should only be presented if doing so provides additional insight regarding the model's uncertainty.

A sample Tornado diagram is shown in Figure 7 1. In this example, six categories of sensitivity analyses were performed and the ranges generated by these sensitivity analyses were plotted. The values considered all represent the budget impact for the three-year time horizon. In addition to plotting the sensitivity analyses, the three-year budget impact value from the main analysis, which was estimated to be $20,000 is also show and is represented using a line that intersects the x-axis at this value. The six sensitivity analyses were ordered along the y-axis such that the larger the range of values obtained for a category of sensitivity analyses, the closer the sensitivity analysis was positioned to the top of the diagram. Using the Tornado diagram, decision makers can quickly identify those assumptions that have the greatest impact on the budget impact model, as well as the expected range in costs (or savings) that will be realized by the drug plan if the new drug is added to the drug formulary.

Figure 7 1. Sample Tornado diagram for presenting sensitivity analyses



BIA Completion Checklist

Following the completion of the BIA, the manufacturer should complete and sign the BIA Completion Checklist presented in Appendix D.

Appendix A

Mark-Ups, Inventory Allowances, Dispensing Fees, and Patient Co-Payments

This table, which has been designed for use with standard BIAs, assumes that the number of filed claims is the same for all investigated treatment strategies (i.e., one drug per treatment strategy and equal time to refill). Analysts must confirm the values presented below with each respective drug plan to ensure that the most current values are utilized.

Table A-1: Mark-ups, inventory allowances, dispensing fees, and patient co-payments to be reported in standard budget impact analyses (Last Updated: October 2006)

Province or Drug Plan	Wholesaler Mark-up	Pharmacy Mark-up	Inventory Allowance	Dispensing Fees	Patient Co-payment
British Columbia	7%	0%	$0.00	$8.60	30%**
Alberta*	7.5%†	0%	See Table A-2	See Table A-2	30%
Saskatchewan	8.5%§	See Table A-3	$0.00	$8.21	$0.00
Manitoba	0%	0%	$0.00	$10.00	$0.00
Ontario	0%	0%	$0.00	$0.00	$0.00
Newfoundland & Labrador	0%	0%	9%§	$0.00	$0.00
Nova Scotia	0%	0%	$0.00	$0.00	$0.00
Prince Edward Island	0%	0%	$0.00	$0.00	$0.00
New Brunswick	0%	0%	$0.00	$0.00	$0.00
Non-Insured Health Benefits Program	0%	0%	$0.00	$0.00	$0.00

* The maximum patient co-payment for a given prescription is $25. In addition, the prescription cost may not exceed the actual acquisition cost of the drug x 5/3 for insulin and oral contraceptives. For injectables other than insulin, the prescription cost may not exceed the actual acquisition cost of the drug x 5/3, to a maximum of $100 more than the actual acquisition cost of the injectable drug. The actual acquisition cost is the cost borne by the pharmacy.[33]

† Included in some of the prices presented within the Alberta Health and Wellness Drug Benefit List[34]

§ Included in the prices presented in the provincial formulary[35,36]

** 25% for seniors (born in or before 1939).

Table A-2: Alberta Health and Wellness: Inventory Allowance and Dispensing Fees

Ingredient Cost (including Wholesaler Mark-up)	Inventory Allowance	Dispensing Fee
$0.00 – $74.99	$0.71	$10.22
$75.00 – $149.99	$2.00	$15.33
$150.00 or more	$5.03	$20.94

Table A-3: Saskatchewan Health: Pharmacy Mark-up

Ingredient Cost (including Wholesaler Mark-up)	Pharmacy Mark-up
$0.00 – $6.30	30%
$6.31 – $15.80	15%
$15.81 – $199.99	10%
$200.00 or more	$20.00

Appendix B

Schematic Representations of Budget Impact Model Calculation and Market Size Estimation

Figure B-1. Calculation of Budget Impact

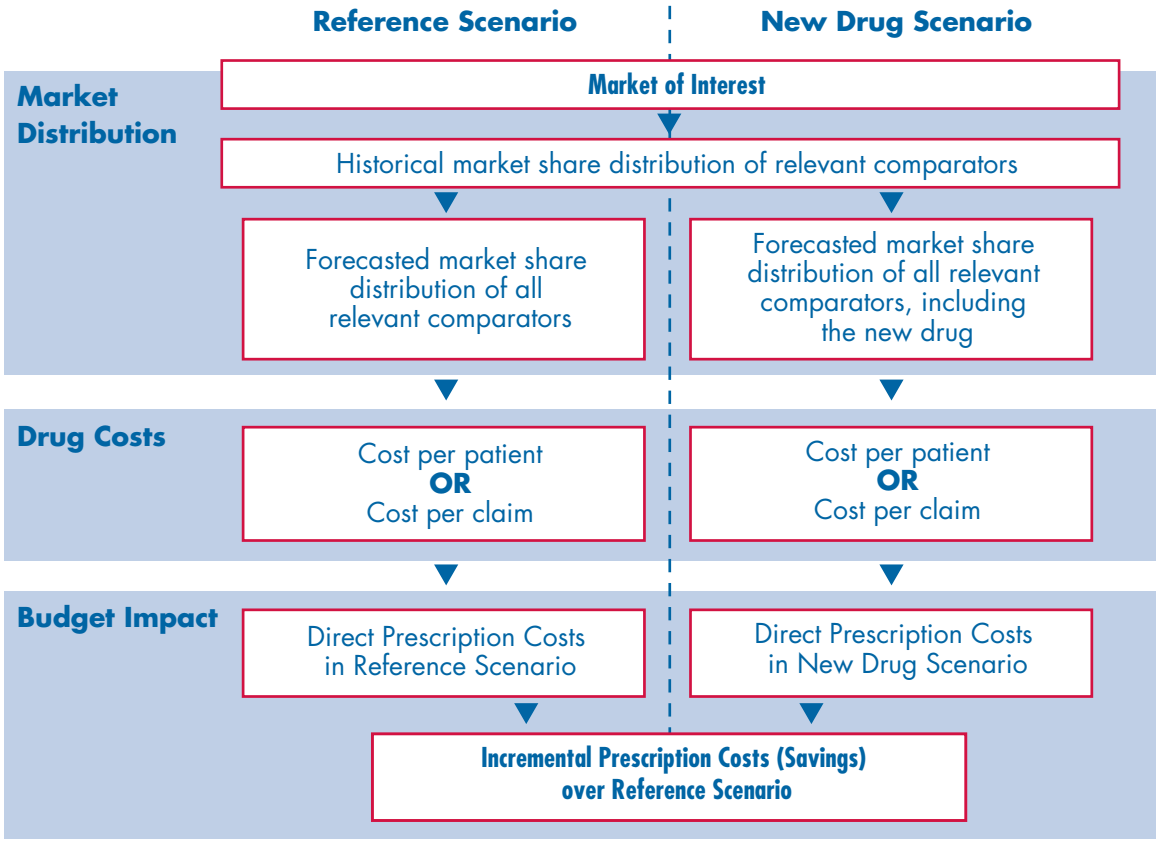
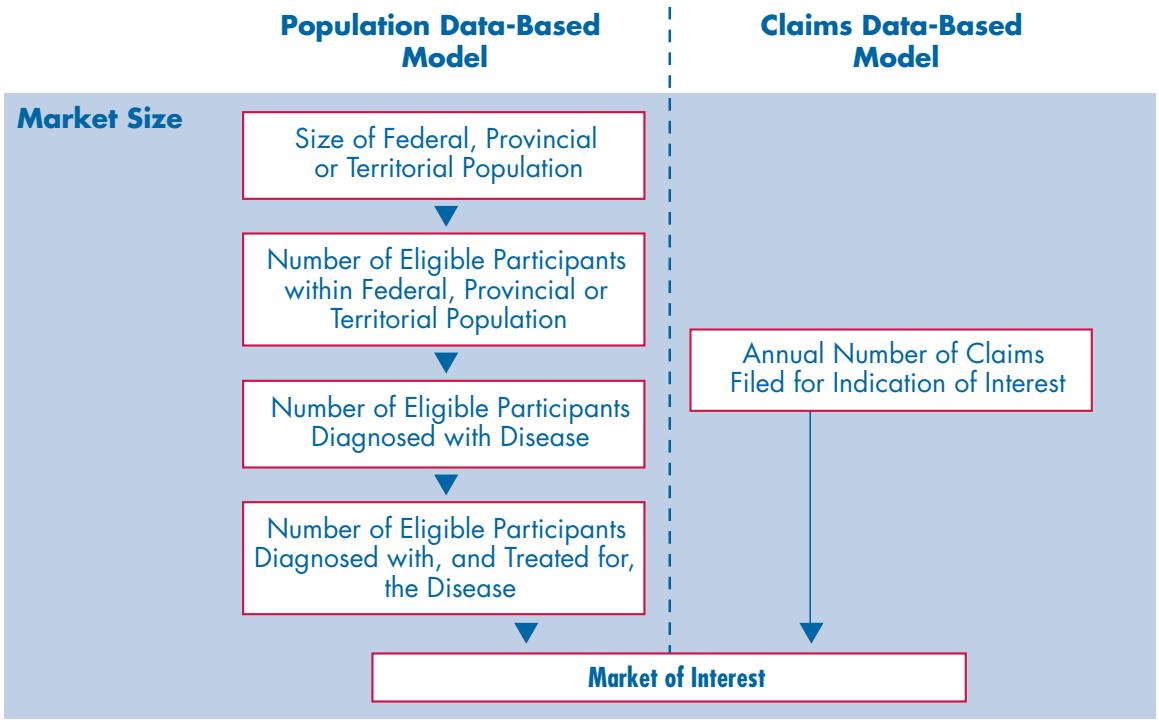


Figure B-2. Estimation of Market Size



Appendix C

Data Sources for Population Statistics and F/P/T Drug Plan Eligible Participant Counts

Table C-1: Selected list of drug plan data (Last updated: April 2007)

F/P/T Drug Plan	Eligible Participant Data Available	Comments
British Columbia	BC STATS: Population and Demographics, http://www.bcstats.gov.bc.ca/data/pop/popstart.asp	Calculated by subtracting the NIHBP population from the general population. Assumes that all those who are eligible to enrol in the program participate in the program and that participants in federal drug programs are negligible relative to the NIHBP population.
Alberta	Alberta Ministry of Health and Wellness - Alberta Health Care Insurance Plan Statistical Supplement 2004/2005, http://www.health.gov.ab.ca/resources/publications.html	
Saskatchewan	Saskatchewan Health, http://www.health.gov.sk.ca/mc_publications_ar_archive.html	Calculated by subtracting the NIHBP population from the general population. Assumes that all those who are eligible to enrol in the program participate in the program and that participants in federal drug programs are negligible relative to the NIHBP population.
Manitoba	Manitoba Health Annual Statistics 2003-2004, http://www.gov.mb.ca/health/annstats/200304/index.html	Calculated by subtracting the NIHBP population from the general population. Assumes that all those who are eligible to enrol in the program participate in the program and that participants in federal drug programs are negligible relative to the NIHBP population.
Ontario	http://www.pmprb-cepmb.gc.ca/CMFiles/PTOR_June_0638MBI-6232006-5829.pdf	Data are not available by age.
Newfoundland & Labrador	Not currently available	Active beneficiary data available at http://www.ag.gov.nl.ca/ag/2005AnnualReport/CH2.11.pdf.

F/P/T Drug Plan	Eligible Participant Data Available	Comments
Nova Scotia	Annual Statistical Report Supplement, http://www.gov.ns.ca/health/reports.htm#ASR%20Supplement	Eligible participant estimates are not available for individuals receiving Special Funding Assistance.
Prince Edward Island	2004/05 Ministry of Health & Social Services Program Profile, http://www.gov.pe.ca/photos/original/Health_PP_0405.pdf	Data are not available by age.
New Brunswick	http://www.pmprb-cepmb.gc.ca/CMFiles/PTOR_June_0638MBI-6232006-5829.pdf	Data are not available by age.
Non-Insured Health Benefits Program (NIHBP)	http://www.hc-sc.gc.ca/fnih-spni/nihb-ssna/index_e.html	

Total eligible participant counts for British Columbia, Alberta, Saskatchewan, Ontario, New Brunswick and the NIHBP are available from the PMPRB in the report: *Pharmaceutical Trends: Overview Report Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, and First Nations and Inuit Health Branch of Health Canada: 1997-1998 to 2003-2004* at http://www.pmprb-cepmb.gc.ca/CMFiles/PTOR_June_0638MBI-6232006-5829.pdf. The drug plan-specific distributions of eligible participants by age and gender are not available from this source.

Selected List of General Population Data and Population Projection Sources

Historical population estimates for Canada and each of its provinces and territories are provided by Statistics Canada. The reference for these data is:

> Statistics Canada, Annual Demographic Statistics, Catalogue no. 91-213-XIB, 2005. (http://www.statcan.ca/bsolc/english/bsolc?catno=91-213-X)

Similarly, population projections for Canada, each of its provinces and territories, and Canada's Aboriginal populations can also be obtained through Statistics Canada. References for these data are presented below.

> Statistics Canada, Population Projections for Canada, Provinces and Territories, Catalogue no. 91-520-XIE, 2005 to 2031. (http://www.statcan.ca/bsolc/english/bsolc?catno=91-520-X)
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Appendix D

BIA Completion Checklist

Upon completion of the BIA, the 'Checklist' should be completed and signed.

- ❑ Data specific to each drug plan are used.
- ❑ Justification is provided where data specific to a drug plan have not been used.
- ❑ Projections are for a 3-year time horizon.
- ❑ Projections are for each F/P/T drug plan.
- ❑ All relevant comparators are stated, including non-drug alternatives.
- ❑ All approved indications are listed, with recommended dosages and durations.
- ❑ Only relevant drug-based comparators are used for forecasting purposes.
- ❑ Total treatment strategy cost/patient/year (or total treatment strategy cost/claim(s)/year) is calculated, for each indication, based on recommended dose and using CURRENT pricing adjustment information for BIAs (i.e., mark-ups, inventory allowances, dispensing fees and patient co-payments).
- ❑ Disease prevalence information, specific to F/P/T drug plans, is provided.
  - ❑ Justification is provided where F/P/T specific data have not been used.
- ❑ Projected market share is reported as total number of patients (or claims), and percentage of total market.
- ❑ Market share is projected for 12 months from proposed listing date.
- ❑ Sources of market share, and proportion of market share from each source, are reported.
- ❑ Total drug costs are reported for F/P/T drug plans.
  - ❑ Lowest cost alternative is used, where applicable.
  - ❑ Projections are calculated using stated prevalence, market share and prescription costs.
  - ❑ All assumptions are listed, and references cited.
- ❑ Net budget impact is reported for F/P/T drug plans.
  - ❑ All assumptions are listed and references cited.

- ❑ Deterministic sensitivity analyses are conducted.
  - ❑ Price of any comparators and/or concomitant medications for which uncertainty exists.
  - ❑ Market share distribution amongst the new drug and its comparators.
  - ❑ Changes in the size of the market over the time horizon.
  - ❑ An explanation of the sensitivity analysis methods is included.
  - ❑ All assumptions are listed and references cited.
- ❑ The conclusions of the BIA are clearly stated.
- ❑ Budget impact model is included with submission.

Optional

- ❑ Additional relevant information may be attached (optional):
  - ❑ Utilization from other jurisdictions.
  - ❑ Treatment or dosage guidelines.
  - ❑ Comments on whether listing will significantly affect health care spending.
  - ❑ Additional BIAs appended that do not conform to this format (if applicable).

Signature: _____ Date: _____

Appendix E

List of Terms and Abbreviations

Active beneficiary – An eligible participant who files a claim

Budget Impact Analysis or BIA – An analysis of the impact of a new drug product on drug plan expenditures

CADTH – Canadian Agency for Drugs and Technologies in Health

CDR – Common Drug Review

CSC – Correctional Service Canada

DIN – Drug Information Number

Discount rate – The amount by which future costs and benefits are adjusted to enable the comparison of different years with each other and with current costs and benefits

DND – Department of National Defence

Drug – An active substance considered to be a drug under the Canadian Food and Drugs Act and Regulations, which is sold for human use

Eligible participant – A person who is eligible for coverage by a given F/P/T drug plan

Ex-factory price – The price charged by the manufacturer for a particular drug

F/P/T – Federal, provincial and/or territorial

Formulary – A list of drugs that are covered as benefits as determined by each F/P/T drug plan

Inflation rate – The average change in the price of goods and services over a period of time

ISPOR – International Society For Pharmacoeconomics and Outcomes Research

Manufacturer – A drug manufacturer

New Drug – A new active substance that has not previously been marketed in Canada

NIHBP – Non-Insured Health Benefits Program

NPDUIS – National Prescription Drug Utilization Information System

PMPRB – Patented Medicines Prices Review Board

RCMP – Royal Canadian Mounted Police

Treatment strategy – One or more active substances used in combination for the treatment of a medical condition

VAC – Veterans Affairs Canada

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