Canadian Agency for Drugs and Technologies in Health

Agence canadienne des médicaments et des technologies de la santé

CADTH

JANUARY 2012

THERAPEUTIC REVIEW FRAMEWORK

Supporting Informed Decisions

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1 Framework for Therapeutic Reviews

Purpose: The purpose of this document is to outline a framework and standardized process for therapeutic reviews that meets the needs of participating jurisdictions. The Canadian Agency for Drugs and Technologies in Health (CADTH) manages the process.

Definition: Therapeutic reviews are another type of review, in addition to the Common Drug Review (CDR) process, to support evidence-based decision-making. A therapeutic review is the review of publicly available evidence regarding a single drug (e.g., enalapril), or a category of drugs (e.g., angiotensin-converting-enzyme inhibitors [ACEIs]), or a class of drugs (e.g., antihypertensive agents). The scope and depth of the review are determined by jurisdictional needs.

An important characteristic of a therapeutic review is that it is conducted to coincide with a CDR submission review and thus, informs the CDR submission review and listing recommendation and informs drug plan decisions. The final outputs of the therapeutic review include one of the following:

- a recommendation(s) from the Canadian Drug Expert Committee (CDEC). The drug plans generally prefer recommendations
- advice from CDEC (based on analysis and synthesis of information)
- a report and conclusions.

Background: Drug plans evaluate and consider the addition of new drugs to their formularies. They do this based on favourable efficacy, safety, and cost-effectiveness analyses of available information, as reviewed and recommended by CADTH. However, decisions are also made in the context of existing coverage policies of therapeutically related drugs. To support drug listing and policy decisions, relevant and timely evidence-based therapeutic reviews that also include drugs without regulatory approval are an important input in the decision-making process.

Therapeutic reviews follow a standardized process by which drugs are periodically evaluated to ensure that they are being reviewed and reimbursed appropriately — i.e., whether their listing status should be more or less restrictive. Associated with changes in listing status, steps to optimize prescribing and use may be required. Generally, a therapeutic class review is undertaken to address, but is not limited to, the following:

- issues regarding effectiveness, either of the class as a whole or of the relative effectiveness of agents within the class
- issues regarding safety, either of the class as a whole or of the relative safety of agents within the class
- issues that affect resource use
- concerns regarding inappropriate utilization of agents within a class.

Key considerations for therapeutic reviews include the following:

- The process must be initiated early enough so that a high-quality product that meets the needs of stakeholders is completed in time for the CDEC meeting at which the CDR drug submission is being considered.

- The process must be streamlined to include appropriate consultation and input; at the same time, it must be efficient and avoid duplication.
- The topic and report must be relevant to the needs of the jurisdictions and to CDEC.

Note: Selected terms in this document are defined in Appendix 1.

Changes to Therapeutic Review Framework: CADTH may amend, from time to time, the Therapeutic Review Framework in consultation with the participating drug plans. Amendments to, and clarifications of, the framework and all related documents may be effected by means of directives (updates) issued by CADTH from time to time.

2 Principles

The following principles were established with input from the jurisdictions:

a) Relevance of Therapeutic Reviews to Jurisdictions

The output content of therapeutic reviews needs to be practical, so that jurisdictions can use it to facilitate decision-making:

- Jurisdictional input and feedback will be sought throughout the therapeutic review.
- Scope and outputs of therapeutic reviews will be determined by jurisdictional needs — i.e., to advise a targeted policy question or to provide context.
- Content and considerations need to be sufficient to support decision-making or, in some cases, to provide information and/or education.

b) Evidence-Based Approach

Therapeutic reviews are rigorous and evidence based, using publicly available evidence and recognizing the levels of evidence:

- highest level of available clinical and economic evidence to be used
- lower levels of evidence to be considered when appropriate, but the level (e.g., case studies versus randomized controlled trial [RCT]) must be explicitly indicated).

c) Time Frames and Timeliness

Note: Time frames for submissions undergoing CDR review for listing recommendations are not affected by time frames for therapeutic reviews. CDR submission reviews follow the targeted time frames posted on the CADTH website.

Outputs of therapeutic reviews need to be produced in a timely manner to align with CDR submission time frames. Time frames are influenced by:

- scope of review (including number of drugs and comparators and outcomes)
- research question
- type and volume of evidence
- need for *de novo* economic reviews
- methodology and rigour
- whether peer review and/or stakeholder feedback is solicited
- whether recommendation(s) is required versus conclusion(s) only.

Note: CDEC may make a recommendation or provide advice, based on a therapeutic review, at the same meeting as it makes a recommendation or provides advice on a CDR submission.

d) Transparency

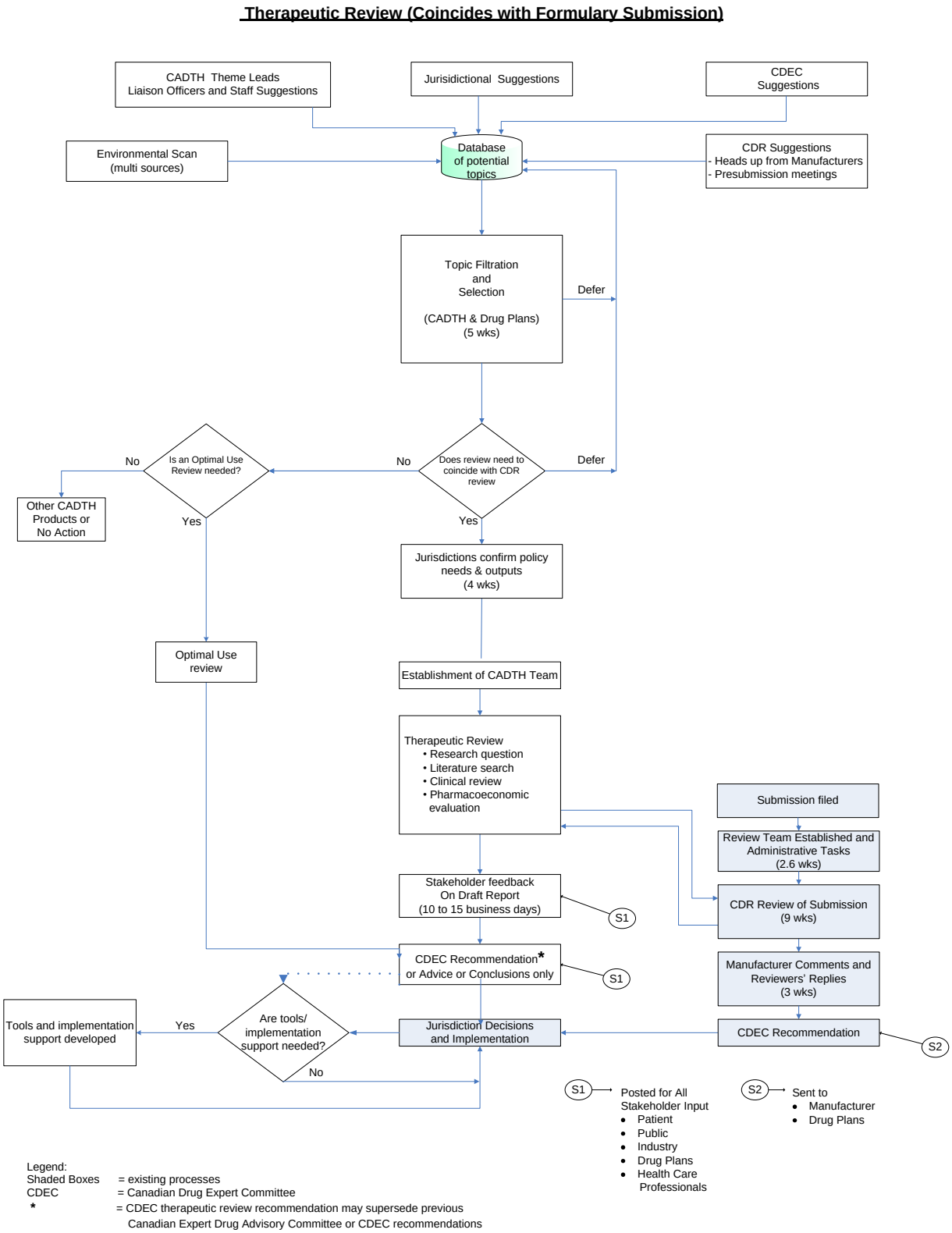
The therapeutic review is conducted in an open and transparent fashion, considering the following:

- Stakeholders' (various — public, patient, expert, industry, etc.) input is sought as required to facilitate a rigorous review.
- The primary source of data is in the public domain. All stakeholders will be given the option of identifying and providing unpublished data on the condition that, if used, it would be included in publicly available reports and documents, related to the therapeutic review.

e) Therapeutic Review Outputs and Usability

- Therapeutic reviews are undertaken to inform drug listing and drug policy decisions and to inform optimization of drug therapy.
  - Therapeutic reviews of a particular drug class can be initiated prior to a new drug, a drug with a new indication, or a Pre-Notice of Compliance (Pre-NOC) drug (i.e., a drug for which a NOC is pending) in that class being submitted for review through the CDR process.
- Outputs can include the following:
  - A recommendation from CDEC, tailored depending on the topic and audience, is generally preferred by most plans.
  - Advice from CDEC (based on analysis and synthesis of information) is another option if a recommendation is not required.
  - A report and conclusions can sometimes meet jurisdictional needs.

3 Flow Chart


Therapeutic Review (Coincides with Formulary Submission)
CADTH Theme Leads
Liaison Officers and Staff Suggestions
Jurisidictional Suggestions
CDEC
Suggestions
Environmental Scan
(multi sources)
Database
of potential
topics
CDR Suggestions
- Heads up from Manufacturers
- Presubmission meetings
Topic Filtration
and
Selection
(CADTH & Drug Plans)
(5 wks)
Defer
No
Is an Optimal Use
Review needed?
No
Does review need to
coincide with CDR
review
Defer
Other CADTH
Products or
No Action
Yes
Yes
Jurisdictions confirm policy
needs & outputs
(4 wks)
Optimal Use
review
Establishment of CADTH Team
Therapeutic Review
• Research question
• Literature search
• Clinical review
• Pharmacoeconomic
evaluation
Submission filed
Review Team Established and
Administrative Tasks
(2.6 wks)
Stakeholder feedback
On Draft Report
(10 to 15 business days)
S1
CDR Review of Submission
(9 wks)
CDEC Recommendation*
or Advice or Conclusions only
S1
Manufacturer Comments and
Reviewers' Replies
(3 wks)
Tools and implementation
support developed
Yes
Are tools/
implementation
support needed?
Jurisdiction Decisions
and Implementation
CDEC Recommendation
S2
No
S1
Posted for All
Stakeholder Input
• Patient
• Public
• Industry
• Drug Plans
• Health Care
Professionals
S2
Sent to
• Manufacturer
• Drug Plans
Legend:
Shaded Boxes = existing processes
CDEC = Canadian Drug Expert Committee
* = CDEC therapeutic review recommendation may supersede previous
Canadian Expert Drug Advisory Committee or CDEC recommendations

4 About the Flow Chart

The flow chart is a schematic depiction of the therapeutic review process. More detailed descriptions of the process are provided in the following text.

5 Identification of Therapeutic Reviews

Early identification of therapeutic reviews is integral to the Therapeutic Review Framework: this facilitates adequate time for a relevant, high-quality therapeutic review to be completed for use as background for a CDR submission. Therapeutic reviews will not be conducted to inform all CDR submissions.

5.1 Identification of Potential Therapeutic Reviews

Through an ongoing worldwide and Canadian scan for new drugs, new indications and emerging issues related to existing drugs, jurisdictions and CADTH work jointly to identify and select therapeutic review topics. To narrow the number of potential therapeutic reviews, jurisdictional input is necessary to identify those therapeutic reviews of most relevance to them.

- Jurisdictions consider factors related to policy issues to help identify potential therapeutic reviews:
  - when two or more new drugs with the same or similar indication are expected for future submission to the CDR
  - when a CDEC "List" or "List with Criteria" recommendation triggers a coverage policy review of existing drugs (i.e., reimbursement policies)
  - if jurisdictional non-policy drug issues need CDEC input
  - if a previous Canadian Expert Drug Advisory Committee (CEDAC) or CDEC Recommendation suggests a therapeutic review of drugs in a class.
- Jurisdictions may consider other factors, including social, legal, ethical and equity, environmental, political, entrepreneurial, and research (innovation) issues.

In association with a therapeutic review, jurisdictions may require implementation support or outreach work. To facilitate the development of these tools, it is desirable that these be identified at the same time as the therapeutic review is identified.

- Factors that may be considered for determining whether implementation support/outreach work is required include:
  - large deviations from optimal utilization (overuse or underuse) when data are available from the Canadian Institute for Health Information (CIHI) or other independent data providers
  - a new intervention having become available
  - size of patient populations
  - impact on health outcomes and/or cost-effectiveness or budgets
  - benefits to multiple jurisdictions
  - measurable outcomes
  - the potential to effect change in prescribing and use (to the extent that evidence is available).

5.2 Background for selecting therapeutic reviews

For each potential therapeutic review topic that the jurisdictions and CADTH identify through consultation, CADTH staff prepares a document that provides background to assist in selecting the therapeutic reviews to be conducted. Developing the document usually requires research of published and non-published information, including communications with jurisdictions to obtain further background such as:

- a jurisdictional survey of coverage status and policies for appropriate comparator products
- a survey of potential policy or non-policy decisions for which jurisdictions require a therapeutic review
- deviation from recommended use of a drug or drugs.

Factors considered in preparing the preliminary workup include:

- **Relevance**
  a) *Clear jurisdictional need*
     - The policy/decision problem(s) explaining why the therapeutic review is needed is described. Evidence of suboptimal health policy or variation in clinical practice that supports the need is provided.
     - The current funding policy, as well as current utilization and practice related to the drug class targeted for assessment, is described.

  b) Aligned with priority themes
  A description of how the topic relates to CADTH priority theme area(s) is provided; however, it should be noted that therapeutic review topics are not limited to priority themes.

- **Timeliness**
  a) *Meet requested timelines*
     - A description of when each deliverable is required, with specific dates, is provided.

  b) *CADTH capacity*
     - An indication of whether and when internal or externally contracted resources are available to undertake the proposed topic is provided.

  c) *Partnerships available*
     - Any knowledge partners who may assist with the development and dissemination of the report are identified.

- **Impact**
  a) *Clinical practice*
     - A description of how project findings and recommendations may change clinical practice (for example, educational program development/academic detailing initiatives aiming to change prescribing behaviour) is included.

  b) *Population*
     - A description is provided of the population in Canada that might benefit from the technology targeted for assessment, the Canadian prevalence of the condition(s), and how Canadians will be affected by anticipated funding, policy, or behaviour changes resulting from CADTH work (e.g., impact on quality- and disability-adjusted life-year).

c) *Cost impact (savings or other) on health care system*
   - A description is included of the type of health care costs (e.g., direct, indirect, governmental, societal), how the impact will occur (e.g., change in purchasing decision, change in drug formulary policy, etc.), and the estimated cost impact.

d) *Duplication of effort*
   - Similar work recently published or undertaken by other organizations is reported. If relevant work is found, opportunities for partnerships in research activities or the dissemination of the information are identified for consideration.

e) *Scope and extent of customer base*
   - A description of the size and composition of who will be affected by the therapeutic review (e.g., policy-makers in publicly funded health services, clinicians, or health care practitioners and patients).

f) *Uptake*
   - The readiness for the uptake of CADTH work (e.g., possibility of changing practice) is estimated.

5.3 Confirmation of therapeutic review project

Following consideration of factors in sections 5.1 and 5.2, the jurisdictions confirm which therapeutic review report(s) need to be undertaken.

6 Procedure for Therapeutic Reviews

(Note: Therapeutic reviews are prepared to coincide with a CDR review of a formulary submission.)

CADTH has developed processes that yield a reproducible, transparent, and rigorous review of the available clinical evidence and cost-effectiveness evidence on a topic through the systematic gathering, analysis, and interpretation of data from research studies and other scientific sources. CADTH processes reflect nationally and internationally recognized standards and methodologies. New methodologies for assessing drugs are continuously monitored and evaluated, and those that are found to enhance current CADTH processes are incorporated.

Each therapeutic review requires customization, depending on the output that is required by the jurisdictions and CDEC, the nature of available information, and available time. CADTH — with input from jurisdictions and CDEC — will consider the most feasible of a range of options for conducting the therapeutic review. These may include simply adapting or supplementing an existing drug class review, or undertaking a CADTH systematic review and/or meta-analysis of available data and a CADTH-generated pharmacoeconomic evaluation or other approaches.

CADTH may collaborate or develop partnerships with other parties to undertake therapeutic reviews.

Following are some points guiding the therapeutic review:

- Jurisdictions play a key role in identifying policy issues, prioritizing them, and ensuring that they are translated into relevant research questions.

- The therapeutic review is based on data in the public domain so that it can be shared with all manufacturers and stakeholders and be published. Stakeholders may provide unpublished data; however, if used, these data will be included in publicly available documents. CDR submissions will not be used in the therapeutic reviews. Confidential information in a CDR submission will be respected and used solely for the purpose of reviewing that particular CDR submission.
- Regular and frequent communications between the CDR Review Team and the Therapeutic Review Team take place throughout both projects.

6.1 Therapeutic Review Team

A Therapeutic Review Team is established for each therapeutic review, taking into consideration the proposed team members' qualifications, expertise, and compliance with the Conflict of Interest Guidelines. Clinical specialists, economists, and other experts (e.g., methodologists and statisticians) are included on the Therapeutic Review Team, as required. The names of the Therapeutic Review Team members are not disclosed.

6.2 Stakeholders Are Notified

Stakeholders are apprised of the therapeutic review — target dates for the different types of input are provided. While notice of the therapeutic review is posted on the CADTH website, affected manufacturers and stakeholders will also be notified directly.

6.3 Protocol Is Developed

- The protocol for undertaking the therapeutic review is developed at the outset of the project. The protocol addresses the scope of the project and describes the strategy for identifying and selecting clinical and economic information and the processes for assessing the data and synthesizing the findings.
- The protocol is adjusted based on inputs and various factors.
- Input is obtained, as required, from CDEC, specialists, and general practitioners and experts, patients, public members and jurisdictions in the development of the protocol, including but not limited to assisting in developing research questions, identifying relevant outcomes, and identifying any issues.

6.4 Evidence Is Assembled

- Based on a search strategy developed in collaboration with the Therapeutic Review Team, an information specialist(s) systematically searches the literature to find all existing clinical and economic evidence, including grey literature relevant to the project's objective.
- The Therapeutic Review Team reviews the identified abstracts and selects the relevant studies.
- Drug utilization data are obtained as required.

6.5 Evidence Is Assessed

- The Therapeutic Review Team systematically gathers, critically appraises, analyzes, and interprets the clinical and economic data from research studies and other scientific sources to generate a reproducible, transparent, and rigorous review of the available clinical evidence and cost-effectiveness evidence. If required, the Team undertakes an economic study by

developing and populating an economic model and analyzing the economic data. The scientific data and research results are included in a written report that is relevant to jurisdictions and/or CDEC.

- Whenever feasible, CADTH uses relevant existing therapeutic reviews.

6.6 Draft Therapeutic Review Report

The draft Therapeutic Review Report is written by the Therapeutic Review Team. The report includes an introduction that provides the context for the therapeutic review; a description of the protocol, search strategy, and methodology used to analyze the evidence; and clinical review and pharmacoeconomic evaluation sections with evidence tables (may be presented as appendices) and results and conclusions.

6.7 Stakeholder Feedback Is Obtained

(Note: The involvement of stakeholders in the therapeutic review process is summarized in Appendix 2.)

Stakeholders are invited to provide comments on the draft Therapeutic Review Report. Stakeholders will have an opportunity to identify any studies or evidence that may have been missed and to identify any errors or misinterpretations.

- The draft report is posted on the CADTH website and also forwarded to targeted stakeholders (e.g., affected manufacturers and patient groups) for feedback and comments.
- Time allowed for comments will be from 10 to 15 business days, depending on project time lines.

6.8 Stakeholder Feedback Is Collated, Reviewed, and Incorporated

The Therapeutic Review Team collates, reviews, and considers all of the feedback provided by stakeholders. Any identified errors or omissions are addressed and relevant comments are incorporated into the final report. The feedback is also shared with CDEC.

7 CDEC

CDEC is a CADTH advisory body; composed of individuals with expertise in drug therapy and drug evaluation, and public members. The mandate of CDEC is advisory in nature and is to provide recommendations or advice to CADTH to inform:

- decisions regarding listing of drugs within the publicly funded health care system in Canada
- decisions and strategies regarding optimal use of drugs in Canada.

The approach is evidence based and the advice reflects medical and scientific knowledge, current clinical practice, economics, ethical considerations, patient perspectives, and social values.

Therapeutic reviews are used to inform strategies regarding optimal use of drugs in a drug-class, for a particular indication. For deliberations on therapeutic reviews, specialist experts, identified and recruited for their expertise and extensive knowledge of the particular subject matter, are appointed to CDEC.

CDEC is apprised of a therapeutic review at its earliest stages and is updated on its status throughout the therapeutic review's life cycle.

The finalized Therapeutic Review Report, as well as other related supporting documents, are provided to CDEC. CDEC uses this information in the following ways:

- as background for making a listing recommendation regarding a submission to CDR for a drug that is in the drug class included in the therapeutic review
- as background for making recommendations or providing advice regarding the class of drugs included in the therapeutic review.

8 Therapeutic Review Outputs

Depending on the needs of the jurisdictions, the outputs resulting from a therapeutic review could be a CDEC recommendation, CDEC advice, or the Therapeutic Review Report with conclusions.

8.1 CDEC Recommendations

A CDEC recommendation based on the Therapeutic Review Report is provided to address research questions raised by jurisdictions.

(Note: A recommendation(s) based on a therapeutic review may supersede a previous CEDAC or CDEC recommendation.)

8.2 CDEC Advice

In some situations, it might be appropriate for CDEC to issue advice regarding the therapeutic review. Advice could also take the form that further CADTH work (e.g., development of implementation tools or guidance on evidence development) be considered.

8.3 Therapeutic Review Report with Conclusions

For some topics, the jurisdictions may simply require a report with conclusions.

9 Stakeholder Feedback on CDEC Recommendations or Advice related to Therapeutic Reviews

The CDEC recommendations or advice related to the Therapeutic Review will be posted for stakeholder feedback. Targeted stakeholders will be contacted directly. The finalized Therapeutic Review Report may be made available to stakeholders as background for the recommendations or advice.

Stakeholders will have from 10 to 15 business days to provide feedback on the CDEC recommendation or advice. Jurisdictions may request clarification of the recommendation or advice. During this time, jurisdictions will not act on the CDEC recommendation or advice.

10 Final Therapeutic Review Documents

The stakeholder feedback is collated and provided to CDEC. At a CDEC meeting, CDEC considers all of the feedback and makes revisions or adjustments to the recommendation or advice as appropriate.
The final recommendations or advice are issued to the jurisdictions and affected manufacturers. They are also posted on the CADTH website. The final Therapeutic Review Report, not necessarily in its entirety, will be posted on the CADTH website.

11 Tracking Therapeutic Reviews

Targeted time frames for the therapeutic review will be posted on the CADTH website.

12 Updating Therapeutic Reviews

Therapeutic reviews may be updated as required based on, but not limited to, the following: new information about the safety and/or effectiveness of the drugs within the class, changes in drug policies, and changes in pricing.

Appendix 1: Definitions

Advice — Advice consists of a statement(s) provided by CDEC (for drugs) that provides direction regarding a policy decision or course of action related to the optimal use of a drug, but does not make a recommendation. Advice is issued based on the assessment of supporting evidence.

Business Day — Any day (other than a Saturday, Sunday, statutory holiday, or company holiday) on which the CADTH office is open for business during normal business hours.

CADTH — The Canadian Agency for Drugs and Technologies in Health is an independent, not-for-profit agency funded by Canada's federal, provincial, and territorial governments. CADTH's role is to deliver reliable, timely, and credible evidence-based information and impartial advice to Canada's health care leaders and decision-makers through a variety of customized products and services.

Canadian Drug Expert Committee (CDEC) Committee — a CADTH advisory body composed of individuals with expertise in drug therapy and drug evaluation, and public members. For drugs reviewed through the CDR process, CDEC makes formulary listing recommendations for use by the participating federal, provincial, and territorial publicly funded drug plans. CDEC also provides other drug-related recommendations or advice, based on CADTH reviews, to inform decisions and strategies including optimal use of drugs in Canada.

Common Drug Review (CDR) — Under the CDR process, CADTH conducts objective, rigorous reviews of the clinical and cost-effectiveness of drugs, and provides formulary listing recommendations to the publicly funded drug plans in Canada (except Quebec).

Health Technology Assessment (HTA) — A health technology assessment (HTA) is an evaluation of the clinical effectiveness, cost-effectiveness, and broader impact of medical technologies and health systems on both patient health and the health care system. HTAs support and inform effective, evidence-based decisions about health policy and purchasing, service management, and clinical practice.

Implementation Tools — These are knowledge exchange tools used to enable health care decision-makers to use the guidance and/or recommendations that are developed. Tools may include summaries, presentations, conferences or workshop materials, continuing education content, and interactive tools (i.e., electronic tools) that allow decision-makers to customize the guidance with their own information.

Jurisdictions — Jurisdictions involved in therapeutic reviews include federal, provincial, and territorial health ministries from across Canada, with the exception of Quebec.

Optimal Use — Use of a drug or health technology that balances maximized benefits with minimized risks for people's health based on quality evidence, taking into account the options, costs, available resources, and societal context.

Product — A deliverable that is provided to a customer.

Recommendation — An evidence-based listing recommendation made by CDEC after consideration of Review Criteria, in response to a Submission or Resubmission made by a Manufacturer, the Formulary Working Group (FWG), or one or more Drug Plans, or in response to a Request for Advice regarding a CDEC Recommendation or Reasons for Recommendation made by

the FWG, or one or more Drug Plans. Recommendations can also be evidence-based recommendation(s) made by CDEC based on a therapeutic review.

Stakeholders — Stakeholders for therapeutic reviews are organizations, institutions, or individuals who have a strong and vested interest in specific therapeutic reviews and their outcomes. Stakeholders may include federal/provincial/territorial Ministries of Health, hospitals and health institutions, health regions, patients' groups and caregivers, health professionals, and industry.

Targeted Stakeholders — Parties who have a vested interest in a specific therapeutic review project. Parties may include the jurisdictions, the requestor, associations, industry groups, patient groups, and/or other interested organizations.

Therapeutic Review — Therapeutic reviews are another type of review that is eligible through the Common Drug Review (CDR) process to support evidence-based decision-making. A therapeutic review is the review of the most recent publicly available evidence regarding a single drug (e.g., enalapril), or a category of drugs (e.g., angiotensin-converting-enzyme inhibitors [ACEIs]), or a class of drugs (e.g., antihypertensive agents). The scope and depth of the review are determined by jurisdictional needs.

An important characteristic of a therapeutic review is that it is conducted to coincide with a CDR submission review and thus, informs the CDR submission review and listing recommendation and informs drug plan decisions. The final outputs of a CADTH therapeutic review include a clinical and economic review with conclusions, a recommendation(s) or advice document, and may include tools if requested. (CDEC recommendations are generally the most valuable output to most drug plans; however, advice from CDEC based on analysis and synthesis of information or a report with conclusions is another option if a recommendation is not required.)

Appendix 2: Stakeholders' Input into Therapeutic Review

Stakeholder	What	Priority*	How	When
Jurisdictions	Policy and listing issues and practice issues	Mandatory	See flow diagram (section 4 of this document)	Throughout the process
CDEC	Input into research question development and guidance for evidence threshold; populations identification; outcomes What information is needed to make a recommendation? Identify any practice issues	Mandatory	Via email or teleconference	When topic has been selected for CDEC review
Clinical Input (specialists, general practitioners)	• Provide context for developing RQ: Understanding of current clinical approach and therapeutics, natural history of disease, comparators, outcomes, interpretation of evidence, populations, upcoming therapeutic or diagnostic trends • Identify therapeutic issues and controversies • Identify clinical practice issues that are not captured by clinical evidence review	Mandatory	Subcommittee (including specialists, plus CDEC members, other experts as required) Clinical consultants as required	Review process (early)
Public	• Societal perspective, such as fairness, equity of access, identification of vulnerable populations • Integrate into RQ as needed	Mandatory	Use CDEC public member	Review process (RQ) and CDEC meeting
Patient	• Provide patient perspective • Provide insight into impact of disease on quality of life and how drug therapy has impact on disease	Mandatory	Use existing CDR patient input process to identify patient groups	Review process
Industry	• Comment on draft Therapeutic Review Report and draft CDEC therapeutic review recommendations or advice	Mandatory	Targeted email (affected mfrs) and web-based	Review process and post-review
All Stakeholders (including health care professionals and speciality clinical groups)	• Draft reports will be posted for stakeholder feedback prior to CDEC • Draft CDEC recommendations will be posted	Mandatory	Web-based Targeted email (health care professionals and specialty groups when relevant)	Post-review process Post-CDEC

* Priority — input is mandatory or optional, depending on the issue.
CDEC = Canadian Drug Expert Committee; FWG = Formulary Working Group; mfrs = manufacturers; ODB = Ontario Drug Benefit Program; OUWG = Optimal Use Working Group; RQ = research question; SMC = Scottish Medicines Consortium.