HOUSE OF COMMONS
CANADA

PRESCRIPTION DRUGS

PART 1 — COMMON DRUG REVIEW:

AN F/P/T PROCESS

Report of the Standing Committee on Health

Joy Smith, MP
Chair

DECEMBER 2007

39th PARLIAMENT, 2nd SESSION

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has the honour to present its

SECOND REPORT

Pursuant to its mandate under Standing Order 108(2), the Committee has studied the subject of Prescription Drugs — Common Drug Review and presents its findings and recommendations.

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PRESCRIPTION DRUGS — PART I

THE COMMON DRUG REVIEW: AN F/P/T PROCESS

INTRODUCTION

In December 2006, the House of Commons Standing Committee on Health decided to pursue its study of prescription drugs, commencing with an examination of the status of, and progress made under, the Common Drug Review (CDR). The CDR is the single Federal/Provincial/Territorial (F/P/T) process that is used to review both the clinical efficacy and cost-effectiveness of new drugs. This review process, which takes place after Health Canada has approved a drug for sale, leads to a recommendation regarding formulary listing under participating publicly funded drug insurance plans. All plans participate in the CDR except Quebec. This includes six federal, nine provincial and three territorial drug plans, with the federal government contributing 30% of the CDR funding. It is estimated that between 9 and 10 million Canadians are affected by CDR recommendations on formulary listing.

The six federal drug insurance plans that participate in the CDR are managed by Health Canada (eligible First Nations and Inuit individuals), Veteran Affairs Canada (eligible veterans), National Defence (members of the Canadian Forces), Royal Canadian Mounted Police (regular members and eligible retired members), Correctional Service of Canada (eligible federal offenders), and Citizenship and Immigration Canada (refugee protection claimants, sponsored convention refugees, and individuals detained by CIC). Altogether, these federal plans represent the fifth largest payer of prescription drug benefits in Canada after: Ontario, Quebec, British Colombia and Alberta. Some 1.1 million clients were eligible for drug benefits under the federal drug plans in 2005-2006, at a cost totalling $563 million.

The CDR process does not exist in isolation. It is one of nine key elements of the National Pharmaceuticals Strategy, which is an integrated, collaborative, multi-pronged F/P/T approach to pharmaceuticals within the Canadian health care system. These key elements are intertwined and include, for example, catastrophic drug coverage, pricing and purchasing strategies, evaluation of real-world drug safety and effectiveness, e-prescribing, etc.

During its hearings on the CDR from April through June 2007, the Committee heard from representatives of federal and provincial governments, the pharmaceutical industry, patient advocacy groups, health professionals, researchers and academics, as well as from CDR officials. The evidence received spanned a number of concerns and

included some conflicting views about the CDR. In this report, the Committee summarizes the testimony heard during these hearings, highlights issues raised by witnesses and identifies action needed by the federal government in response to these issues.

PART I: THE CDR: A GOOD START

1. What is the CDR?

A. An Advisory Body to Public Drug Plans

The CDR provides advice to participating drug insurance plans about the clinical efficacy and cost-effectiveness of a drug against other drug therapies so that public funds are optimally used. This drug review process is distinct from Health Canada's drug approval and licensing process. Health Canada is responsible for ensuring that marketed drugs in Canada meet established standards for efficacy, safety and the quality of manufacturing. Its decisions are made on the basis of information from clinical trials as provided by the manufacturer. These clinical trials compare the impact of a drug on health and safety relative to a placebo.

Health Canada does not compare the new drug to other available therapies, and cost is not a consideration under its drug approval process. Rather, this is the role of the CDR which helps determine whether or not the therapeutic improvement offered by the new drug compared to an alternative drug therapy justifies its cost or represents value for money when considered within the broader context of the health care system. For this reason, the approval for the marketing of a drug by Health Canada does not automatically lead to a CDR recommendation to list the drug.

B. CDR Goals/Objectives

The vision and mandate for the CDR came from the F/P/T Ministers of Health in September 2001. At the time, four goals were envisioned for the CDR:

- To establish a consistent and rigorous approach to drug reviews;
- To reduce duplication across publicly funded drug plans;
- To maximize the use of limited resources and expertise; and
- To provide equal access to expert advice.

The CDR was established in March 2002 and began accepting drug submissions in September 2003. From its creation up to April 2007, the CDR accepted submissions and performed reviews only for new drugs. Its mandate was recently expanded to review submissions for new indications for old drugs and this will commence later in 2007. There are plans under the National Pharmaceuticals Strategy to eventually expand the CDR to all drugs.

C. CDR Governance and Funding

The CDR is the responsibility of the Canadian Agency for Drugs and Technologies in Health (CADTH), which is an independent, not-for-profit corporation with an annual operating budget of $24.2 million. It is funded by federal, provincial and territorial governments (except Quebec) and is governed by a 13-member jurisdictional Board of Directors appointed by the F/P/T Deputy Ministers of Health.

Federal funding for CADTH is provided through a Named Grant and is distributed among the Agency's three core business activities — Common Drug Review (CDR), Health Technology Assessment (HTA), and Canadian Optimal Prescribing and Utilization Service (COMPUS). According to Health Canada's Report on Plans and Priorities for 2006-2007, CADTH will carry out and submit to the federal Minister of Health, no later than June 30, 2007, an independent evaluation of its core business activities from 2003 to 2007. This evaluation will not include the CDR as it was previously evaluated in 2005 by EKOS Research Associates.

As indicated previously, the funding formula for the CDR is 70% provincial/territorial and 30% federal contribution. The initial total CDR budget of $2 million per year was augmented to $3.4 million for the last two years, as the number of new drugs submitted for review increased. As of April 1, 2007, with the expansion of the CDR to cover new indications for old drugs, the total budget increased to $5.1 million. For 2007-2008, this corresponds to federal funding for CDR of about $1.5 million.

2. What Process Does the CDR Use in Reviewing New Drugs?

A. Initial CDR Review

The CDR process is usually initiated when a drug manufacturer files a submission for a new drug to the CDR Directorate. (See Appendix A for a schematic representation of the CDR process.) Participating drug plans can also make a submission. A review team — involving both external and internal reviewers — is established within the Directorate. While the names of the review team members are not disclosed, the make-up of the team is acknowledged in all CDR documents. The team usually includes epidemiologists, pharmacists, physicians, health economists and information specialists. At least one physician with expertise in the relevant clinical area is included in all reviews.

The review team undertakes a systematic review of the clinical evidence and the pharmacoeconomic data provided in the manufacturer's drug submission or retrieved through an independent literature search. The information in the manufacturer's submission may be confidential, and, for this reason, may have proprietary protection. The results of the review are sent to the manufacturer for comment after which CDR reviewers prepare a reply.

B. CEDAC Review and Recommendation

The dossier of the drug submission and its assessment by the review team is then forwarded to the Canadian Expert Drug Advisory Committee (CEDAC), which is housed within CADTH. CEDAC is an independent advisory body composed of 13 individuals with expertise in drug therapy and drug evaluation, including two members of the general public. The names and biographies of CEDAC members are publicly available on the CADTH website. CEDAC undertakes deliberations and makes a formulary listing recommendation to the participating drug plans.

In its deliberations, CEDAC considers the following three review criteria for each new drug: 1) clinical studies, which assess safety and/or efficacy of the drug in appropriate populations and, when available, effectiveness data are compared with current accepted drug therapy; 2) therapeutic advantages and disadvantages relative to current accepted drug therapy; 3) cost-effectiveness relative to current accepted drug therapy.

CEDAC may recommend that: 1) a drug be listed; 2) a drug be listed with criteria and conditions; or, 3) a drug not be listed. A recommendation may also be deferred pending clarification of information. The final recommendation and reasons for the recommendation are sent to the manufacturer and participating drug plans and are also released publicly. While CDR provides formulary recommendations, the final decisions rest with the provincial, territorial and federal governments, taking into consideration their jurisdictional needs, priorities and resources.

CADTH officials told the Committee that, as of April 2007, after almost four years of operation, the CDR had received 95 drug submissions; 70 final recommendations were issued; positive formulary listing was recommended for approximately 50% of all the drugs reviewed; and, drug plans' decisions have followed CDR recommendations 90% of the time.

C. CDR Conflict of Interest and Confidentiality Guidelines

It is important to note that all CDR reviewers and CEDAC members must abide by strict conflict of interest guidelines and a code of conduct. The conflict of interest assessment includes a focus on real, potential and perceived conflicts. It requires disclosure of personal, occupational and financial connections, or interests with pharmaceutical companies or affected organizations.

Perhaps more importantly, CADTH has developed confidentiality guidelines to protect confidential information obtained for the CDR. A manufacturer will be deemed to have consented to the guidelines when he/she files a submission or supplies other information to the CDR Directorate. However, if any reasons for a CDR recommendation are based on unpublished confidential information and/or confidential price, the manufacturer will be asked for permission for disclosure in the final recommendation and accompanying reasons. The information will be kept confidential at the manufacturer's request, thereby restricting the ability of the CDR to report to the public on the price or clinical evidence used for the CEDAC recommendations.

3. How is Cost-Effectiveness Determined?

A. The Method

The clinical review and pharmacoeconomic assessment undertaken by the CDR is extensive. Before the cost-effectiveness of a drug is considered, the drug must first be shown to be clinically effective and demonstrate improved healthcare outcomes. Experts explained that the central concept around cost-effectiveness is value for money and is not simply price or budgetary cost. The internationally accepted gold standard for expressing cost-effectiveness of a new drug is by the cost per Quality Adjusted Life Year (QALY), compared to other drug therapies. The cost per QALY estimates the cost of a new drug relative to improvements in survival and quality of life. An expensive drug can still be cost-effective if it demonstrates an improved health outcome over its comparator. A relatively inexpensive drug may not be cost-effective if it offers little or no improvement in health outcomes compared to a less costly treatment.

B. Expanded to Incorporate Other Outcomes

The pharmaceutical industry claimed that the CDR process places too much emphasis on cost and not enough on patient outcomes. In the view of the industry, this leads the CDR to recommend that innovative drugs not be listed. Industry representatives explicitly recommended that the CDR incorporate mechanisms that recognize the value of pharmaceutical innovation into its mandate.

Health professionals and patient advocacy groups told the Committee that the clinical and pharmacoeconomic assessment should compare not only a drug's performance to other drugs in the same class, but also to other available non-drug therapies. They suggested that the review consider a drug's impact on overall health care utilization. For example, if a drug reduces a patient's hospital stay, helps an otherwise disabled patient to return to work, or replaces costlier or invasive procedures, this should be considered in evaluating its overall cost-effectiveness.

CADTH officials clarified, however, that their cost-effectiveness does look at the other costs to the health care system such as doctors' visits and hospitalization. They also pointed out that the CDR has, in fact, recommended expensive drugs that demonstrate improved health outcomes and that, in their view, it is clear that drug cost alone does not drive CDR recommendations.

Other witnesses emphasized the challenges of reviewing new drugs that do not have clear evidence of long term health outcomes. Health Canada can approve a new drug on the basis of surrogate end points (surrogate markers) of effectiveness and require a future commitment by the manufacturer to collect ongoing data. In such cases, initial assessment of a new drug may indicate an early and positive change in one aspect of a disease or one system of the body. The longer term effectiveness with respect to improved morbidity and decreased mortality are not known.

C. Incorporating Human Values into the Review Process

The determination of the cost per QALY generated considerable interest. Several witnesses noted that there are problems with applying economic analysis to complex issues around quality of life such as putting a value on the ability to dress or feed oneself. Furthermore, although QALY has a widely validated scientific methodology, they stated that it has no explicit connection to ethical analysis. Many agreed that the CDR process could be moved from one that has been technical, scientific and clinical to one that incorporates an analysis of competing human values within an ethical framework. However, it was also acknowledged that these human values and ethical considerations must be balanced with resource allocation challenges, pressures from the pharmaceutical industry to promote innovative medicines and the interests of patients.

D. Committee View

The Committee acknowledges that pharmacoeconomic assessment is a valid method when weighed against clinical effectiveness of the drug. Governments have a legitimate role in ensuring that public resources are appropriately used. For drugs that are publicly reimbursed, this includes verifying that they offer good therapeutic and monetary value relative to their benefits over existing therapies. This is a dilemma that is frequently faced by public policy makers when they must decide how best to spend taxpayer money.

On the one hand, if two drugs in the same class achieve similar therapeutic outcomes, it is not unreasonable to expect that the less expensive drug should be preferentially covered and/or prescribed. On the other hand, the Committee agrees with witnesses in that some flexibility is also needed. Consideration should be given to allowing patients to access off-formulary drugs if, in the opinion of the attending physician, the recommended product is not the right choice for them. Moreover, pharmacoeconomic assessment must continue to take into account the potential savings to the publicly funded health care system resulting from, for example, reduced hospitalization or fewer surgical interventions. Finally, the Committee sees an opportunity for including values through increased public involvement in the review process, as mentioned under the section on public participation in CEDAC.

4. Has the CDR Reduced Duplication?

A. Single F/P/T Review of New Drugs

Before the creation of the CDR, the federal government and the provinces/territories had separate processes for reviewing and recommending new drugs to their respective drug plans. Pharmaceutical companies had to file a submission for review of each new drug to each individual drug plan. In setting up a single review process, the CDR was expected to benefit drug manufacturers since they would only be required to make a single submission to the CDR rather than to each individual drug insurance plan. In principle, therefore, the pharmaceutical industry should have been positively impacted by this new approach.

Pharmaceutical industry representatives and individuals representing patient advocacy groups, however, told the Committee that the CDR is an additional layer of bureaucracy which is redundant. They claimed that participating drug plans are still conducting their own reviews of new drugs.

In contrast, officials from federal and provincial drug insurance plans told the Committee that this criticism is unfounded. They confirmed that the 18 separate drug plan processes for reviewing overall cost-effectiveness and making formulary listing recommendations on new drugs have been replaced by the single CDR process. In their view, the CDR process saves time, effort and money. It has reduced duplication of effort across the provincial, territorial and federal drug plans and has allowed all jurisdictions — large and small — to have equal access to a high level of evidence and expert advice from the CDR. They also told the Committee that the CDR has rapidly become a respected peer among review processes on the global stage.

B. Different Drug Insurance Plan Reviews

Federal and provincial officials further explained that their respective drug reviews for clinical and cost-effectiveness have remained in place only for those drugs that do not fall under CDR's mandate of new drugs. They also stated that they do continue to assess drugs for formulary listing based on the appropriateness for their different client populations and with a view to the distinct budget needs of each plan. Health Canada estimated, with respect to the First Nations and Inuit drug plan, that it spent approximately 50% less on its drug review activities per year since the creation of the CDR.

C. Committee View

The Committee heard clearly that the CDR is meeting the needs of participating federal, provincial and territorial drug plans and that, in most cases, CDR has provided a higher quality review than the individual plans could have achieved with their own resources. According to the participating plans, the CDR has reduced their human and financial resource requirements for data collection and scientific assessments. In addition to responding to the limited capacity in smaller drug plans, the CDR has achieved its goal of reducing duplication of drug review processes for new drugs.

5. Has the CDR Resulted in Longer Waits for New Drugs?

A. Overall Time-to-Listing

During the hearings, the pharmaceutical industry and many patient advocacy groups claimed that reimbursement of new drugs through public plans has been delayed under the CDR. The Committee was told that this issue relates to the "time-to-listing" which involves three steps: 1) the time it takes the manufacturer to file a submission after a Notice of Compliance has been issued by Health Canada; 2) the time it takes for the CDR to review the drug submission; and 3) the time it takes a participating drug plan to make and announce its listing decision.

According to CADTH data, the average total time from Health Canada approval to drug plan listing decision is essentially unchanged since the CDR was established — 471 days before versus 479 days now. The CDR process represents only about one-third of this total time period. Once the CDR has released a recommendation, it is the drug plans that make the decisions whether to list the drug on their formularies. The timeframe for this remains solely the responsibility of each drug plan and CDR has no role.

B. CDR Review Timelines

Officials from CADTH explained that they are responsible only for the second step of the overall time-to-listing and have no control over the first step initiated by the manufacturer or the last step of final decision-making by the plans. They stressed that, although the CDR process is highly detailed and involves many different stakeholders, the time from review initiation to recommendation is only 19 to 25 weeks. (For an overview of the CDR timelines, please see Appendix B.) They explained that the CDR has developed timelines on the basis of the best practices of the participating drug plans and that it has consistently met these timelines. They summarized the key stages and timing of the CDR process as follows:

- Clinical and pharmacoeconomic reviews are prepared within nine weeks;
- Reviews are provided to the manufacturer for written comments within two weeks;
- The CDR reports are finalized, based on these comments, within two weeks;
- The initial CEDAC recommendation and the reasons for the recommendation are sent to the manufacturer and the drug plans, and held in confidence for two weeks;
- During this two-week period, drug plans may request clarification of the recommendation and the manufacturer may request that CEDAC reconsider the recommendation on the drug. In this case, CEDAC reviews its recommendation at a subsequent meeting; and,
- The final recommendation and reasons for the recommendation are released publicly.

C. Health Canada and the CDR

Some witnesses referred to an apparent overlap in the separate and sequential roles of Health Canada and the CDR as contributing to overall time-to-listing for new drugs. They called for greater coordination between the Health Canada approval process and the CDR review process. The Committee heard that if the CDR review process could commence in the latter stages of the Health Canada's drug approval process (that is, before Health Canada issues a Notice of Compliance), then CDR recommendations could be made to participating drug plans more quickly once the drug is on the market. It was suggested that a more unified approach involving greater and timelier sharing of information between the two processes could eliminate some of the time lags between

Health Canada and the CDR. This could eventually result in faster drug plan determination for reimbursement eligibility. As a matter of fact, a CDR representative told the Committee about a recent collaboration with Health Canada which has permitted the CDR to start its review process in the latter stages of the Health Canada approval process and to incorporate evidence from the regulatory review. Thus, for a drug that offers the potential for treatment of life-threatening or very serious conditions, the CDR review can complete its process and reach a recommendation within months of the market approval by Health Canada.

D. Drug Insurance Plans

Representatives from CADTH and participating federal and provincial drug plans told the Committee that, prior to the CDR, the reviews often took longer, and the level of rigour varied considerably across the jurisdictions. It is their view that the total time to formulary listing has not increased since the inception of the CDR. This is despite establishing a standardized process that has both increased the level of rigour of the review and added many transparency elements to the process.

E. Committee View

The Committee understands the anxiety of clients of participating federal, provincial and territorial drug plans when they are waiting for a drug to be listed on a formulary. While acknowledging that the CDR has consistently met its timelines, the Committee also encourages CDR to reduce its timeline through measures such as closer collaboration with Health Canada.

6. What is the Impact of CDR Recommendations?

A. Patient Access

Of the estimated nine to ten million Canadians who are affected by CDR recommendations, most are seniors and low income individuals eligible for provincial and territorial drug insurance plans. These individuals first must wait for a CDR recommendation and then wait again for their plan's final listing decision. The pharmaceutical industry and patient advocacy groups contended that those Canadians who depend on a CDR participating plan have far less access to new drugs than the rest of the population who can seek coverage by a private drug plan or pay from their own pockets.

In their view, Canadians should have access to new drugs as soon as they are approved for sale by Health Canada and marketed by the manufacturer. Industry representatives also told the Committee that they find it troublesome when CDR makes a

negative listing recommendation after Health Canada has already approved the drug for sale. According to them, Canadians who have private plans have more choice and better access than those who must rely on publicly funded drug plans. Other witnesses mentioned that Quebec lists more drugs on its formulary than any of the CDR participating drug plans.

B. Clinical Guidelines and Physician Practice

The Committee heard from some physicians and patient advocacy groups that the CDR review process should include experts with clinical expertise in the disease areas relevant to the new drug under review. They pointed to several examples of new drugs that had been recommended by expert committees responsible for the development of clinical practice guidelines for specific diseases that were not recommended for listing by the CDR. In their view, the CDR should not make a negative ("not to list") recommendation when guidelines already exist that support prescribing the drug. The Committee was told, however, that currently in Canada there are marked differences in provincial clinical practice guidelines for the treatment of cancer, diabetes and other conditions. These guidelines vary greatly even though they are developed by experts analyzing similar medical databases. Patient advocacy groups suggested that the development of national clinical practice guidelines would provide uniformity across the country and provide the basis for patients to demand that their provincial governments pay for the drugs that are recommended in the guidelines.

A CDR representative emphasized that the body of evidence available to physicians and to the developers of clinical practice guidelines is not the same as the evidence reviewed by the CDR. The CDR has the advantage of having access to unpublished information that pharmaceutical companies are compelled to supply in their submission.

Furthermore, several academics noted that the development of clinical practice guidelines may be financially influenced by pharmaceutical companies. They pointed out that it is important to separate guideline development from the vested interest of the industry as well as from patient advocacy groups.

C. Drug Plans

There have been criticisms that participating drug plans do not necessarily adopt CDR recommendations. However, the Committee was told that the drug plans are not obliged to do so. Witnesses indicated that decisions by public drug plans are entirely within the authority of their respective jurisdictions, and the CDR has no role in, or influence on, the nature or timing of decisions by those drug plans. According to CADTH officials, the drug plan decisions have, to date, followed CDR recommendations 90% of the time. There are some exceptions made and this shows that the drug plans take into

account their local jurisdictional considerations. Federal drug plans explained that they do not all implement the CDR recommendations in the same way, due to their varied client groups. They believe that this is a strength of the CDR process, rather than a weakness.

According to officials from CADTH, there is no evidence that the CDR has created a new and more challenging threshold for drug access compared to what was occurring before CDR existed. In fact, in the five years preceding CDR, the largest public plan in Canada, the Ontario Drug Benefit Program, listed 44% of new drugs that they reviewed. To date, the CDR rate for positive recommendations is approximately 50%.

D. Drug Plans in Other Countries

Pharmaceutical industry representatives provided a commissioned study that suggested that the CDR recommends fewer drugs than international comparators. However, CADTH representatives and academic researchers replied that the positive recommendations rate for Canada is in the midrange of all countries studied, and is higher than for those countries with similar health care systems, such as Australia and New Zealand. They also stressed that one must be very careful in doing such comparisons as some countries may list a drug, but only for partial reimbursement with the remainder being paid by the patient. For example, France has a three level reimbursement model. Other countries undertake national price negotiations which influence reimbursement decisions.

E. Committee View

The Committee heard the claim that the CDR is a barrier between patients and potentially life-saving new drug therapies. The Committee understands the frustration of patients and their advocates when the CDR recommends against public reimbursement or even more when the CDR approves a drug but individual drug plans refuse to include that drug on their own formularies. The Committee empathizes with these frustrations. It also acknowledges that sustainability of the health care system is an important and valid consideration.

PART II: LOOKING FORWARD

1. Is the CDR Accountable to Governments?

A. F/P/T Corporate Governance

Government officials explained to the Committee that CADTH is a corporation owned by the Conference of F/P/T Deputy Ministers of Health (CDM) and is governed by a 13-member jurisdictional Board of Directors, which reports to the CDM. All F/P/T governments participate except Quebec. Each member of the CADTH Board of Directors has an equal vote in overseeing the affairs of the corporation. The 13 Directors are each appointed by a Deputy Minister of Health who is a member of the CDM. The Committee was also told that, while CEDAC is an independent committee, it is appointed by and accountable to CADTH Board of Directors. Thus, the CDR is accountable to the CDM through CADTH Board of Directors. CADTH and provincial government representatives argued that this corporation meets the primary criteria for accountability through annual reporting of investments by F/P/T partners and by its ability to assign responsibility, to fulfill objectives and to provide consistent reporting.

B. Call for a Review

During the Committee hearings, the pharmaceutical industry and patient advocacy representatives raised concerns about a lack of accountability of the CDR and CADTH to governments. They contended that CADTH and the CDR have no formal reporting relationship to a single government body. Further, they indicated that neither CADTH nor the CDR are subject to review or audit by any one government or a single oversight body. They also noted that they are not bound by access-to-information legislation. Furthermore, they told the Committee that it is unclear how federal funding for the CDR is allocated.

These witnesses recommended that the federal share of CDR funding be frozen immediately and that, in the meantime, an independent review of the CDR be undertaken to assess its objectives, accountability, value for money and health outcomes. Several other witnesses knowledgeable about the CDR and other drug review processes acknowledged that, now that the CDR has been in place for almost four years, a comprehensive evaluation is necessary to determine the value of the review process.

C. Committee View

The Committee heard considerable testimony in regard to accountability. However, as the CDR is a F/P/T entity, the Committee understands that the federal government is limited in its scope of authority. Members of the Health Committee have requested that the federal Office of the Auditor General (OAG) conduct an audit of the CDR and the OAG has agreed to consider this request. In the absence of direct accountability to the federal government, the Committee feels that ongoing, external, performance evaluations at regular intervals, coupled with increased public involvement and greater access to the technical and scientific evidence used for recommendations,(as recommended below) will serve to address many of the accountability concerns.

Therefore, the Committee recommends that:

The federal government work with its provincial and territorial CDR counterparts to require an independent, external performance evaluation of the CDR within a year, and at five year intervals, and to make them immediately available to the public.

2. Is the CDR Process Open and Transparent?

A. Current Situation

CADTH representatives told the Committee that pharmaceutical manufacturers currently review and provide feedback on CDR reports. Prior to the CDR, federal and provincial drug plans did not provide an opportunity for manufacturers to comment on their reviews, and none of them publicly released reasons for their recommendations.

Furthermore, some information is posted on the CADTH website, including: CDR procedures and submission guidelines, which were all developed in consultation with the participating drug plans, the industry and the public; a search tool for drugs reviewed by the CDR; weekly reports on the status of each drug submission; biographies and conflict of interest disclosures for each CEDAC member; and, CEDAC recommendations and reasons for each of the recommendations.

B. More Accessible Information Needed

Despite these improvements introduced by the CDR, representatives of the pharmaceutical industry and patient advocacy groups were critical of the openness and transparency of the CDR process. In their view, information about policies, practices and decisions is not communicated in an open and timely manner. For example, they told the Committee that there is no way for the pharmaceutical industry and the general public to

know which specific experts the CDR consulted before making their listing recommendation, even after the drug review process has been completed and the recommendation made public. CADTH officials emphasized that, while CEDAC names and biographies are publicly available, revealing the names of reviewers would jeopardize the process by exposing them to external influences by the pharmaceutical industry and harassment by patient advocates.

Patient advocacy groups also called for more access to the information used to make formulary listing recommendations. They indicated that Canadians cannot readily find which published articles the CDR used in their review to make the listing recommendation. CADTH officials told the Committee that, to further enhance transparency and better communicate decisions and recommendations to the general public, they will publish in the coming year lay versions of the CDR recommendations, the review materials considered by CEDAC and the CEDAC minutes.

Researchers familiar with centralized drug review processes in other countries emphasized that more transparency would be possible if the pharmaceutical industry was willing to disclose the clinical trial data, prices, and other information that is currently protected under confidentiality agreements with CADTH. The Committee heard that in the United Kingdom, the National Institute for Health and Clinical Excellence (NICE) — which is CADTH's counterpart — posts the initial assessments and final appraisal recommendations on its website, and that these detailed documents contain some cost, clinical and economic data.

C. Committee View

The Committee acknowledges that the CDR involves signing confidentiality agreements with the manufacturers who make submissions. Therefore, public participation, input and information sharing must be balanced against the manufacturers' need to protect confidential or proprietary information. Despite some published reports, most data from various phases of clinical trials on drugs remain confidential and unavailable to the broader public. Pharmaceutical companies argue that confidentiality is essential to limit the acquisition of knowledge by their competitors. The confidentiality requirement leaves no avenue for Canadians to assess the completeness or reliability of data submitted to the CDR and used for the final listing recommendation.

The Committee supports the CDR's intent to publish more information regarding its decisions, including lay-language versions of its recommendations, it agrees that greater transparency is needed in the CDR process. It understands that CADTH would like to increase the level of transparency but is somewhat restricted by the limitations put on it by the pharmaceutical industry. However, this obstacle has been addressed by NICE in the United Kingdom and the Committee therefore feels that a reasonable level of disclosure should be negotiable with industry as they have already agreed to such in the United Kingdom.

Therefore, the Committee recommends that:

The federal government work with its provincial and territorial CDR counterparts to enhance transparency by increasing the level of scientific and price information disclosure through discussions with pharmaceutical manufacturers at the time of submission.

3. Is the General Public Involved in the CDR Process?

A. Current Public Participation in CEDAC

During the hearings, several representatives of patient advocacy groups and the pharmaceutical industry called for greater public participation in the CDR. The Committee was told that, in response to the concern about the lack of public involvement in the CDR process, CADTH appointed two public representatives to CEDAC in November 2006. These two members were selected from a diverse group of applicants. They are expected to represent the broader public interest and to serve as a member of the general public, not as a representative of any specific interest group or organization. These two members, who were trained as participants, have full CEDAC membership, with similar responsibilities and expectations, and are subject to the same terms and conditions as other committee representatives.

Although witnesses welcomed the addition of two public representatives on CEDAC, many felt that this was not sufficient. Some suggested that specific patient advocacy groups participate in the CDR, arguing that individuals affected by the CEDAC recommendations on formulary listing currently have no access to the decision-making process that will assess the value of new drugs to them. They recommended that CEDAC meetings become completely public, allowing Canadians to fully follow CDR deliberations and/or express their views by making presentations to CEDAC.

B. Other Jurisdictional Examples of Public Participation

Other witnesses told the Committee that Australia, Sweden and the United Kingdom include public members in some part of their review process. In the United Kingdom, NICE works with its Citizens Council in making formulary recommendations on new drugs. The Citizens Council is made up of 30 members, representative of diverse age, ethnic, socio-economic and other groups. Its role is to insert social value judgements into the Institute's decision-making process. It does not get involved in the technical and scientific review of individual drug therapy and does not make decisions about the final listing of drugs. The Committee also heard that the Ontario government is in the process of establishing a similar citizens' council that will advise the executive officer who oversees the decisions for inclusion or removal of drugs from the provincial formulary.

C. Committee View

The Committee supports the recent appointment of two members of the public to CEDAC. It also heard from CADTH that the Conference of Deputy Ministers of Health — the owners of the CDR — could be asked to consider the cost and process implications of more enhanced public involvement in the CDR process. All members of the Committee agree that public participation could create greater understanding of the CDR process, provide increased input of individual and societal values, and foster expanded trust in the CDR. By engaging members of the broader public in the process and in the determination of criteria for making recommendations on formulary listing, they can understand how decisions are made in a process that must weigh scientific, cost and quality of life evidence. They will gain a clearer knowledge of the calculations and trade-offs that are part of decision-making in the health care sector.

Therefore, the Committee recommends that:

The federal government work with its provincial and territorial CDR counterparts to increase the current level of public involvement in the CDR through public attendance at open CEDAC meetings and the creation of a public advisory body.

4. Is there an Appeal Process under the CDR?

A. Manufacturer Reconsideration

In Canada, every manufacturer whose drug is the subject of a CDR recommendation has the right to file a request for reconsideration. The Committee was told that such a request may be made on the following grounds: 1) the CDR failed to act fairly and in accordance with its procedures in conducting the review; or 2) the recommendation is not supported by the evidence that had been submitted or the evidence identified in the reviewers' reports. In the United Kingdom, decisions by NICE can be appealed by the sponsoring company, other drug manufacturers, health professionals, patient advocacy groups and the Department of Health.

Representatives from the pharmaceutical industry cited concerns about the request for reconsideration process. In particular, they told the Committee that the current appeal process appears unfair as the manufacturer's appeal is made directly to the same people on CEDAC who made the initial listing recommendation. They suggested that an independent administrative appeal process for CEDAC recommendations be established. CADTH officials acknowledged this concern and indicated that a reassessment of this process might be appropriate.

B. Public Appeal

Patient advocacy groups were concerned that any appeal of a recommendation to list or not to list is limited to the industry manufacturer who submitted the initial application for review. In contrast to the United Kingdom, there is currently no formal process for Canadians to raise their concerns or ask questions about why or how the CDR reached their conclusion in a recommendation. In their view, organizations who speak on behalf of millions of Canadians should have the ability to appeal a CDR recommendation given the immediate impact on their members and patients.

C. Committee View

While the Committee appreciates that appeal processes are at present not the norm in centralized drug review processes around the world, it nonetheless feels strongly that such a process should be in place. Currently, manufacturers are limited to an appeal for reconsideration to the same individuals who did the initial review. Moreover, there is no mechanism for consumers to substantively dispute a CDR recommendation. The Committee believes that the limits placed on manufacturers and the absence of an appeal process for the affected public are adding to frustrations over the perceived lack of transparency and accountability. However, the Committee is aware that a process that is completely external to the CDR could be costly and time-consuming for the federal, provincial and territorial partners.

Therefore, the Committee recommends that:

The federal government work with its provincial and territorial CDR counterparts to create a set of specific appeal criteria which, if met, would lead to a new and distinct appeal process for CEDAC recommendations which will:

- **Require a separate group of expert reviewers;**
- **Extend requests for appeal beyond manufacturers to the public; and,**
- **Establish a clear timeframe for an appeal decision.**

5. Are Separate Processes Needed For Some Categories of Drugs?

A. Cancer Drugs

In March 2007, provincial and territorial drug plans established the interim Joint Oncology Drug Review (JODR). It was explained that the CDR reviews only a small subset

of new oncology drugs — oral agents. However, most cancer drugs, as they are delivered by injection at cancer clinics or within a hospital setting, are reviewed outside of the CDR. As such, drug plan administrators felt that the JODR would help address the inconsistent review of cancer drugs across the country. The JODR will be undertaken by the Ontario Committee to Evaluate Drugs, in collaboration with Cancer Care Ontario.

The Committee was told that the CDR has an observer seat on the JODR Steering Committee and will continue to provide its clinical and economic reviews of new oral cancer drugs (the subset of cancer drugs that previously would have been submitted directly to the CDR) to both the JODR and the federal plans. In these instances, the CDR reviews will be provided to the JODR which will make the formulary listing recommendation. The JODR will publicly release their recommendations on cancer drugs and the federal plans will be able to use these recommendations to make formulary decisions. An independent evaluation of the JODR will be conducted after one year with the intent of developing a permanent national review of oncology drugs. One option will be that this be a part of the CDR.

B. Drugs for Rare Diseases

The Committee heard that there are also other categories of drugs that do not fit as well within the existing CDR process, and for which different assessment tools might be more appropriate. This is particularly true for drugs for rare diseases (orphan drugs). Patient advocacy groups and industry representatives expressed frustration that the CDR has recommended very few of the orphan drugs reviewed. They explained that clinical trials are more difficult to design, undertake and complete for drugs for rare diseases than for more common disorders. They also questioned whether cost-effectiveness can be appropriately measured for these drug therapies. This is due in part to the nature of rare diseases, as they affect only a very small proportion of the population at any time. The frequency of many disorders is so low that it is almost impossible in the short term to gather enough patients to measure statistically significant clinical benefits or harms of a therapy.

Some witnesses suggested that international cooperation should be encouraged so that patient groups can be pooled for clinical trial data. The Committee was told that the National Pharmaceuticals Strategy set up a task group to examine the issues surrounding drugs for rare diseases; this task group is expected to present its report to the Conference of Deputy Ministers of Health in June 2007.

C. First-in-Class or Breakthrough Drugs

In addition, the Committee heard that the CDR process for reviewing first-in-class or breakthrough drugs may not be appropriate, and that a separate process for these drug therapies should also be considered. The CDR compares the drug under review with an existing drug therapy to assess its clinical benefit and cost-effectiveness. Manufacturers

told the Committee that first-in-class drugs do not always have an appropriate drug comparator and, in their view, the CDR is unfairly assessing these breakthrough drugs.

D. Committee View

On the one hand, the Committee welcomes the JODR process and the subsequent evaluation of its effectiveness. On the other, members understand the frustrations expressed by those who suggested that the current CDR process is inappropriate for certain types of drugs. It agrees that different review processes need to be considered if the weight of evidence or a comparator drug is not available when reviewing drugs for rare diseases or first-in-class drugs.

Notwithstanding the National Pharmaceuticals Strategy task group report, the Committee recommends that:

> **The federal government work with its provincial and territorial CDR counterparts to urge CADTH to establish a specifically designed approach for the review of drugs for rare disorders and for first-in-class drugs.**

CONCLUSION

The CDR is not a new concept in terms of its mandate, processes and results. It performs assessments of both clinical efficacy and cost-effectiveness, just as the drug plans have always done. However, the collaborative approach that consolidates federal and provincial/territorial drug review processes into one process is new and it aims to utilize limited expertise efficiently. Participating drug plans believe that the CDR is a positive example of intergovernmental cooperation that provides valuable service to the Canadian public.

The Committee was told that, to dismantle the review process entirely would be unacceptable, both economically and politically. Despite this, members strongly agree with witnesses that further improvements are necessary. The Committee hopes that its recommendations help the CDR to achieve a higher level of satisfaction among those who are affected by its work and to maintain its international reputation for high quality work. Further, the Committee hopes that the Office of the Auditor General will conduct a value for money review of the CDR as requested earlier.

LIST OF RECOMMENDATIONS

Recommendation 1:

The federal government work with its provincial and territorial CDR counterparts to require an independent, external performance evaluation of the CDR within a year, and at five year intervals, and to make them immediately available to the public.

Recommendation 2:

The federal government work with its provincial and territorial CDR counterparts to enhance transparency by increasing the level of scientific and price information disclosure through discussions with pharmaceutical manufacturers at the time of submission.

Recommendation 3:

The federal government work with its provincial and territorial CDR counterparts to increase the current level of public involvement in the CDR through public attendance at open CEDAC meetings and the creation of a public advisory body.

Recommendation 4:

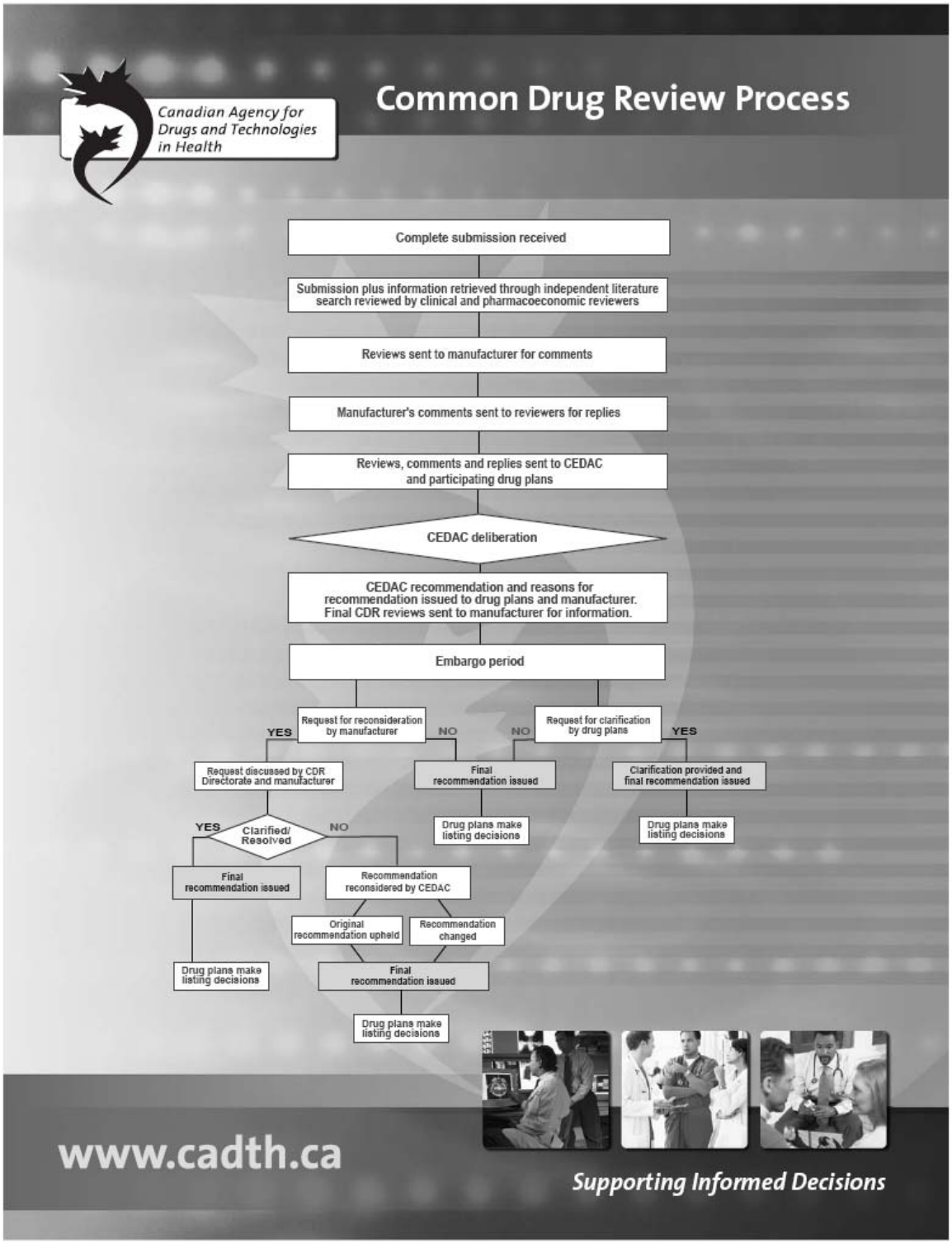
The federal government work with its provincial and territorial CDR counterparts to create a set of specific appeal criteria which, if met, would lead to a new and distinct appeal process for CEDAC recommendations which will;

- **Require a separate group of expert reviewers;**
- **Extend requests for appeal beyond manufacturers to the public; and,**
- **Establish a clear timeframe for an appeal decision.**

Recommendation 5:

The federal government work with its provincial and territorial CDR counterparts to urge CADTH to establish a specifically designed approach for the review of drugs for rare disorders and for first-in-class drugs.

APPENDIX A: COMMON DRUG REVIEW PROCESS



APPENDIX B: TIMEFRAMES FOR COMMON DRUG REVIEW PROCEDURE

Canadian Agency for Drugs and Technologies in Health

Common Drug Review Process

Timeframes for Common Drug Review Procedure

	Task within Review Process	Timeframe (in Business Days)	Weeks
Administrative Tasks*			
1	Submission deemed complete	5	1
	Resubmission deemed complete	10	2
2	Manufacturer's binders received by CDR	5	1
3	Manufacturer's binders received by CDR Reviewers	3	0.6
Review Process			
4	CDR Reviewers' Reports completed • Reviewers selected and contracted • Literature search and selection completed • Systematic review of clinical data completed • Critical appraisal of pharmacoeconomic (PE) data completed • Clinical and PE reports written • Reports edited and finalized • Reviewers' reports sent to manufacturer	45	9
5	Comments from Manufacturer on Reviewers' Reports received by CDR	7	1.5
6	Reviewers' Reply to Manufacturer's comments completed	7	1.5
7	CEDAC Brief completed and sent to CEDAC Members and Participating Drug Plans	5	1
8	CEDAC meeting (placement on CEDAC agenda)	10 to 40	2 to 8
9	CEDAC Recommendation and Reasons for Recommendation sent to Drug Plans, ACP and Manufacturer; Final CDR Reviews sent to Manufacturer for information	5	1
10	Embargo Period† Manufacturers may make Request for Reconsideration, and Drug Plans may make Request for Clarification of Recommendation and Reasons for Recommendation	10	2
11 (a)	Final Recommendation sent to Drug Plans, ACP, and Manufacturer (no Requests for Clarification AND no Request for Reconsideration; or Request for Reconsideration resolved)	5	1
	OR		
11 (b)	Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer (Clarification requested, no Request for Reconsideration)	5	1
	Total Review Time for Submissions*	**94 to 124 days**	**19 to 25 weeks**
	Total Review Time for Resubmissions*	**94 to 124 days**	**19 to 25 weeks**
	OR		
11 (c)	Placed on CEDAC agenda for Reconsideration (at Manufacturer's request)	25 Depends on Meeting Dates	5
12	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	1

*Administrative Time is not included in the calculations of the Total Review Times

†The Recommendation and Reasons for Recommendation are to be held in confidence and not acted upon until after the CDR Directorate has issued the Notice of Final Recommendation

February 2007

www.cadth.ca

Supporting Informed Decisions

APPENDIX C:
LIST OF WITNESSES

Organizations and Individuals	Date	Meeting
AMGEN Canada Inc.	2007/04/16	47
Daniel Billen, Vice-President and General Manager		
BIOTECanada		
Peter Brenders, President and Chief Executive Officer		
Sean Thompson, Director, Corporate Development, YM Biosciences Inc.		
Canada's Research-Based Pharmaceutical Companies (Rx & D)		
Mark Ferdinand, Vice-President, Policy, Research, Regulatory and Scientific Affairs		
Russell Williams, President		
Canadian Generic Pharmaceutical Association		
Jim Keon, President		
Department of Health	2007/04/23	49
Scott Doidge, Manager, Pharmacy Group, Non-Insured Health Benefits Directorate, First Nations and Inuit Health Branch		
Abby Hoffman, Executive Coordinator and Associate Assistant Deputy Minister, Pharmaceuticals Management Strategies, Health Policy Branch		
Ian Potter, Assistant Deputy Minister, First Nations and Inuit Health Branch		
Department of National Defence		
Lieutenant-Colonel Dave Cecillon, Pharmacy Policy and Standards		
Department of Veterans Affairs		
Verna Bruce, Associate Deputy Minister and Chair of the Federal Healthcare Partnership		
British Columbia Ministry of Health	2007/04/25	50
Robert Nakagawa, Assistant Deputy Minister, Pharmaceutical Services		
Canadian Agency for Drugs and Technologies in Health		
Braden Manns, Chair, Canadian Expert Drug Advisory Committee		
Jill M. Sanders, President and Chief Executive Officer		

Organizations and Individuals	Date	Meeting
Canadian Agency for Drugs and Technologies in Health	2007/04/25	50
Mike Tierney, Vice-President, Common Drug Review		
Conference of Deputy Ministers of Health		
Ed Hunt, Chair of the Board of Directors, Canadian Agency for Drugs and Technologies in Health, and Assistant Deputy Minister, Department of Health and Community Services, Government of Newfoundland and Labrador		
John Wright, Co-Chair and Deputy Minister of Health, Government of Saskatchewan		
Canadian Breast Cancer Network	2007/04/30	51
Diana Ermel, President		
Jackie Manthorne, Executive Director		
Cancer Advocacy Coalition of Canada		
William Hryniuk, Director and Past Chair		
Cancer Care Ontario		
Debbie Milliken, Director, Provincial Drug Reimbursement Programs		
Colorectal Cancer Association of Canada		
Barry D. Stein, President		
Princess Margaret Hospital		
Jennifer Knox, Oncologist, University Health Network		
Canadian Diabetes Association	2007/05/02	52
Michael Howlett, President and Chief Executive Officer		
Karen Philp, Vice-President, Public Policy		
Canadian Organization for Rare Disorders		
Durhane Wong-Rieger, President		
The Fraser Institute		
Brett Skinner, Director, Pharmaceutical and Insurance Policy Research		
Best Medicines Coalition	2007/05/09	54
Louise Binder, Chair		
Linda Wilhelm, Operations Committee member		

Organizations and Individuals	Date	Meeting
University of Toronto	2007/05/09	54
Janis Miyasaki, Associate Clinical Director and Chair of the Technology and Therapeutics Assessment Subcommittee, American Academy of Neurology		
Ward Health Strategies		
Elisabeth Fowler, Vice-President, Health Policy		
York University		
Joel Lexchin, Professor, School of Health Policy and Management		
As individuals		
David Bougher, former member of the Federal, Provincial and Territorial Pharmaceutical Issues Committee		
Linda Tennant, former member of the Federal, Provincial and Territorial Pharmaceutical Issues Committee		
Canadian Medical Association	2007/05/14	55
John Haggie, Chair, Board Working Group on Pharmaceutical Issues		
Briane Scharfstein, Associate Secretary General		
Hit the slope for hope		
Michelle Calvert, Chair		
Sarah Calvert, Spokesperson		
Mood Disorders Society of Canada		
Phil Upshall, National Executive Director		
St. Michael's Hospital		
Andreas Laupacis, Director, Li Ka Shing Knowledge Institute and former Chair of the Canadian Expert Drug Advisory Committee		
University of Alberta	2007/05/16	56
Devidas Menon, Professor, School of Public Health		
University of British Columbia		
Steve Morgan, Assistant Professor, Centre for Health Services and Policy Research		
As an individual		
Jean-Claude St-Onge, Author and Professor at Lionel-Groulx College		
Canadian Agency for Drugs and Technologies in Health	2007/06/06	60
Jill M. Sanders, President and Chief Executive Officer		

Organizations and Individuals	Date	Meeting
Canadian Agency for Drugs and Technologies in Health Mike Tierney, Vice-President, Common Drug Review	2007/06/06	60
Conference of Deputy Ministers of Health John Wright, Co-Chair and Deputy Minister, Saskatchewan Health, Government of Saskatchewan		

APPENDIX D:
LIST OF BRIEFS

Organizations and Individuals

ACTION for People with Neuropathic Pain

AMGEN Canada Inc.

Best Medicines Coalition

BIOTECanada

Bougher, David

British Columbia Ministry of Health

Canada's Association for the Fifty-Plus

Canada's Research-Based Pharmaceutical Companies (Rx & D)

Canadian Agency for Drugs and Technologies in Health

Canadian Breast Cancer Network

Canadian Diabetes Association

Canadian Hospice Palliative Care Association

Canadian Medical Association

Canadian Organization for Rare Disorders

Canadian Society of Hospital Pharmacists

Cancer Advocacy Coalition of Canada

Cancer Care Ontario

Castalia

Colorectal Cancer Association of Canada

Conference of Deputy Ministers of Health

Crémieux, Pierre-Yves

Government of Manitoba

Organizations and Individuals

Government of Newfoundland and Labrador

Government of Nova Scotia

Government of Saskatchewan

Hit the slope for hope

Mood Disorders Society of Canada

New Brunswick Department of Health

Novartis Pharmaceuticals Canada Inc.

PeoplewithDiabetes.ca

Princess Margaret Hospital

Sanofi-aventis Canada Inc.

St. Michael's Hospital

St-Onge, Jean-Claude

Tennant, Linda

The Fraser Institute

University of Alberta

University of British Columbia

Ward Health Strategies

York University

REQUEST FOR GOVERNMENT RESPONSE

Pursuant to Standing Order 109, the Committee requests that the government table a comprehensive response to this Report.

A copy of the relevant *Minutes of Proceedings* (Meetings Nos. 47, 49, 50, 51, 52, 54, 55, 56, 58, 60 and 61 of the First Session of the Thirty-ninth Parliament and Meetings Nos. 2 and 4 of the Second Session of the Thirty-ninth Parliament) is tabled.

Respectfully submitted,

Joy Smith, MP
Chair

COMMON DRUG REVIEW

SUPPLEMENTARY OPINION

Presented by the MP for the Bloc Québécois

Christiane Gagnon (Québec)

Vice-Chair of the Health Committee

Context

- The House of Commons Standing Committee on Health conducted a study of prescription drugs, starting with an assessment of the Common Drug Review (CDR).

- The Committee held hearings from April to May 2007 and heard representatives of federal and provincial authorities, pharmaceutical companies, patients' rights groups, health-care professionals, researchers and academics, as well as representatives of the CDR.

- The CDR examines the clinical effectiveness and cost effectiveness of new drugs.

- All the public health plans participate in the CDR, except Quebec's.

- Quebec has its own drug review process, the Medication Council, and is thus not affected by this study.

- The Council functions independently of the Quebec Minister of Health and Social Services and reviews application for inclusion on the drug benefit list, which must be pre-approved by Health Canada. The Council meets three times a year.

- The Council's duties consist of helping the Minister to update the drug benefit list (the Liste de médicaments du régime général d'assurance médicaments, which includes those drugs covered by the basic prescription drug insurance plan, and the Liste de médicaments-établissements) and encouraging the most effective use of medications.

- The Medication Policy also offers measures to ensure that Quebec pays a fair and reasonable price to subsidize medications.

- Drug insurance is mandatory in Quebec, where two plans co-exist: the public and the private.

- All private plans must at a minimum cover all the drugs on the list of drugs put out by the Régie de l'assurance maladie du Québec (RAMQ), including the government's public insurance plan, which provides basic insurance to people who do not have access to a private plan.

- The Council thus lists the drugs covered by Quebec's drug insurance plan and by the private plans.

- As mentioned in the Committee's report, Quebec has its own drug review system and is not subject to the CDR. The recommendations for ways to improve the CDR, including national committees and strategies, do not therefore apply to Quebec.

The Common Drug Review (CDR) does not affect the Quebec system.

The Bloc Québécois's position:

The Bloc Québécois supports the report's recommendations:

- because they make certain corrections that will improve the process and reflect the criticisms and observations expressed by many witnesses, including experts, patients' groups and associations, and the pharmaceutical industry.
- moreover, the Bloc Québécois motion, adopted by the Committee, calling for the Auditor General of Canada to review the mandate, costs, management and effectiveness of the Common Drug Review will surely further add to the analysis of the process.

However, the Committee's refusal to agree to the Bloc Québécois proposal to add the following paragraph after paragraph 1 on page 1:

  - Whereas Quebec has had its own drug review process, the Medication Council, and its own drug policy, since February 2007, it is agreed that the recommendations for ways to improve the CDR, including national committees, programs, guides, strategies, etc. does not apply to Quebec.

  - Quebec therefore has the right to withdraw without conditions and with full compensation from the CDR and any new national initiatives in this area.

The Bloc Québécois has no other choice than to attach a supplementary opinion to this report.