Evaluation of the First Year of Operation for the Common Drug Review

FINAL REPORT

Submitted to:

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EXECUTIVE SUMMARY

Overview of CDR

The Canadian Coordinating Office for Health Technology Assessment (CCOHTA) was formed in 1989 to assess health technologies and receives funding from Canadian federal, provincial and territorial governments. It has since become a key source for unbiased, evidence-based information on drugs, devices, healthcare systems and best practices. Decision makers for Canadian healthcare rely on CCOHTA to help them make well-informed health technology choices. It provides unbiased, relevant and timely information through three programs, one of which is the Common Drug Review (CDR). The CDR was designed and established with extensive input from the publicly funded Canadian drug plans and consultations with industry and consumer groups.

The CDR is a process for both reviewing new drugs and providing formulary listing recommendations to participating publicly-funded federal, provincial and territorial drug benefit plans in Canada with the exception of Quebec. Its objectives are as follows:

- To provide a consistent and rigorous approach to drug reviews and evidence-based listing recommendations;
- To reduce duplication of efforts by drug plans;
- To maximize the use of limited resources and expertise; and
- To provide equal access to the same high level of evidence and expert advice by all participating plans.

The CDR, Health Canada and the Patented Medicine Prices Review Board (PMPRB) play distinct roles in the review of drugs in Canada. Health Canada is responsible for evaluating and monitoring the safety, efficacy, quality and regulatory compliance of pharmaceuticals. Based on the review of a manufacturer's submission of pre-clinical and clinical evidence, it determines if a drug is safe, efficacious and of sufficient quality to be licensed for sale in Canada and continues to monitor the drug after it is marketed. The price charged for a patented drug is regulated by the PMPRB, a federal agency. The CDR's role is to determine if the new drug is cost effective, i.e., provides value for money, compared to existing therapies in Canada and to make a recommendation in this regard to the participating drug plans. The CDR uses information supplied by manufacturers and supplements this with an independent literature search.

One of the requirements when the CDR was established was that the program be evaluated against its objectives following the first year of operation. This independent evaluation responds to this commitment.

Methodology

Evaluation Advisory Committee

The development of the evaluation methodology and the data collection tools (survey and interview questions) was guided by an Evaluation Advisory Committee (EAC) representing the Canadian Expert Drug Advisory Committee (CEDAC) , Advisory Committee on Pharmaceuticals (ACP) , and CCOHTA as they are directly involved in the CDR.

Key Informant Interviews and On-Line Survey

A total of 35 interviews were conducted with a broad range of stakeholders. Names of potential interviewees were compiled by CDR staff and were chosen to represent the range of CDR stakeholders. Specific individuals were chosen based on previous contact or communication with the CDR. Categories of interviewees represented and the breakdown of interviews are reported in Figure 1.

Interviews averaged about 45 minutes in duration. The interview protocol can be found in Appendix B of this report.

In addition to interviews, a survey of CDR stakeholders was conducted via the Internet. For the purposes of this survey, participants were all subscribers to the *CDR Update,* a periodic newsletter. A total of 133 respondents completed the survey corresponding to a response rate of 30 per cent. Figure 1 summarizes the survey respondents by category of CDR stakeholders.

Figure 1 Interviewees and On-line Survey Respondents by Category

	Total	Industry	Advocacy Groups	Government Stakeholder	Other
Number of Respondents to On-line survey	133	70	15	34	14
Number of interviewees, by category	35	8	3	21	3

Categories of respondents are described as follows:

- Industry respondents include manufacturers, consultants working with manufacturers and industry association representatives;
- Advocacy Group respondents include representatives of patient advocacy groups;
- Government stakeholders include Health Ministry representatives, drug plan representatives, Health Canada staff, Patented Medicine Prices Review Board (PMPRB) representatives, Canadian Institute for Health Information (CIHI) representatives, Advisory Committee on Pharmaceuticals (ACP) members and CEDAC members; and

- Others include researchers, university staff/academics, healthcare providers.

The survey of CDR stakeholders can be found in Appendix C of this report.

Conclusions

The CDR has gone to great lengths to develop a process that is consistent and rigorous. The CDR has developed a number of publicly available documents that are used as templates or guides in the conduct of evidence-based reviews. In addition CEDAC recommendations and reasons for the recommendations are posted on the Internet and are publicly available. Opinion is divided on whether the CDR has met its objective of a consistent and rigorous review process: the government stakeholders and others perceive the process as rigorous and consistent while industry and advocacy groups hold the opposite view. Those who argue that the process lacks rigor cite the lack of expertise on the part of reviewers and the lack of multiple reviewers. We note that these interviewees have little basis on which to assess the reviewers since the CDR does not divulge the identity of reviewers. Those who feel the process lacks consistency note the differing levels of evidence/data required for a second entry product versus a new entry product and that CEDAC may make a recommendation not to list even if all reviews by CDR reviewers tend to be favourable. It is noted however that CEDAC is the appointed, national, independent advisory body of health and other professionals with expertise in drug therapy and drug evaluation, tasked with making the formulary listing recommendations to each of the Federal, Provincial and Territorial (F/P/T) publicly funded drug plans with the exception of Quebec.

CDR stakeholders are divided on whether the CDR process is fair, objective and transparent. Those who represent industry and advocacy groups feel strongly that the process lacks fairness, objectivity and sufficient transparency, other stakeholders have the opposite view. Those who feel the process lacks fairness, objectivity and transparency feel this way largely because of the lack of public input into the process as well as, in their opinion, the lack of qualifications on the part of reviewers. The pharmaceutical industry in particular feels they need information on the identity and qualifications of reviewers in order to assess their expertise and to identify any potential conflicts of interest on the part of reviewers.

The CDR was intended to reduce duplication of reviews across participating drug plans. From the perspective of the participating drug plans, the CDR has succeeded in doing this. However, a few of the larger drug plans, are conducting analyses of CEDAC listing recommendations, that is, they have not completely adopted the CDR process. There are, however, indications that these drug plans will fully adopt the CDR process once a level of comfort with the process and recommendations has been reached. Despite the lack of universal adoption of the CDR process by participating drug plans, there is an overall perception that the CDR has decreased duplication. Besides drug plans having access to recommendations, which all are using, manufacturers are no longer required to prepare a different submission for each drug plan. They are, however, asked to send copies of submissions made to the CDR to participating drug plans. Pharmaceutical companies have argued that the CDR is duplicating reviews conducted by Health Canada,

however, the CDR contends that they are simply using all available data, including Health Canada data, to conduct a thorough review.

Although the CDR process is seen as being relatively efficient by all those directly involved some feel it can be made more efficient. Currently all reviews are conducted in the same manner regardless of their complexity. Some interviewees suggested that the CDR could structure reviews according to the level of complexity of the submission with less complex reviews taking less time and fewer resources than more complex reviews.

There is frustration over the lack of timely adoption of CEDAC recommendations by participating drug plans. Advocacy groups and industry argue that the drug plans have been quick to act on negative recommendations but slow to act on positive recommendations. It is beyond the mandate of the CDR to influence or force participating drug plans to make recommendations in a timely manner. Based on its relationship with drug plans, the CDR may be in a position to use moral suasion to the extent that it can to encourage drug plans to act. As well, the CDR continues to work with participating drug plans to ensure that reviews and recommendations meet their needs.

Industry and advocacy groups argue that the CDR has resulted in longer times to listing. However, data on the historical time to listing and current time to listing do not support this view. In fact, these data indicate that the time to listing has decreased since the implementation of the CDR. The historical time to listing (prior to the CDR) ranged from 346 calendar days in Saskatchewan to 744 calendar days in Prince Edward Island. The current average times to listing, as of April 2005, range from 284 calendar days in British Columbia to 351 in Saskatchewan. However, the number of listings decisions to date has been relatively small and so these data should be treated with some caution. The time to list is defined as the time from the date that the NOC was issued to the date the product was listed on a provincial formulary; therefore, included in this timeframe is the time that the manufacturer takes to file a submission. CDR statistics indicate that for the submissions it has received, the time for a manufacturer to file after the NOC is issued has ranged from 1 day to 727 business days with the average being 93 business days. The time for the manufacturer to file a submission and the time for a drug plan to make a listing decision after the CDR recommendations and reasons are issued are beyond the control of the CDR. The CDR has been meeting its performance target with reviews taking an average of 99 business days.

The majority of respondents argue that there is a need for active and meaningful input and participation in the CDR process by the public. This view was expressed by all groups of stakeholders. However, there are significant challenges in doing this since public participation, input and information sharing must be balanced against the drug companies' desire to protect confidential or proprietary information. In addition, advocacy groups are demanding more information but the information on the CDR web site, specifically the recommendations, are not geared to the general public. Further, there is also the challenge of who or which organizations, represent the public. Patient advocacy groups, by definition represent particular illness, disease, or disability groups and not necessarily the general public.

According to manufacturers, the impacts of the CDR on pharmaceutical companies include a greater administrative burden, difficulty in getting products listed, impacts of a recommendation not to list and a slowed review process. A CEDAC recommendation of "not to list" has significant impacts for drug companies within the Canadian market and possibly internationally. The fact that recommendations are publicly available means they are accessible by privately insured plans as well as policy makers in other countries. Prior to the CDR, a decision not to list a drug on a public formulary in one jurisdiction did not necessarily imply a negative decision by all Canadian drug plans since drug plans did not share information in a consistent manner.

This evaluation found some evidence that drug companies are hesitant to provide all available data to the CDR in a timely manner. Representatives from the CDR and CEDAC noted that data provided by manufacturers as part of their submissions is often incomplete or of poor quality. There is a need for manufacturers to conduct relevant 'head-to-head' comparator trials, to provide better quality data, particularly the pharmacoeconomic evaluations of the drug under review.

According to advocacy groups the most significant impact of the CDR on patients is delayed access to drugs. This is directly linked to the perception that the CDR process has resulted in a longer time to listing, which as noted above, cannot be proven based on currently available data.

Impacts on participating drug plans, have, according to drug plan representatives, been wholly positive. Drug plan representatives responding to the on-line survey note that the CDR has resulted in increased homogeneity and increased efficiency.

This evaluation found evidence of much frustration and misunderstanding with respect to the CDR process and recommendations. The patient advocacy groups in particular appear to have little awareness of the purposes and benefits of an evidence-based review. This points to a need for the CDR to better communicate information about the CDR process and its benefits to the general public and that the CDR develop a more consistent communication strategy.

Recommendations

1. Currently, decisions and recommendations are geared towards drug plans and manufacturers, and are in highly technical language which is difficult for the general public to understand or appreciate. The CDR should develop a process to communicate decisions and recommendations to the general public.

2. The CDR should work with the pharmaceutical industry and individual companies towards making the CDR process more transparent for all stakeholders.

3. CCOHTA/CDR should assess how best to incorporate public input into the CDR process.

4. The CDR should explore different approaches for undertaking reviews depending on the complexity of the submission. Reviews of simpler products/submissions should be less time and labour intensive than more complex submissions.

1. INTRODUCTION

1.1 OVERVIEW OF CDR

The Canadian Coordinating Office for Health Technology Assessment (CCOHTA) was formed in 1989 to assess health technologies and receives funding from Canadian federal, provincial and territorial governments. It has since become a key source for unbiased, evidence-based information on drugs, devices, healthcare systems and best practices. Decision makers for Canadian healthcare rely on CCOHTA to help them make well-informed health technology choices. It provides unbiased, relevant and timely information through three programs, one of which is the Common Drug Review (CDR). The CDR was established in response to a January 2002 directive from the premiers. All publicly-funded provincial, territorial and federal formularies, with the exception of Quebec, participate.

The CDR is a process for both reviewing new drugs and providing formulary listing recommendations to participating publicly-funded federal, provincial and territorial drug benefit plans in Canada. Its objectives are as follows:

- To provide a consistent and rigorous approach to drug reviews and evidence-based listing recommendations;
- To reduce duplication of efforts by drug plans;
- To maximize the use of limited resources and expertise; and
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The CDR process begins upon the receipt of a submission. For a drug to be eligible for submission, it must have a Notice of Compliance (NOC) or a NOC with conditions from Health Canada and currently the CDR is reviewing only new drugs that have not been previously marketed in Canada. The CDR process consists of a systemic review of the available clinical evidence and a critique of manufacturer

submitted pharmacoeconomic studies and budget impact analyses. These reviews are then submitted to Canadian Expert Drug Advisory Committee (CEDAC) for use in forming a recommendation to participating drug plans. Once the recommendation has been made public, each of the drug benefit plans that participate in CDR makes its own formulary listing and benefit coverage decisions based on the CEDAC recommendation and the plan's mandate, priorities and resources. Each drug plan is independently responsible for advising the manufacturer of its listing decision and the coverage status of the drug.

CEDAC is an appointed, national, independent body of physicians, pharmacists and other professionals. CEDAC uses the CDR reviews to make common formulary listing recommendations to participating drug plans.

One of the requirements when the CDR was established was that the program be evaluated against its objectives following the first year of operation. This independent evaluation responds to this commitment.

1.2 METHODOLOGY

a) Evaluation Advisory Committee

The development of the evaluation methodology and the data collection tools (survey and interview questions) were guided by an Evaluation Advisory Committee (EAC) consisting of a CEDAC member, Advisory Committee on Pharmaceuticals (ACP) member, and CCOHTA as they are directly involved in the CDR.

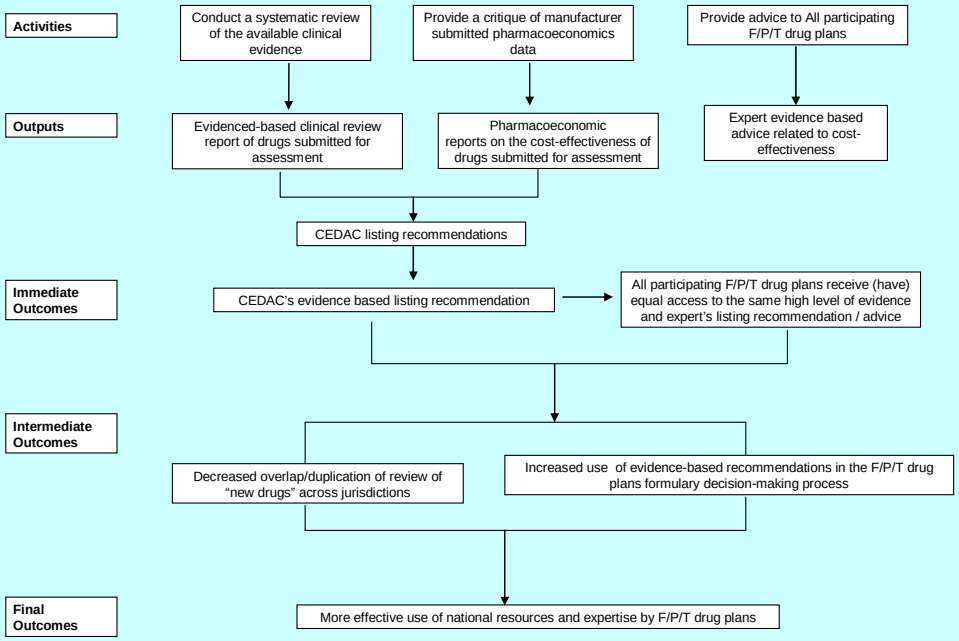
A second element of this study, beyond the evaluation of the CDR, was to revise the CDR logic model. A logic model (not to be confused with a process model) identifies the linkages between the activities of a program and the achievement of its outcomes. It clarifies the set of activities that make up a program and the sequence of outcomes that are expected to flow from these activities. The logic model serves to illustrate the chain of results connecting activities to the final outcomes or objectives and, thus, identifying the steps that would demonstrate progress towards their achievement. The logic model serves to provide a common understanding of what the program does and is intended to produce or result in. A logic model includes the following:

- Activities: these are the key activities that staff are engaged in under the program, the key activities intended to contribute to the achievement of the outcomes. We note that these are different from the administrative activities.
- Outputs: these are what demonstrate that the activities have been undertaken.
- Immediate outcomes: these are the short-term outcomes that stem from the activities and outputs. Outcomes in a logic model typically have an action word associated with them and represent the consequences of the activities and outputs.

- Intermediate and final outcomes: these flow from the immediate outcomes and generally take a longer period of time to achieve. This generally includes the ultimate goals or objective of the program.

The revised logic model for the CDR is illustrated in Figure 1-I below.

Figure 1-I Logic Model for the Common Drug Review (CDR)



b) Evaluation Questions

The fist step in the evaluation process was to identify the evaluation questions. The focus of this evaluation is the CDR's achievement of its stated objectives, specifically:

- Providing a consistent and rigorous approach to drug reviews and an evidence-based listing;
- Reducing duplication of effort by drug plans;
- Maximizing the use of limited resources and expertise; and
- Providing equal access to the same high level of evidence and expert advice by all participating drug plans.

The starting point for the development of the questions to be addressed by the evaluation were the objectives of the CDR. In addition, questions related to the cost-effectiveness of CDR and CDR's communication strategy were identified as of interest to stakeholders and CDR management. Finally, general questions related to the impacts of the CDR on stakeholders were added for completeness. The evaluation matrix, including evaluation questions as well as indicators and data sources was developed under the guidance of an Evaluation Advisory Committee (EAC). The Evaluation Matrix is illustrated in Appendix A.

c) Key Informant Interviews and On-Line Survey

A total of 35 interviews were conducted with a broad range of CDR stakeholders. Names of potential interviewees were compiled by CDR staff and were chosen so as to represent the range of CDR stakeholders. Specific individuals were chosen based on previous contact or communication with the CDR. Categories of interviewees represented and the breakdown of interviews are reported in Figure 1-II.

Interviews averaged about 45 minutes in duration. The interview protocol can be found in Appendix B of this report.

In addition to interviews, a survey of CDR stakeholders was conducted via the Internet. For the purposes of this survey, participants were subscribers to the *CDR Update*, a periodic newsletter. In terms of logistics, CCOHTA sent an email to all potential survey respondents alerting them to the survey and to expect an email from EKOS Research Associates who would provide them with the URL link and PIN necessary to complete the survey. CCOHTA representatives also alerted stakeholders to the survey in the periodic newsletter sent by CCOHTA to stakeholders. In addition, CDR posted the *CDR Update* on its web site and invited all those who were not currently on the electronic mailing list and who wished to participate in the survey to contact EKOS Research Associates for a PIN to allow them access to the survey. EKOS provided PINs on request. A total of 133 respondents completed the survey. The total number of contacts, excluding CDR and CCOHTA staff, in the CDR database of *CDR Update* subscribers was 437. However 18

emails in this database were not valid and an additional 23 individuals requested PINs. This amounts to an effective sample size of 442 and a response rate to the survey of 30 per cent. Figure 1-II summarizes the survey respondents by category of CDR stakeholders.

Figure 1-II Interviewees and On-line Survey Respondents by Category

	Total	Industry	Advocacy Groups	Government Stakeholder	Other
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- Others include researchers, university staff/academics, and healthcare providers.

The survey of CDR stakeholders can be found in Appendix C of this report.

2. RESULTS

This chapter provides an assessment of the extent to which the CDR has achieved its stated objectives. The key sources of information or data used to assess the results achieved by the CDR include key informant interviews, the survey of CDR stakeholders and background documents provided by the CDR and downloaded from the Internet.

2.1 EXTENT TO WHICH REVIEWS ARE CONSISTENT AND RIGOROUS

a) Results from Interviews

There is general agreement among most of those interviewed, particularly CDR, CEDAC and drug plan representatives, that the CDR process is consistent. One interviewee representing CEDAC noted that, if anything, the CDR review process was too consistent, i.e. too rigid and did not allow for sufficient flexibility to adapt the process to specific situations or products under review.

Drug manufacturers and industry association representatives interviewed noted what they see as inconsistencies in the review process. Two interviewees representing drugs manufacturers and industry associations believe there are inconsistencies in the level of evidence required for a second entry product versus a new product. Another inconsistency cited by interviewees is that CEDAC may make a recommendation not to list even if either the clinical or the pharmacoeconomic or both reports are favourable. This is also noted as an issue in a review of CDR published in the *Provincial Reimbursement Advisor*[1]. These interviewees also noted that this points to a lack of objectivity in the CDR process.

There are also differing opinions on whether the CDR process is rigorous, with the majority of CDR staff, CEDAC members and drug plan representatives believing it is rigorous and other categories of interviewee disagreeing. Five (of nine) representatives from drug plans noted that the CDR process is more rigorous than what was performed in their jurisdiction prior to CDR, particularly in smaller jurisdictions such as the Atlantic provinces and Saskatchewan that lacked sufficient resources to conduct rigorous reviews. Those who feel the process lacks rigour, most often representatives from the pharmaceutical industry, cite the lack of adequate expertise on the part of some reviewers. These interviewees feel that the CDR should ensure that reviewers have direct expertise and experience related to the disease or condition for which the drug being reviewed is intended. The pharmaceutical industry would like to see the identity of reviewers revealed along with the recommendations so there can be a public assessment of their qualifications. As

[1] David Chown, "The Common Drug Review – One Year Later" in Provincial Reimbursement Advisor, November 2004, p.27.

noted earlier, it is CEDAC and not the CDR reviewers that make the listing recommendation, and the identity and qualification of CEDAC members are publicly available on the CCOHTA website. A recent article in the in *Provincial Reimbursement Advisor* on CDR's performance also noted the pharmaceutical industry's concerns about potential conflicts of interest that could be avoided if reviewers' identities were provided to manufacturers[2]. However, the CDR has established explicit rules regarding conflict of interest and it sends reviewers' reports, including a list of all documents reviewed, to pharmaceutical firms for comment prior to sending the reports to CEDAC. Drug manufacturers/sponsors are not sent the final reviews, including revisions based on their comments, prior to these being sent to CEDAC.

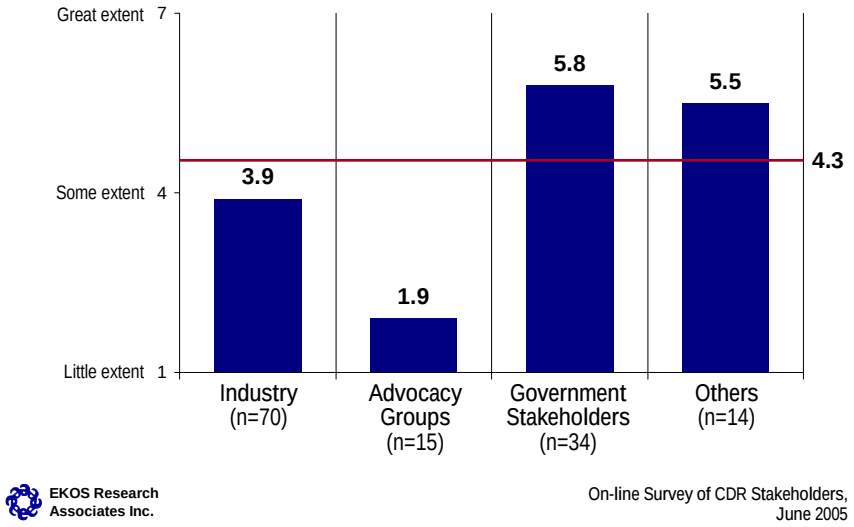
Another concern related to rigour cited by the majority of interviewees representing the pharmaceutical industry is the lack of multiple reviewers for each drug submission. Drug manufacturers, industry representatives, consultants and representatives from advocacy groups feel there is potential for bias in economic reviews since the interpretation is often subjective. Contrary to this view, the CDR has indicated that steps are in place to minimise bias as much as possible. For instance, the CDR Review Team consists of at least two clinical reviewers, at least two economic reviewers, at least one clinical specialist, other experts as required and an information specialist along with other CDR Directorate staff. The number of members and their backgrounds are considered in establishing a team to mitigate bias.

b) Results from On-line Survey

The differences in opinion with respect to how well CDR has met its objective of a rigorous approach to drug reviews, is echoed in the results of the on-line survey of CDR stakeholders. Respondents from the government stakeholder category indicated that they believed that CDR has met this objective to a great extent, versus the respondents representing patient advocacy groups who feel that the CDR has met this objective to little extent. These survey results are summarized in Figure 2-I below.

[2] David Chown, "The Common Drug Review – One Year Later" in Provincial Reimbursement Advisor, November 2004, p.27.

Figure 2-I
Perceptions of the Rigour of the CDR Approach



c) Results from Other Sources

A key objective in setting up the CDR was that all reviews of new drugs would be conducted in a consistent and rigorous manner. In order to facilitate meeting this objective, the CDR has developed a number of documents that guide the review process, many of which are publicly available on the CDR website.

All recommendations and the reasons for the recommendations are publicly available on the CDR web site. As well, drug plan representatives are permitted to observe the deliberations of CEDAC. CDR and CEDAC members report that the CDR continues to work on refining and improving the review process.

d) Discussion

The CDR has made great efforts to put in place structures and processes to ensure the rigour and consistency of the review process. Opinions on whether the CDR has been successful at conducting reviews in a consistent and rigorous manner differ according to the category of stakeholder with government stakeholders viewing the process as consistent and rigorous and industry and advocacy groups disagreeing.

The concerns of those who feel the process lacks rigour relate to the reviewers' expertise and the number of reviewers assigned to each review. Drug manufacturers in particular would like to see the identity and qualifications of each reviewer revealed so that they may be vetted and that any potential conflicts of interest be identified. The CDR shares the reviewers' reports with drug manufacturers and seeks

comments on the reviews prior to sending them to CEDAC, thus manufacturers are provided with the opportunity to comment on the work of the reviewers. With respect to conflict of interest, the CDR has established conflict of interest guidelines for the reviews. Given the high profile nature of some of the reviews conducted recently by the CDR, it would not be realistic to risk subjecting reviewers to pressure or lobbying which could compromise the reviews. A Review Team consisting of multiple reviewers is currently assigned to each submission.

2.2 PROCESS IS FAIR, OBJECTIVE AND TRANSPARENT

a) Results from Interviews

Interviewees were split between those who feel the CDR process is fair and those who do not. Those who feel the process is fair generally represent drug plans, CEDAC and CDR whereas those who feel the process lacks fairness represent pharmaceutical companies and industry associations, and patient advocacy groups.

Those who feel the CDR process is fair cite the opportunity for manufacturers to comment on reviews; the mix of different perspectives on CEDAC and the fact that manufacturers are given the opportunity to appeal any recommendations of not to list made by CEDAC. In addition, the drug industry is given the opportunity to nominate individuals for membership on CEDAC. However, three interviewees representing CEDAC, CDR and drug plans, although noting the process is fair, feel there is a need for more public input, but not necessarily from patient advocacy groups, and a need for better communication to the general public on the part of CDR of the benefits of CDR and how CDR works.

Interviewees who believe the CDR process lacks fairness cite a lack of expertise and information about reviewers and their qualifications. Pharmaceutical companies and consultants noted that there is a shortage of experts that are able to conduct reviews of specialty products and thus the fairness of the reviews is diminished since reviewers used by CDR may not have the necessary qualifications. Another area where drug manufacturers and industry associations felt the process was unfair was the perception that drug products submitted to the CDR are held to what is seen as a higher standard in terms of the quality of data that must be presented relative to older products that did not have to go through the CDR process. CDR points out that its reviews and conclusions for all submissions, including those for specialty products, are based on the best available evidence.

Another area in which the pharmaceutical industry feels the CDR process is unfair is the appeal process. Currently, appeals go to the same CEDAC members as those who made the initial decision. However, as one CEDAC representative noted, there are difficulties associated with finding qualified individuals in the first instance and this challenge would be compounded by using different members to re-assess the recommendation and reasons for recommendation. Manufacturers have appealed most negative recommendations.

Opinions on the objectivity of the CDR process are similarly split with drug plan representatives, CEDAC members and CDR staff viewing the process as objective and drug companies, industry representatives and advocacy groups believing the process lacks objectivity. The main issue for those who feel the process lacks objectivity is the lack of social perspective in the assessment, however we note that the inclusion or exclusion of a "social perspective" does not affect objectivity. Patient Advocacy groups would like to see the process include factors that impact the quality of life of patients such as ability to work, care for family, and participate in society as well as cost savings associated with decreased use of the healthcare system. Patient advocacy groups feel that the best mechanism to ensure these factors are taken into account is to include patient/consumer input directly into the process. Advocacy groups and pharmaceutical companies and industry representatives feel that the driving force behind the reviews is cost-containment. Interviewees from CDR and CEDAC note the challenge of including or not including the social factors. As one reviewer explained, "CDR does not, nor is it intended to, assess the ethical or social issues related to drugs approved or listed. I'm not certain that the CDR can incorporate these issues and still remain evidence-based." CDR notes that social factors are rarely reported objectively thus this type of "evidence" is difficult to include in an "evidence-based" reports. Another CDR representative noted that the biggest challenge for CDR is communicating what the evaluation and decision is based upon. We note that when quality of life is an outcome in the clinical reviews and included in the pharmacoeconomic evaluations, it is assessed by the CDR reviewers. According to CDR staff, these data provided by firms are often flawed or not substantiated, thus limiting the ability of the CDR to incorporate the societal aspects into the review.

The vast majority of those interviewed representing drug plans, CDR, CEDAC and consultants believe that the CDR process is transparent. This view is echoed in a review of CDR published in the *Provincial Reimbursement Advisor*[3]. These interviewees noted the process is transparent since drug plan representatives are able to observe CEDAC deliberations, recommendations and the reasons for recommendations are publicly available and feedback from pharmaceutical firms is sought on the reviews prior to sending them to CEDAC. Of the 21 CEDAC, CDR and drug plan representatives interviewed, three commented that any lack of transparency is the direct result of the pharmaceutical firms' refusal to share information and data or to share it in a timely manner. These interviewees report that there are situations where pharmaceutical companies have refused to publicly share key information citing confidentiality. CCOHTA and the CDR Directorate have developed *Confidentiality Guidelines* aimed at ensuring the protection of confidential information obtained under the CDR program. These guidelines are detailed in the *CDR Submission Guidelines for Manufacturers*. Since CCOHTA is a private, non-profit organization, it is not subject to either federal access to information or provincial/territorial freedom of information statutes. However, according to the *Guidelines*, manufacturers are asked to consent to their information being exchanged with federal/provincial/territorial governments, federal/provincial/territorial health authorities, drug plans, Health Canada and the PMPRB by signing a letter. These bodies have their own confidentiality procedures and are subject to provincial or federal freedom of information and access to information legislation. CEDAC members, although provided with access to confidential information, are not permitted to refer to this information in their recommendations. One CEDAC member has noted in the past that CEDAC

[3] David Chown, "The Common Drug Review – One Year Later" in Provincial Reimbursement Advisor, November 2004, p.26.

members find this frustrating since this does not allow for incorporating all information into explaining the rationale for a recommendation[4].

Other categories of interviewees, particularly advocacy groups, feel strongly that the CDR process lacks sufficient transparency. These interviewees feel that one key area where there is a lack of transparency is in the lack of a public forum for the CEDAC deliberations. This, according to these interviewees, means that the public, pharmaceutical firms and other interested parties have no sense of how decisions were arrived at and does not provide them with a mechanism for voicing opinions or concerns. Suggestions for remedying this include the sharing or publication of the minutes of CEDAC meetings and opening the meetings to the public. Advocacy groups also recommend that consumer representation be included in CEDAC with the same voting rights as other CEDAC members. In addition, interviewees from patient advocacy groups recommend that CDR establish a Consumer Advisory Committee that would be composed of consumers. This advisory committee would provide input and advice to CDR on policies and procedures as well as feedback on decisions and their impacts on consumers. The CDR has commissioned a study to assess the public's involvement in the CDR process.

With respect to public engagement in the CDR process, CCOHTA engaged public stakeholder and consumer advocates when developing the CDR process, and in response to comments received, modified the CDR process and created mechanisms to keep stakeholders informed. These mechanisms, which are available on the CCOHTA web site, include:

- Electronic CDR newsletter; and
- Submission status tracking forms.
- CEDAC Recommendation and Reasons for Recommendation

CCOHTA has also commissioned a project to identify options for public engagement.

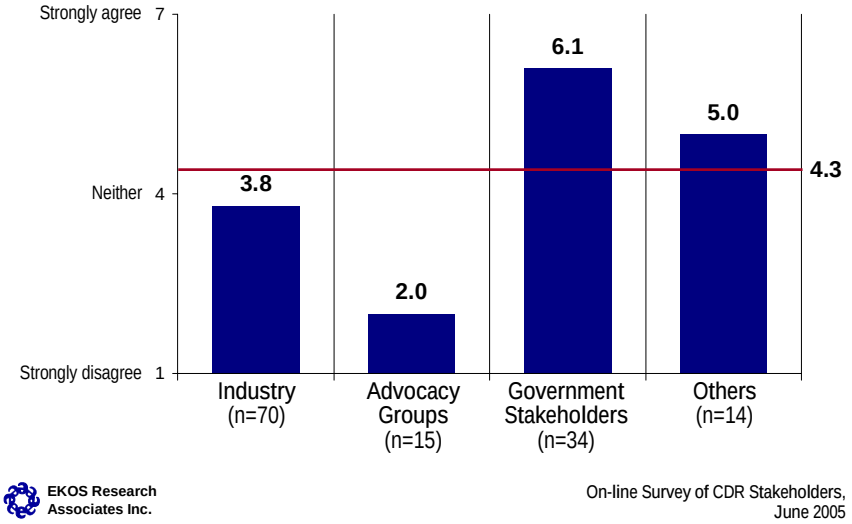
Another area where interviewees representing the pharmaceutical industry and consultants felt the CDR process lacked transparency was in the identity of reviewers. The pharmaceutical industry would like the identity of reviewers to be shared, at the very least, with the manufacturers submitting drugs for review to the CDR. This would allow them to assess the appropriateness of the reviewers' qualifications. The CDR currently has no plans to reveal the identity of reviewers and its process does not permit pharmaceutical companies to evaluate the qualifications of reviewers or any potential conflict of interest. In the past the CDR has stated that it believes the objectivity of the CDR process can best be served by not revealing reviewers' names. However, for each submission, the CDR Review Team consists of at least two clinical reviewers, at least two economic reviewers, at least one clinical specialist, other experts as required and an information specialist along with other CDR Directorate staff. The number of members and their backgrounds are considered in establishing a team to mitigate bias.

[4] Provincial Reimbursement Advisor, "Meet the Manager", May 2005, p. 44.

b) Results from On-line Survey

A difference in findings regarding the fairness of the CDR process is reflected in results from the survey of stakeholders, where on average, respondents from the government stakeholder category agreed that the CDR process was fair and those from industry and the advocacy groups did not agree that the CDR process was fair. These results are summarized in Figure 2-II.

Figure 2-II
Fairness of the CDR Process



Survey respondents who indicated that they feel the CDR process is unfair were asked to explain why they felt the process was unfair. The majority of responses to this question were answered by respondents from industry and advocacy groups, since these respondents generally feel the process is unfair. The most frequently cited reason for why the process is unfair is the lack of consumer input and the second most frequently cited response is the seeming lack of suitably qualified reviewers. These responses support the perspectives of those interviewed. Responses to this survey question are summarized below in Figure 2-III.

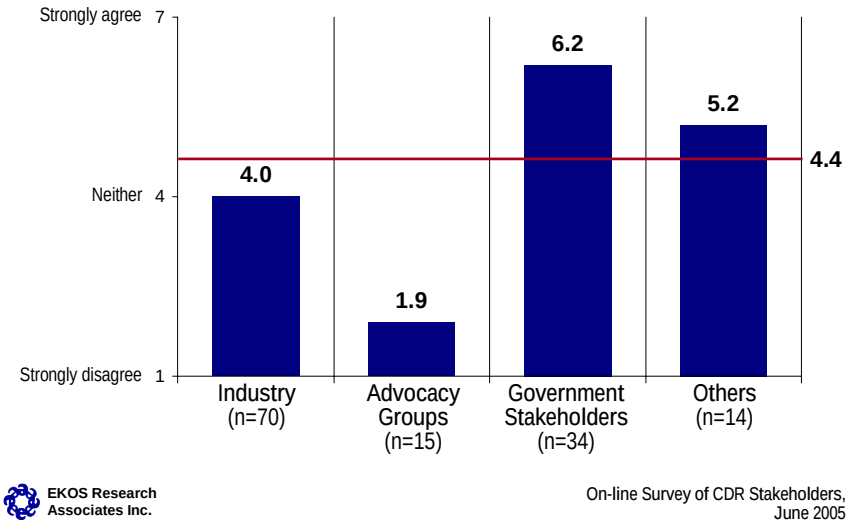
Figure 2-III Opinions on Why the CDR Process is Unfair

	Total (n=45)	Industry (n=31)	Advocacy Groups (n=12)	Government Stakeholder (n=1)	Other (n=1)
No consumer input	9	6	2	1	-
Reviewers not qualified	5	5	-	-	-
Biased against manufacturers	5	2	3	-	-
Too focused on cost	4	2	2	-	-
Not adapted to orphan drugs	3	2	1	-	-
Appeal process flawed	3	3	-	-	-
Reviewer not identified	2	2		-	-

Source: Survey of CDR Stakeholders, EKOS Research Associates, June 2005.
Note: respondents were able to provide more than one response.

The differing perspectives expressed by interviewees on the objectivity of the CDR process are echoed in the results of the survey of CDR stakeholders. Respondents from the pharmaceutical industry and advocacy groups feel the process lacks objectivity, while respondents representing government stakeholders and others feel the process is objective. These results are summarized in Figure 2-IV below.

Figure 2-IV
Perceptions of the Objectivity of the CDR Process



Survey respondents, who responded that they felt the CDR process was not objective, were asked to explain why they felt the process lacked objectivity. The majority of those who responded to this question represented industry and advocacy groups. The most frequently cited reason for why these respondents felt the CDR process lacks objectivity is because of the influence of drug plans, the second reason was that the process is too focused on cost. These responses are summarized in Figure 2-V below.

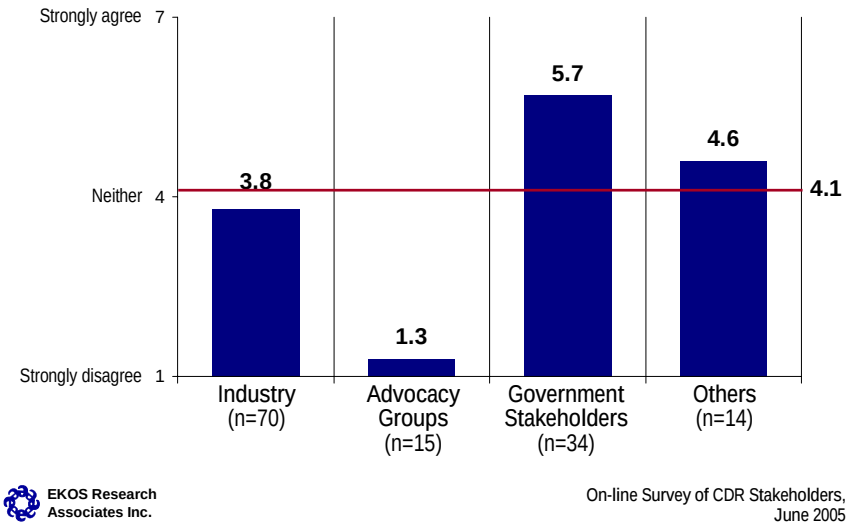
Figure 2-V Opinions on Why the CDR Process Lacks Objectivity

	Total (n=38)	Industry (n=22)	Advocacy Groups (n=14)	Government Stakeholder (n=1)	Other (n=1)
Influenced by drug plans	10	5	5		
Too focused on cost	6	3	2		1
No consumer input	5	3	1	1	
Use of data and bias	4	3	1		
Lack of expertise	3	3	-		
Not adapted to orphan drugs	1	1	-		

Source: Survey of CDR Stakeholders, EKOS Research Associates, June 2005.
Note: Respondents were permitted to provide more than one response.

Results of the survey of stakeholders indicate that government and other stakeholders feel the process is transparent while industry and advocacy categories of survey respondents generally feel the CDR process lacks transparency. Survey results are presented in Figure 2-VI below.

Figure 2-VI
Perceptions of the Transparency of the CDR Process



Survey respondents who indicated that they feel the CDR process lacks transparency were asked why they felt this to be the case. Those from industry and advocacy groups represented the vast majority of those who feel the process lacks transparency with the most frequently cited reasons being the lack of public involvement and the lack of public identity of the reviewers. These responses are consistent with the opinions expressed by interviewees. Survey responses to this question are summarized in Figure 2-VII below.

Figure 2-VII Opinions on Why the CDR Process Lacks Transparency

	Total (n=51)	Industry (n=32)	Advocacy Groups (n=15)	Government Stakeholder (n=2)	Other (n=2)
No public involvement	17	11	5	1	
Reviewers unknown	9	6	2		1
Information not made public	7	4	3		
Decision-making unclear	7	3	3		1
Firms not given access to process	4	4	-		

Source: Survey of CDR Stakeholders, EKOS Research Associates, June 2005.
Note: Respondents were permitted to provide more than one response.

c) Discussion

There is a distinct split between those who feel the CDR process is fair, objective and transparent and those who do not. Those representing industry and advocacy groups are largely dissatisfied with the CDR process while others are satisfied with the fairness, objectivity and transparency of the process. A frequent complaint about the CDR process with respect to fairness, objectivity and transparency is the lack of consumer or public input into the process. This is a complaint cited by both advocacy groups and the pharmaceutical industry. The CDR is currently working on developing a mechanism for incorporating public involvement into the CDR process, however, reconciling the desire for public involvement and the need to maintain the confidentiality of much of the information provided by industry will likely be a challenge.

A key issue for the CDR is balancing the competing need to provide the public with as much information as possible while ensuring the confidentiality of the information provided by pharmaceutical firms. There is a risk that opening CEDAC meetings to the public could compromise the confidentiality of this information provided by firms. A related risk is that pharmaceutical firms will provide only the minimum information if they know the information may end up in the public domain.

Two (of eight) pharmaceutical industry representatives argue that the CDR process is biased against new drugs because they must undergo a more stringent review than that required prior to the implementation of the CDR and that the quality of data required is greater. This argument, although true, implies that the CDR process should reflect the lowest level or standard of review that was conducted by drug plans prior to the CDR. This would in effect be contrary to the objective of the CDR to conduct rigorous reviews since prior to the CDR some jurisdictions lacked the necessary resources to conduct rigorous reviews.

2.3 EVIDENCE-BASED RECOMMENDATIONS

a) Results from Interviews

CEDAC members and drug plan representatives feel the CEDAC recommendations are clear, relevant, evidence-based and unbiased. CEDAC members interviewed noted that the recommendations are good and getting better and more standardized as a result of feedback from drug plans and industry. Drug plan representatives believe that the recommendations are of good quality however two drug plan representatives (of twelve interviewed) feel that more information on the basis of the recommendation would be helpful in order to help demonstrate the unbiased nature of the recommendation. These interviewees recognize that the limiting factor on providing more information is the confidentiality of the information provided by pharmaceutical firms. One suggestion for dealing with the issue of confidentiality is to send background information only to the drug plans for review. We note that CDR is permitted to do this under the confidentiality guidelines described in the Submission Guidelines for Manufacturers. Two drug plan representatives (of twelve interviewed) also indicated that the "Of Note" section in the recommendations report is confusing; however they also noted that CDR is working to clarify this section.

Drug manufacturers, consultants and advocacy group representatives tend to have a less favourable view of the CDR process with respect to the clarity, relevance, and bias of CEDAC recommendations. Issues noted by these respondents include a lack of information included in the review and the lack of information used to produce the reviews and recommendations shared publicly. These interviewees feel that CDR should be sharing more information about how decisions were arrived at and what information was taken into consideration. They suggest that the minutes of CEDAC meetings be shared and/or CEDAC meetings be open to all stakeholders, not just drug plans as they are currently. Two interviewees representing pharmaceutical firms and consultants (of 8 interviewed) noted that CEDAC recommendations fail to take into consideration the societal perspective and instead take a narrow perspective focused on cost-effectiveness and cost-minimization at the drug plan level.

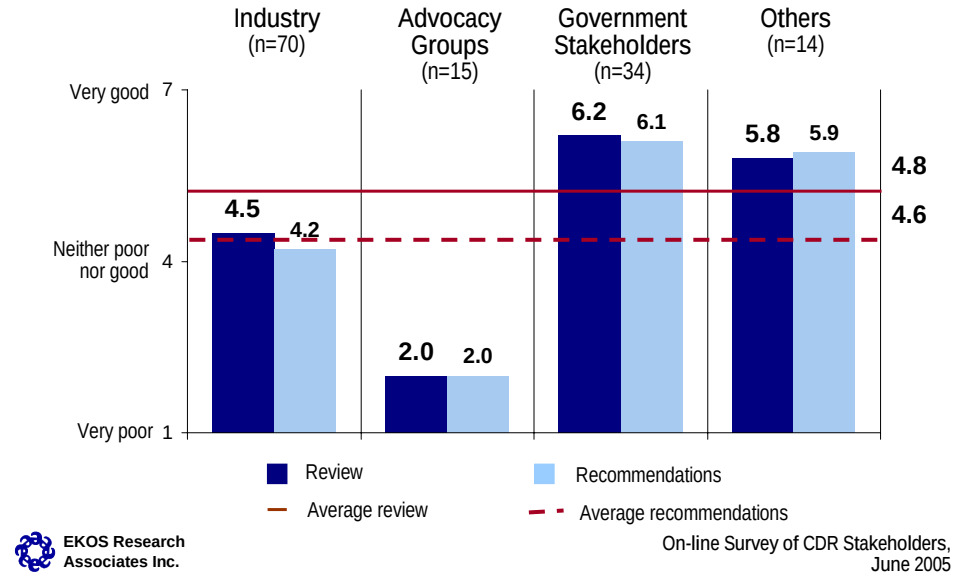
We note that drug manufacturers, although in favour of increased sharing of information by the CDR, are not in favour of sharing all information publicly. Much of the information provided to the CDR by manufacturers is deemed proprietary or confidential.

b) Results from On-line Survey

Survey respondents were asked to rate the performance of CDR with respect to evidence-based reviews. There is a distinct difference of opinion with government stakeholders and others giving the CDR's performance a good rating and respondents representing advocacy groups giving it a poor rating. Industry provided a neutral rating. This is consistent with interviewees' comments and perspectives. Survey respondents were also asked about CDR's performance with respect to providing evidence-based

recommendations. These results mirror those of the previous question with government stakeholders and others giving CDR a positive rating and advocacy groups a poor rating. Results from both these questions are summarized in Figure 2-VIII below.

Figure 2-VIII
Perceptions of Performance with Respect to Providing Evidence-Based Reviews and Recommendations



c) Results from Other Sources

As of August, 2005, CDR has received 39 submissions. The number of recommendations made by CDR is 28 with sixteen recommendations being not to list. Notably, a majority of CDR recommendations are not to list, with twice as much of recommendations to list with conditions versus to list. There is also a clear tendency for recommendations not to list to be resubmitted for reconsideration by the drug manufacturers. A breakdown of the drug submissions received and decisions by CEDAC are summarized in Figure 2-IX below.

Figure 2-IX Summary of CDR Activity, August, 2005

Number of drug submissions received	39
Number of drug submissions requesting Priority Review	10
Number of drugs granted Priority Review	5
Number of drug reviews with Notice of Final Recommendation issued	28
Number of drug submission currently under review	9
Number of re-submissions received	3
Number of submissions withdrawn	3
Number of requests for reconsideration received	14
Decisions	
To list/list in a similar manner as drug plans list other drugs of the same class	8
To list with criteria/conditions	4
Not to list	16
Total decisions	28

Source: CDR Program database, August 24, 2005

d) Discussion

Stakeholders representing advocacy groups tend to be very dissatisfied with the reviews and recommendations provided by the CDR. Based on evidence from interviews, much of this dissatisfaction stems from the opinion that the CDR does not make enough information related to the reviews and recommendations public. These interviewees would like more information on the basis for the recommendations made by CEDAC. Four of those interviewed, including advocacy groups, drug plan representatives and drug companies, suggest that the minutes of CEDAC meetings should be shared. We note that drug companies did not suggest that these minutes be shared publicly but rather with the drug manufacturers only since there is frequently discussion of confidential or proprietary information at CEDAC meetings.

The challenge for the CDR is to reconcile the request for more information on the part of some of its stakeholders against issues of confidentiality of the proprietary information provided by drug firms to the CDR. Some of this may be resolved by better communicating this issue and its challenges to the public and thus leaving the decision on whether to share more information to the manufacturers making the submissions.

2.4 DECREASED DUPLICATION

Another objective of CDR is to reduce duplication of effort by drug plans.

a) Results from Interviews

Based on comments provided by interviewees, particularly drug plan representatives and CEDAC members, there is anecdotal information that a few of the larger drug plans (Ontario and British Columbia) continue to conduct some form of review of new drugs. The drug plans that continue to conduct some form of review tended to have fairly sophisticated and well-established review processes in place prior to the CDR. According to interviewees representing drug plans and CEDAC, the rationale for continuing to conduct drug reviews even though CDR is conducting reviews and providing drug plans with recommendations, is to allow for a transitioning process. Two interviewees representing CDR and drug plans noted that it is their understanding that some of these drug plans intend to conduct their own reviews until there is a level of comfort with the CDR process and recommendations, after which time they will cease conducting reviews on new drugs. Smaller drug plans with fewer resources have, according to those we interviewed, generally adopted the CDR process and are no longer conducting their own drug reviews. So it is clear that with a few exceptions, most of the participating drug plans have universally adopted the CDR process.

Despite the lack of universal adoption of the CDR process by participating drug plans, there is an overall perception among CDR, CEDAC and drug plan representatives that the CDR has reduced duplication. Besides drug plans having access to CDR recommendations, drug companies are no longer required to prepare a different submission for each drug plan. However, according to the *Submission Guidelines for Manufacturers*, drug sponsors or companies are asked to send copies of submissions to participating drug plans after receiving confirmation from CDR that the submission is complete. We note that drug plan representatives are best placed to comment on the extent to which duplication has been decreased.

An area where pharmaceutical firms and industry representatives feel there is duplication is in the reviews conducted by Health Canada and the CDR. Health Canada reviews the safety, efficacy and quality of a drug and provides a NOC or NOC with conditions. Health Canada does not assess the cost-effectiveness of a drug. According to two interviewees representing the pharmaceutical industry the CDR is, in addition to cost-effectiveness, reviewing the safety and efficacy of drugs. As an article on the CDR's performance noted, this could expose the drug companies to safety or efficacy-related liability[5]. This same article noted that the CDR reports that it does not, in general, review Health Canada data, but it does conduct independent reviews of any reliable and available data, in addition to the materials provided by the manufacturers in their submissions. Because good head-to-head comparisons of the agent under review

[5] David Chown, "The Common Drug Review – One Year Later" in Provincial Reimbursement Advisor, November 2004, p.26.

with accepted therapy are lacking and this important information for an economic evaluation, CDR confirms that it looks at all available evidence to determine comparative effectiveness, safety and cost-effectiveness of the agent under review.

b) Discussion

As noted the CDR was implemented, in part, in order to decrease the duplication of reviews across participating drug plans. Smaller drug plans, with fewer resources available for conducting reviews, have generally fully incorporated CDR reviews and recommendations for new drugs into their Submission Review Process. Larger drug plans have, in general, modified their existing review processes to include results and recommendations from the CDR. Larger drug plans, because they have greater resources available, are able to phase in the CDR process. There are indications, based on comments from drug plan representatives interviewed, that there is an intention for all drug plans to fully incorporate the CDR process and recommendations once there is a level of comfort with the CDR.

A concern expressed by five interviewees, other than drug plans, is the length of time for the implementing CEDAC recommendations. Drug plans do not act immediately on CEDAC recommendations for a variety of reasons including: the drug plan review cycle (some update their listings on a quarterly or semi-annual basis while some do it continuously); drug plans or the jurisdictions may have different priorities; there may be differences in available resources both human and fiscal to deal with recommendations. These are challenges that the Canadian healthcare system must deal with and are not within the mandate of the CDR. The best that the CDR can do is to use moral suasion to the extent that it can to push for drug plans to implement recommendations. However this could risk having drug plans withdraw support for the CDR.

Representatives of drug manufacturers interviewed argue that there is duplication between the reviews conducted by Health Canada and the CDR. However, according to the CDR, its reviews use all available data, including the data provided to Health Canada for the review of the safety and efficacy of drugs. This, according to the CDR, does not mean that the safety and efficacy of the drug is re-assessed by CDR, simply that the data are reviewed in order to determine the comparative safety, efficacy, or effectiveness (if data is available) so that the cost-effectiveness can be established. We note that the use and analysis of these data do not impact the manufacturers making the submissions since these are existing data that have been provided to and generated by Health Canada and so should not adversely impact drug companies in terms of effort or cost of making the submission to the CDR. Given the availability of Health Canada data and the fact that it is viewed as credible and objective, the CDR should continue to use these data. If there are issues of efficacy-related liability, these should be addressed with the manufacturers on a case-by-case basis.

2.5 IMPROVED USE OF RESOURCES AND EXPERTISE

a) Results from Interviews

In decreasing the duplication of reviews across drug plans, the CDR was expected to improve the overall use of resources in the healthcare system. Opinions on whether the CDR has improved the use of available resources and expertise are, as with many other aspects of the CDR, mixed.

An issue noted by five interviewees representing CEDAC, CDR, and the pharmaceutical industry is the delayed uptake of CDR recommendations by participating drug plans. These interviewees noted that there is a time lag between when CEDAC makes the recommendations and when participating drug plans act on the recommendation or use the recommendation as input into their own reviews. This is, according to interviewees representing pharmaceutical companies, industry representatives and advocacy groups, particularly true of positive CEDAC recommendations. We note that this delay does not necessarily mean a lack of uptake of CDR recommendations on the part of participating drug plans.

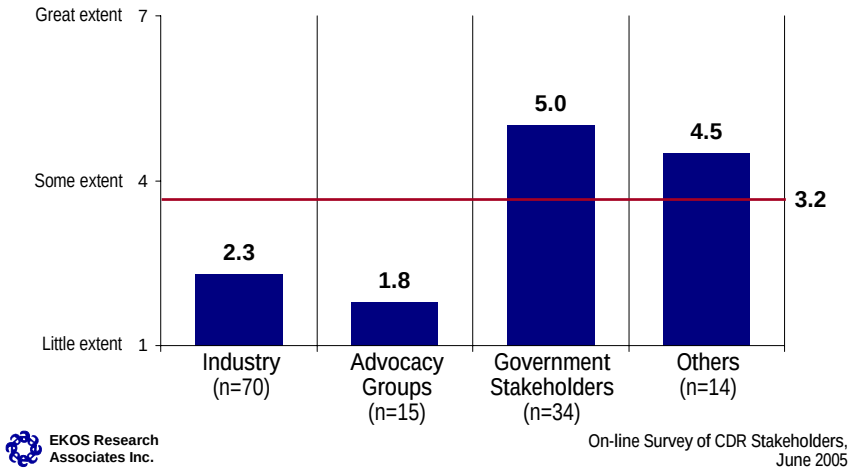
A number of interviewees, specifically those from pharmaceutical companies and industry and advocacy groups (three of 11), argue that participating drug plans are acting quickly on "do not list" recommendations and slowly on the positive recommendations. In order to provide a fair and accurate assessment, data on the Time to List (TTL) for decisions to list and decisions not to list would be required. At present no such data are available. Currently CEDAC has made recommendations on 28 products, 16 (do not list), eight have been recommended for limited listing and four for full listing or list in same manner as other similar agents. Based on this relatively small number of recommendations it would be difficult to draw strong conclusions across all of the participating drug plans.

Interviewees representing participating drug plans report that small drug plans in particular have benefited from an increase in the sharing of information and expertise as a result of the CDR. One of the consultants interviewed noted that there is increased information sharing by the CDR and noted the information available on the timelines for reviews, information on issues related to submission, the identity of products filed for review as well as other information is now available to all stakeholders on the Internet. This consultant also noted that drug manufacturers or the consultants who submit on behalf of the drug companies must also agree to provide access to files and other information such as the Health Canada reviewer reports that were not previously required.

b) Results from On-line Survey

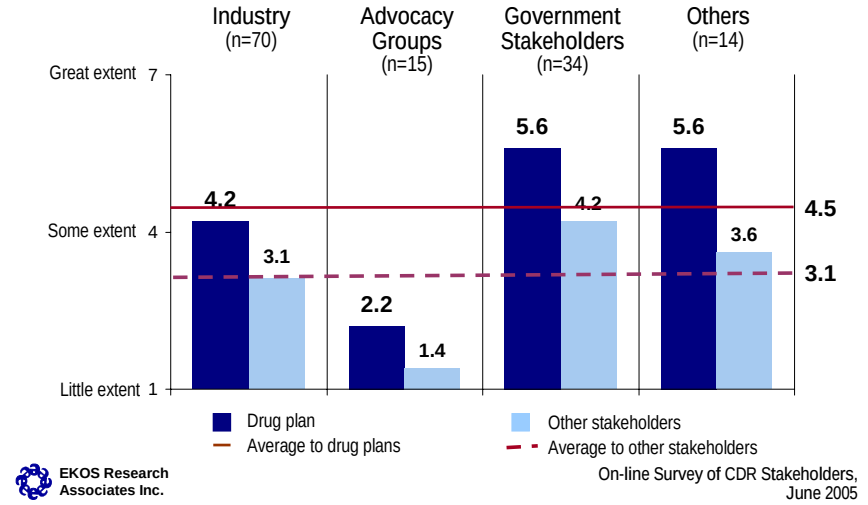
Respondents to the survey of CDR stakeholders were asked to rate the extent to which the CDR increased the efficiency of the drug review process on a scale of one to seven, where one is to little extent and seven is to a great extent and four is somewhat. Respondents representing advocacy groups and industry generally feel that there has been little change. While those representing government stakeholders feel the CDR has impacted efficiency (positively). These results are summarized in Figure 2-X below.

Figure 2-X
Perceptions on the Extent to Which CDR Has Impacted Efficiency



Survey respondents were asked to rate the extent to which the CDR has resulted in increased sharing of information among drug plans and with other stakeholders. On a scale of one to seven, where one is to little extent, seven is to a great extent and four is somewhat, only respondents representing public advocacy groups feel there has been little change in the level of information sharing among drug plans. Similarly for the impacts on the sharing of information with other stakeholders, respondents representing advocacy groups feel there has been little increase in the sharing of information with stakeholders. These results are summarized in Figure 2-XI below.

Figure 2-XI
Perceptions of the Increase in Information Sharing Attributable to the CDR



c) Results from Other Sources

The most recent published data on the average Time to Listing (TTL), defined as the time (in calendar days) since the NOC was issued, has actually declined in all jurisdictions, except Saskatchewan, since the CDR was implemented. We note, however, that these data are based on a small number of decisions and so one should treat those results with extreme caution. The TTL includes the time it takes the manufacturer to file a submission after the NOC is issued plus the CDR review time plus the time it takes a drug plan to make and announce its listing decision. These data are summarized in Figure 2-XII below.

The concordance, defined as a positive CDR recommendation resulting in some type of benefit listing, or a negative CDR recommendation resulting in the product being declined benefit listing, has occurred 95 per cent of the time[6]. We note however that the majority of CDR recommendations have been "do not list" and that a large number of products that have been reviewed by CEDAC have yet to receive a

[6] Provincial Reimbursement Advisor, May 2005, p. 68.

drug plan listing. These data are summarized in Figure 2-XII below. This implies that drug plans are taking up CEDAC recommendations.

Figure 2-XII Provincial Uptake Summary (as at April 22, 2005)

	BC	AB	SK	MB	ON	NB	NS	PEI	NL
Number of listing decisions	1	5	10	2	2	0	13	0	1
Number of listings	1	5	6	2	2	0	5	0	1
Average time to listing	284	349	351	310	328	-	302	-	300
Historical time to listing	450	406	346	551	494	592	428	744	352
Concordance with CDR recommendation	1/1	5/5	10/10	2/2	2/2	-	11/13	-	1/1

Note: Cancer and AIDS treatments in British Columbia and Alberta are published in separate lists and are not captured in this table.
Historical TTL (Time to Listing) is defined as average provincial TTL for products launched September 1, 2001 to August 31, 2003.
Source: Provincial Reimbursement Advisory, May 2005, p. 68.

The CDR targeted timeframes for issuing recommendations is 99 to 129 business days, or 20 to 26 weeks, from when the submission is deemed complete. Overall the CDR is meeting this performance target. The average time to complete a review, as of August 2005 was 99 business days, excluding drugs submitted for reconsideration which adds to the average time. For drugs granted reconsideration, the average time to complete a review was 128 business days.

d) Discussion

The fact that not all drug plans have fully incorporated the CDR process and recommendations is a source of frustration for five individuals we interviewed. These interviewees noted the lag between the time CEDAC makes the recommendations and the time it takes for participating drug plans to act on the recommendations. Two interviewees representing the pharmaceutical industry argue that participating drug plans tend to act quickly on the negative recommendations but very slowly on the positive listing recommendations. The data are insufficient to support or refute this contention. However, it should be noted that drug plans do not act immediately on CEDAC recommendations for a variety of reasons including: the drug plan review cycle (some update their listings on a quarterly or semi-annual basis while some do so continuously); drug plans or jurisdictions may have different priorities; those may be differences in available resources both human and fiscal to deal with recommendations; among other reasons. We note that how participating drug plans treat the recommendations provided by CEDAC is outside of the mandate of the CDR to influence. At best CDR can encourage participating drug plans to act more quickly and work to ensure that its reviews and recommendations meet the needs of participating drug plans while maintaining a fair and objective process.

Government stakeholders, for whom the CDR was implemented and who are best placed to comment on its impact on the efficiency of the drug review process, feel that it has had a positive impact.

Participating drug plans also indicate that the CDR has increased the sharing of information and expertise among drug plans.

The CDR has been successful at meeting the targeted timelines for reviews. The average number of days for the conduct of reviews by the CDR is 99 business days. The time between a drug receiving an NOC or NOC with conditions and the time participating drug plans make their listing decisions is often significant, however, not all of this can be attributed to the CDR. The average time for drug companies to submit drugs for review to the CDR is approximately three months from the time the NOC or NOC with conditions is issued by Health Canada. As noted elsewhere, the CDR cannot influence the time drug companies take to make their submission, nor can it force participating drug plans to act on their recommendations, given the current mandate of the CDR.

2.6 Equal Access to Evidence and Expert Advice

The CDR was intended to provide all participating drug plans with access to the same high level of evidence and expert advice on drug reviews. The CDR does this by providing participating drug plans with drug reviews and CEDAC recommendations and allowing participating drug plans to provide feedback to CDR and CEDAC on how well the information provided is meeting their needs. Representatives from participating drug plans are permitted to attend CEDAC meetings where reviews are assessed and recommendations discussed and formulated by CEDAC members.

a) Results from Interviews

As noted in previous sections, drug plan representatives are generally satisfied with the quality of CEDAC recommendations and the information provided. However one interviewee representing a drug plan noted that having access to the minutes of CEDAC meetings would provide them with more complete information in assessing the CEDAC recommendations and would allow them to better defend the sometimes difficult and controversial decisions made. Drug plans, particularly smaller drug plans, feel that CEDAC recommendations are useful. As one drug plan representative commented, “Before CDR, we were at the mercy of the interest groups, we really didn’t have a basis for rationalizing why we did or did not cover a drug.” However, one industry representative interviewed feels that the CDR is providing the same level of information that is released publicly and that this is insufficient to allow drug plans to make a fair assessment based on all the information available. According to this interviewee the information provided by the CDR is insufficient for drug plans to make an assessment of the benefits of a particular product to Canadians and how that product can contribute to the healthcare system. None of those we interviewed feel CEDAC recommendations are of use to other stakeholders. However, it should be noted that CEDAC recommendations are not intended for use by any stakeholder group other than participating drug plans.

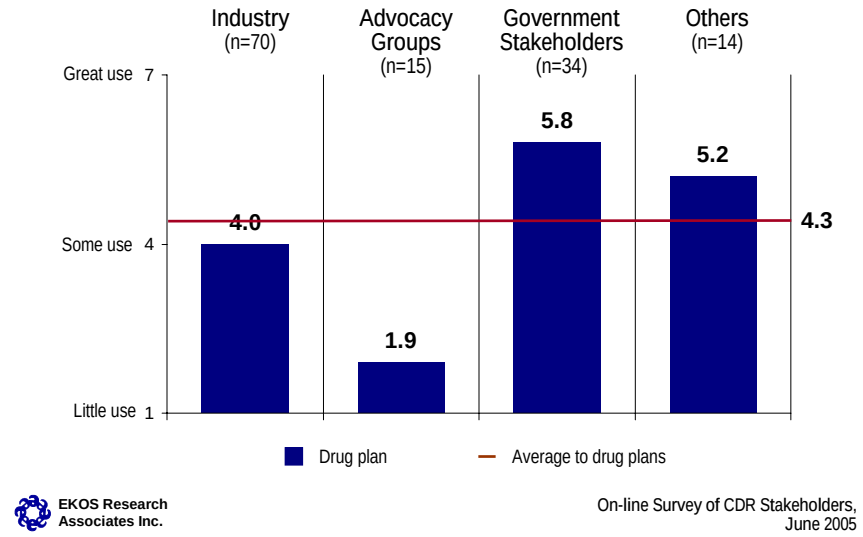
Based on comments by interviewees, drug plans are using CDR information and recommendations. The smaller drug plans are, in general, adopting recommendations without further review

while in the case of some larger drug plans such as Ontario and British Columbia, CDR information and recommendations are used by drug plan review committees. There is a sense, however, that regardless of whether drug plans implement CEDAC recommendations directly or whether they conduct further reviews, they are still left with some difficult decisions as to how to incorporate the CEDAC recommendations. Advocacy groups and the pharmaceutical industry feel strongly that drug plans are accepting negative CEDAC recommendations and reviewing the positive recommendations. The extent to which this is true is difficult to assess since this information is not collected by the CDR and not made publicly available by the drug plans.

b) Results from On-line Survey

Respondents to the survey of CDR stakeholders were asked to rate on a scale of one to seven, where one is little extent, seven is to a great extent and four is somewhat, the usefulness of CDR listing recommendations to drug plans and stakeholders. Government stakeholders responded most favourably and respondents representing advocacy groups the least favourably. We note however that government stakeholders are generally the best placed to assess to usefulness of CDR recommendations since this category of respondent includes drug plan representatives. The remaining categories of respondents are generally not well placed to assess the usefulness of CDR recommendations to drug plan. Representatives from advocacy groups feel that the CDR recommendations are of little use. The CDR shares the information with other stakeholders but the information is not produced for these stakeholders. These results are summarized in Figure 2-XIII below.

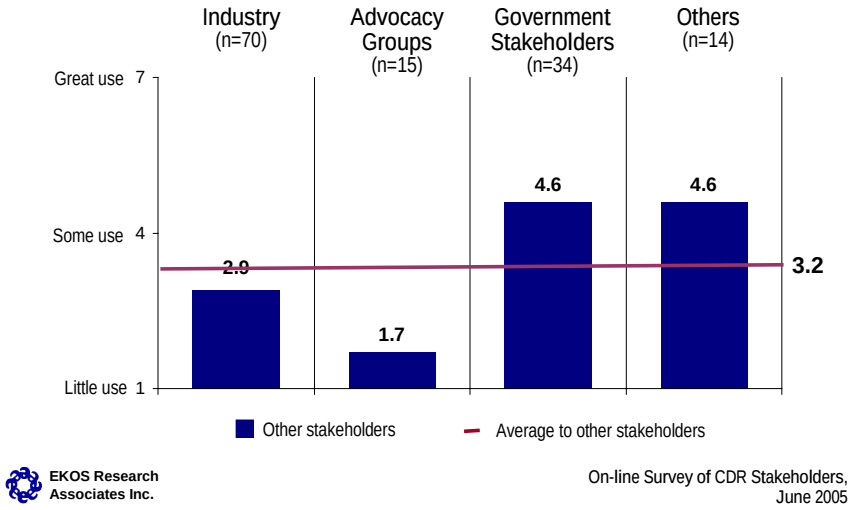
Figure 2-XIII
Perceptions of the Usefulness of CDR Information to Drug Plans



EKOS Research Associates Inc.

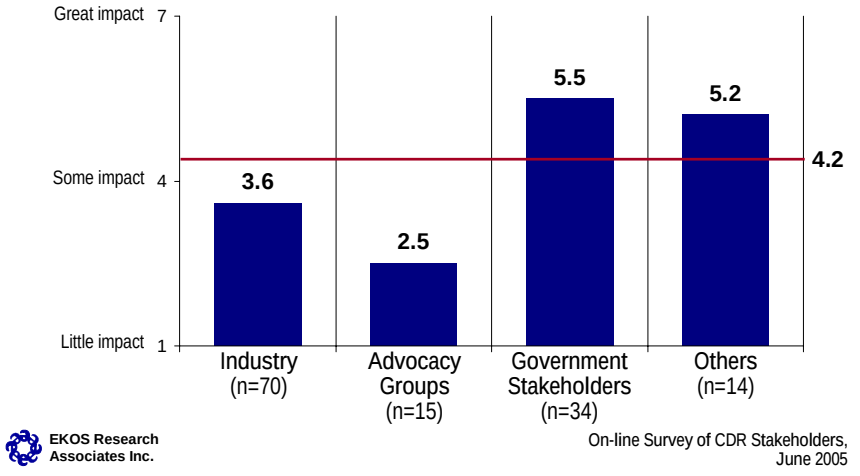
On-line Survey of CDR Stakeholders, June 2005

Figure 2-XIV
Perceptions of Usefulness of CDR Information to Other Stakeholders



According to survey results from the survey of CDR stakeholders, there is evidence that the CDR has improved access to expert advice and information by drug plans. Using a scale of one to seven, where one is little extent, seven is to a great extent and four is somewhat, respondents from the government stakeholder category, who are the best placed to comment on this aspect of the CDR, gave the CDR the best rating relative to other categories of respondents. These results are summarized in Figure 2-XV below.

Figure 2-XV
Perceptions of the Impact of CDR On Access to Expert Advice/Information by Drug Plans



c) Discussion

Based on interviews and the on-line survey of CDR stakeholders, the information and recommendations provided by the CDR to participating drug plans is seen as useful by the drug plans. Other stakeholders feel that the information they are provided with is of little use. However, it should be noted that the CDR was intended to provide a service and information to participating drug plans, not to advocacy groups, the general public, pharmaceutical firms or other stakeholders. The CDR provides a significant amount of information on its web-site, however much of the information related to the reviews and recommendations is not directed at a public audience. This evaluation found clear evidence of a need on the part of the CDR for more appropriate information sharing between CDR and the other stakeholders, other than participating drug plans.

3. DESIGN AND DELIVERY

This section addresses issues related to the design and delivery of the CDR, specifically cost-effectiveness and communications. Although not directly related to the attainment of the stated objectives, an assessment of these issues will provide CDR managers with information for possible improvements or fine-tuning how the CDR is delivered. Key sources of information for this section are key informant interviews and the on-line survey of CDR stakeholders.

3.1 COST-EFFECTIVENESS OF CDR

a) Results from Interviews

Overall, the majority of those interviewed as part of this evaluation feel that the CDR is delivered in a cost-effective manner. However, two interviewees, including a representative from CDR feel that the review process is very labour intensive. These interviewees feel that the process used by the CDR to conduct reviews and produce recommendations is generally appropriate; however it would be more efficient and cost-effective to have different processes for reviews depending on the complexity of the product. Currently all products undergo the same process.

Interviewees were split on whether the CDR provided the best 'bang for the buck.' Interviewees, representing the drug plans feel that the CDR is cost-effective since it eliminates the need for each drug plan to conduct its own review. The other categories of interviewees representing the pharmaceutical industry and patient advocacy groups disagree. Of those who feel the process is inefficient, the main reason cited is the perceived duplication of reviews between the CDR and participating drug plans. However, we note that there is little evidence to indicate that drug plans are repeating reviews conducted by CDR. Other interviewees, including consultants who file submissions on behalf of firms and advocacy groups feel that the CDR is not cost-effective since the "recommendations are of poor quality and thus of little use" to them.

b) Discussion

The general view is that the CDR is a cost-effective process for the review of new products. However, the cost-effectiveness of the entire review and listing process could be greatly improved if participating drug plans fully adopted the CDR process and CEDAC recommendations and if a simplified review process was developed for less complex submissions. There is evidence to suggest that participating drug plans intend to move in the direction of fully adopting the CDR process once there is a level of comfort with the process among managers of drug plans.

3.2 COMMUNICATIONS

a) Results from Interviews

The CDR was developed in consultation with the participating F/P/T drug plans since the CDR is intended, in part, to replace the separate reviews of new products conducted by drug plans. Once the general structure of the CDR was developed, a consultation process with various stakeholder organizations was conducted, including the pharmaceutical industry and consumer groups. CDR conducts annual information sessions for the pharmaceutical industry but none directed at advocacy groups.

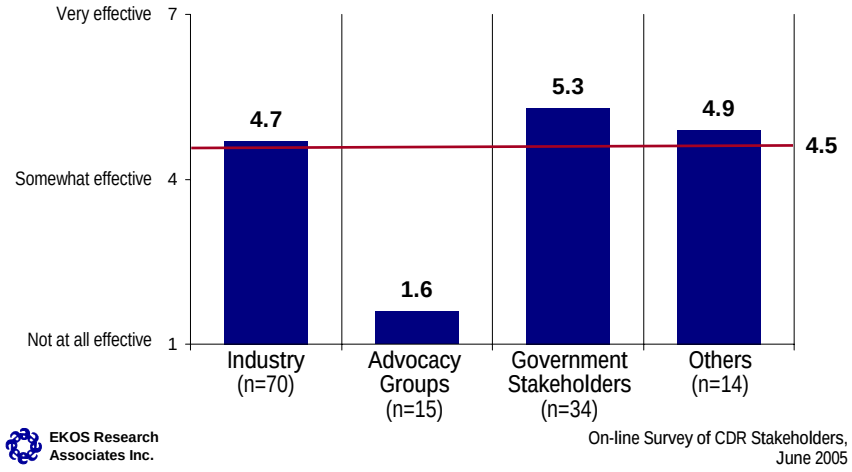
All pharmaceutical industry representatives and patient advocacy representatives interviewed feel that the CDR consultation approach is inadequate. These interviewees feel that the CDR has made little effort to meaningfully consult with them. Three representatives from participating drug plans agreed, noting that the consultation process used by the CDR could be improved through increased, structured input from stakeholders. As one interviewee commented, "…manufacturers, suppliers and patients are not really equal partners in the process." Representatives from both the pharmaceutical industry and advocacy groups feel that CDR invitations for consultation are put forward by the CDR after decisions have been made, thereby making consultation sessions more like information sessions and not permitting them to provide meaningful input. Representatives from the CDR interviewed noted that the CDR is working on improving their consumer/public input and consultation process.

Drug plan representatives who were interviewed feel that the CDR is providing them with sufficient and appropriate information.

b) Results from On-line Survey

Respondents to the survey of CDR stakeholders were asked to rate, on a scale of one to seven, where one is not at all effective, seven is very effective and four is somewhat effective, the effectiveness of the CDR communication strategy. While Government stakeholders believe that the communication strategy is effective, respondents representing the pubic view the CDR's communication as ineffective. These results are summarized in Figure 3-I below.

Figure 3-I
Perceptions of the Effectiveness of the CDR Communication Strategy



c) Discussion

The communications of the CDR to the drug plans are seen to be good. However, communication and consultation with other stakeholders is felt to be inadequate, as has been noted elsewhere in this report. The CDR has not been successful at communicating details about the reasons for the process, how the reviews are conducted and the benefits of conducting cost-effectiveness assessments on drugs. As a result, there is misinformation about the CDR process on the part of CDR stakeholders other than participating drug plans. There is a strong desire on the part of advocacy groups to play an active and meaningful role in the CDR process. However, this needs to be balanced against the pharmaceutical companies' need to protect the confidentiality of proprietary information provided to the CDR as part of its submissions.

4. OTHER ISSUES

This chapter addresses other issues that CDR management and EAC members identified as important and that went beyond the objectives of the CDR and the design and delivery of the CDR. These issues relate to the impacts of the CDR on drug plans, drug manufacturers and consumers. The principle sources of information for addressing these questions are key informant interviews and the on-line survey of CDR stakeholders.

4.1 INTEGRATION OF CDR PROCESS INTO DRUG PLAN REVIEWS

a) Results from Interviews

As noted in previous sections, the extent to which drug plans have integrated the CDR process into their own formulary listing process varies across drug plans. According to those we interviewed, smaller drug plans have tended to integrate the CDR recommendations more fully and a few larger drug plans have tended to use CDR recommendations as additional information in conducting their own assessments. Two drug plan representatives indicated provincial review committees are focusing on existing drugs with new indications and using CDR recommendations for new drugs. Thus the CDR has served to streamline the drug review process and allowed some drug plans to reallocate resources away from conducting reviews of new drugs. In the case of one drug plan, the provincial review committee continues to function because it was thought to be more prudent to let the CDR operate for a period of time before moving completely away from conducting reviews.

Although participating drug plans have to varying degrees integrated the CDR process, interviewees representing consultants who make submission on behalf of firms and patient advocacy groups feel that the CDR process should be more fully integrated into the drug plans' processes. We note however, that these groups of interviewees are not necessarily well-positioned to assess the extent of the integration between the CDR and participating drug plans. Interviewees representing drug plans report that the CDR process has been well integrated. Representatives from the pharmaceutical industry suggest that the CDR should recommend a timeframe within which participating drug plans should make a listing decision.

Based on comments by interviewees, the CDR may have resulted in some decrease in the workload of participating drug plans. However, there is likely variability across drug plans. As well, it is not possible to assess with certainty that these changes in listing times are directly attributable to the CDR. As one drug plan representative noted, "It (CDR) has changed the workload in that we no longer do the reviews ourselves, but it really hasn't changed the timing of actually implementing some recommendations because of fiscal reality."

b) Discussion

Although an important crowning element for the success of the CDR, the CDR cannot force participating drug plans to adopt its process or recommendations because that is beyond its mandate. However, based on information from interviews, the CDR process has had a positive impact on all participating drug plans with respect to using the reviews and recommendations. Not all participating drug plans are automatically accepting CEDAC recommendations. There are indications that these drug plans will move away from conducting this type of analysis once they are fully confident in the reviews and recommendations provided by the CDR. In fact, given that participating drug plans are jointly funding the CDR, it would be inefficient and of little purpose for them to continue to fund the CDR unless they are prepared to use the services of the CDR.

4.2 IMPACTS ON MANUFACTURERS

a) Results from Interviews

In setting up a single review process to replace the existing review processes conducted by participating drug plans, the CDR was expected to benefit drug manufacturers since they would only be required to make a single submission to the CDR. Representatives from the pharmaceutical industry groups and drug companies interviewed do not feel that they have been positively impacted by the CDR. One industry representative agreed that the CDR submission guidelines have streamlined the process for submitting drugs. However, others argue that the CDR submission requirements are far more onerous than those of the drug plans and CDR is requiring according to one representative additional information, such as Health Canada reports, which were not required by drug plans. Pharmaceutical firms noted that they are still required to file submissions with drug plans and so the CDR has increased their workload.

The impact of the transparency of the CDR review process and the fact that the recommendations are publicly available may, according to four interviewees, have negative impacts on the drug companies internationally as well as implications for reimbursement under privately insured drug plans. Decision makers from other countries and private insurance companies are able to look at the CDR recommendations over the Internet and use the information in their own decisions. Prior to the implementation of the CDR, a decision to not list a particular product in one jurisdiction did not necessarily imply a negative decision by all Canadian drug plans since drug plans did not share information in a consistent manner.

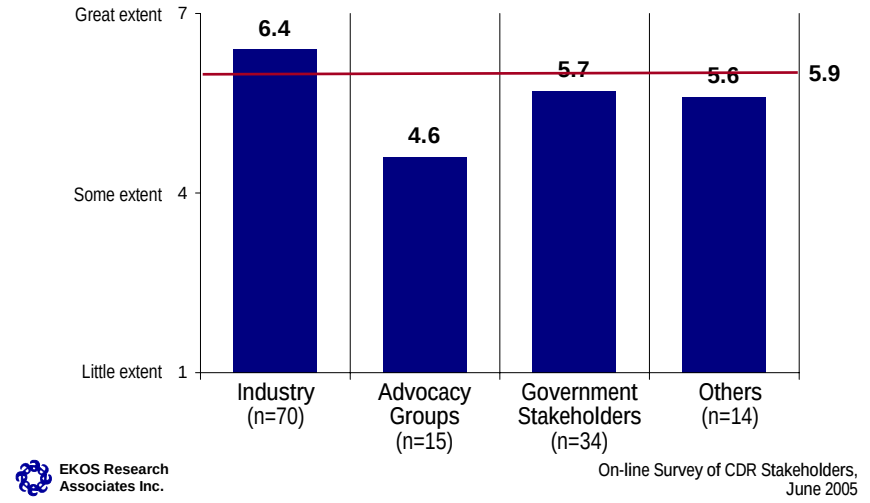
Pharmaceutical firm and industry representative interviewed also argue that the CDR process, because of the focus on cost, has made it more difficult for the industry to bring innovative products into Canada. Four interviewees representing the pharmaceutical industry and patient advocacy groups suggested that the pharmaceutical industry no longer has any incentive to further develop their market in Canada, nor to introduce products in Canada. However, the fact that the product is not listed on a formulary does not mean it cannot be sold in Canada. The expenditure on prescribed drugs by the public sector,

although significant, represents only part of the pharmaceutical market in Canada. According to data from the Canadian Institute for Health Information (CIHI), the publicly funded market for prescribed drugs was forecasted as 47.3 per cent of the Canadian prescribed drug market in 2004. (From: Drug Expenditure in Canada 1985 to 2004; Canadian Institute for Health Information, 2005).

b) Results from On-line Survey

Respondents to the survey of CDR stakeholders were asked to rate the extent to which the CDR has impacted drug manufacturers. While all categories of respondents indicated that CDR had an impact of more than some extent on industry, industry respondents reported that CDR impacted on manufacturers to a great extent. These results are summarized in Figure 4-I below.

Figure 4-I
Perceptions of the Extent to Which CDR Has Impacted Firms



Survey respondents who indicated that they feel the CDR has had an impact on pharmaceutical companies (firms) were asked to explain how the CDR process has impacted drug companies . The most frequently cited impact was an increase in the administrative burden. Other impacts noted by survey respondents include the impacts of negative recommendations and a slower review process. These results are summarized in Figure 4-II below.

Figure 4-II Opinions on How the CDR Has Impacted Firms

	Total (n=112)	Industry (n=65)	Advocacy Groups (n=10)	Government Stakeholder (n=27)	Other (n=10)
Administrative burden	17	16	1	-	-
Impacts of negative recommendations	17	11	2	2	2
Slowed review process	16	12	-	2	2
Difficulty getting products listed	14	8	2	3	1
Streamlined submission process	10	4	1	5	-
Improved data requirements	8	2	-	4	2
Better data generated	6	2	1	3	-
Negative impact on R&D in Canada	5	3	2	-	-

Source: Survey of CDR Stakeholders, EKOS Research Associates, June 2005.
Note: respondents were permitted to provide more than one response.

c) Discussion

According to results of interviews the CDR has had an impact on drug manufacturers through the potential impacts of recommendations not to list. Interviewees representing CEDAC and manufacturers note that recommendations not to list can impact the listing of a product across Canadian drug plans as well as within private insurance plans and international organizations' listing decisions or reviews of drugs.

Drug companies feel that the CDR process has increased the level of effort required because submissions must be provided to all participating drug plans as well as the CDR resulting in an increased administrative burden. Also, the CDR is requiring more information than required previously by participating drug plans, further adding to the required effort. However, there is no evidence to suggest that the information required by participating drug plans goes beyond what is required by the CDR for its submissions.

Drug companies also feel that the CDR has slowed the review process. However, according to the CDR, drug companies take an average of three months to file a submission after receiving a NOC or NOC with conditions. None of the drug companies interviewed provided an explanation as to why this was the case. As well, there are indications from existing data that the review times have decreased overall as a result of the CDR. Overall, based on the available information, there is little evidence for a slower review process as a result of the CDR.

4.3 IMPACTS ON CONSUMERS/PUBLIC

a) Results from Interviews

Those we interviewed were divided on whether the CDR has benefited consumers/the public. Four interviewees representing CDR and participating drug plans believe that the CDR has benefited consumers by having a consistent process for reviewing the cost-effectiveness of new drugs and providing better information on new drugs. However, these interviewees recognize that the CDR has not done an adequate job of communicating the benefits of the CDR and how CDR works to the general public.

Interviewees representing the pharmaceutical industry and patient advocacy groups feel that the CDR process is denying patients access to drugs that could help them. In addition, patient advocacy groups feel that the CDR process has not taken into consideration the impacts on patients and that the reviews are entirely focused on cost-effectiveness. We note that the CDR Pharmacoeconomic assessments include social and quality of life factors if these data are included in the manufacturers' submissions. According to CDR staff, these data are often not included and when they are, are often poor quality and based on unsubstantiated assumptions.

b) Results from On-line Survey

Survey respondents were asked to rate the impact of the CDR on consumers/the public. Based on a scale of one to seven, where one is little impact, seven is great impact and four is some impact, respondents feel that the CDR has had some impact on consumers/the public. There was agreement across all categories of survey respondents. Those who indicated that there had been an impact on consumers/the public were asked to explain how the CDR has impacted the public. The most frequently cited response was that the CDR has delayed access to drugs. However, it must be noted that the average time elapsed between a drug obtaining a NOC or NOC with conditions from Health Canada and filing a submission with the CDR is three months. Other impacts noted include increased consistency and increased transparency in the drug review process.

c) Discussion

Impacts on consumers/the public are focused on the availability of products in Canada. All of those interviewed representing the pharmaceutical industry and patient advocacy groups argued that the CDR is preventing patients from accessing much needed new drugs in Canada. It is impossible to assess whether the CDR is preventing patients from having access to drugs since drug plans continue to be free to list specific drugs regardless of CEDAC recommendations. As well, it is impossible to assess what proportion of products reviewed by the CDR and receiving recommendations not to list would have been listed in provincial formularies prior to the CDR.

We note that all drugs approved by Health Canada for sale in Canada continue to be available regardless of the CDR process and CEDAC recommendations. However, drugs that are costly, i.e. beyond the financial means of most patients, may or may not be available to patients since if these drugs are not listed by drug plans they are effectively unavailable to patients. Drug plans and pharmaceutical companies continue to be able to use their discretion in deciding whether to fund or provide specific drugs to patients.

4.4 IMPACTS ON DRUG PLANS

a) Results from Interviews

The CDR was expected to have the greatest impact on drug plans that would no longer need to review new drugs but would instead use CEDAC recommendations in making listing decisions for new drugs. As has been noted elsewhere in this report, participating drug plans adoption of the CDR process and recommendations has varied.

There is general agreement among interviewees that the CDR has increased efficiency, decreased duplication and increased rigour, particularly in the smaller jurisdictions. These impacts can be expected to increase as drug plans adopt the CDR process more completely. As one representative from a drug plan commented, “It (CDR) will definitely have an impact and I think it will be positive in the long run, but many of us haven’t made our changes yet to really improve efficiency.”

b) Results from On-line Survey

Respondents to the survey of CDR stakeholders were asked to rate the extent to which they feel the CDR has impacted participating drug plans. Using a scale of one to seven, where one is to little extent, seven to a great extent and four to some extent, overall respondents indicated that the CDR has impacted drug plans to some extent. Respondents from the government stakeholder category indicated that the CDR has impacted them to a great extent. Respondents, who indicated that drug plans were impacted, were further asked to describe these impacts. The most frequently cited responses are summarized in Figure 4-III below.

Figure 4-III Opinions on How the CDR Has Impacted Drug Plans

	Total (n=90)	Industry (n=45)	Advocacy Groups (n=8)	Government Stakeholder (n=29)	Other (n=8)
Fewer drugs listed	27	19	5	1	2
Increased homogeneity	16	6	-	9	1
Slower decision times	11	6	3	2	-
More efficient	11	3	-	7	1
Not all adopt recommendations	3	2	1	-	-
Free up F/P/T resources	3	1	-	1	1

Source: Survey of CDR Stakeholders, EKOS Research Associates, June 2005.
Note: respondents were permitted to provide more than one response.

c) Discussion

From the perspective of participating drug plans the impacts of the CDR are entirely positive. According to drug plan representative interviewed and government stakeholders surveyed, the CDR has decreased duplication, increased efficiency, increased consistency and increased rigour. It has had a particularly positive impact on smaller drug plans which now have access to a higher level of expertise and information.

5. CONCLUSIONS AND RECOMMENDATIONS

5.1 CONCLUSIONS

- The CDR has gone to great lengths to develop a process that is consistent and rigorous. The CDR has developed a number of publicly available documents that are used as templates or guides in the conduct of reviews. In addition CEDAC recommendations and reasons for the recommendations are posted on the Internet and are publicly available. Opinion is divided on whether the CDR has met its objective of a consistent and rigorous review process with government stakeholders perceiving the process as rigorous and consistent and industry and advocacy groups holding the opposite view. Those who argue that the process lacks rigor cite the lack of expertise on the part of reviewers and the lack of multiple reviewers, although the CDR process does use a Review Team for each review. Those who feel the process lacks consistency note the differing levels of evidence/data required for a second entry product versus a new entry product and that CEDAC may make recommendations not to list even if the CDR Reviewers Reports are favourable.
- CDR stakeholders are split on whether the CDR process is fair, objective and transparent. Those who represent industry and advocacy groups feel strongly that the process lacks fairness, objectivity and transparency; other stakeholders have the opposite view. Those who feel the process lacks fairness, objectivity and transparency feel this way largely because of the lack of public input into the process as well as the, in their opinion, the lack of qualifications on the part of reviewers.
- The CDR was intended to reduce duplication of reviews across participating drug plans. From the perspective of the participating drug plans, the CDR has succeeded in doing this. However, a few of the participating larger drug plans, are conducting analyses of CEDAC listing recommendations, that is, they have not completely adopted the CDR process. There are, however, indications that these drug plans will fully adopt the CDR process once a level of comfort with the process and recommendations has been reached.
- Although the CDR process is seen as being relatively efficient by all those directly involved, currently all reviews are conducted in the same manner regardless of their complexity. This may be resulting in a less efficient process for some less complex, submissions.
- There is frustration over the seeming lack of timely adoption of CEDAC recommendations by participating drug plans. Advocacy groups and industry, argue that the drug plans have been quick to act on negative recommendations but slow to act on positive recommendations. It is beyond the mandate of the CDR to influence or force participating drug plans to make

recommendations in a timely manner. The CDR is, however, in a position to use moral suasion to the extent that it can to encourage drug plans to act. As well, the CDR continues to work with participating drug plans to ensure that reviews and recommendations meet their needs.

- Industry and advocacy groups argue that the CDR has resulted in longer times to formulary listing. Data on the historical time to listing and current time to listing do not support this view. In fact, these data indicate that the time to listing has decreased since the implementation of the CDR. However, the number of listings decisions to date has been relatively small and so this result should be treated with some caution.

- Based on evidence from interviews and Survey of CDR Stakeholders there is a need for active and meaningful input and participation in the CDR process by the public. This view was expressed by all groups of stakeholders. However, there are significant challenges in doing this since public participation, input and information sharing must be balanced against the manufacturers' need to protect confidential or proprietary information. In addition, advocacy groups are demanding more information but the information on the CDR web site, specifically the recommendations, are not geared to the general public.

- According to the drug manufacturers, the impacts of the CDR on pharmaceutical companies include a greater administrative burden, difficulty in getting products listed, impacts of negative recommendations and a slowed review process.

- According to advocacy groups the most significant impact of the CDR on patients is delayed access to drugs. This is directly linked to the perception that the CDR process has resulted in a longer time to listing, which as noted above, cannot be proven based on currently available data.

- Impacts on participating drug plans, have, according to drug plan representatives, been wholly positive. Drug plan representatives responding to the on-line survey note that the CDR has resulted in increased homogeneity and increased efficiency.

- This evaluation found evidence of much frustration and misunderstanding with respect to the CDR process and recommendations. The public and advocacy groups in particular have little understanding of the purposes and benefits of an evidence-based review. The increasing politicization of the formulary listing process requires that the CDR better communicate information about the CDR process and its benefits to the general public and that the CDR develop a more consistent communication strategy.

- This evaluation found some evidence that drug companies are hesitant to provide all available data to the CDR in a timely manner.

5.2 RECOMMENDATIONS

1. Currently, decisions and recommendations are geared towards drug plans and manufacturers, and are in highly technical language which is difficult for the general public to understand or appreciate. The CDR should develop a process to communicate decisions and recommendations to the general public.

2. The CDR should work with the pharmaceutical industry and individual companies towards making the CDR process more transparent for all stakeholders.

3. CCOHTA/CDR should assess how best to incorporate public input into the CDR process.

4. The CDR should explore different approaches for undertaking reviews. Reviews of simpler products/submissions should be less time and labour intensive than more complex submissions.

APPENDIX A
EVALUATION MATRIX

Evaluation Matrix – Common Drug Review

Evaluation Issue/Question	Indicators	Data sources/data collection methods
Success		
1. To what extent has CDR provided a consistent and rigorous approach to drug reviews?	› Evidence of consistent and rigorous approach › Perceptions of the consistency and rigour of CDR reviews › Opinions on how the CDR process may be improved with respect to approach, etc.	› Document and review templates from CDR › CDR Review working group feedback form) › Key informant interviews › Survey of stakeholders
2. Is the process of reviewing submissions fair, objective and transparent?	› Evidence of fairness, objectivity and transparency › Evidence of communication and mfr involvement in review process › Perceptions of the fairness, objectivity, and transparency of the review process	› Document and literature review › Administrative data, online submission resources/aids from CDR › Key informant interviews › Survey of stakeholders
3. To what extent has CDR provided evidence-based listing recommendations?	› Number of listing recommendations provided by CDR › Number of decisions by participating drug plans › Perceptions of the usefulness of CDR recommendations › Perceptions of the quality of CDR recommendations (clarity, being unbiased)	› Administrative data from CDR and participating drug plans › Key informant interviews › Survey of stakeholders
4. To what extent has CDR resulted in decreased duplication of efforts by drug plans?	› Evidence of reduced *(or extent of reduction of)* duplication of efforts by drug plans › Perceptions of the extent to which the level of duplication has decreased. › # of reviews conducted by participating drug plans on CDR reviewed drugs	› Administrative data from CDR and participating drug plans › Key informant interviews
5. To what extent has CDR resulted in improved use of resources and expertise?	› Opinions on the extent to which CDR has capitalized on resources and expertise available › Perceptions of the improvement/worsening of efficiency of the drug review process › Extent to which CDR has resulted in improved sharing of information and expertise	› Key informant interviews › Survey of stakeholders

Evaluation Issue/Question	Indicators	Data sources/data collection methods
6. To what extent has the CDR resulted in equal access to the same high level of evidence and expert advice by all participating plans?	› Opinions on the access to information and advice by provincial/territorial plans › Extent to which the federal/provincial/ territorial plans use/access CDR information and advice › Extent to which federal/provincial/territorial plans questions (if any) related to drugs reviewed by the CDR have been addressed by the CEDAC recommendations and reasons for the recommendations	› Key informant interviews › Survey of stakeholders › Administrative data
Design and Delivery/Cost-effectiveness		
7. Is CDR delivered in the most cost-effective manner?	› Perceptions of cost-effectiveness › Suggestions for improving cost-effectiveness	› Administrative data › Key informant interviews
8. Is CDR communications effective? Are any improvements necessary?	› Communications strategies used by CDR › Evidence of effectiveness of communication and sharing of information	› Background documents/files › Key informant interviews › Survey of stakeholders
Other Evaluation Issues (Not related to CDR objectives)		
9. To what extent have the participating drug plans integrated the CDR process into their own drug reviews? How has the formulary decision process of drug plans changed? Has the CDR process changed the timing or workload associated with implementing formulary listings?	› Extent to which the provincial/territorial plans have modified previous procedure for reviewing new drugs › Opinions on (*or perceptions of*) the extent to which drug plans have integrated the Common Drug Review Process › Opinions on (or perceptions of) the extent to which the CDR process has changed the timing or workload associated with implementing formulary listings.	› Drug plans documents › Key informant interviews
10. How has the CDR process impacted manufacturers?	› Opinions on (*or perceptions of*) the extent to which drug manufacturers have been impacted by the Common Drug Review Process	› Key informant interviews › Survey of stakeholders
11. How has the CDR process impacted consumers/public?	› Opinions on (*or perceptions of*) the extent to which consumers/public have been impacted by the Common Drug Review Process	› Key informant interviews › Survey of stakeholders › Administrative data on media (CDR to provide)

Evaluation Issue/Question	Indicators	Data sources/data collection methods
12. How has the CDR process impacted the federal/provincial/territorial drug plans?	› Opinions on (or perceptions of) the extent to which drug plans listing decisions process has changed/been impacted by the Common Drug Review Process with respect to timing, workload, ease, etc › Extent to which CDR has "Freed time" to enable drug plan staff to get other work done.	› Key informant interviews › Survey of stakeholders

APPENDIX B
INTERVIEW PROTOCOL

Evaluation of the Common Drug Review (CDR)
Interview Guide

The Canadian Coordinating Office for Health Technology Assessment (CCOHTA) has commissioned EKOS Research Associates, Inc. to conduct an evaluation of the extent to which the Common Drug Review (CDR) has met its objectives after its first year of operations.

As part of the evaluation process EKOS Research Associates will be conducting key informant interviews with approximately 40 individuals represents CDR staff, CEDAC, federal/provincial/territorial drug plan representatives, and other stakeholders. The purpose of these interviews is to collect more detailed information on how well the CDR has performed relative to its objectives than is being collected through the on-line survey of stakeholders.

Your name and that of your organization were provided to EKOS by the CDR for the purposes of this evaluation only. Although your participation is voluntary, your responses are very important. The interviews should take approximately 45 to 60 minutes. You will be asked all the questions below, however we encourage you to respond only to questions you feel able or qualified to answer. Interviewees are being asked all questions in order to avoid the bias in choosing which interviewees are asked which questions. Your responses will be kept strictly confidential by EKOS and the final report will present the findings in aggregate form only.

A. RESULTS

1. To what extent has the CDR provided a consistent and rigorous approach to drug reviews? Please explain. Can the CDR approach be improved with respect to consistency and rigor? If yes, how?

2. In your opinion, is the process of reviewing CDR submissions transparent? Please explain.

3. In your opinion, is the process of reviewing CDR submissions fair? Please explain.

4. In your opinion, is the process of reviewing CDR submissions objective? Please explain.

5. In your opinion, to what extent are CDR listing recommendations useful to participating federal/provincial/territorial drug plans? To other stakeholders?

6. With respect to CEDAC recommendations, in your opinion, are they clear? Relevant? Evidence based? Unbiased? Please explain, how any of these qualities could be improved?

7. To what extent do you feel the CDR has resulted in increased efficiency of the drug review process? Have CEDAC recommendations resulted in faster decision-making on the part of drug plans? Please explain. Can efficiency be improved? If yes, how?

8. To what extent has the CDR improved or increased sharing of information and expertise among drug plans and other stakeholders? Please explain. Can the sharing of information and expertise be improved upon? If so, how?

9. In your experience, to what extent does federal/provincial/territorial drug plans use CDR information and recommendations? To what extent have CEDAC recommendations and reasons for the recommendations addressed questions that the participating drug plans may have had related to the drugs reviewed by the CDR? Please explain.

10. To what extent do you believe the CDR has provided access to evidence and expert advice by all participating plans? In your opinion, to what extent can this be improved upon? Please explain.

B. Design and Delivery/Cost-effectiveness

11. Given general cost-benefit issues, do you believe that the CDR is providing the best "bang for it's buck"? How, if at all, can cost-effectiveness of CDR be improved?

12. Do you believe the CDR approach to consultation is effective? Why do you feel this way? Can you provide any suggestions for improvement?
13. Do you feel you or your organization receives sufficient and appropriate information from CDR? If not, can you suggest areas for improvement?

C. Other Evaluation Question (not related to CDR Objectives

14. To what extent have the participating federal/provincial/territorial drug plans modified previous procedures for reviewing drugs as a direct result of the CDR? Please explain/describe.

15. To what extent do you feel that federal/provincial/territorial drug plans have integrated the CDR process into their own review process? Please explain. In your opinion, what can the CDR do to facilitate better integration between the CDR review process and the processes of federal/provincial/territorial drug plans?

16. To what extent do you feel that federal/provincial/territorial drug plans are using CDR reviews and recommendations to shorten decision times? Please explain. What, if anything, can the CDR do to improve these times?

17. To what extent have participating federal/provincial/territorial drug plans implemented formulary listing decisions using CDR reviews and recommendations? Has the CDR process changed the timing or workload associated with the implementing formulary listing decisions? What, if anything, can CDR do to facilitate the decision process?

18. In what ways has the CDR process impacted drug manufacturers? Please explain.

19. To what extent do you believe the CDR Process has impacted the public/consumers? Please explain.

20. In what ways has the CDR process impacted the participating federal/provincial/territorial drug plans? Please explain.

21. What areas of the CDR do you believe have been particularly successful?

22. What areas of the CDR do you believe require improvement? Please explain

THANK YOU FOR YOUR PARTICIPATION

APPENDIX C
ON-LINE SURVEY OF CDR STAKEHOLDERS

Evaluation of the Common Drug Review – A Survey of Stakeholders

Welcome to the Evaluation of the First Year of Operation for the Common Drug Review. The Canadian Coordinating Office for Health Technology Assessment (CCOHTA) has commissioned EKOS Research Associates, Inc. to conduct a survey of stakeholders to provide information on the perceptions and opinions of individuals who have a significant role or experience with the CDR.

This stakeholder survey is one component of a multi-modal approach to the evaluation the extent to which the CDR has met its objectives. The objectives of the CDR are to:

- Provide a consistent and rigorous approach to drug reviews and an evidence-based listing;
- Reduce duplication of effort by drug plans;
- Maximize the use of limited resources and expertise; and
- Provide equal access to the same high level of evidence and expert advice by all participating drug plans.

Please be assured that all your responses to these questions will be kept in the strictest of confidence and that any information you provide will be administered in accordance with the Privacy Act and any other applicable privacy laws. If you have any questions or concerns regarding this project, please contact Mira Svoboda, research consultant, at 613.235.7215, or at msvoboda@ekos.com.

1. First of all, please indicate your primary role with respect to the CDR.
   (Please select only one)

   a) Industry (i.e. manufacturer, consultant working with manufacturers, industry association representative)
   b) Public (i.e. consumer, representative of a consumer advocacy group)
   c) Publicly funded stakeholders (i.e. Health Ministries, Drug plans/representative, Health Canada, PMPRB, CIHI, Advisory Committee on Pharmaceuticals (ACP) member)
   d) CEDAC Member
   e) Other (Please specify)_____ (e.g. researchers, university personnel, healthcare provider)

Success of the Common Drug Review

These first questions will address your thoughts on the success of the CDR in meeting its roles and responsibilities.

2. Please rate the CDR Directorate in terms of its performance regarding the following roles and responsibilities. Use a scale from 1 to 7, where 1 is “very poor”, 7 is “very good” and the midpoint 4 is “neither good nor poor”.

a) Performing evidence-based reviews of submissions

1 Very poor 1
2 2
3 3
4 Neither poor nor good 4
5 5
6 6
7 Very Good 7
9 Not Applicable 9

b) Providing evidence-based recommendations

1 Very poor 1
2 2
3 3
4 Neither poor nor good 4
5 5
6 6
7 Very Good 7
9 Not Applicable 9

3. Please indicate your level of agreement with each of the following statements using a scale from 1 to 7, where 1 is “strongly disagree”, 7 is “strongly agree” and the midpoint 4 is “neither agree nor disagree”.

The process used by the CDR Directorate to review submissions is…

a) …Fair

1 Strongly disagree 1
2 2
3 3
4 Neither agree nor disagree 4
5 5
6 6
7 Strongly agree 7
9 Not Applicable 9

b) …Objective

1 Strongly disagree 1
2 2
3 3
4 Neither agree nor disagree 4
5 5
6 6
7 Strongly agree 7
9 Not Applicable 9

c) …Transparent

1 Strongly disagree 1
2 2
3 3
4 Neither agree nor disagree 4
5 5
6 6
7 Strongly agree 7
9 Not Applicable 9

4. Why do you believe that the CDR review process is unfair? What do you suggest for improvement? (EQ2)

SKIP IF Q3A=4,5,6,7,9

_____
_____
_____

5. Why do you believe that the CDR review process is not objective? What do you suggest for improvement? (EQ 2)

SKIP IF Q3B=4,5,6,7,9

_____
_____
_____

6. Why do you believe that the CDR review process is not transparent? What do you suggest for improvement? (EQ2)

SKIP IF Q3C=4,5,6,7,9

_____
_____
_____

7. On a scale of 1 to 7, where 1 is “a little extent”, 7 is “a great extent” and the midpoint 4 is “somewhat”, to what extent do you feel the CDR has increased efficiency of the drug review process?

1 Little 1
2 2
3 3
4 Somewhat 4
5 5
6 6
7 Great 7
9 Don’t know / no response 9

8. To what extent has CDR met its objective of a rigorous approach to drug review?

1 Little 1
2 2
3 3
4 Somewhat 4
5 5
6 6
7 Great 7
9 Don’t know / no response 9

9. Using the same scale, to what extent are CDR listing recommendations useful to…

a) Federal/provincial/territorial drug plans?

1 Little 1
2 2
3 3
4 Somewhat 4
5 5
6 6
7 Great 7
9 Don’t know / no response 9

b) Other stakeholders? (e.g., manufacturers, consumer advocacy groups)

1 Little 1
2 2
3 3
4 Somewhat 4
5 5
6 6
7 Great 7
9 Don’t know / no response 9

10. To what extent do you feel that the existence of the CDR has resulted in increased sharing of information among …

a. Federal/provincial/territorial drug plans?

1 Little 1
2 2
3 3
4 Somewhat 4
5 5
6 6
7 Great 7
9 Don't know / no response 9

b. Other stakeholders? (e.g., consumer advocacy groups, industry)

1 Little 1
2 2
3 3
4 Somewhat 4
5 5
6 6
7 Great 7
9 Don't know / no response 9

11. To what extent do you feel that the CDR has provided access to expert advice/information by participating drug plans?

1 Little 1
2 2
3 3
4 Somewhat 4
5 5
6 6
7 Great 7
9 Don't know / no response 9

12. On a scale of 1 to 7, where 1 is "not at all effective", 7 is "very effective" and the midpoint 4 is "somewhat effective", please rate the effectiveness of the CDR communication approach.

1 Not at all effective 1
2 2
3 3
4 Somewhat effective 4
5 5
6 6
7 Very effective 7
9 Don't know / no response 9

Impact of the CDR Process

These next questions gather your opinions on the impact of the CDR on various stakeholders.

13. On a scale of 1 to 7, where 1 is "a little extent", 7 is "a great extent" and the midpoint 4 is "somewhat", to what extent do you think the CDR process has impacted …

a. Federal/provincial/territorial drug plans

1 Little 1
2 2
3 3
4 Somewhat 4
5 5
6 6
7 Great 7
9 Don't know / no response 9

b. Drug manufacturers

1 Little 1
2 2
3 3
4 Somewhat 4
5 5
6 6
7 Great 7
9 Don't know / no response 9

c. Consumers / the public

1 Little 1
2 2
3 3
4 Somewhat 4
5 5
6 6
7 Great 7
9 Don't know / no response 9

14. Can you explain how the CDR process has impacted Federal/provincial/territorial drug plans?

SKIP IF Q13A = 1,2,3,9

_____
_____
_____

15. Can you explain how the CDR process has impacted drug manufacturers?

SKIP IF Q13B = 1,2,3,9

_____
_____
_____

16. Can you explain how the CDR process has impacted consumers / the public?

SKIP IF Q13C = 1,2,3,9

_____
_____
_____

17. Do you have any other comments related to the CDR process?

_____
_____
_____

THANK YOU FOR TAKING THE TIME TO PARTICIPATE IN THIS SURVEY!