A REPORT OF THE ONTARIO CITIZENS’ COUNCIL

THE ETHICS OF DRUG REVIEW PRIORITIZATION

Submitted to:

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EXECUTIVE SUMMARY

The Ontario Citizens’ Council is mandated to provide advice to the Executive Officer of the Ontario Public Drugs Program about issues surrounding government funded drug benefits. Its advice is based on the values that reflect the needs and concerns of ordinary citizens of Ontario. Council reports are used by the Ontario Ministry of Health and Long Term Care to assist in the development of drug funding policies and programs that ensure a sustainable and effective drug system for Ontario.

This report presents the deliberations and outcomes of the Sixth Working Session of the Council, held Friday November 1 to Sunday November 3, 2013. In this session Council members were asked to provide values-based advice on the factors that the ministry should consider if it were to prioritize the timing of drug funding reviews in Ontario.

Funding applications for brand name drugs are largely handled on a first come, first served basis and an assessment typically takes three to four months. However, there are a limited number of experts who can conduct drug reviews, and periodically it may become impossible to accommodate all requests on a timely basis.

The question put to the Council was: What are the factors that the Ministry should consider in ranking or prioritizing the timing of drug funding reviews?

In essence, the Council was asked to consider under what conditions it would be justifiable to diverge from the current practice, and on the basis of which principles should prioritization of drug reviews be considered.

Section 1 of the report provides background information, an overview of the current situation, and insight into why these issues are of importance to the Ministry at this time.

To enable intelligent and informed discussion of this complex topic Council members were provided with printed information, heard several expert presentations, and participated in facilitated workshops and discussions. Sections 2 and 3 provide the details.

Council members agreed that maximizing operational efficiencies, reducing duplication, and increasing transparency should be primary considerations in moving the drug review process forward, with a view to avoiding queuing to the greatest extent achievable. However, it was also agreed that when these process issues have been addressed and there is still a backlog of reviews, there are reasonable criteria under which review prioritization might take place. Various implications of drug review prioritization were also examined and Section 4 presents the results of the deliberations on these.

Acknowledging that priority setting is a values-laden process, the Council based their deliberations and subsequent recommendations on the social and ethical Values Framework developed in earlier working sessions. This framework is reviewed at each meeting of the Council and affirmed or

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1 See page 8, for a description of the existing rapid review process.
updated to ensure that it adequately reflects new information or insights. In this way, the framework provides an anchor that ensures continuity over time and provides a consistent approach to discussion and recommendations. Section 5 provides the Council’s values-based advice to the Executive Officer.

Recommendations

The Citizen’s Council recommends:

1. The first-come-first-served approach to drug funding reviews should be altered to include priority criteria that would best meet the health needs of the people of Ontario.

2. A drug review should be expedited only if the essential criterion(a) can be identified and clearly documented.

3. Criteria for queuing or priority review should be apolitical. The review should continue to be evidence-based and objective.

4. The recommended criteria in order of priority are:
   - Therapeutic Gap
   - Prevention
   - Drug and Health System Savings
   - Improvement in QALY
   - Ease Drug Shortage

5. Recognizing that the criteria for prioritizing a review are not mutually exclusive, drugs that meet a number of criteria should receive higher priority.

6. Strategic queuing which can result in a delay in the drug review process for a particular drug is also an acceptable criterion. However the length of maximum delay time should be related to the significance of the proposed improvement for the drug in question.

7. The following values must be upheld:
   - Transparency
   - Evidence-based decision-making – clinical, economic, social
   - Fiscal responsibility
   - Improved Quality of Life
   - Equity and Fairness
   - Efficiency (and cost-effectiveness)
   - Public good

8. The Council recommends that the Ministry place more emphasis on prevention, with a particular focus on drugs that can prevent or delay a disease onset, or disease progression.
1.0 INTRODUCTION AND THE QUESTION

For the sixth time since its inception, The Ontario Citizens’ Council (the Council) met to consider an ethical question posed by Diane McArthur, Executive Officer for the Ontario Public Drug Programs (OPDP) and Assistant Deputy Minister.

The Council reports to the Executive Officer of the OPDP and to the Minister of Health. As with all such meetings, the ultimate goal was for the Ministry of Health and Long Term Care (MOHLTC) to glean perspectives of ordinary Ontario citizens, pertaining to policies of the province’s public drug program.

While the MOHLTC gathers available health and scientific information related to its work, it wants to ensure that the values of Ontario residents are considered in its drug decisions. For that reason, Council members\(^2\) - who represent a diverse mix of individuals from across Ontario - are asked to be forthright with their viewpoints on community needs, culture, and attitudes. Throughout meeting discussions, Council members are reminded that their perspectives must not simply be for personal or individual benefits, but must be for the good of the people of Ontario.

At this meeting Council members were asked to respond to the key question:

**What are the factors that the Ministry should consider in ranking or prioritizing the timing of drug funding reviews?**

Up to now, drug reviews have been largely considered on a first-come-first-served basis. That means that, except in the case of a public health emergency or rapid review designation, all drugs are treated equally and are evaluated one at a time. One of the challenges is that the drug pipeline for reviews is unpredictable. Sometimes the number of drugs submitted for review is manageable; at other times, there may be many submissions at the same time. Then drugs are put in a queue based on date of submission.

In light of the key question, the Council was asked to consider:

- Whether first-come-first-served was, in fact, the best way to continue – particularly when resource demands are high
- Whether some drugs were worthy of being given more priority than others, and if so,
- Under what conditions should priority be given?

In essence, the Council was asked to help determine whether or not more structure and predictability were needed for the drug funding review prioritization process (also called queuing in this report.)

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\(^2\) For a list of the current Council members, see Appendix 1.
2.0 PREPARING FOR DELIBERATION

2.1 Advance Reading Materials

To prepare for deliberations, the Council needed to understand the current review process, the dilemmas leading to the core question and the range of factors affecting the review process.

Council members were provided with a range of background information for advance reading. Reading material included information on the following:

- Ontario’s Public Drug Programs
- Priority Review
- Drug Approval Process
- Roles and Responsibilities of Expert Groups who are part of the process
- Types of Drug Submissions

2.2 Presentations: Ideas and Issues Related to Prioritizing Drug Reviews for Funding

Beginning Friday evening and continuing Saturday morning, the Council heard from the following presenters\(^3\). This helped to provide for an informed deliberation and to become aware of some different perspectives on the questions of prioritizing reviews. Opportunities to ask questions were also built into the process. A short summary of each presentation is provided following the table below.

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<tr>
<th>TITLE</th>
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<tbody>
<tr>
<td>Drug Reimbursement Review and Approval Process</td>
<td>Christine Seager</td>
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<td>Update and Introduction to Topic</td>
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<td>What would queuing or prioritizing mean for the CED and other regulators?</td>
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<td>Impact on Drug Manufacturers</td>
<td>Ilona Torontali</td>
<td>Vice-President, Public Affairs, Roche Canada, and Former Director of Drug Programs</td>
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\(^3\) See Appendix 3 for the session agenda
\(^4\) On Friday evening, there was also a presentation of The Ontario Drug Policy Research Network, made by Tara Gomes and Sarah Knowles. This was an invitation for Council members to be involved in drug class reviews. As it did not deal directly with the session topic, it has not been included in the list of presentations.
A. **Drug Reimbursement Review and Approval Process**

Health Canada reviews drugs for efficacy and quality. If a drug receives a Notice of Compliance (NOC) and a Drug Identification Number (DIN), it is approved for sale in Canada. This review typically takes up to two years and is not transparent. After approval for sale, Health Canada monitors the safety of the drug in “real” world usage.

All new drugs approved for use by Health Canada are first reviewed under the national Common Drug Review (CDR) process or for cancer drugs by the pan Canadian Oncology Drug Review (pCODR). The overall assessment of evidence for non-cancer drugs is decided by the Canadian Drug Expert Committee (CDEC), and by the pCODR Expert Review Committee (pERC) for cancer drugs.

The Common Drug Review process looks at clinical data, cost effectiveness data and patient input. This review can take up to a year and is transparent.

Once CDEC or pERC makes a recommendation, it is up to each province to decide whether to fund the drug product under its own provincial plans. In Ontario, the Committee to Evaluate (CED) drugs examines the fundamental question: Will the drug provide good clinical value and good use of scarce health care resources if it is funded? It then makes a recommendation on whether or not the drug should be funded, with the final funding decision made by the Executive Officer based on the CED’s recommendation, the overall budget and public interest.  

This review typically takes up to 3 months and is transparent.

For a graphic illustrating the drug funding process, see Appendix 4.

B. **Introduction to the Topic**

Diane McArthur highlighted a number of considerations related to drug review prioritization:

- The volume and timing of drug submissions can be difficult to predict
- The CED may be asked to review numerous submissions from drug manufacturers, which may require agenda prioritization
- In circumstances where the CED is unable to accommodate the volume of requests for drug reviews, some queuing may be needed to determine the order
- Any changes to the current approach are likely to have significant impact on the business model of pharmaceutical companies.

Currently, drug reviews are considered on a “first-come-first served” basis, with priority given to first reviews of a drug product. A growing number of submissions is anticipated and the Ministry asked Council members to provide feedback on considerations that would underpin any potential changes to the current approach, including a possible national framework of criteria.

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5 The Committee to Evaluate Drugs has 17 members and includes 2 patient members. It meets monthly for 4 hours to consider drug submissions. It focuses on new drug products. (Generic drugs have a different process).
Ms McArthur emphasized that the role of the Council in this discussion was to weigh the different criteria that could be used in deciding how the Ministry ranks or prioritizes the reviews of some products over other products, based on the values identified by Council, with the starting point being the Values Framework (see Appendix XX).

C. **Prioritizing Drug Reviews: Ethical Considerations**

Jennifer Gibson emphasized that the Council’s task is to provide advice on what principles and values should guide decisions about how priorities – if any – ought to be set among drugs under review.

She noted that “first-come-first-served” treats all drugs equally, treats all patient groups who might benefit from these drugs equally, and evaluates each drug in itself and one at a time.

She encouraged the Council to consider the conditions under which it is justifiable to diverge from first-come-first served, and if justifiable, on the basis of which values/principles in the Council’s values framework (or new ones pertinent to the question). She also asked the Council to assume that the CED has integrity as a review body and that the efficiency of the process of the review not be our focus.

Jennifer presented the following graphic representation of the current Values Framework:
D. **Exploring Prioritization in the Review of Cancer Drugs**

Cancer is increasingly viewed as a serious, life-threatening but chronic disease. With many new cancer drugs and treatments coming forward and a lack of consistency across the country in their funding, the pan Canadian Oncology Drug Review (pCODR) was created in 2010 for two key purposes:

- To assess cancer drugs and make recommendations to provinces and territories to guide their drug funding decisions
- To bring consistency and clarity to the assessment of cancer drugs by looking at clinical evidence, cost effectiveness and patient perspectives.

When cancer drugs are submitted to pCODR for review, the submissions are placed on the meeting agenda of the pCODR Expert Review Committee and are generally reviewed in the order received. There is also a process with clear criteria for requesting priority review.

Dr Sabarwhal also addressed some of the challenges with managing queuing and indicated that de-prioritizing certain reviews could be a possible approach to dealing with the rapid increase in cancer therapies and new high-cost cancer drugs, for example if a new drug does not offer improvements in significant outcomes or where effective treatments already exist.

E. **What Would Queuing or Prioritizing Mean for the CED and Other Regulators?**

Christine Seager took Council members more deeply into the CED review process and described the rapid review process that tempers the first-come-first-served process. As with pCODR, there are criteria for rapid reviews:

- New chemical entities effective for treating an immediately life-threatening disease or other serious disease for which it offers substantial improvements on significant outcomes, including improved efficacy, safety and tolerability and quality of life over other available drug therapies in Canada, or for which no treatment or no other effective drug therapy is currently available in Canada.
- A new product that would save or create efficiencies for the Government of Ontario, an average of at least $2.5 million per year for the first three years the product is marketed in Ontario, e.g. by offsetting “system costs” such as reduced hospital stays.
- A new product that would save the drug program an average of at least $250,000 per year for the first three years it is marketed in Ontario.

Thus, at CED meetings, rapid review submissions are considered first, followed by first reviews and then by drugs resubmitted for further consideration. Within each of these groups, submissions are ranked by the date or time the Ministry considers the submission to be complete.
The CED also takes into account how reviews take place in other jurisdictions. It particularly references the principles identified by the Citizens’ Council of the National Institute for Clinical Evaluation (NICE) in the UK (on which this Citizens’ Council is modelled).⁶

Since 2006 there have been 55 submissions for provincial Rapid Review- 15 were approved, 35 were rejected (primarily for incomplete information) and 5 were withdrawn.

Christine described a number of prioritization issues - related to evidence (clinical, value for money, patient evidence/social impact), type of submission (new vs resubmission, individual drug vs class review, economic vs clinical benefits), and process issues such as who decides, transparency and consistency, implementation and resources.

Finally, she noted that prioritization would have important impacts on the CED as well as the larger drug review system: it would change the workload and/or focus of CED reviews; it would promote alignment with the rest of Canada; and it would promote co-ordination of pan-Canadian initiatives.

F. IMPACT OF PRIORITIZATION ON DRUG MANUFACTURERS

The Council had previously indicated interest in hearing from drug manufacturers /pharmaceutical companies to get their perspectives on the topics being discussed. Drug manufacturers are very interested in the topic of prioritizing drug reviews (several observers from the industry attended the public part of this Council session) and the Council was eager to learn what prioritizing reviews would mean to them.

Ilona Torontali highlighted the need for reasonableness and accountability in drug reviews as well as the values and principles that should characterize drug reviews and any efforts at prioritization.

Manufacturers struggle to develop their submissions because they may not know exactly what the government is looking for, and if clearer guidance were provided, review times might be shortened.

Overall, drug manufacturers want a clear, transparent and equitable framework for drug prioritization for the large number of drugs potentially coming up for review. They want a process that is objective, sustainable and reproducible. They want to maximize efficiency and reduce duplication. They do not want to waste money or time and feel that they can work together with government to resolve any issues re: prioritization in times of calm rather than in times of crisis.

⁶ There are eleven principles: it increases quality of life; other innovations may be developed from it in future; a large number of people will benefit from it; it saves your life; it increases life expectancy; it meets a previously unmet need; it prevents a condition; it cures a condition; there are few other treatment options; it reduces risk to the patient; it has a one-off cost rather than ongoing costs.
2.3 Questions and Answers

Council members had many questions for presenters and this section highlights only a few key questions.

**Question:** Does a pharmaceutical firm require Ontario’s approval before selling their product in the province?

If a drug is approved by Health Canada, it receives a Drug Identification Number (DIN), and a Notice of Compliance (NOC), indicating that it is safe and effective. At that point it can be sold anywhere in Canada to those who pay for it themselves or who are covered by private insurance. The issue the Council is addressing in this session was not about the availability of a drug in Ontario, but rather the availability of the drug to patients who have their prescriptions paid for by OPDP.

**Question:** Should the government get involved in recommending which drugs the manufacturers are working on?

Most drug manufacturers supply a global market in which Canada plays a relatively small part and therefore has relatively little influence in, for instance, pushing for the development of a drug that would address a perceived public need.

**Question:** Would the prioritization of drug reviews impact both name-brand drugs and generics?

This discussion only applies to the process for reviewing name-brand drugs. Generics undergo a different review process, since they are equivalent to the name brand they are replacing, and are generally approved very quickly.
3.0 HOW THE COUNCIL DID ITS WORK

Once the Council members clearly understood the approval processes and associated challenges at national and provincial levels, and from a drug manufacturer’s perspective, they were able to focus on the values considerations related to drug review prioritization.

As with other sessions of the Council, the conversation was a series of facilitated dialogues in plenary and in small groups on many considerations emerging from the key question, “What are the factors that the Ministry should consider in ranking or prioritizing the timing of drug funding reviews?” The agenda is provided in Appendix 2.

In the first round of dialogue, members divided into two groups and moved to break-out rooms for a four-step process of values and ethics exploration:

Step 1 was an opportunity for Council members to share initial reflections on the topic and identify things that stood out or that puzzled them.

In Step 2, Council members worked in pairs to discuss values relevant to this issue. For each value already part of the Values Framework, members were asked to answer three questions:

- Is this value relevant to this issue? Why or why not?
- Are there any particular considerations or nuances?
- How could the OPDP apply this value to the issue?

Worksheets were provided to record key conclusions. Each group started with a different value so that across each breakout group, all the values were considered.

This was not intended to be a comprehensive discussion on values, but rather meant to concretely inform values-based discussions throughout the day and into Sunday.

Step 3 had the pairs coming together to talk about the values that members found relevant along with their rationale for these choices.

Step 4 took place in plenary where the entire group was able to share the highlights of their discussions with one another.

The next phase of deliberations asked Council members to consider potential criteria for drug review prioritization (aka queuing). The following four criteria were suggested by the OPDP for discussion, and the description provided to members is provided in Appendix 6.

- Therapeutic Gap
- Strategic Queuing
- Economic Impact on the Manufacturer
- Drug System Savings
Council members were divided into four groups, and four “stations” were established, each with a different potential criterion to be considered in making recommendations about queuing. Using a “carousel process,” each group moved from station to station and recorded their responses to four questions:

- Pros – What do you like about making this a criterion for queuing?
- Cons – What don’t you like about making this a criterion for queuing?
- Which values are at play? Which are most important? Least important?
- Proposed advice – Should it be a criterion or not? Any conditions or considerations?

As the groups rotated, they quickly reviewed what the previous group had noted, and built on previous groups’ discussions. After all groups had toured all four stations, each group remained at its final station to pull out areas of convergence and divergence for that criterion.

At the end of the day on Saturday, the facilitators pulled together the points of common ground and areas of possible divergence as a starting point for Sunday’s conversation. Through an intensive dialogue process the common ground, including criteria, were refined by the Council. Members were then asked to rank the criteria, keeping in mind the need to weigh them one against the other and to consider if and why one should be a priority over another, e.g. would a review for a new drug that could have a significant impact in reducing expenditures be delayed to allow for a comparative review of other similar products?

The results were then assessed against a number of possible implications to arrive at key points of advice and common ground. The Council shared its discussions with the Executive Officer, and she responded to outstanding Council comments and questions, after which the advice was refined into recommendations.

Finally, the Council reviewed its Values Framework to determine if any adjustments were needed.
4.0 RESULTS OF DELIBERATION

The Council’s conclusions on specific questions it was asked to address are as follows:

**Question:** Should the ministry make queuing a permanent feature of drug reviews? Why or why not?

Yes - so that drug companies know what the process is and queuing does not happen arbitrarily. Predictability is important. The process needs to be fair, consistent, objective and transparent. It should not be vulnerable to outside influence such as large, vocal and influential advocacy groups or other sources of persuasion. The criteria highlighted in Section 5 would be recommended as the basis for queuing.

**Question:** Who should trigger a priority review?

Either the drug company or the drug program should be able to trigger, based on clear criteria. Members also discussed whether others such as patient groups could request a priority review, but felt such a request would need to be made through proper channels to the drug program which would consider each case and trigger the priority review when appropriate. However members also suggested that if a process was set-up for this, it needed to be streamlined so as not to burden the program and potentially delay drug reviews overall.

**Question:** What is an acceptable length of “queue” for a drug, i.e. when does the wait get too long?

First and foremost, members reinforced that the current review process needed to be efficient and effective, making best use of available resources. Therefore, for the strategic queuing criteria, it was felt that the maximum delay time be related to the significance of the proposed improvement the new drug is offering; i.e. the more significant the improvement, the shorter the wait time should be. (See Principle in Section 5.) The Council referred the question of whether there is a maximum wait time overall to the experts who better understand the constraints on the system.

**Question:** Should the review process overall be revised? If so, on what basis?

While the Council respects the integrity of the CED as a review body and is focusing on which criteria might be used to rank the drugs for priority review, there is some concern that the many levels of review (Health Canada, CADTH (or pCODR), CED) should be considered. There are also concerns about the limited number of experts not associated with pharmaceutical companies able to comment on some types of drugs. Overall the Council would urge that the review process be streamlined as much as possible, while still ensuring it is evidence-based and grounded in Ontario’s context. However, it was also felt that there are many factors to be worked through in considering the question and that a more thorough deliberation would be required before making any recommendations on the review process overall.
**Question:** Should additional resources be allocated to drug reviews, and who should pay for this, e.g. manufacturer, government (taxpayers)?

While Council members agreed that it is in the interest of Ontarians to get prompt access to new drugs, there was mixed reaction to whether additional resources for drug review should be a priority. One option discussed was to require drug companies to help pay for the cost of a review, e.g. 50% of costs, as this would inject more resources without their coming directly from taxpayers. However, members felt that this possibility deserved a deeper deliberation than was possible at the session.

**Question:** What is the place of transparency?

There was general agreement that transparency is essential in order to demonstrate that the values in the Values Framework and the guiding principle of accountability to patients, health care funders and the public are being addressed. Council members emphasized the need for transparency at all levels of drug reviews and were concerned that a lack of transparency at the Health Canada level was making it difficult for other levels of the overall drug review process (CDR/pCODR/OPDP) to know what was coming down the pipeline and when. Members agreed that greater transparency would allow these bodies to better prepare for highs and lows in the number of drug submissions.
5.0 RELEVANT SOCIETAL VALUES AND COUNCIL’S RECOMMENDATIONS

The Ontario Citizens’ Council’s advice to the Executive Officer is framed in terms that reflect the Council’s Values Framework, and with the understanding that decision makers will take these values into account as they address the issue under consideration.

Setting priorities is all about choices, and choices necessarily reflect human values and judgments. Acting as a voice for the Ontario public requires the Council to express itself in terms of the overarching social and ethical values that are fundamental to just process, and not in terms of collective individual perspectives.

To this end, in earlier working sessions of the Council, a Values Framework was developed on which to base subsequent deliberations and recommendations. By committing to a common set of values, and by regularly reviewing and updating them to reflect new information that comes to light, the Council has been able to move through personal and emotional perspectives that reflect the significant diversity of its members, to the establishment of solid common ground.

All of the values identified in the Council’s Framework are important and any of them could become a top priority, depending on the context and issue at hand. The values are not mutually exclusive, nor do they operate in a vacuum. They must be applied in a manner that respects the real-life experience of patients, always keeping the public good in mind. Striking a balance between competing values will be an ongoing challenge for the Council, and having the framework lends coherence and continuity to the Council’s deliberations and recommendations. The existing Values Framework is provided in Appendix 5.

Briefly, the Council’s guiding values have fallen into four categories as follows:

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<thead>
<tr>
<th>Science-Oriented</th>
<th>Economic-Oriented</th>
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<tr>
<td>Evidence-based decision-making</td>
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<td>Advancing medical knowledge</td>
<td>Accountability to taxpayers</td>
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<td>Sharing responsibility</td>
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<th>Society-Oriented</th>
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<tr>
<td>Quality of life</td>
<td>Transparency</td>
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<tr>
<td>Freedom for Individual choice</td>
<td>Public safety</td>
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5.1 Deliberation on Criteria

As the Council worked through the question about the factors that the Ministry should consider in ranking or prioritizing the timing of drug reviews and talked with the Executive Officer about the advice that would be most useful to her, we recognized that the question we had to address was this:

“Under what conditions is it justifiable to diverge from the standard practice of first-come-first-served drug reviews, and on the basis of which principles should divergence be considered? “

Four potential criteria were provided for Council members to consider (see Appendix 6 for more detail):

- If an existing therapeutic gap could be addressed
- If significant savings to the drug and/or health system would result
- If it is part of a broader strategy to simultaneously review multiple drugs within one therapeutic class (strategic queuing)
- If it could prevent a negative economic impact on the manufacturer

The results of the Council’s deliberation on these criteria is provided below.

When an existing therapeutic gap would be addressed

Council members agreed that a therapeutic gap is a valid reason to expedite a drug review. This would apply for a new drug, or new indication of a drug, which is effective for the treatment of an immediately life-threatening disease or other serious disease if the drug offers substantial improvements in terms of effectiveness, safety, tolerability or quality of life for a select group of patients.

Council agreed that this would meet several key values including:

- Advancement of medical knowledge (i.e. offers substantial improvement)
- Improvements in patient quality of life
- Effectiveness, in terms of treatment for the disease, since there would be substantial improvements over what is currently available.

When savings to the drug and/or health system would result

Council agreed that this too is a valid reason for expediting a funding review. The drug would have to offer significantly reduced expenditures for the overall drug plan. Council members were clear that the savings had to be verifiable, obvious and significant to the ODBP and/or to the health care system generally. The assumption is that these savings would be redistributed to other areas in the drug or health care system.
The relevant values reflected here are:

- Fiscal responsibility;
- Efficiency (i.e. same or better results for significantly less cost);
- Accountability to taxpayers;
- Evidence-based (verifiable economic data to justify the decision);
- Public good;
- Sustainability of OPDP

**When It Is Part of a “Strategic Queuing” Process**

Council members agreed that *delaying* a drug funding review would be acceptable if it were to allow for a comparative review of multiple products within a therapeutic class. In this situation, several key values would be upheld including:

- Public good – as it would mean selecting the best therapy, rather than the one that got there first
- The decision would be evidence-based – comparison within a therapeutic class would ensure the best available product is selected, which is preferable to “first-come-first-served”
- Objective – Council members agreed that the rationale for prioritization of the review must be apolitical and objective
- Efficiency – simultaneous review of drugs of similar category or type could reduce review time, and potentially save money

However, in furthering the discussion on this criterion, an important principle was articulated. Members felt that any delay in order to consider a class of drugs should be related to the proposed benefits of the drug in question. That is, if there is likely to be a significant and immediate benefit, the review should not be delayed. This was expressed as a recommended principle:

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**Principle: Length of maximum delay time is related to the significance of the proposed improvement for the drug in question (for strategic queuing)**

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In addition, members recognized that while strategic queuing might hold a drug back as the program waited for other drugs for a comparative review, it could also mean that those drugs being submitted at a later date would be expedited as part of the comparative review. Again the significance of the proposed improvement would affect this decision.
WHEN IT WOULD PREVENT A NEGATIVE ECONOMIC IMPACT ON THE MANUFACTURER

The Council considered a hypothetical case wherein a new product submitted for review for funding consideration is the only product made by a particular manufacturer. Delays to the review of this product as a result of queuing, and the subsequent delay in funding from public drug plans, could mean the difference between the company succeeding or going under.

Council members agreed that the economic impact on the manufacturer should not be a prime consideration in the timing of a drug review. There was consensus that the role of the MOHLTC is to benefit the people of Ontario, not industry. Expediting a review to benefit the industry does not reflect the values in the Values Framework, nor does it reflect the values of the general public in regards to health care.

5.2 Additional Criteria

Through the course of the conversations, other potential criteria were raised and discussed. Three made it into the ranking round. These were:

PREVENTION

Council members have stressed the importance of both prevention and the delay of disease onset in previous sessions. While preventive measures, such as exercise, do not directly impact the drug program, they do offer cost savings to the health system. In addition, in this session, members heard that a number of pharmaceutical companies are looking at preventive products, e.g. for genetic testing and bio-markers. While this research is in the early stages, members agreed that prevention could be an important criterion in the future for drug review prioritization. Several key values would be upheld:

- Improvements in quality of life – big bonus to citizens if they can prevent or delay disease onset
- Fiscal responsibility- potential savings to health care system, even though impact on the drug program itself is less clear (e.g. cost of genetic testing is variable).
- Accountability to taxpayers.
- Public good – prevention helps to reduce the impact of disease on broader societal measure such as productivity, i.e. has a ripple effect in society.

IMPROVEMENT IN QALY7 OVER COMPARABLE TREATMENTS - HOW SIGNIFICANT AN IMPROVEMENT AND AT WHAT COST?

Throughout the two days of deliberation, Council members stressed the importance of using objective, evidence-based methods when determining whether a drug is eligible for a priority drug review. One such method already used in making decisions for drugs to be put on the formulary is

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7 A Quality Adjusted Life Year – or QALY – is a measure that relates the patient benefits of a drug treatment to its cost. QALYs are considered to be a measurement of how effective a particular drug treatment is. Drug funding reviews may compare the QALYs (effectiveness) of a treatment against the cost of the treatment to decide whether a product should be funded publically by the province.
the Quality Adjusted Life Year (QALY). Given that QALYs examine both effectiveness and cost, members felt a significant improvement in QALY could also be a useful criterion. Members discussed whether such a criterion could in fact replace the one on drug and health system savings, but in the end suggested that experts would be better suited to make that determination.

The values that underpin the proposed use of QALYs as justification for divergence from the first-come-first-served process include:

- Cost-effective – which is contained in the Council’s understanding of efficiency in the Values Framework
- Quality of life – which in the case of QALYs also contained the notion of the quantity of life
- Evidence-based - QALYs are evidence based, and thus result in objective, consistent, comparable, universal and quantifiable measures.

The desire for an objective process resulted in another recommended principle:

**Principle: Criteria for queuing or priority review should be apolitical. The review should continue to be evidence-based and objective.**

**Drug Could Ease Drug Shortages In Treatment For A Particular Disease**

It was brought to the Council’s attention that there are times when a particular drug is not available. If that is the sole drug available for a particular illness, this can put patients relying on that drug in a very difficult situation. For this reason, members agreed that drug review prioritization could be applied if a proposed drug could ease a shortage (current or likely). At the same time, members recognized that this is a rare situation and that this criterion would not often be used, e.g. there needs to be a valid, objective reason to be concerned about a potential shortage.

The relevant values reflected here are based on concern for the patient who might not have the needed drug:

- Compassion
- Quality of life

**5.3 Ranking of Criteria**

The Citizens’ Council recognizes that even using the previously discussed criteria, there may be competing demands on the drug review process. For that reason, members ranked the criteria. The Council recommends that prioritization of a drug review should be considered, for the following reasons, ranked in order of priority:

1. Therapeutic Gap
2. Prevention
3. Drug and Health System Savings
4. Improvement in QALY
5. Ease Drug Shortage

Strategic queuing was removed from the ranking process as it is a criterion for delaying a drug review, rather than for expediting a drug review. However it is also an acceptable criterion for divergence from the first-come-first-served standard of review.

It was recognized that these were not mutually exclusive criteria, e.g., a preventive drug could also result in health systems savings. Therefore a further principle emerged:

**Principle: Recognizing that criteria are not mutually exclusive, drugs that meet a number of criteria would receive higher priority.**

### 5.4 Summary of Recommendations

The Citizens’ Council recommends:

1. The first-come-first-served approach to drug funding reviews should be altered to include priority criteria that would best meet the health needs of the people of Ontario.

2. A drug review should only be expedited if the essential criterion(a) can be identified and clearly documented.

3. Criteria for queuing or priority review should be apolitical. The review should continue to be evidence-based and objective.

4. The recommended criteria in order of priority are:
   - Therapeutic Gap
   - Prevention
   - Drug and Health System Savings
   - Improvement in QALY
   - Ease Drug Shortage

5. Recognizing that the criteria for prioritizing review are not mutually exclusive, drugs that meet a number of criteria should receive higher priority.

6. Strategic queuing, which can result in a delay in the drug review process for a particular drug, is also an acceptable criterion. However the length of maximum delay time should be related to the significance of the proposed improvement for the drug in question.

7. The following values must be upheld:
   - Transparency
   - Evidence-based decision-making – clinical, economic, social
   - Fiscal responsibility
   - Improved Quality of Life
- Equity and Fairness
- Efficiency (and cost-effectiveness)
- Public good

8. The Council recommends that the Ministry place more emphasis on prevention, with a particular focus on drugs that can prevent or delay a disease onset, or disease progression.

Finally, while the following points were not given the weight of recommendations, (as they fall somewhat outside the direct question of priority drug reviews the Council was asked to consider), they are strong suggestions from the Council:

- That the OPDP and drug manufacturers work together to consider the possibility of cost recovery for drug reviews.
- That the OPDP work with Health Canada to make Health Canada’s process more transparent so that CDR/pCODR/OPDP can better prepare for highs and lows in drug submissions.
- That maximizing operational efficiencies, reducing duplication, and increasing transparency should be primary considerations in moving the drug review process forward, with a view to avoiding queuing to the greatest extent achievable before considering prioritization of reviews.
6.0 VALUES FRAMEWORK

Council members agreed that the Values Framework seems to be standing the test of time and continues to reflect the values the Council feels most benefit the citizens of Ontario, while making best possible use of available resources, both human and monetary. It was agreed that, as an evergreen document, it will be revisited at each session of the Council in order to ensure that the values reflected continue to be accurate in light of new issues and information presented.

From this session, members agreed to two changes to the Values framework:

- Equity and fairness are currently together as one value. Members recognize that they do not always work together and therefore the two values will be separated in the next iteration of the Values Framework.
- Prevention will be added as a value. This includes both the role of drugs and individual responsibility for health. Members have repeatedly expressed (across the Council sessions) the importance on putting more emphasis on prevention both to prevent suffering (e.g. delay or prevent disease onset) and to achieve a public drug program that can be financially responsible and sustainable into the future.

7.0 CONCLUSION

This report has provided details of the sixth working session of the Citizens’ Council. It identifies the question that was posed by the Executive Office and explains why this is an important matter for the Ministry to consider at this point in time. Council members received advance reading materials, expert presentations, and answers to questions that arose in the course of their deliberations. The report outlines the various steps in their deliberations, and the processes used to reach the Council’s recommendations.

The Ontario Citizens’ Council was pleased to be asked to comment on this emerging issue for the Ontario Drug Programs and to discuss the values important to the people of Ontario.
APPENDIX 1

MEMBERS OF THE ONTARIO CITIZENS’ COUNCIL

Benita Baker
Nigel Berrisford
Shelley Blidner
Jeff Bondett
Beverly Browne
Prem Lachhman
Sherry Marshall
Debbie Marson
Dorothy Modritsch
Robert Moore
Josephine Quercia
Abe Schwartz
Theresa Tasse
Gerri Gershon (Chair Citizens' Council)
Nazih Nasrallah
Mark Roberts
Prem Dhir
Remy Boulbol
Gary Spergel
Marilyn Wood
Isabel Metcalfe
APPENDIX 2

LIST OF ADVANCED READING MATERIAL

- Ministry of Health and Long-Term Care, Ontario Public Drug Programs Drug Approval Process
- The Ethics of Drug Review Prioritization, an MOHLTC Backgrounder
APPENDIX 3

AGENDA
ETHICS OF DRUG REVIEW PRIORITIZATION
CITIZENS’ COUNCIL

Royal York Hotel (Tudor 7 Room)
Toronto, ON
November 1-3, 2013

*Key Question:* What are the factors that the ministry should consider in ranking or prioritizing the timing of drug funding reviews?

<table>
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<tr>
<th>FRIDAY NOVEMBER 1, 2013</th>
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<tr>
<td>5:30 p.m.</td>
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| 6:50 p.m.               | Drug Reimbursement Review and Approval Process  
                          | Christine Seager, Senior Manager, Drug Programs, OPDP |
| 7:20 p.m.               | Stretch Break |
| 7:30 p.m.               | Update and Introduction to the Topic  
                          | Diane McArthur, Executive Officer, MOHLTC |
| 8:15 p.m.               | Class Reviews by the Ontario Drug Policy Research Network  
                          | Presenter: Tara Gomes |
| 9:00 p.m.               | Adjourn |

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| 8:50 a.m.                 | Ideas and Issues Related to Prioritizing Drug Reviews for Funding  
                          | Values Considerations  
                          | Presenter: Jennifer Gibson, Interim Director, Joint Centre for Bioethics, University of Toronto  
                          | Exploring Prioritization in the Inter-provincial Review of Cancer Drugs  
                          | Presenter: Mona Sabharwal, Executive Director, Pan-Canadian Oncology Drug Review (pCODR) |
| 10:10 a.m.                | Break |
| 10:30 a.m.                | What would queuing or prioritizing mean for the CED? And for other regulators?  
                          | Presenter: Christine Seager, Senior Manager, Drug Programs, OPDP  
                          | Impact on Pharmaceuticals  
<pre><code>                      | Presenter: Ilona Torontali, Vice-President, Public Affairs, Roche Canada, and Former Director of Drug Programs |
</code></pre>
<p>| 11:50 a.m.                | Open discussion with presenters |
| 12:20 p.m.                | Lunch |</p>
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<tr>
<td>1:00 p.m.</td>
<td>Introduction to the Afternoon’s process</td>
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<td>1:15 – 2:50 p.m.</td>
<td>Values and Ethics Exploration (with a break from 2:10 to 2:30)</td>
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<td>2:50 p.m.</td>
<td>Carousel Process</td>
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<td>4:40 p.m.</td>
<td>Wrap up</td>
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<td>5:00 p.m.</td>
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SUNDAY, NOVEMBER 3, 2013

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<th>Time</th>
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<tr>
<td>8:00 a.m.</td>
<td>Breakfast</td>
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<tr>
<td>8:30 a.m.</td>
<td>Morning Check-in and Review of Agenda</td>
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<td>8:50 a.m.</td>
<td>Validation of Where We’re At</td>
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<td>9:05 a.m.</td>
<td>Ranking Factors/ Criteria</td>
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<td>9:40 – noon</td>
<td>Common Ground on Ranking and Possible Implications (with a break at 10:30)</td>
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<tr>
<td>12:00 p.m.</td>
<td>Lunch</td>
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<tr>
<td>1:00 p.m.</td>
<td>Finalizing Council Advice for Diane</td>
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<tr>
<td>2:00 p.m.</td>
<td>Revisit the Values Framework</td>
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<td>2:30 p.m.</td>
<td>Review Format and Process for Council Report</td>
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<tr>
<td>2:45 p.m.</td>
<td>Wrap-up and Evaluation</td>
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<td>3:00 p.m.</td>
<td>Adjourn</td>
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APPENDIX 4

DRUG FUNDING PROCESS

Drug Funding Process

- Manufacturer submits
  - Health Canada Issues NOC & DIN
- Manufacturer submits

- pCODR Products (NCE / new combination product / new indication)
  - pERCr recommendation to drug plans specific to oncology drugs
- Common Drug Review products (NCE / new combination product / new indication)
  - CDEC recommendation to drug plans
- Non-CODR products / non-pCODR products

- Ontario’s CED reviews Health Canada status, CDR recommendation, pCODR recommendation and conducts Ontario-specific review.
  - CED provides recommendation to Executive Officer to reimburse (or not) through publicly funded program
    - Interim decision made by Executive Officer
    - Negotiations
    - Final decision made by Executive Officer

NOC = Notice of Compliance — indicating drug is safe and effective
DIN = Drug Identification Number
CDR = Common Drug Review
CDEC = Canadian Drug Expert Committee
pCODR = pan-Canadian Oncology Drug Review
PERC = pCODR Expert Review Committee
NCE = New Chemical Entity

Up to 2 years — Non-transparent
Up to 1 year — Transparent
Up to 2 mths — Transparent
~ 1 month
Open ended
APPENDIX 5

ONTARIO CITIZENS COUNCIL
PRELIMINARY VALUES FRAMEWORK,
DEVELOPED FROM COUNCIL MEETING OF JUNE 17-19, 2011

1.0 EXECUTIVE SUMMARY

The Ontario Citizen’s Council is composed of twenty-five Ontarians from all walks of life appointed by the Minister of Health and Long-Term Care. The mandate of the Council is to provide values-based perspectives on questions put to it by the Executive Officer of the Ontario Public Drugs Program (OPDP).

To assist in this mandate, the Council has begun to develop a values framework to bring increased clarity to its values-based deliberations. It is hoped that the framework will also be useful for the OPDP to use in considering citizens’ values in their decision-making and be applicable to the whole OPDP including stewardship of the drug formulary.

The framework is a work-in-progress. It will evolve as the Council considers further issues and values and will be updated as needed. We hope over time that it will provide a way to assess/measure which values have been the most important in the Council’s advice.

2.0 PREAMBLE

Each society upholds a set of values that define it and help guide decisions on how to share limited goods and services. Values help us decide what should do. They often set standards or norms of behaviour, e.g. compassion, freedom of choice, equity. They represent what we most care about.

Values are often divided into three groups: personal (“my” values), social (“our” values) and ethical (universal values). As the Council represents the public voice on behalf of Ontarians, our focus is on the social and ethical values that should help guide OPDP and our own deliberations.

Working with values poses a number of challenges. The first is creating a shared understanding of what a value means and how it is being interpreted/used. As a Council we have started this process and have captured our thinking to date in this document. It gives us language to explain our advice and recommendations and provides a shared vocabulary for communicating what we care about as Ontarians to the OPDP. It helps make our values more explicit.

The second challenge is that values can overlap and conflict. They don’t always take us in the same direction as we think about an issue and what is important to consider in resolving it. For example, should we maximize health benefits for the largest number of people or should we help the most vulnerable? We have found that while we often share a common set of values, there can be real differences in how we apply those values in a particular context on a particular issue. The weighing of values is very context-specific and so while the framework contains important values and some sense of priority; it is conditional based on context. The framework will help us be more explicit
about our deliberations on competing values and how we have weighed them in determining our recommendations on a particular issue. It will also help us compare our deliberations and ultimately draw out some principles that can be applied more broadly. This preliminary framework offers a couple of starting points for this.

**RELATIONSHIP TO THE ONTARIO DRUG FORMULARY**

As we developed the preliminary framework, we wrestled with whether we needed to consider the values that are embedded in the Ministry’s mandate regarding the Ontario Drug Benefit Formulary. At this stage, we determined that our own value deliberations could take as a given that the Ministry must manage the drug program in a manner that is fiscally responsible and accountable to taxpayers and contributes to the fostering of a sustainable health system for the health benefit of Ontarians. Thus the economic values of fiscal responsibility, accountability and sustainability are already mandated and will figure less into our own deliberations.

We also recognize that good stewardship of the drug Formulary requires:

- The need for feasibility/ practical application
- The need for a balance of values
- The need for responsiveness – the ability to act quickly based on new information
- The importance of context – each value must be applied in its context and applied with reason and clarity
- The need for regular review (in terms of how we operationalize or justify advice)

**3.0 KEY VALUES**

In the Council’s deliberation to date, several values have risen to the fore. The Council reaffirms the importance of all these values and recognizes that any of them may be deemed a top priority depending on the context and issue at hand. We also recognize that these values are not mutually exclusive, nor do they operate in a vacuum. They must be applied in a manner that respects the real-life experience of both patients and the public good. Striking a balance between competing values will be an ongoing challenge.

In trying to organize our own thinking about values, we categorized the key values as follows (in no particular order):

**Science-Oriented**

- Evidence-based decision-making
- Advancing medical knowledge
- Shared responsibility
Economic-Oriented

- Fiscal responsibility
- Accountability to taxpayers
- Sustainability
- Efficiency

People-Oriented

- Compassion
- Equity and fairness
- Quality of life
- Individual choice

Society-Oriented

- Public good
- Informed public
- Transparency
- Public safety

Appendix 1 provides a summary of how these values were interpreted on the two substantive issues brought before the Council so far. This again underscores the importance of context.

4.0 PRIORITIZING AND CLARIFYING VALUES

Given the importance of context, it is extremely difficult to determine absolute priorities in terms of values. However, given the caveat that a number of the economic-oriented values are covered off in OPDP’s own mandate (as well as public safety), the following six values seemed both high priorities and demanding of greater clarity. While the work to understand and clearly define these values in relationship to OPDP has only started, the following descriptions are offered as a starting point:

**EVIDENCE-BASED DECISION-MAKING**

This should include:

- Systematic expert review of the relevant published literature as well as grey literature (informal or unpublished evidence, including evidence gleaned from real life drug use).
- Full range of both positive and negative aspects including ongoing reporting of adverse events
And recognize that the:

- Standard of acceptability for a particular drug may vary depending on particular situations, but still needs to be defensible and based on good and comprehensive data, derived from both clinical sources as well as real world experience.

**Equity**

- The provision of equitable access to drugs and treatments for all citizens while protecting the vulnerable and being non-discriminatory.
- Equity does not necessarily mean identical – how equity is achieved may be different in different places or situations.
- In application, drug formulary decisions should not further existing inequities in drug accessibility, and should mitigate health inequities when possible – e.g. those due to income, geography, or other factors.

**Compassion**

- While this is an emotion of sympathy towards the plight of others, as a value it reflects concern for a society’s vulnerable members.
- However given its strong emotional pull, the value of compassion needs to be weighed in with all factors and a judgment made based on thought and consideration that does not just look at any one factor.
- Over time a procedure could be put in place to integrate compassion in decisions made. This would increase the consistency and predictability of decisions and hence their defensibility.

**Public Good**

- Public includes all Ontarians
- Good includes the health of the population
- Requires prudent use of all the resources available, that include but are not limited to evidence based resources, for the health benefit of most people in Ontario

**Quality of Life**

- One’s quality of life and how that is valued is very subjective. Therefore patients’ perspective needs to be considered and balanced along with medical expertise. This needs to be taken into account in the decision making process.
- It is very hard to put a dollar value on quality of life and determine what weight to put on it when making drug funding decisions. The Council recognizes one way to do this in a more objective way is through Quality Adjusted Life Years (QALY) - the number of years of living to expect on a particular treatment and how well the patients are living during that period.
EFFICIENCY

- This includes the notion of maximizing the results achieved with a minimum of wasted effort or time. It encompasses how well the system works in a cost effective manner, ensuring that taxpayers’ money is used well.
- It is important to consider efficiency as a means to an end – a valued way to achieve valued results. Making sure that these results align with our values must also be considered. Decisions should not be based solely on evidence of their relative costs and benefits.
- Having an efficient system usually requires the buy-in and involvement of all stakeholders (e.g. citizens province wide, patients, administrators of the program), which means being user-friendly and transparent.

5.0 PRINCIPLES

As we have noted earlier, we consider the application of values to be context-dependent. However, even given this, we have found that it is possible to begin to develop some principles of application. Key to this is the notion of balance – perhaps another value in its own right.

Two principles have emerged for us to-date:

**Balance the common good with the needs of particular individuals:** The government has a mandate to serve all citizens, including those with special needs, but it must provide prudent management of available resources for the benefit of all.

**Balance evidence-based decisions and compassion:** When making effective drugs accessible for compassionate reasons and when normal evidence standards cannot be met, programs should encourage the collection of real-life data to advance the overall evidence base and medical knowledge.
6.0 CONCLUSION

The values framework will be an important contribution to the Council’s future work. We expect to use this framework in future sessions as a guidepost for our recommendations and advice. We want to use the framework as a standing item at each meeting to consider whether new values have emerged during that meeting’s “deliberations”, and as a way to identify any particular values relevant to the topic at hand. Since the framework will be “evergreen,” (that is an iterative document, reviewed and revised over time), there will be ongoing opportunities to refine it and to develop principles which exemplify citizens’ values.

The framework is important from several perspectives:

- It assists the Citizens’ Council in providing common language for the Council’s deliberations and lending consistency to its recommendations.
- For MOHLTC, if can provide defensible decisions based on identifiable and consistent evidence and values-based reasons.
- For the public, it can provide a rationale for funding decisions that considers both evidence and values important to citizens.

Council members respect the scope, importance and challenge of building a values framework and are committed to continuing this rich dialogue as we deliberate on issues concerning the Ontario Drugs Program.
APPENDIX 6

POSSIBLE CRITERIA FOR DISCUSSION AT CAROUSEL STATIONS

STATION 1: THERAPEUTIC GAP
A drug funding review would be expedited for a new drug, or new indication of a drug, which is effective for the treatment of an immediately life-threatening disease or other serious disease. The drug offers substantial improvements in terms of effectiveness, safety, tolerability or quality of life for a select group of patients.

STATION 2: STRATEGIC QUEUING
A drug funding review would be delayed to allow for a comparative review of multiple products within a therapeutic class that are about to be approved for the Canadian market.

STATION 3: ECONOMIC IMPACT ON THE MANUFACTURER
Consider a hypothetical case wherein a new product submitted for review for funding consideration is the only product produced by a particular manufacturer. Delays to the review of this product in a queue, and the subsequent delay in funding from public drug plans, could mean the difference between the company succeeding or going under. Should the economic impact on the manufacturer be considered as a criterion for queuing?

STATION 4: DRUG SYSTEM SAVINGS
A drug funding review would be expedited for a new drug or indication which offers a minor improvement over available products, but will have a significant impact in reducing expenditures for the drug plan. The savings may be used to expand access or fund other new drugs for broad segments of the population.