Dear Ms. Gershon:

Please find attached the comprehensive Executive Officer response to the Ontario Citizens’ Council’s report on QALYs and Drug Funding Decisions in Ontario.

I appreciate the patience of members of the Ontario Citizens’ Council as I have transitioned into the role of Assistant Deputy Minister and Executive Officer of the Ontario Public Drug Programs. While I did not initially pose this question to the Council, I have reviewed the materials provided to the Council by my predecessor and am providing a response to the recommendations and values presented in the Council’s report. It is my intention to provide feedback on the recommendations provided by the Council, while identifying potential next steps or developing work as it relates to issues and questions raised by Council members.

In addition to being my first report response, this report represents the first contribution for a number of Citizens’ Council members who were newly appointed at the time. Based on the materials provided, it appears that the adoption of new members as part of the rotating membership for this advisory committee was handled seamlessly by the members and our facilitators, and the contribution of Council members both new and old towards the development of this report was highly commendable.

The Council reports serve as an important point of reference to inform public sector decision-makers of some of the key values and ideas of Ontario’s citizenry. We will refer to this report as we at the ministry, and in particular our expert reviewers at the
Committee to Evaluate Drugs (CED), review and reflect upon the criteria utilized in drug funding decisions.

I would like to thank all of the Council members for their hard work and I look forward to meeting with you again in 2015.

Sincerely,

Suzanne McGurn
Assistant Deputy Minister and Executive Officer
Ontario Public Drug Programs
The Ontario Citizens’ Council Report: QALYs

The purpose of the 5th session of the Citizens’ Council was to engage Council members in a detailed discussion of the drug review process in Ontario, with a focus on how decisions are made in this process. For many Council members, this was their first topic of discussion, and served as an introduction to the process by which a decision is made for funding of a drug product through the Ontario Public Drug Programs (OPDP).

Several new members were provided orientation on Ontario's public drug programs. The discussions over the course of the meeting served to both educate and engage new members as they considered various aspects of the drug review process in Ontario, and deliberated with seasoned members on the values considerations at the core of drug funding decisions.

The Importance of this Topic

This topic was selected as a means for Council members to deliberate upon the ethical dilemmas that the ministry faces in drug funding decisions, and reflect upon how their values would inform this decision-making process.

The discussion of this topic gave Council members the opportunity to focus on the drug funding decision-making process in Ontario, and explore how and why decisions are made as they are. They were then given the opportunity to weigh and discuss various criteria utilized in drug funding decisions.

Council members were asked to discuss the extent to which the OPDP should consider a common economic estimate that is often used to assess the cost-effectiveness of a drug, Quality Adjusted Life Years (or QALYs) in drug funding decisions. QALY is a measure of the disease burden experienced by a patient, and considers the quality of life for an individual and the length of life following a particular treatment. The Council deliberated on the use of QALYs in drug funding decisions, and consideration for how their values as citizens of Ontario may inform this process. Council members were challenged to consider situations that could present conflict or issues in drug funding decisions, and to weigh criteria and metrics such as QALYs as mechanisms to provide standardized measures to inform difficult decisions.

As stated in the materials provided to Council members in advance of the meeting, there are different perspectives on the usefulness of QALYs for public drug plans. Trends have shown that early provincial drug plan adopters of QALYs appear to be moving away from the promise and simplicity of QALYs. Concerns with QALYs are currently leading to a re-evaluation by national and provincial bodies in regards to the perceived value of QALYs in drug and health funding decisions. The recommendations of the Council in this report can inform decision-makers at the public drug programs as we continue to deliberate the role that QALYs may take within our drug review system.

The Council Recommendations:

1. QALYs should continue to feature prominently in making decisions for drugs to be put on the formulary. However they should not be the only consideration or even the primary consideration.
2. Clinical evidence and safety considerations should be paramount criteria in decision-making, with safety being looked at over the long-term as drugs are used in real life. Therapeutic gap (or need) is an essential consideration. Disease severity is too subjective a measure to be useful.

3. A clear, transparent decision-making process should be established. It should be premised on procedural fairness, possibly using the A4R as an approach.

4. Both prevention of disease and individual responsibility for health need to be recognized and considered as important aspects of ensuring a sustainable drug program. To this end, the Council would urge the government to consider prevention as a critical ingredient in achieving a public drug program that can be financially responsible and sustainable into the future.

Ontario has an established process for reviewing requests for drug funding under the public drug program. Funding recommendations for new drugs approved by Health Canada are initiated through the national Common Drug Review (CDR) process, with an overall assessment of the clinical, cost-effectiveness, and patient evidence completed by the Canadian Drug Expert Committee (CDEC). All new cancer drugs approved for use by Health Canada are first reviewed under the pan-Canadian Oncology Drug Review (pCODR) processes. Following the release of the final national recommendation, it is up to each province to decide whether to fund the drug product as a benefit under its own provincial drug plan.

When the ministry receives a submission requesting funding consideration of a drug or indication from a manufacturer, the ministry’s expert advisory committee, the Committee to Evaluate Drugs (CED), reviews and considers the drug’s clinical value and conducts a thorough assessment of the scientific and clinical evidence contained in the manufacturer’s submission, as well as the impact on health services compared to existing treatments. Criteria considered in funding recommendations may include the following:

- Quality of clinical evidence
- Effect size (differentiate between outcomes for two different clinical interventions, as an example)
- Therapeutic gap/Need
- Safety
- Cost effectiveness
- Budget impact

The ministry shares the Council’s view that all of the criteria considered in drug funding decisions have some utility, and also notes that the drug review process considers QALYs where appropriate as one component of an overall, comprehensive review. The recommendations of the Council in regards to QALYs provide some important insight into the values considerations of Ontario citizens as it relates to the criteria considered in drug funding decisions. In the report, the Council reiterated the importance of metrics such as QALYs in the review process from a values perspective. The Council clearly identifies a primacy of review criteria such as effectiveness, safety, and need in the drug review process, but also recognizes the importance of cost-effectiveness decisions as well. The complexity of the decisions that are
made as it relates to drug funding decisions require a method to synthesize the knowledge available both on treatment effects and costs for the public program. QALYs can play an integral role in this assessment as a tool of economic evaluation that informs optimal decision-making for funding decisions.

There are still some significant issues in regards to QALYs that require additional consideration by the Citizens’ Council, CED, and at the ministry. There continues to be some controversy around how much public drug plans should pay per QALY, or how QALYs should be valued. There are no clear ‘thresholds’ for cost per QALYs in Canadian jurisdictions as there is in some other jurisdictions internationally, but informal thresholds do influence decisions to varying degrees. The topic of the valuation of QALYs came up during the Council deliberations in conversations around treatments used at the end of life, or for ultra-orphan conditions, that are often are expensive and not particularly cost-effective. Additionally, valuation of QALYs will come into play in decisions around the funding of new products that may not offer significant advances with respect to improved QALYs for a new treatment.

The Council’s recommendation around the adoption of a form of procedural justice in health technology assessment, known as the Accountability for Reasonableness (A4R) assessment, will be shared with the CED. The A4R principles were presented to the members as a set of procedural mechanisms that will help to set priorities and values in health technology assessment and drug funding decisions. It is worth noting that elements of these values are already intrinsic in our drug funding reviews: for example, transparency in the process of posting CED recommendations and the Executive Officer’s rationale for funding decisions on the ministry’s website along with the statuses of drug submission reviews, and empowerment through the inclusion of patient members on the CED and through the patient evidence submission process. Further discussions at CED meetings, or retreats such as their discussion on QALYs, are warranted to consider the impacts and implementation of process-oriented approaches to ethics and priority-setting such as A4R.

In regards to the Council’s recommendations on disease prevention, the ministry realizes that there is a growing consensus that while chronic diseases are among the most common and costly health problems facing Canadians, they are also among the most preventable. Major chronic diseases such as cardiovascular disease (heart disease and stroke), diabetes, arthritis, asthma, and osteoporosis share common risk factors and conditions. Interventions to reduce risk factors and prevent chronic disease can be extremely successful. While these kinds of initiatives go beyond the traditional role of the OPDP, there may be opportunities for the Council to weigh-in on this topic or other related subjects that explore the broader health system. The capacity of the system to deal with acute conditions versus chronic conditions presents one such opportunity for discussion. As discussed by Council members during the meeting, medical practices tend to be designed to respond to clients’ acute illnesses, which can be short, urgent, easily diagnosed and treated with a cure being the likely outcome. This focus of care is arguably inappropriate for tackling chronic disease. Additional consideration for the changing role of the health system to address the need for chronic care has wide-reaching implications that impact all aspects of health care, including prescription drug plans. Recommendations from the Council on detection and interventions to reduce risk factors related to chronic diseases can be shared with Public Health Ontario and other government programs aimed at chronic disease prevention and health promotion.
Patients First: Action Plan for Health Care

It is worth noting that as part of the next phase of Ontario’s plan for changing and improving Ontario’s health system, the Patients First: Action Plan for Health Care, a number of recommendations have been developed that will help to strengthen the ministry’s commitment to put people and patients first by improving their overall health care experience. This includes access to new drug therapies, integrated care (which was subsequently a topic of discussion at our last Citizens’ Council meeting), and the support of additional home, community and residential care services for seniors.

Questions from the Ontario Citizens’ Council:

In addition to the recommendations posed by the Council, a number of questions were raised by Council members for the Executive Officer. Some of these questions shed light on broader discussions that may be suitable for additional discussion in future meetings.

1. **Question: Who should be responsible for ongoing drug evaluation over time?**

   It depends on the drug, but the industry, prescribing doctors and government all have a role to play. For example, doctors will see Adverse Drug Reactions (ADRs) and are required to report those. Government can ensure information is disseminated.

2. **Question: How can drugs be removed from the Formulary?**

   Unless there are clear safety issues, or even if there are, it can be quite difficult to remove drugs from the Formulary. The drug may be effective for some people. Others may be willing to run the risk of ADR. Risk and pain tolerance are both key in people making individual choices about drugs and it is difficult for government to weigh in at this level.

The two questions posed by Council members in regards to ongoing evaluation of drugs and drug classes and the removal of products from the Formulary build upon the discussions both from this meeting and the previous Council report, *Managing the Drug Formulary*.

The ministry is currently working with the Ontario Drug Policy Research Network (ODPRN) to conduct a series of comprehensive drug class reviews that explore the cost, effectiveness, safety, utilization trends, and experiences of using medications from a drug class. As Council members are already aware, work has begun in this regard and there are several opportunities for further engagement of the Council on this subject. The ministry engaged the ODPRN to present to the Council members at a subsequent meeting in regards to this work in November of 2013. The ODPRN provided an overview to the Council members of the work they do, and their role in providing relevant evidence to decision-makers at the OPDP to facilitate informed decisions relating to the administration of Ontario’s public drug system.

The ODPRN also outlined some of their upcoming work, including a series of comprehensive drug class reviews that will lead to the development of a set of policy recommendations for the
OPDP to inform future decision-making for drugs in these classes. Twelve drug class reviews are expected to be conducted between now and 2016. At this point, reviews of Triptan for migraines and Testosterone Replacement Therapy for hypogonadism have been completed. Respiratory reviews are near completion, and all remaining reviews are ongoing or in the planning stage.

As discussed at the Council meeting, the ODPRN is engaging some members of the Citizens’ Council to participate in these drug class reviews. Council members can have a substantial role in these class reviews by providing feedback on the social acceptability of any proposed policy recommendations made by the ODPRN. By providing their perspectives as Council members, and as the general public, participating members will have an opportunity to take part in ongoing drug evaluation – something they have recommended in multiple reports.

As stated in response to prior recommendations around the re-evaluation of drugs currently funded by the OPDP, the ministry has conducted numerous formulary modernization reviews over the last decade and will continue to do so as a mechanism to support clinical benefit, patient safety, and value for money. The ministry continues to work with the CED and researchers, such as the ODPRN, in the monitoring and re-evaluation of drugs reimbursed by publicly funded drug programs with regard to their continued therapeutic value and cost-effectiveness. The input from Council members into this process speaks to an ongoing role for the Council to participate in ministry-initiated class reviews to ensure that the drugs reimbursed by the ministry are kept up to date with the latest evidence in terms of efficacy, safety, cost-effectiveness, and public opinion.

I would like to reiterate that the recommendations of the Council as it relates to delisting drugs, which have been voiced on multiple occasions, can and will play a role in informing future decisions around delisting or limiting the use of a currently funded drug. As we have stated previously, decisions around delisting and limiting the use of a publically funded product require careful consideration of values.

3. Question: Are there products that are helping certain diseases that would be better treated in palliative ways?

Government is looking at the drug system and a rational decision-making process. There are many drugs that exceed the cost of home care and offer little in terms of increased length of life. Many oncology drugs are thousands of dollars a day and are not cost effective. If the drug is a major advancement or innovation however, it could still be worthy of funding.

Palliative care is comparatively inexpensive. However, in its current form it relies heavily on volunteers. The end-of-life decision-making process is one that we as a society have not grappled with effectively. Quebec is currently looking into this issue, having introduced end-of-life legislation.

The question of end-of-life care can be a challenging and value-laden issue that presents itself as a topic for exploration at a future Council meeting. While the formal health care system, including drug treatment, plays an important role for individuals and their families approaching
end-of-life, 80% of the support needed by people who are dying is provided by family and informal caregivers. Evidence indicates that the majority of Canadians would prefer to die at home if supports were available; however, many Canadians die in hospital. Receiving palliative care at home or in the community is more aligned with many people’s wishes, associated with better experiences for patients and caregivers, and more cost effective. Caring for individuals in the last month of life at home costs approximately $100 per day, compared to $1,100 per day when care is provided in a hospital bed.

The Council has recognized some of the challenges as it relates to end-of-life drugs, however as the issue relates to Ontario’s public drug plans, decisions around end-of-life treatment tend to focus on issues of evidence versus patient demand.

Given the nature of treatments of last resort, the impact on longevity of life or progression of disease is often unlikely. Despite this, however, many patients may rightly feel that they are entitled to have public funding for possible treatments for remission.

It must be considered that for treatments of last resort and end-of-life care, there often is a lack of strong evidence to demonstrate that a drug is effective for use for a particular indication or in a specific case. Additionally, there will be concerns around availability of data indicating what the short or long-term side effects there might be for a given treatment.

Decisions around the funding of treatments for end-of-life must balance values of access against that of evidence-based decision-making. Some interesting considerations that could be discussed on this topic include the level of evidence required for decisions on end-of-life treatments, and the onus for public funding of these medications without evidence of impact on longevity or disease progression.

Advance care planning (ACP) can play a key role in supporting decision making with respect to end-of-life treatment. ACP reflects a person’s wishes about their care at the end of their life and can include detailed instructions about whether to continue or discontinue medical treatment. Understanding a person’s wishes about their care at the end of their life, combined with timely access to quality palliative care, enables people to die in the location and circumstances of their choice.

This topic has some natural connections to the discussion on QALYs, as it will entail a consideration of the criteria that should form the basis of decisions for end-of-life treatments such as the state of the disease, cost, evidence, and patient circumstance. Much of the Council’s discussion on disease severity as a criterion for drug funding decisions would relate to deliberations on this topic, as well.

4. **Question: Does the Committee to Evaluate Drugs (CED) look at the potential for abuse of the drug in society?**

One example is Oxycontin. It was initially perceived to be less addictive than comparable medications, and this was the primary reason it was introduced, despite prior hesitancy around opioids.

The CED does a good job of looking into issues such as this from a public safety perspective, and takes these kinds of issues into consideration. But we often run into a
scenario where we don’t know how a drug is going to work in the broader population. There are a variety of risks that exist for products as they are made widely available and some of these risks are hard to predict.

While considerations such as potential for abuse are certainly taken into account during drug reviews by provincial public drug plans, it should be noted that decisions made in this regard would only impact the public funding status of the product. Health Canada is ultimately responsible for authorization of a product to be available for sale in Canada, and oversees safety and efficacy concerns related to drugs. As indicated within the background materials provided for this session, the federal review process (i.e. Health Canada review) is intended to determine if a product is safe for sale in Canada. This would include an assessment of the potential for abuse of a product. A drug must first receive a positive CDEC recommendation and Notice of Compliance to be made available in Canada (for purchase or funding through public or private drug plans). After this approval, it is up to each province to decide whether to fund the drug product under their provincial drug plan. CDR and pCODR reviews provide context and direction for evaluations for public reimbursement.

The ministry acknowledges that the inappropriate use, abuse and diversion of prescription narcotics and controlled substances are critical public health concerns, and to this effect introduced new regulations in 2013 requiring that long-acting oxycodone products be tamper resistant as a condition for funding consideration. Much of the work involved with addressing these issues occurs outside of the drug review process, however. As an important first step in addressing the inappropriate use of prescription narcotics and other controlled substance medications, the government passed the Narcotics Safety and Awareness Act, 2010 (NSAA). This legislation enables the ministry to track prescribing and dispensing activities relating to prescription narcotics and other controlled substance medications in Ontario. The Narcotics Monitoring System (NMS) was developed under the NSAA as a means to collect dispensing information from pharmacies in relation to all prescription narcotics and other controlled drugs. Information collected by the NMS may be used to detect unusual or inappropriate behaviour, identify trends, enhance education initiatives, and develop harm reduction strategies. By understanding how monitored drugs are being prescribed and dispensed, and to whom, the ministry can help make the prescribing, dispensing and use of monitored drugs safer and more secure.

5. Question: Could OPDP work with pharma to draw attention to disease areas lacking attention?

We currently have limited contact with manufacturers in regard to some key areas such as chronic disease, vaccines and prevention of disease, and mental health (e.g. Alzheimers and dementia products).

Often the discovery process by manufacturers is organic. Society also determines where investments are made based on market principles.
The ministry regularly consults and meets with patient advocacy groups, professional associations, and manufacturers to discuss priorities and concerns related to the provincial public drug plans. Our discussions with manufacturers and advocacy groups largely relates to priority-setting for the OPDP as a public payor for drug benefits for seniors and those in need.

As the Council is aware, the majority of drug reviews for public funding are initiated by manufacturer submissions. The ministry however may on occasions consider submissions from physician groups to request that a drug be publicly funded. This allows those closest to patients to draw attention to the unfunded products that patients may require. Health care professionals, their respective associations, and patient advocacy groups are best equipped to identify gaps in public funding for particular disease areas or products available for sale in Canada that are not available for public drug plan recipients (for example, in cases where a manufacturer has not made a submission). As such, the ministry considers reviews based on submissions provided by physician groups on a case-by-case basis.

In general, submissions made by physician groups follow the usual drug submission requirements and process. The submission should include a systematic review of currently available clinical evidence supporting the use of the requested product for a particular indication, economic evidence (e.g. estimated number of patients and potential utilization information) along with the physician group’s recommendation. Once this is received and the ministry decides to initiate a CED review based on the submission, the ministry will contact the relevant manufacturer(s) to invite the company to provide any clinical, safety, cost-effectiveness, and budget impact analysis, if available, to support the review.

How We Will Use the Council’s Report

The recommendations and values outlined in the Council’s report on QALYs both support and provide thoughtful comment on various aspects of the drug review process and criteria for drug reviews considered in Ontario. The recommendations from this report will be helpful as we consider any future changes to Ontario’s drug review process and the criteria utilized in drug funding reviews at the CED. These recommendations will be of particular utility to the CED as they continue to discuss the role of review criteria such as QALYs and consider issues such as the valuation of a QALY or the adoption of A4R principles.

It is worth noting that the CED also discussed a similar topic at a meeting in June of 2013. The report of the Council on QALYs will compliment these discussions, and additional reflection on the part of the CED, particularly in regards to a public acceptability standpoint for their current review criteria, may be warranted in light of the Council’s recommendations.