

**MOHLTC - Ontario Public Drug Programs
Public Comment on the Proposed Lead Time
Between the Formulary Update and Effective Date**

Introduction

As a result of the introduction of the *Transparent Drug System for Patients Act, 2006* (Bill 102), amendments to the regulations under the *Drug Interchangeability and Dispensing Fee Act* (DIDFA) and the *Ontario Benefit Drug Act* (ODBA) were made effective October 1, 2006, to support the government's plan to reform the drug system. As of October 1, 2006, changes to the Formulary no longer require regulatory amendments to the DIDFA and the ODBA. The Executive Officer has the authority to keep, maintain and publish the Formulary. The Formulary system decisions are based on scientific and economic considerations that achieve appropriate, safe and cost-effective drug therapy. On a go-forward basis, the Formulary is being updated monthly with the inclusion of new generic and single source drug products as well as house keeping changes. On the approval of the Executive Officer, the Formulary Update is communicated via the Bulletin Board System (BBS) to all subscribers and posted on the Ministry of Health and Long-Term Care's (Ministry) website.

The Executive Officer on behalf of the Ministry invites public comment regarding the desired lead time between the release date of the Formulary Update and the effective date. The Executive Officer recognizes that this issue is a concern for a number of stakeholders and will review all comments submitted before or on the closing date.

Background

Historically, changes to the Formulary were made on a quarterly basis. Any change to the benefit list contained in the Formulary required regulation changes to be made under the DIDFA and the ODBA; and therefore, any changes to the list required Cabinet and Lieutenant Governor in Council approval. In 2004, as a result of legislative changes to the DIDFA and the ODBA, the Ontario government implemented an expedited process for listing new generic drug products in the Formulary on a monthly basis. The government amended the DIDFA and the ODBA to permit the Minister, by way of regulation, to declare drugs to be interchangeable with another drug product and to declare interchangeable drugs as listed drugs on the Formulary. The power of the Lieutenant Governor in Council to declare a drug to be interchangeable in section 18(1)(c) of the ODBA (as it was enacted at the time) was retained.

As a result, implementation of Formulary changes occurred in tandem with regulation changes. A Formulary release date was not communicated externally prior to Cabinet approval. Upon Cabinet approval, the Ministry sent a notice with the updates to stakeholders to advise them of the changes and the effective date. This mechanism was lengthy in terms of the approval process and resulted in stakeholders having, on average, between seven (7) to thirty-three (33) calendar days' notice prior to implementation of the effective date of an update or new Edition of the Formulary.

With the enactment of Bill 102, the *Transparent Drug System for Patients Act, 2006*, the Executive Officer has the authority to update the Formulary on a monthly basis, or other basis as established by the Executive Officer. Due to this streamlining approach, the average lead time for a Formulary Update is approximately seven (7) calendar days. Consequently, the Ministry proposes to review the timeframe for the lead time in order to assist stakeholders in preparing for the Formulary Update.

Invitation to Provide Written Comments

Interested parties are invited to provide written comments on this matter on or before September 7, 2007 at 5:00 p.m. EST (“comment period.”)

When preparing your response, please consider the following questions:

- What is the recommended lead time between the release date of the Formulary Update and the effective date? Please explain your reasons for the proposed timeframe.
- What are the main factors that should be taken into consideration for the proposed timeframe?
- Are there any specific categories of drug products that are most impacted by a short lead time?

Please provide any other relevant comments you think might be useful. Please be as specific as possible and provide a full rationale for the proposed recommendations.

Please note that the publication of the Formulary, including updates to the Formulary, as well as the timing of those updates, are in the sole discretion of the Executive Officer. While all comments are appreciated and will be considered by the Executive Officer, the Executive Officer is in no way bound to act on any of the comments or proposals put forward.

The Executive Officer reserves the right to make any change at any time to the lead time as is deemed necessary.

Submission of Written Comments

Please submit your written comments to:

Helen Stevenson
Executive Officer, Ontario Public Drug Programs
Ontario Ministry of Health and Long-Term Care
415 Yonge Street, Suite 1601
Toronto, Ontario
M5B 2E7
Fax: (416) 325-6647
E-mail: PublicDrugPrgrms.moh@ontario.ca

Please note that only comments and submissions received during the comment period will be reviewed and considered. Please also note that submissions deviating from this issue will not be considered.

Statement about Comments

Please note that unless requested and agreed otherwise by the Ministry, all materials or comments received from organizations in response to this Notice will be considered public information and may be used and disclosed by the Ministry to assist in reviewing and evaluating the proposed framework for the lead time with respect to the Formulary Update. This may involve disclosing materials or comments, or summaries of them, to other interested parties during and after the request for public comment process.

An individual who provides materials or comments and who indicates an affiliation with an organization will be considered to have submitted those comments or materials on behalf of the organization so identified.

Materials or comments received from individuals who do not indicate an affiliation with an organization will not be considered public information unless expressly stated otherwise by the individual. However, the Ministry may use and disclose materials or comments provided by individuals to assist the Ministry in reviewing and evaluating the proposed framework for the lead time with respect to the Formulary Update. The Ministry will not disclose personal information of those who do not specify an organizational affiliation, such as an individual's name and contact details, without the individual's consent unless required by law.

If you have any questions about the collection of this information, you can contact the Ministry's Freedom of Information and Privacy Coordinator at (416) 327-7040.

Helen Stevenson
Executive Officer
Ontario Ministry of Health and Long-Term Care