CAPDM Driving | Healthcare

February 15, 2021

Re: PMPRB Consultations on Proposed Consequential Amendments to the January 1, 2021 Guidelines: Definition of Gap Medicines and Compliance Timelines for Grandfathered and Gap Medicines:

To whom it may concern;

The Canadian Association for Distribution Management (CAPDM) and its members are very much concerned with the proposed shortened transition period for grandfathered and gap medicines. A 6-month timeline is impractical and highly disruptive to pharmaceutical supply chain stakeholders, including distributors. CAPDM recommends that the PMPRB revert to its original 12-month transition period.

Impacts of a compressed transition timeline

While the regulations and guidelines are now scheduled to take effect July 1, 2021, we anticipate that the PMPRB will only be able to confirm new price ceilings to patentees later in 2021. Rather than a 6-month transition period, the effective timeline would be much shorter. As manufacturers submit their semi-annual report by July 31, 2021 for the first reporting period of 2021, the PMPRB will have 45 days to provide them with their compliance reports and the new price ceilings. Given that patentees will only receive compliance information on the new price ceilings by mid-September 2021 at the earliest, we project the following processes to ensue:

1. manufacturers to review compliance information for all of their patented medicines
2. determine if a Maximum List Price (MLP) calculation has been significantly impacted
3. potentially submit a review under Guidelines section 75 for an MLP increase if applicable
4. otherwise, reduce MLP where necessary in all provincial/territorial jurisdictions as per their respective policies and timelines.
5. secure global approvals
6. communicate with customers and formularies
7. amend product listing agreements and commercial contracts
8. determine if floor stock protection is required for each customer which requires an inventory count of each impacted product in each location across the country

The process will then trigger a similar chain of events and communication between distributors and their pharmacy customers. Each distributor will have hundreds if not thousands of customer and pricing files to update. Industry will need to determine a systematic process to announce and affect price conversions to ensure orderly transition and avoid errors and rework.

The next step will be for pharmacies to update their product and pricing files accordingly with their relevant customers, adjudicators and payers. Multiple concurrent price changes are disruptive to distributors and pharmacies.

A 6-month transition timeline to comply is simply not feasible or reasonable.

Furthermore, these changes would need to take place at a time when the industry organizes a higher load of inventory to allow supply chain players to carry through the December and early January time period when there are manufacturer shutdowns. With insufficient lead time, late year price changes are difficult to execute due to year end inventory planning processes, floor stock protection clauses throughout the supply chain, typical vacation period and exceptionally now under pandemic circumstances.

Recommendations

The PMPRB Guidelines communicated in October 2020 provided twelve months of transition from the date of the entering into force of the amended Patented Medicines Regulations. The current proposal suggests limiting this important transition period to only six months without justification. While it is recognized that the PMPRB reforms will have considerable unintended negative consequences on pharmaceutical distributors (see CAPDM's previous submissions to PMPRB), it is unacceptable to further burden this sector with a compressed transition timeline that further exacerbates the detrimental impacts. This is also contemplated at a time of great supply chain uncertainty during a global pandemic.

In light of the above, CAPDM recommends:

1. PMPRB to maintain 12-month transition timeframe from date that Guidelines and Regulations come into force
2. Form multi-stakeholder group to plan effective and consistent transition process
3. PMPRB to uphold commitment to evaluating and monitoring the impact of the reforms on the broader eco-system and particularly on the unintended consequences to the essential pharmaceutical distribution infrastructure

A minimum twelve-month transition period from the date that the Regulations come into force is needed to allow all parties to effectively plan and execute a multitude of pricing conversions. Many actors will be affected by such changes and the work involved requires much coordination. Lastly, given the ongoing pandemic, resources that could be assigned to planning and executing the PMPRB reforms are otherwise consumed to ensure Canadian patients do not go without their required medication and will have ready access to COVID-19 vaccines when they are available at scale. The transition period should remain at 12 months and provide a minimum of two full reporting periods.

CAPDM and its members would be available to work with the PMPRB staff as part of a multi-stakeholder group to effectively plan such a transition. We welcome the opportunity to submit our comments on the PMPRB's latest proposal and are available to meet to answer questions or provide further clarification.

Sincerely,

Daniel Chiasson
President and CEO
Canadian Association for Pharmacy Distribution Management
3800 Steeles Ave. W. Suite 301A
Woodbridge, ON, L4L 4G9
daniel@capdm.ca
(905) 265-1706