Canada First Priority Regulatory Review

CPMEA

The federal government has stepped up with new programs designed to *Build Canada Strong* and construct a self-sufficient Canadian economy through procurement, regulatory reform and business incentives.

It is time to do the same for Canadian pharmaceutical producers and exporters.

CPMEA recommends the establishment of a priority review mechanism for new generic drug applications submitted by Canadian manufacturers. As it stands now, there is no distinction between applications submitted to Health Canada (HC) by a Canadian producer and those submitted by importers, even though domestic manufacturers invest significantly in local infrastructure, workforce development, and supply chain resilience.

Health Canada recently informed stakeholders of a new program called *'Reliance'* which is intended to reduce red tape by relying on the decisions of Foreign Regulatory Agencies (FRA) to provide support for drug submissions filed to Health Canada.

The members of the CPMEA welcome efforts to speed up approvals and reduce red tape. The Reliance program, however, will inadvertently harm local producers by prioritizing applications from importers which have received approval for their drugs in other jurisdictions, and even provides a financial benefit to importers by leveraging the investment costs of clinical work done elsewhere. This will give preference in the approval process to importers and will discourage local production of critical medicines and undermine Canada's health and industrial policy goals.

To balance this unintended consequence and provide a meaningful incentive to manufacture pharmaceuticals in Canada, CPMEA recommends the following amendment to the HC Priority Review guidance:

This policy applies to a New Drug Submission (NDS) or Supplemental New Drug Submission (S/NDS) that

I. for a serious, life-threatening or severely debilitating disease or condition for which there is substantial evidence of clinical effectiveness that the drug provides:
   - effective treatment, prevention or diagnosis of a disease or condition for which no drug is presently marketed in Canada; or
   - a significant increase in efficacy and/or significant decrease in risk such that the overall benefit/risk profile is improved over existing therapies,

preventatives or diagnostic agents for a disease or condition that is not adequately managed by a drug marketed in Canada.

II. ***is submitted by a "Canadian producer" and is intended to incentivize domestic drug production to improve Canadian supply chain resilience.***

As Health Canada considers the best way to implement this recommendation, we provide a definition for a "Canadian Producer" that will encourage companies to manufacture their products in Canada.

Definition of "Canadian Producer":

- At least 30% of manufacturer's gross revenue generated through the sale of drug products manufactured in Canada.
- For a DIN to contribute towards the value of gross sales manufactured in Canada, the finished goods must be manufactured in Canada, with substantial transformation of the product having occurred in Canada.
- Packaging of finished goods manufactured outside of Canada should not count towards the value of gross sales manufactured in Canada.

This is not a new idea. The FDA in the U.S. recently announced the establishment of a new program to prioritize the review of generic drug submissions for products manufactured and tested in the U.S. The FDA's rationale for the program was made clear - overreliance on foreign drug manufacturing creates risks to national security and patient access and undermines investment in research manufacturing and production. The program is part of a series of actions intended to revitalize American industry and ensure a strong domestic drug supply.