(1) General Comment	The International Society for Pharmaceutical Engineering (ISPE) Drug Shortages Initiative Team appreciates the opportunity to provide comments on the Health Canada Regulations Amending Certain Regulations Made Under the Food and Drugs Act (Shortages and Discontinuation of Sale of Drugs and Medical Devices) and commends Health Canada's efforts to increase supply resiliency for the Canadian market. Since 2012, ISPE has assisted industry and engaged with regulators with the goal of reducing drug shortages globally through technology, quality, manufacturing innovation and regulatory compliance. In reviewing the proposed amendments, we were pleased to observe: • expectations balanced with respect to the criticality and vulnerability of drug products • the acceptance of internationally recognized formats of shortage prevention and mitigation plans which include essential core elements, and addition of an annex or appendix for shortage risks specific to Canada, as needed ISPE also thanks Health Canada for the reference to the ISPE Drug Shortages Prevention Model (DSPM) and previous publication, *Business Continuity Planning to Prevent Drug Shortages*. Other ISPE resources that may be of assistance include: • A Quality Risk Management (QRM) Guidance based on the International Conference on Harmonisation (ICH) guideline, Quality Risk Management Q9(R1), to be published by ISPE shortly. • ISPE Drug Shortages publications ▪ *A Holistic Mindset is Key to Supply Resiliency* ▪ *Global Convergence Opportunities* ▪ *Risk Management for Avoidance of Drug Shortages*

(9) Implementation, compliance and enforcement, and service standards	ISPE supports an extended implementation period for companies to transition to new expectations for Shortage Prevention & Mitigation Plans and minimum safety stock requirements. Because existing circumstances may restrict implementation within the proposed implementation periods (*e.g.*, manufacturer portfolios containing a large volume of critical and vulnerable products, complications involved in revising quality agreements with multiple manufacturing partners, procurement of suitable storage locations, revision of a high volume of procedures and operations…*etc.*), an option to document extenuating circumstances and qualify for an alternate, exceptions-based implementation timeline is recommended.
(11) Comment for the Food and Drug Regulations section	**Critical and Vulnerable Drug List (CVDL)** ISPE supports a lean CVDL list, with rigorous criteria and ongoing stakeholder consultation, to ensure the scope of the CVDL remains focused on the most therapeutically significant and vulnerable products. **Shortage Prevention and Mitigation Plans (SPMP)** ISPE supports a periodic refresh of SPMPs, as well as reviews/revisions of SPMPs prompted by significant events or significant disruptions in supply. To allow for optimizing manufacturer resources* and maintain focus on ensuring uninterrupted supply of the most significant medications at any time, ISPE suggests for consideration that the periodicity for SPMP updates be established by manufacturers. *Examples of optimizing resources: staggering the timeline of SPMP reviews across the entire portfolio to avoid compressed, or possibly unattainable, refresh activities due to unmanageable volumes of work, ensuring sufficient capacity and attention to address products undergoing significant changes, providing flexibility to deprioritize products with diminishing patient impact or demand **Safety Stock List** ISPE supports the opportunity for stakeholder consultation on the development and updates to the Safety Stock List. We suggest providing additional information on the frequency and process for updating the Safety Stock List, to level-set expectations and prepare manufacturers.

	ISPE recommends that the quantity of required safety stock be based on future forecast/forward demand, while taking into account historical demand (when available), to effectively align safety stock with evolving market consumption patterns. Additionally, since historical data may be lacking for new product launches and products nearing their sunset stage, relying solely on past sales may lead to excess inventory. Manufacturers also consider various indicators, including market trends, to determine optimal safety stock levels. Therefore, a combined strategy will allow industry to meet consumer needs and manage inventory risks. ISPE would like to clarify that safety stock is not separate inventory or batches; it is extra inventory on hand. Therefore, MAH holders should report that their on-hand inventory in Canada each month met the safety stock level for the product of interest. **Discontinuation Reporting** ISPE recommends maintaining the requirement to report a discontinuation at least 6 months in advance or as soon as practicable. Significantly earlier public disclosure of discontinuations may result in unintended consequences, such as panic-buying and rapid or erratic depletion of remaining inventory. With this in mind, and because it is often complex to predict discontinuation plans at earlier timepoints, ISPE has recommended global harmonization for required discontinuation reporting to be set at least 6 months in advance or as soon as practicable (voluntary reporting may always be accepted earlier). As described in *Global Convergence Opportunities*, a majority of markets outside of Europe have set their discontinuation reporting at 6 months in advance. Should an earlier notification timepoint still be of interest, ISPE suggests for consideration that a manufacturing application holder would notify Health Canada at the preferred timepoint (or as soon as practicable) and that public disclosure would occur at a later date, as discussed and agreed upon between Health Canada and the manufacturer.