From: linda.rheaume@canada.ca **On Behalf Of** HPIL Consultation / IPSOP (HC/SC)
Sent: August 5, 2020 12:22 PM
Subject: Health Canada regulatory proposal on drug exports/ Projet règlementaire sur l'exportation de médicaments

(le français suit)

Dear Stakeholder,

As a player in the industry of pharmaceutical exports, Health Canada is seeking your input to learn more about the drug export landscape and inform a regulatory proposal impacting drugs manufactured in Canada solely for the purpose of export. Your feedback will also help us understand whether the COVID-19 pandemic has or is expected to have an impact on this industry.

In recent years, section 37 (exports) of the *Food and Drugs Act* (FDA) was updated to align with requirements of international treaties such as World Trade Organization's Trade Facilitation Agreement and the Comprehensive Economic and Trade Agreement by clarifying additional requirements for drugs manufactured solely for export. Health Canada is now developing a regulatory proposal under the authority set out in subsection 37(1.2) that would amend the *Food and Drug Regulations (FDR)* to extend the requirement for Drug Establishment Licensing (DEL) and application of Good Manufacturing Practices (GMP) to drugs manufactured in Canada intended solely for export. This initiative would align requirements that apply to Canada's drug exports with international best practices and is one of several that would modernize Canada's DEL framework: https://www.canada.ca/en/health-canada/corporate/about-health-canada/legislation-guidelines/acts-regulations/forward-regulatory-plan/plan/drug-device-establishment-licensing-frameworks.html

In the interest of renewing Health Canada's intent to move forward with the regulatory proposal, particularly in the wake of the COVID-19 pandemic, we ask that you respond to questions (attachment) that will help us learn more about the reasons you need or have needed section 37 of the *FDA,* and to better understand the potential impacts to your business or your members. We welcome an opportunity to have an informal call with you in follow up, if needed.

Thank you in advance for completing the attached consultation questions and contributing to the development of this regulatory proposal.

Please send responses via email to hc.hpil.consultation-ipsop.sc@canada.ca by August 28, 2020. If you prefer to discuss your responses by phone, please indicate so by sending an email. If you represent an association, we ask that you distribute the questions to applicable members who may rely on section 37 to conduct their activities.

Madame, Monsieur,

En tant qu'acteur dans l'industrie des exportations de produits pharmaceutiques, Santé Canada sollicite votre avis pour en savoir plus sur le paysage de l'exportation de médicaments et pour fournir des renseignements sur un projet de règlement ayant une incidence sur les médicaments fabriqués au

Canada uniquement à des fins d'exportation. Vos commentaires nous aideront également à comprendre si la pandémie de COVID-19 a ou aura des répercussions sur cette industrie.

Ces dernières années, l'article 37 (Exportation) de la *Loi sur les aliments et drogues* (LAD) a été mis à jour pour satisfaire aux exigences de traités internationaux comme l'Accord sur la facilitation des échanges de l'Organisation mondiale du commerce et l'Accord économique et commercial global en ajoutant des exigences concernant les médicaments fabriqués uniquement à des fins d'exportation. Santé Canada élabore actuellement un projet de directive en vertu du pouvoir conféré par le paragraphe 37(1.2) qui modifierait le *Règlement sur les aliments et drogues* (RAD) afin d'étendre l'exigence relative à la Licence d'établissement de produits pharmaceutiques (LEPP) et l'application des bonnes pratiques de fabrication (BPF) aux médicaments fabriqués au Canada et destinés uniquement à l'exportation. Cette initiative permettrait d'harmoniser les exigences qui s'appliquent aux exportations de médicaments du Canada avec les pratiques exemplaires internationales et constitue l'une des nombreuses initiatives qui moderniseraient le cadre des LEPP du Canada : https://www.canada.ca/fr/sante-canada/organisation/a-propos-sante-canada/legislation-lignes-directrices/lois-reglements/plan-prospectif-reglementation/plan/drogues-instruments-infrastructure-agrement-etablissements.html

Dans le but de renouveler l'intention de Santé Canada d'aller de l'avant avec le projet de directive, particulièrement dans le sillage de la pandémie de COVID-19, nous vous demandons de répondre aux questions (pièce jointe) qui nous aideront à en savoir plus sur les raisons pour lesquelles vous avez besoin ou avez eu besoin de l'article 37 de la LAD, et à mieux comprendre les répercussions possibles sur votre entreprise ou les entreprises de vos membres. Nous serions heureux de pouvoir vous appeler de manière informelle afin d'assurer un suivi, le cas échéant.

Nous vous remercions à l'avance de bien vouloir répondre aux questions de consultation ci-jointes et de contribuer à l'élaboration de ce projet de directive.

Veuillez envoyer vos réponses par courriel à hc.hpil.consultation-ipsop.sc@canada.ca avant le 28 août 2020. Si vous préférez discuter de vos réponses par téléphone, veuillez l'indiquer en envoyant un courriel. Si vous représentez une association, nous vous demandons de distribuer les questions aux membres concernés qui peuvent invoquer l'article 37 dans l'exercice de leurs activités.

Sincerely/Cordialement,

Kim Godard, Director/ Directrice
Health Product Inspection and Licensing/ Division de l'inspection des produits de santé et de l'octroi des permis
Regulatory Operations and Enforcement Branch/ Direction générale des opérations réglementaires et de l'application de la loi

Consultation questions on the proposed amendments to the *Food and Drug Regulations* (section 37 – Exports)

QUESTION	RESPONSE
Do you use s.37 of the FDA for drugs that you export? If so, please specify the reason you require the exemption as well as the dosage form of the exported drugs (e.g. API, finished dosage form, injectable, tablets, etc.).	
Which of the following activities do you conduct in Canada in relation to the drugs intended for export: manufacture, package, label, test, distribute?	
Do you follow good manufacturing practices as set out in Part C, Division 2 of the *Food and Drug Regulations* for all exported drugs? If no, please specify which quality standard is followed (e.g. PIC/s, ICH, other).	
If not, what would be the estimated additional cost to your company, if any, to bringing your operations into compliance with requirements set out in Part C, Division 2 of the *Food and Drug Regulations* ?	
All Canadian drug establishments must hold an establishment licence to fabricate, package, label, perform tests, distribute, import, or wholesale a drug.[1] What would be the impact on your company if you were required to hold and maintain a DEL in accordance with Part C, Division 1A of the *FDR*?[2]	

[1] Drug Establishment Licenses: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/drug-establishment-licences.html

[2] Fees and payments associated with DELs are outlined in the *Guidance document, Fees for the Review of Human and Veterinary Drug Establishment Licence Applications*

Other than application fees, what would be the estimated cost to your company to apply for and maintain a DEL?	
Value of drugs exported in the past 12 months	
Have the impacts of the COVID-19 pandemic had any impacts on your exports or your ability to comply with GMP for exported drugs? If so, please specify.	
Are you aware of any other companies in Canada conducting export-only activities for drugs? If yes, please provide us with the names and contact information for these companies, if possible. We would like to invite them to participate in this consultation.	
Are you a member of any Canadian industry associations? If so, please specify.	