

Gerry Frenette

From: Debbie Gates
Sent: December 20, 2022 10:22 AM
To: MedtechCanada
Subject: Consultation on Proposed Agile Regulations and Guidance for Licensing of Drugs and Medical Devices

Dear Regulatory Affairs Committee Members,

Thank you to Charles Tam for sharing some holiday reading.

From what David Boudreau had signalled previously, this open consultation touches on those “terms and conditions” to impose requirements on medical devices and to publicly publish information about them. From the page, *“Health Canada is proposing new targeted provisions and regulatory amendments to the Food and Drug Regulations and Medical Devices Regulations. These changes will continue to advance our modernization agenda and help to reduce regulatory irritants and roadblocks to innovation.”*

- Consultation Main Page: <https://www.canada.ca/en/health-canada/programs/consultation-proposed-agile-regulations-guidance-licensing-drugs-medical-devices.html>
- Draft Guidance Medical Device T&Cs: <https://www.canada.ca/en/health-canada/programs/consultation-proposed-agile-regulations-guidance-licensing-drugs-medical-devices/draft-terms-conditions-medical-devices.html>

The public consultation opened on Friday last week and runs until 27-March-2023.

1. *There are few ways to submit comments:*

- a. *Public Posting of “General Comments” (max 20000 characters):* <https://canadagazette.gc.ca/rp-pr/p1/2022/2022-12-17/html/req1-eng.html>
- b. *PDF:* <https://www.canada.ca/content/dam/hc-sc/documents/programs/consultation-proposed-agile-regulations-guidance-licensing-drugs-medical-devices/submission-comments.pdf>
- c. *Word:* <https://www.canada.ca/content/dam/hc-sc/documents/programs/consultation-proposed-agile-regulations-guidance-licensing-drugs-medical-devices/submission-comments.docx>
- d. *Mail (Postal):* Bruno Rodrigue, Executive Director, Office of Legislative and Regulatory Modernization, Policy, Planning and International Affairs Directorate, Health Products and Food Branch, Health Canada, Holland Cross, Suite P2108, 11 Holland Ave, Ottawa ON K1A 0K9
- e. *Email (while not explicitly stated, it was listed:* hpfb.engagement-mobilisation.dgpsa@hc-sc.gc.ca

Regards,
Charles Tam
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From: hc.hpfb.engagement-mobilisation.dgpsa.sc@canada.ca <hc.hpfb.engagement-mobilisation.dgpsa.sc@canada.ca>
Sent: Monday, December 19, 2022 6:01

Subject: [EXTERNAL] Consultation on Proposed Agile Regulations and Guidance for Licensing of Drugs and Medical Devices

You are receiving this message because you joined the Health Canada and the Public Health Agency of Canada's stakeholder registry.

We would like to inform you that we have recently launched a consultation on one of the topics of interest to you.

To find out more about this consultation on the proposed Agile Regulations and Related Guidance for the Licensing of Drugs and Medical Devices, please click on the following link: <https://www.canada.ca/en/health-canada/programs/consultation-proposed-agile-regulations-guidance-licensing-drugs-medical-devices.html>

Questions or comments? Contact us at hpfb.engagement-mobilisation.dgpsa@hc-sc.gc.ca

If you no longer wish to receive notifications of consultations on this topic, you can do so by logging in to your [CSIMS](#) account and revising your "Areas of Interest".

Issues logging in to your account? Please email: CSIMS-External@hc-sc.gc.ca.

Health Products and Food Branch/Direction générale des produits de santé et des aliments

Health Canada/Santé Canada