Health Products and Food Branch

Direction générale des produits de santé et des aliments

> Marketed Health Products Directorate A.L. 1906 C OTTAWA, Ontario K1A 0K9

April 18, 2021

21-107368-129

To whom it may concern,

Re: Health Canada will publish a summary safety review regarding AstraZeneca and COVISHIELD COVID-19 vaccines

As an ongoing commitment to openness and transparency, Health Canada would like to notify you that a summary safety review (SSR) regarding AstraZeneca and COVISHIELD COVID-19 vaccines and the potential risk of thrombosis in combination with thrombocytopenia will be published (see attached document). The SSR is intended to provide Canadians with a sufficient understanding of the safety review conducted by Health Canada, specifically what was assessed, what was found and what action was taken. The SSR will be posted in subsequent days.¹

This advance notification is being sent for your information only. A broader dissemination to your members would be greatly appreciated.

Any question related to the SSR process or requests for further information on the safety review should be directed to the Marketed Health Products Directorate; e-mail: https://hc.mhpdssrcoordinator-dpscreicoordinateur.sc@canada.ca



.../2

Please feel free to contact us, should you require further information.

Sincerely,

E-signed by

Jason Berg Associate Director Office of Policy, Risk Advisory and Advertising Marketed Health Products Directorate Health Canada

Tel.: 613-790-8384 Fax: 613-948-7996

E-mail: jason.berg@canada.ca

Attachment:

Summary Safety Review- AstraZeneca and COVISHIELD COVID-19 vaccines – Assessing the potential risk of thrombosis in combination with thrombocytopenia