Health Canada's response to a request for information made by the Subcommittee on Veterans Affairs on November 30, 2022

Question

Senator Anderson: You spoke of 13 ongoing clinical trials. What are the timelines and in what areas of Canada are these trials happening? How are the participants chosen?

Ms. Reynolds: Thank you very much, senator, for the question.

I do not have that level of detail with me today on those particular clinical trials. I would need to commit to follow up.

Senator Anderson: That would be great if you can follow up in writing.

Response

Although 13 trials were mentioned by officials, Health Canada has only authorized **12** clinical trials to date investigating the use of psychedelics in conjunction with psychotherapy for the treatment of Post Traumatic Stress Disorder (PTSD). Out of the 12 trials, 10 trials are currently ongoing. More specifically:

- Psilocybin has been authorized in 3 trials investigating the use of the drug in the treatment of PTSD, of which 2 are ongoing and 1 has been completed.
- MDMA has been authorized in 8 trials investigating the drug for use in the treatment of PTSD, of which 7 are ongoing and 1 has been completed.
- Ketamine has been authorized in 1 trial investigating the drug for use in the treatment of PTSD, which is still ongoing.

None of the trials were exclusive to veterans, however, veterans were not excluded from enrolling in the clinical trials. The trials opened principally in British Columba, Ontario, and Alberta.

Health Canada issues a decision on Clinical Trial Applications (CTAs) within 30 days of receipt of a complete application. However, prior to opening the clinical trial, the sponsor is required to identify the trial sites, obtain Institutional Research Ethics Board (REB) approval at each clinical trial site, and complete any required contracting agreements with qualified investigators and manufacturers, as needed.

Once these activities are completed, the trial opens for participant recruitment. Participants are chosen by the qualified investigator at each site based on the inclusion and exclusion criteria as outlined in the study protocol. The timelines for completion of recruitment often last several months.

The overall timeline from submission of a CTA to Health Canada and the actual conclusion of the clinical trial varies based on the complexity of the trial and may take up to several years.

Health Canada, through its Clinical Trials Database, provides to the public a listing of specific information relating to Canadian clinical trials involving human pharmaceutical and biological drugs. The database may assist Canadians in finding clinical trials that might be relevant to their medical condition