

Notice to Industry: Health Canada and CADTH launch new initiative to provide early parallel scientific advice

Improving Access to Medicines

Health Canada's [Regulatory Review of Drugs and Devices \(R2D2\)](#) initiative aims to provide more timely access to medicines for Canadians. Under this initiative, greater collaboration is being sought between organizations that play a role in drug access, including Health Canada and the health technology assessment (HTA) organizations, the Canadian Agency for Drugs and Technologies in Health (CADTH) and l'Institut national d'excellence en santé et en services sociaux (INESSS). A number of R2D2 initiatives have provided opportunities for collaboration among these organizations.

What is Early Parallel Scientific Advice?

Currently, Health Canada and CADTH offer separate processes for drug sponsors seeking early advice to ensure that they're obtaining the type of evidence needed for decisions to be made on market authorization and reimbursement in Canada.

Through this new initiative, drug sponsors can obtain advice from the regulator and the HTA in parallel. This process will enable Health Canada and CADTH to collaborate and share perspectives while each formulating independent advice regarding a sponsor's specific drug development plan. It will also provide sponsors with an opportunity to have a joint meeting with Health Canada and CADTH to discuss the advice.

INESSS does not currently have a scientific advice process in place and will participate in the initiative as an observer in the initial phase to evaluate its future involvement in the process. Building on CADTH's [Scientific Advice](#) Program, the Early Parallel Scientific Advice initiative will follow the same general processes and timelines, including CADTH's eligibility criteria and [fee requirements](#).

Early Parallel Scientific Advice could be sought on such topics as:

- target population
- choice of comparator
- trial design and duration
- end points
- statistical issues (stratification, subgroups).

Sponsors will submit briefing materials to all three organizations. Health Canada and INESSS will participate in preparatory meetings with CADTH and the experts engaged by CADTH. Towards the end of the process, Health Canada and CADTH will present and discuss their draft scientific advice with the sponsors at a face-to-face meeting, with INESSS observers in attendance. At the conclusion of the process, Health Canada and CADTH will each provide the sponsors with a written Record of Scientific Advice. In the role as observer, INESSS will not be providing verbal or written advice to the sponsor during this process.

As with CADTH's existing scientific advice process, Early Parallel Scientific Advice will be [non-binding](#) and [confidential](#).

In the first phase of the Early Parallel Scientific Advice initiative, Health Canada will seek feedback from involved sponsors in order to refine the scope and optimize the process around future activities. The longer term goal is to build an efficient, sustainable process for all organizations to provide scientific advice in parallel.

Which Products Are Eligible?

The following drug products are eligible candidates:

- new drug products
- existing drug products with new indications
- drugs for rare diseases
- oncology products.

Early Parallel Scientific Advice would be most beneficial for drugs for rare diseases or conditions and other challenging clinical populations; new therapeutic areas; complex, adaptive or unusual trial designs; or development plans that may include the use of real-world evidence.

Applications must be filed early in the drug development cycle, when adjustments to protocols for pivotal trials are still feasible.

Are You Interested?

Companies wishing to participate in the Early Parallel Scientific Advice initiative should read the [FAQ](#) about CADTH's Scientific Advice Program and contact CADTH at scientificadvice@cadth.ca.