

Collaboration and Alignment Across Health Canada, CADTH, and INESSS

PARALLEL SCIENTIFIC ADVICE

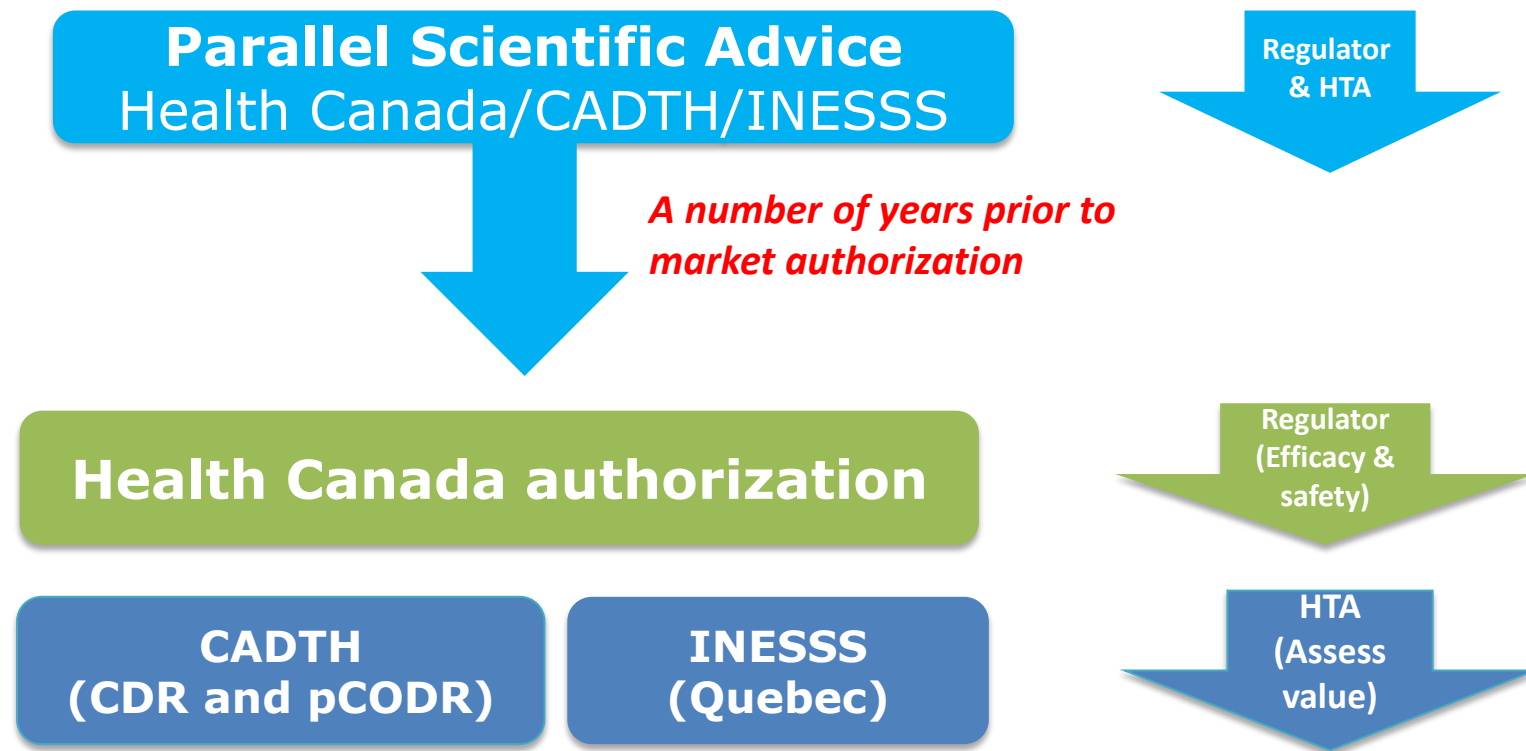
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CADTH

Engaging in Early Collaboration



Early Collaboration with Health Canada, CADTH and INESSS

- Launch of new initiative by Health Canada and CADTH to provide early parallel scientific advice with INESSS initially in an observatory role.
- One of the Health Canada Regulatory Reviews of Drugs and Devices (R2D2) Projects: Early scientific advice to manufacturers
- February 28, 2019 - Health Canada Notice to Industry:
<https://www.canada.ca/en/health-canada/corporate/transparency/regulatory-transparency-and-openness/improving-review-drugs-devices/notice-early-panel-scientific-advice.html>

Parallel Scientific Advice

Advice provided to pharmaceutical companies on early drug development plans simultaneously by at least 2 organizations; includes a joint F2F meeting and separate advice reports

Value-add for companies to streamline process

Opportunity to discuss similarities in advice, reasons for differences and confirming a single approach

Examples of International Programs for Scientific Advice

HTA Only Scientific Advice

Single Country

France	Haute Autorité de Santé (HAS)
UK	The National Institute for Health and Care Excellence (NICE)
Italy	L'Agenzia Italiana del Farmaco (AIFA)

HTA Only Parallel Advice

Multi-Country

EUnetHTA
(European network of HTA agencies)

Regulatory-HTA Parallel Scientific Advice

Single Country

Sweden (TLV + MPA)
Germany (G-BA + BfArM)
UK (Joint: NICE + MHRA)

Multi-Country

EMA-EUnetHTA Parallel Consultation
European Medicines Agency and EUnetHTA (France, Germany, UK, Italy, Hungary, Belgium/Netherlands...)

CADTH Scientific Advice Program

- Standard Offerings:
 - Parallel Scientific Advice with CADTH and Health Canada (including INESSS initially in an observer role)
 - Parallel Scientific Advice with CADTH and NICE (U.K.)
 - Standard Scientific Advice from CADTH only
- Voluntary, non-binding, confidential

Eligibility for Parallel Scientific Advice

Health Canada, CADTH, INESSS

Same eligibility requirements as for Standard CADTH Scientific Advice

Timing of applications prior to finalizing protocols for pivotal trials

Eligible Drug Products

New drug products

Existing drug products with new indications

Drugs for rare disease

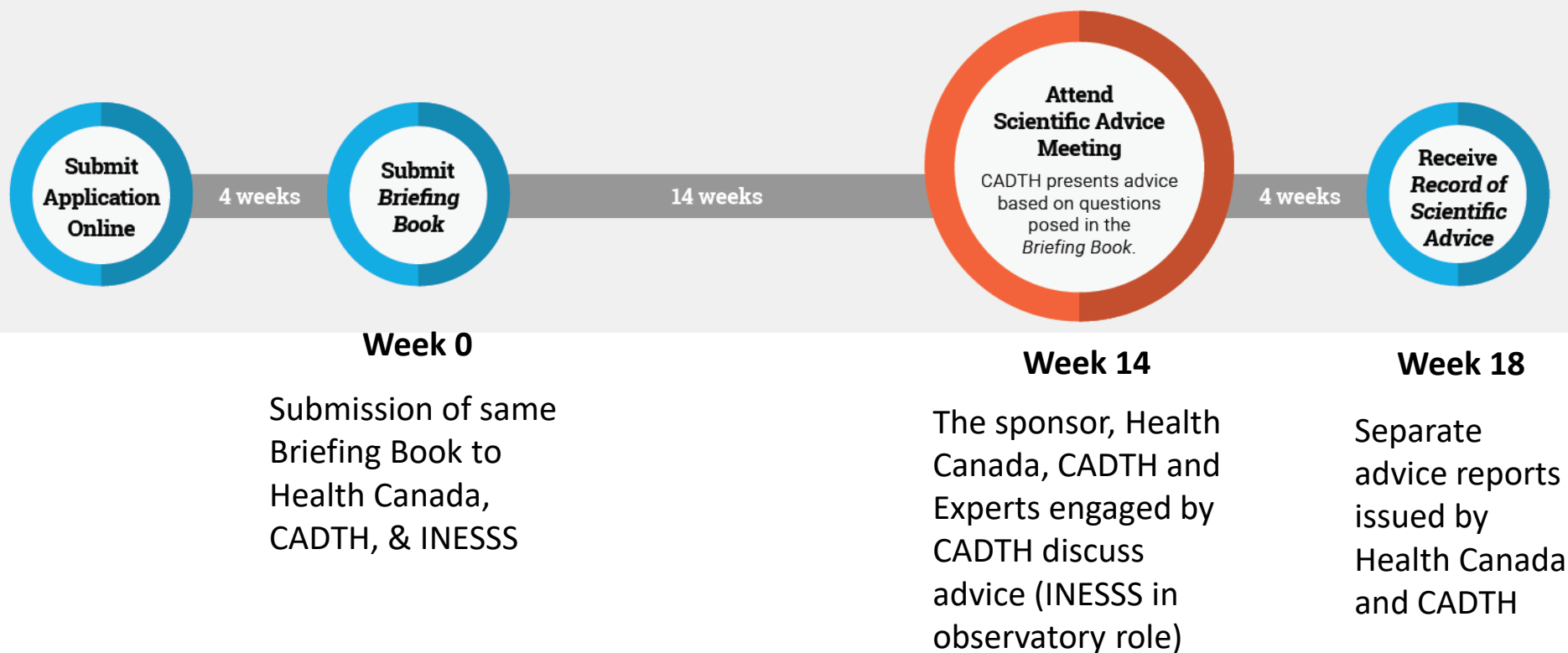
Oncology products

Expert and Patient Involvement in Parallel Scientific Advice Process

- Similar to Standard CADTH Scientific Advice
 - CADTH engages up to 3 experts
 - CADTH interviews 1 to 2 patients
- Health Canada and INESSS will
 - have an opportunity to join CADTH's meetings with experts
 - receive the patient interview summary provided that consent from the patient is given

Health Canada, CADTH & INESSS Parallel Scientific Advice Timelines

Follows CADTH Scientific Advice standard timelines



Parallel Process: Briefing Book



Week 0

- Single Briefing Book
 - Joint questions to Health Canada and CADTH and optional questions specific to each organization
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- Optional Appendices
 - Pre-clinical information for Health Canada
 - Economic evaluation plans for CADTH

Parallel Process: Joint F2F Meeting



Week 14

- Attendees: Sponsor, Health Canada, CADTH, INESSS and experts engaged by CADTH
- Discussion of preliminary advice from CADTH and Health Canada
- Location: Ottawa, Canada

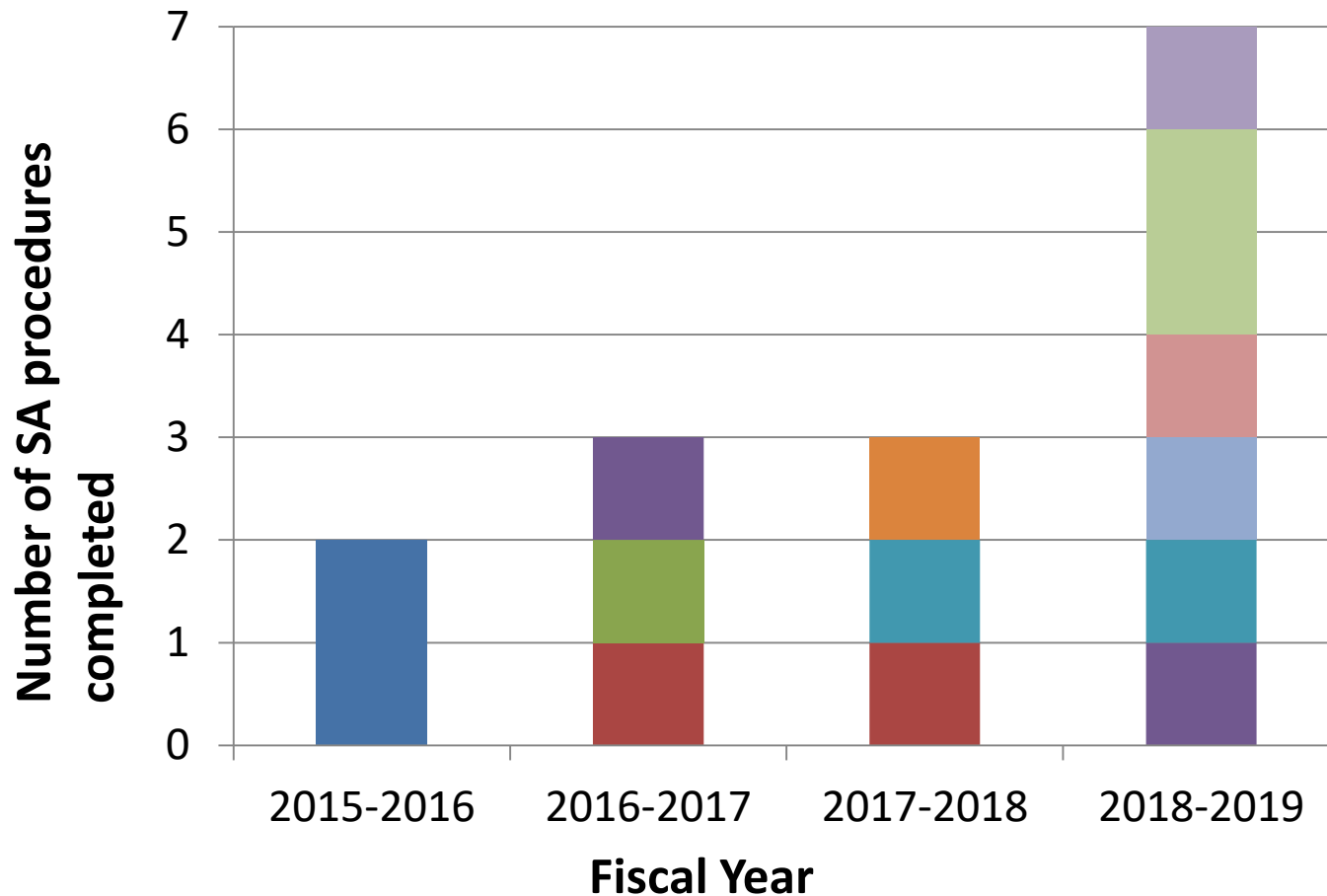
Parallel Process: Final Advice



Week 18

- 4 weeks after the F2F meeting
- Separate final Advice Reports from Health Canada and CADTH
- Request for feedback on the parallel process

CADTH Scientific Advice Program



15 Projects:

5 companies
came twice

6 oncology
9 non-oncology

1 'Light' Advice

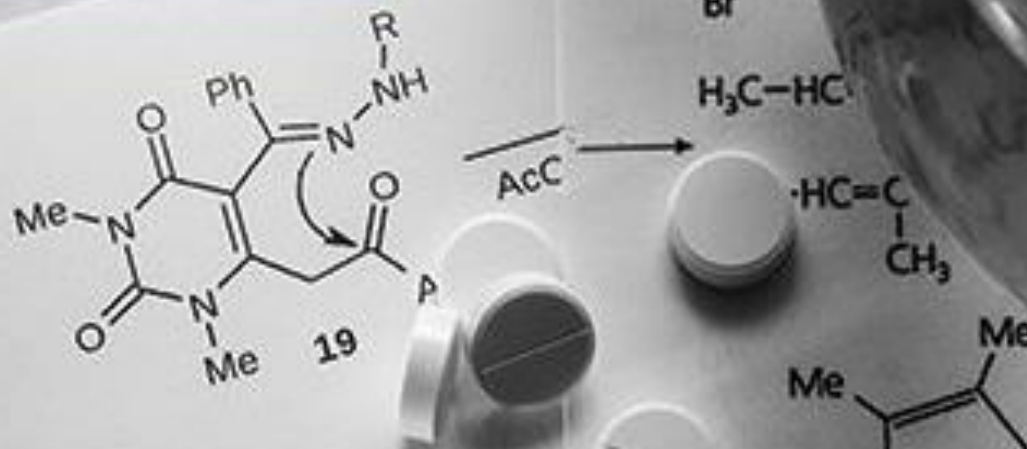
1 Parallel
process with
CADTH / NICE

CADTH and NICE (UK)

Parallel Scientific Advice

- First project completed Jan 2019
- Feb 6, 2019 launched as a standard offering by CADTH and NICE
<https://www.cadth.ca/news/new-opportunity-parallel-scientific-advice-cadth-and-nice>
- Key features:
 - **Week 0:** Single Briefing Book
 - **Week 10:** Joint exploratory F2F meeting (Toronto or England)
 - **Week 20:** Joint summary of key areas of alignment in advice and two separate detailed advice reports from each agency

Scientific Advice



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www.cadth.ca/scientific-advice

Thank you!

CADTH