HC-HTA Alignment

ALIGNED REVIEWS BETWEEN HEALTH CANADA (HC) AND HEALTH TECHNOLOGY ASSESSMENT ORGANIZATIONS (HTAs)

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CADTH Evidence Driven.

Agenda

- Presentation
  - Background and Objectives
  - Evolution of Initiative
  - Summary of Process
  - Information of Value to HTAs
  - What HTAs do with the information
  - Opportunities/Next Steps

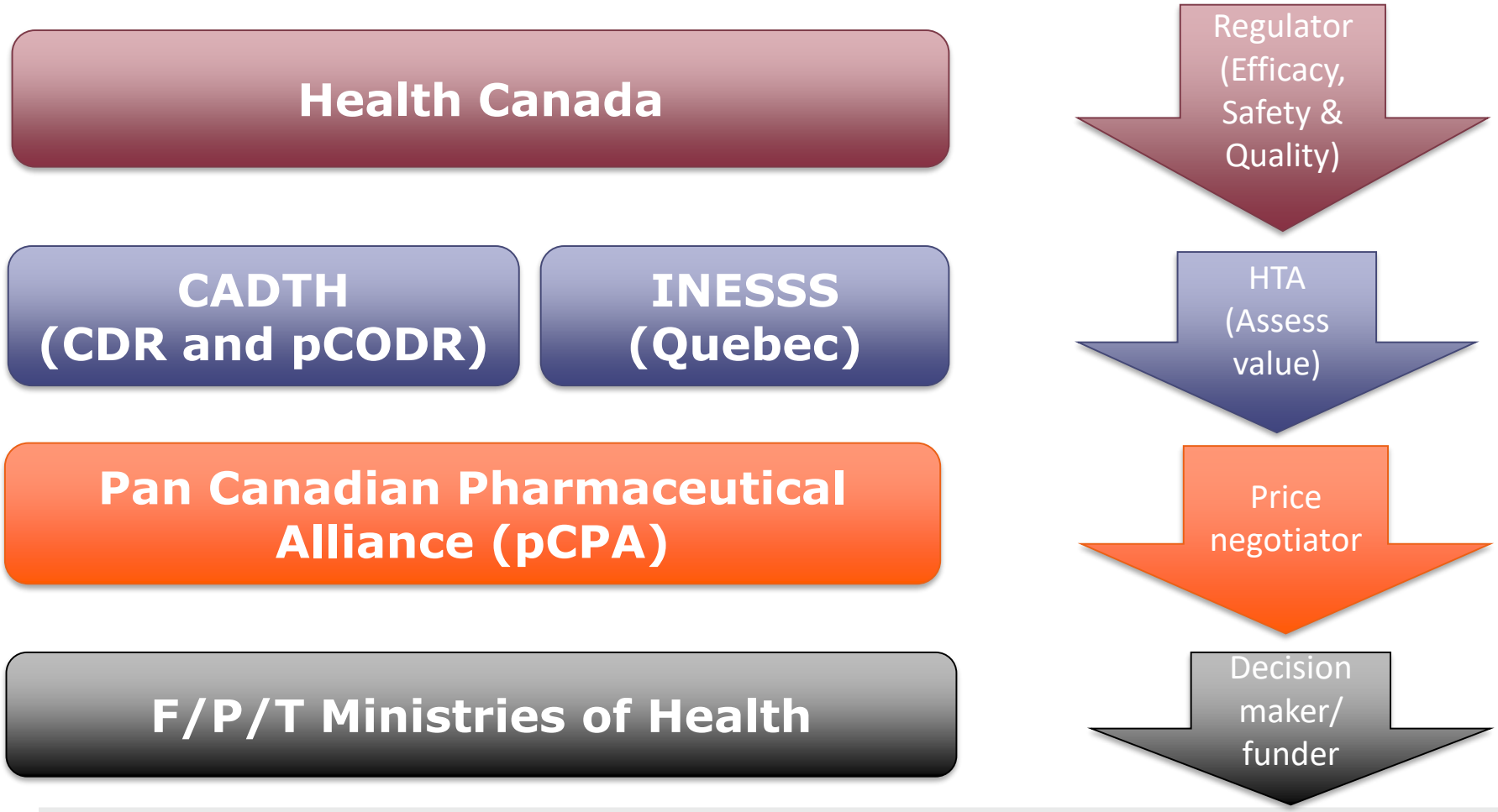
- Questions and Answers

Part of HC initiative to improve Regulatory Review by increasing collaboration with health system partners

Purpose

- Minimize time between HC market authorization and HTA recommendations
  - ➢ Respond to recognized need for greater coordination in review processes
  - ➢ May facilitate faster public drug plan funding decisions and more timely access to prescription drugs

Who Does What in the Drug Access Continuum



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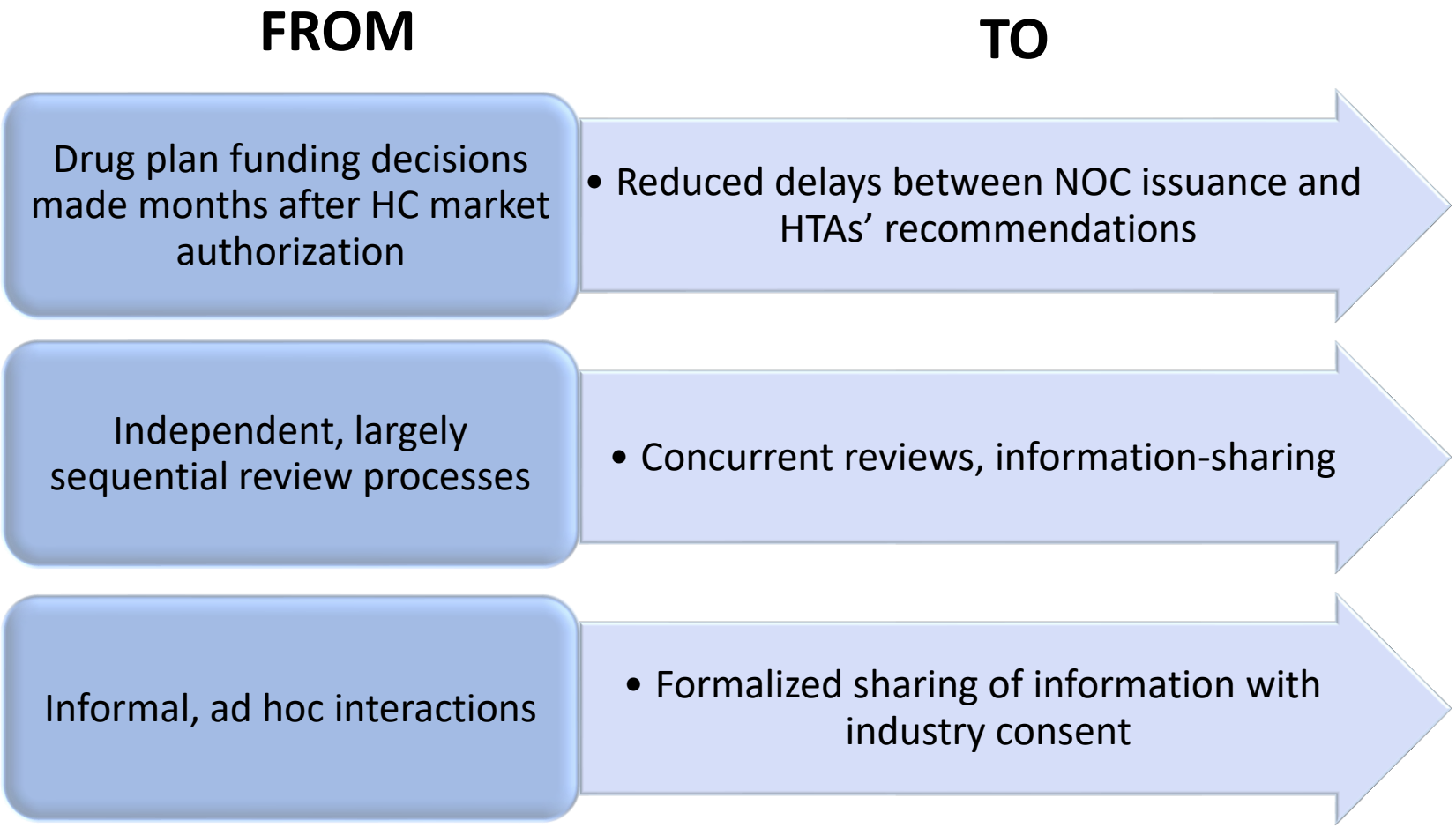
HC-HTA Alignment Goals



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Benefits of Aligned Reviews

Decreased Delays	Dependent on timing of industry filing to HTAs. Helps reduce time between HC's approval and HTAs' recommendations. Opportunities for HC to adjust milestones (e.g., to support pERC/CDEC meetings/INESSS scientific committee meetings).
Improved Communication	Real time discussions between HC and HTAs, information sharing, more efficient resolution of review issues, and reduced duplication.

Evolution of the Initiative

Successes of the Pilot (2017-2018): Bureau of Metabolism, Oncology and Reproductive Sciences (BMORS)/pan-Canadian Oncology Drug Review (pCODR)

- Process for Reciprocal Information Sharing
  - Previously pCODR could share information with BMORS but not vice versa
- Improved timing/coordination of decisions
  - Open dialogue regarding timelines
- Targeted information sharing to maintain HTA timelines
  - E.g. important information on changes in indication could be shared
- Sharing reports
  - Sharing of Health Canada reports (e.g. pre-submission meeting minutes, priority review reports)

Evolution of the Initiative (2)

- A formalized, transparent process was developed following the pilot

- CADTH and INESSS change in process - accepting submissions up to 180 days prior to anticipated NOC (pre-NOC basis)
  - ➢ Includes oncology and non-oncology (CDR, pCODR and INESSS)

- HC and HTAs developed a **Notice to Industry**, as well as a **consent letter** *(template authorizing sharing of information)* which was posted in June 2018

https://www.canada.ca/en/health-canada/corporate/transparency/regulatory-transparency-and-openness/improving-review-drugs-devices/notice-aligned-reviews-health-canada-health-technology-assessment-organizations.html

Summary of the Process

Scope

- New drug submissions and supplemental new drug submissions for new indications made to HC where the sponsor intends to seek a coverage recommendation from the HTAs, on a pre-NOC basis
- Pharmaceutical and biological drugs, including biosimilars*

*CADTH recently announced that they will no longer be reviewing biosimilar submissions (as of June 1, 2019), however INESSS continues to do so.

- **Participation in an aligned review is voluntary**
- Participation is dependent on the submission of consent using the template authorizing the sharing of information
  - Consent is submission specific
  - Consent needs to be filed with the HC drug submission and/or up to 30 days after market authorization by HC (Module 1.2.6)

Summary of the Process (2)

- The timing of the sponsor's submission to the HTAs affects how much the benefits of an aligned review are maximized
  - ➢ Sponsors are strongly encouraged to file with each of the HTAs around the same time. They are also encouraged to provide consent as early as possible
- Consent allows HC to share certain information with CADTH and INESSS, and vice versa with authorization.
- An aligned review will not alter the independent requirements, decision making, or respective processes maintained by HC and HTAs
- HC and HTAs are committed to transparency
  - ➢ Sponsor participation in aligned reviews will be made public. Since the Fall of 2018, HC indicates which submissions on the Submissions Under Review lists are undergoing an aligned review

HTA Advance Notification Process

- Required for pre-NOC filing

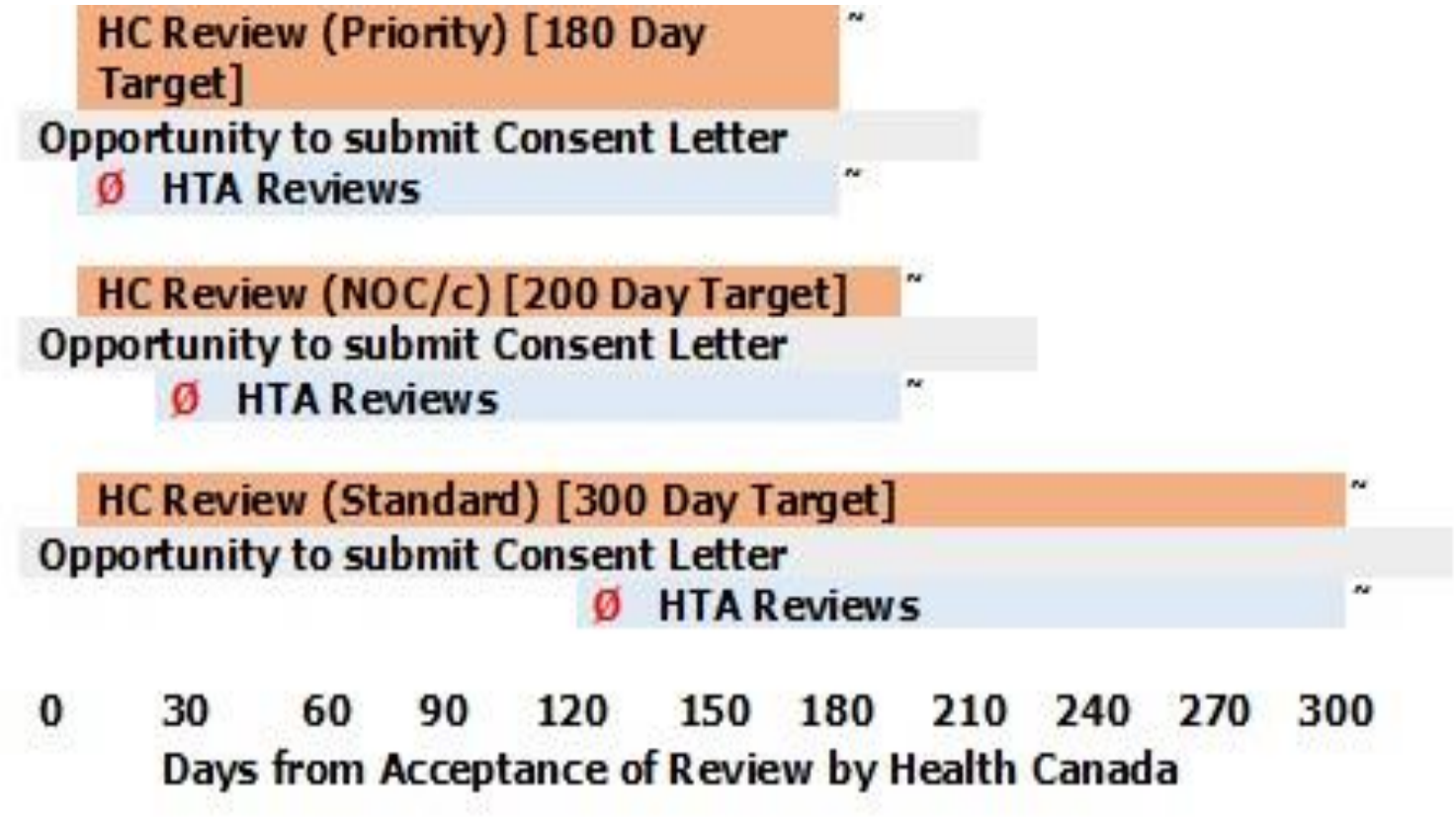
CADTH

- Manufacturers required to complete and submit an advance notification template
- A section has been added to indicate willingness to participate in the information sharing process between HC and CADTH
- Minimum advance notification for CADTH:
  - 30 business days for CDR
  - 120 calendar days for pCODR

INESSS

- At least 2 months prior to the planned submission date, the manufacturer has to notify INESSS of its intention to submit an evaluation request.

Timing of HTA submissions to maximize benefits of aligned review



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Information of value to HTAs

The HTAs would benefit from the earliest possible notification of any changes to the following during HC review:

- Wording of the indication
- Dosage range in the product monograph
- Dosage strengths that will be approved
- Dosage forms that will be approved
- NOC/c qualifying studies

Why?

- Changes to any of these items can require revisions to the clinical and pharmacoeconomic review reports

Information of value to HTAs (2)

The HTAs would benefit from access to:

- priority review or NOC/c eligibility assessment reports
- pre-submission meeting minutes
- proposed Product Monographs (PMs)
- final clinical review reports and manager's memo

Why?

- Important component of critical appraisal (particularly for aspects related to the internal validity of pivotal trials)
- Used to reflect on the clinical relevance of the effect sizes reported in the pivotal trials
- Can assist in interpreting the language used in the approved indications (e.g., target population)

Information of value to HTAs (3)

The HTAs would benefit from earliest possible notification and access to the following:

- A NOD* will be or has been issued
- A NON* will be or has been issued
- Other changes to the anticipated timelines for completing review

* manufacturing process information included in a NON/NOD would generally not be shared as it is typically not needed by the HTAs

Why?

- Non-issuance of market authorization typically requires the manufacturer to withdraw from CADTH's review processes (or CADTH will stop the review). The INESSS evaluation would also be stopped.
- Anticipated timelines assist in planning for completion of the review, and can help with the coordination of pERC/CDEC expert committee meetings/INESSS scientific committee meetings

What does CADTH do with this information?

- Information is received and transmitted using a secure distribution portal (i.e., Collaborative Spaces)
- CADTH may share this information with those who are currently included in the list of authorized recipients for the CDR and pCODR processes
  - For example: public drug plans, cancer agencies, pCPA
- Information is stored in accordance with CADTH document retention policies
- Any confidential information in CADTH reports will be handled in accordance with existing policies (e.g., redaction at manufacturer's request)

What does INESSS do with this information?

- All information made available from Health Canada will be taken into consideration during the INESSS assessment process
- Upon receipt of an authorized consent form, INESSS may discuss the submission with Health Canada or CADTH, as needed
- Confidential information will be redacted from the final report prior to publishing
- Information is transmitted between HC and INESSS through a secure e-post connect platform
- Information is stored in accordance with INESSS standard practices
- The **alignment process** is in accordance with the “Stratégie québécoise des Sciences de la vie 2017-2027” which favours faster access to drugs. INESSS and CADTH recommendations should not have more than a 1 month difference in time to issuance.

Opportunities/Next Steps

- HC and HTAs will monitor and adjust the aligned review process as needed to ensure that it provides benefits to HC, HTAs, and industry. They will also ensure the process supports the goal of collaborating more with health partners
- The impact of the alignment initiative will continue to be measured
  - Reduction in time between HC's approval and HTAs' recommendations for aligned reviews (analysis to be undertaken in June 2019)
- Industry participation has been strong so far
  - As of May 2019, there are 21 completed aligned reviews and 13 ongoing

Acronyms

- CADTH: Canadian Agency for Drugs and Technologies in Health
- INESSS: l'Institut national d'excellence en santé et en services sociaux
- CDR: Common Drug Review
- pERC: pCODR Expert Review Committee
- CDEC: Canadian Drug Expert Committee
- pCODR: pan-Canadian Oncology Drug Review
- NOC: Notice of Compliance issued by Health Canada
- NOC/c: Notice of Compliance with conditions issued by Health Canada
- NON: Notice of Non-Compliance issued by Health Canada
- NOD: Notice of Deficiency issued by Health Canada