CADTH Oncology Biosimilars Review Process

2019 CADTH SYMPOSIUM: ENHANCING ACCESS TO THE ONCOLOGY BIOSIMILARS IN CANADA—CHALLENGES AND OPPORTUNITIES

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CADTH

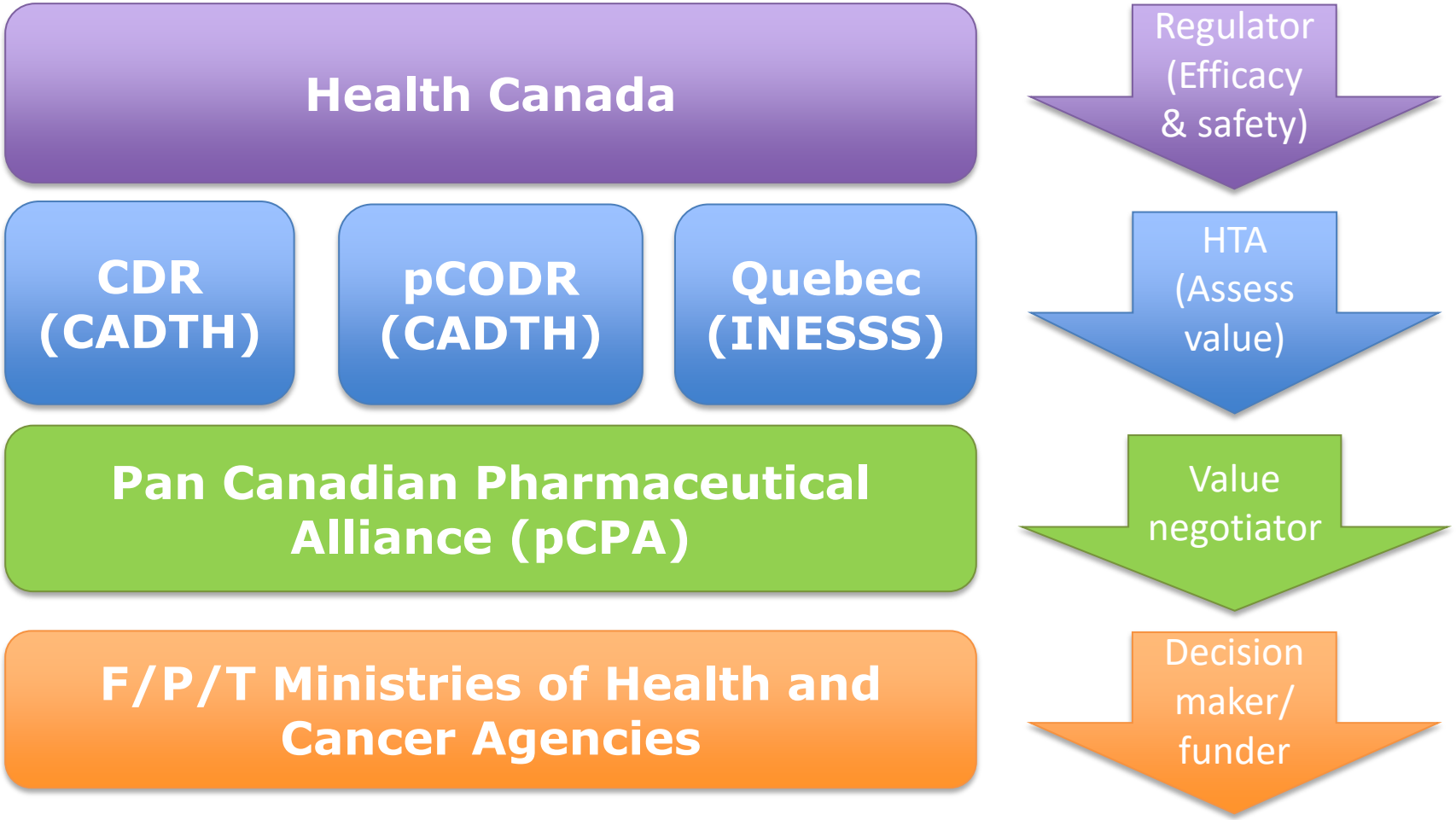
Disclosure

- The speaker has no financial or other conflict of interest to report.

Outline

1. Public Reimbursement Pathway for Biosimilars
2. CADTH's Oncology Biosimilars Review Process
   - New process
   - Output
3. CADTH's Experience with Oncology Biosimilars

Public Reimbursement Pathway for Biosimilars: Where does CADTH fit in?



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Public Reimbursement Pathway for Biosimilars: Review Processes

Health Canada

Assessment: Quality, safety, and efficacy

Output: Issuance of NOC / NOC(c)

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Assessment: Clinical effectiveness, cost effectiveness, patient input, clinician input, jurisdictional input (pCODR)

Output: Biosimilar Summary Dossier

Public Payers

Assessment: value negotiation (through the pCPA office), implementation considerations, budget impact analysis, may review products individually

Output: Final funding decision

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CADTH's Biosimilars Review Process

Streamlined process launched on February 13, 2018

Objective

- To reduce duplication of work, optimize resources, and ensure that all participating jurisdictions benefit from a single approach to evidence review, which in turn would facilitate decision-making for biosimilars

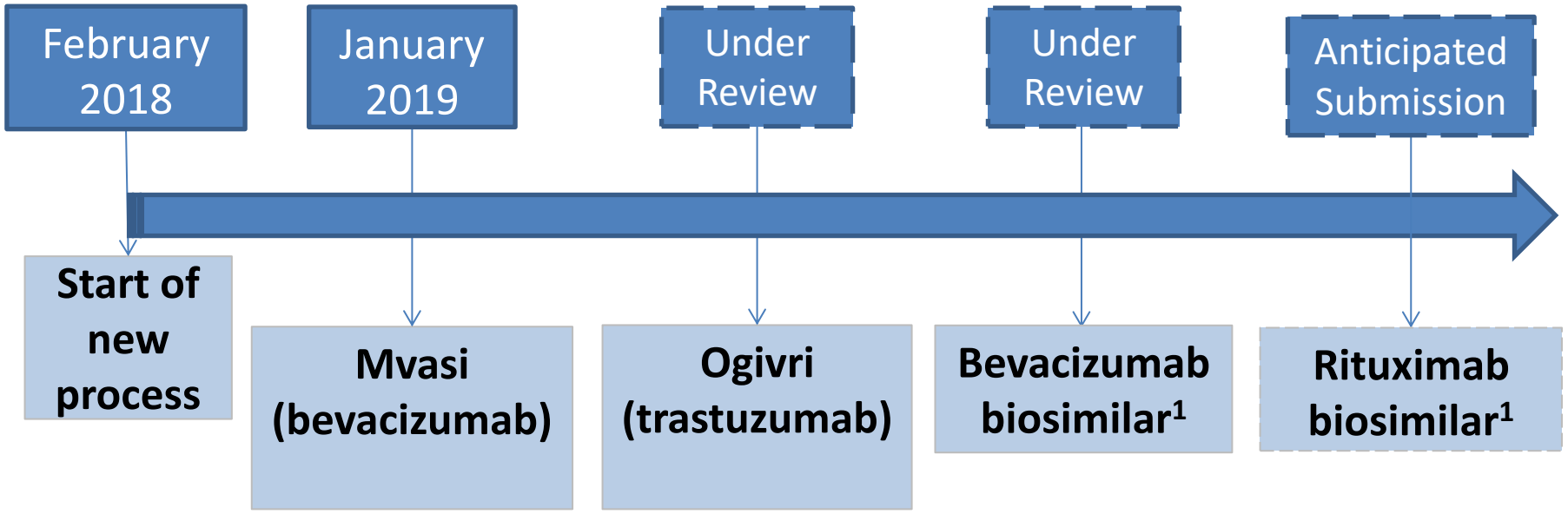
Purpose

- A streamlined approach for biosimilar reviews would support improved access for patients

CADTH's Biosimilar Process – Biosimilar Summary Dossier

- To gather all relevant information on the biosimilar for pCPA and participating jurisdictions to inform decision-making:
  - Cost information for biosimilar
  - Input from stakeholders:
    - Patient Groups
    - Registered Clinicians
    - Public Drug Programs and Cancer Agencies
  - Consolidate potential implementation issues
  - Transparency – information is made publicly available

CADTH pCODR Biosimilar Review Experience



Notes:

1. Brand name to be decided.

Source: CADTH pan-Canadian Oncology Drug Review. www.cadth.ca/pcodr/find-a-review.

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CADTH pCODR Biosimilar Review Experience – Stakeholder Input - Mvasi

Patient Input:

- Decision is between treating oncologist and the patient
- Efficacious and safe; not based on price reductions alone
- Availability of patient support programs with biosimilar
- Further patient education on biosimilars is needed

Clinician Input:

- Decision to use a biosimilar is not always up to the clinician—may be made by the hospital
- Demonstrated bioequivalence (efficacy/safety)
- Differences in pre-medications may be a barrier
- Cost savings reinvested into health system

Source: CADTH pan-Canadian Oncology Drug Review. www.cadth.ca/pcodr/find-a-review.

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CADTH pCODR Biosimilar Review Experience – Stakeholder Input - Mvasi

Jurisdictional Input:

- Potential for cost savings that can be reinvested for reimbursement of new drugs
- Availability of patient support program
- Evidence regarding effectiveness and safety of switching to the biosimilar

Source: CADTH pan-Canadian Oncology Drug Review. www.cadth.ca/pcodr/find-a-review.

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Next Steps

- Mvasi is currently undergoing negotiation with pCPA
- Continuing to learn from and evaluate CADTH's biosimilar review process.

Source: Morse consulting. https://morseconsulting.ca/pcpa-negotiation-status-update-january-2019-two-oncology-negotiations-closed-without-loi/.

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Thank You & Questions

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