Canada's
Drug and Health
Technology Agency

Pharmaceutical Reviews

Brent Fraser

Vice President – Pharmaceutical Reviews

Information Session

FY2021-22: Pharmaceuticals

Highlights:

- 86 drug reviews initiated (+15), 73 drug reviews completed (+15), and 8 panels/algorithms conducted (+7) *[brackets display change vs. FY2020-21]*
- 27 Rapid Responses, 8 Health Technology Reviews, and 34 Reference Lists/Horizon Scans published
- Procedures adapted to increase efficiency & fit for purpose
- COVID-19: New implementation advice panel process and reviews; 31 newsletter entries on microsite

Legend:

- Reviews Initiated
- Reviews Completed
- Panels/Algorithms
- Procedural Update
- Rapid Response
- Health Technology Reviews
- Reference Lists & Horizon Scans
- Highlights

	April	May	June	July	August	September	October	November	December	January	February	March	Totals
Reviews Initiated	6	5	7	10	6	5	6	9	5	6	8	13	86
Reviews Completed	5	6	8	5	9	7	2	5	4	4	11	7	73
Panels/Algorithms	1	1	0	0	0	0	0	1	0	1	1	2	7
Rapid Response	7			10			7			3			27
Health Technology Reviews	3			1			2			2			8
Reference Lists & Horizon Scans	13			3			11			7			34

Process Improvements
- Procedure to assist sponsors in preparing to review CADTH reports

Process Improvements
- Efficiency/transparency updates to processes
- New evidence permitted in reconsiderations

Process Improvements
- New Complex Review process
- Expanded "Provisional Funding Algorithm" process

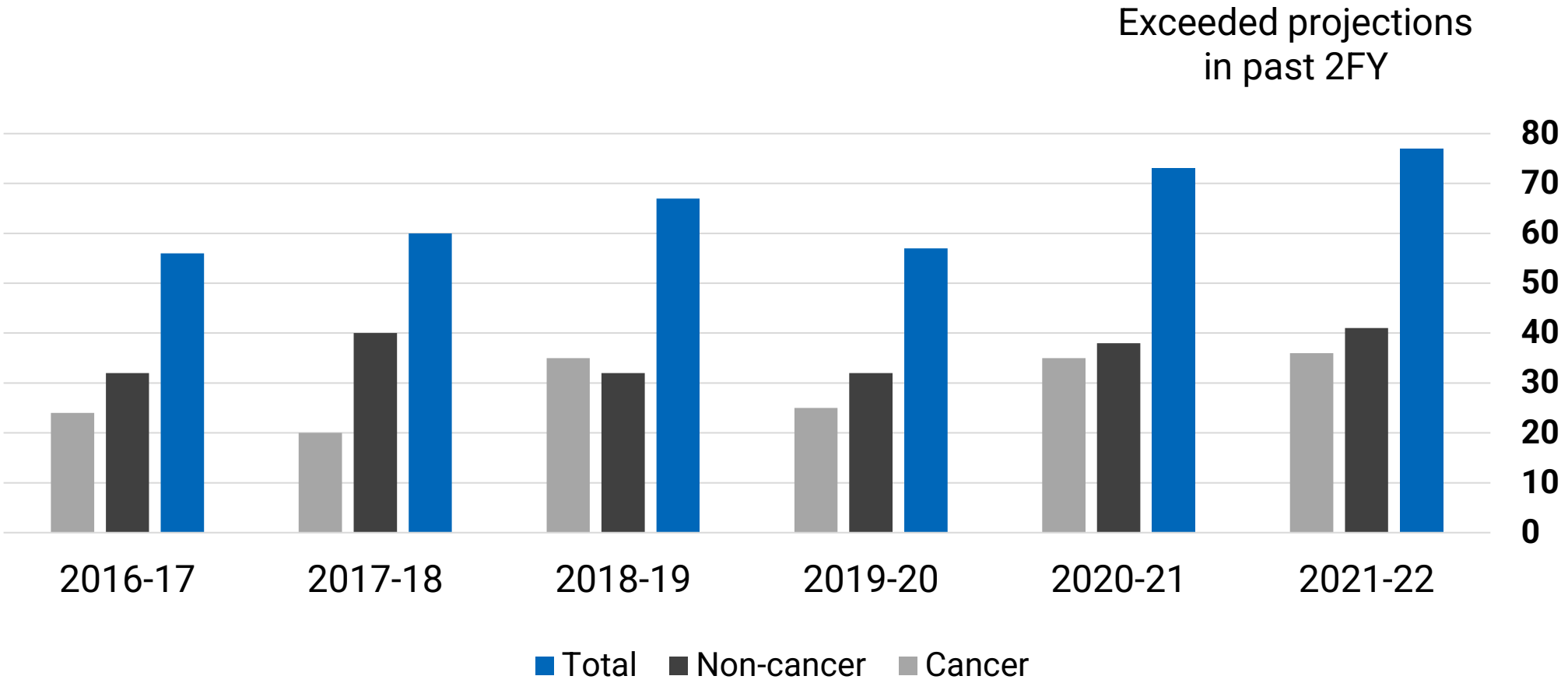
COVID-19
- Interim Procedures for Implementation Advice for COVID-19 Drugs

Process Improvements
- 2 new OU procedures developed for FY2022

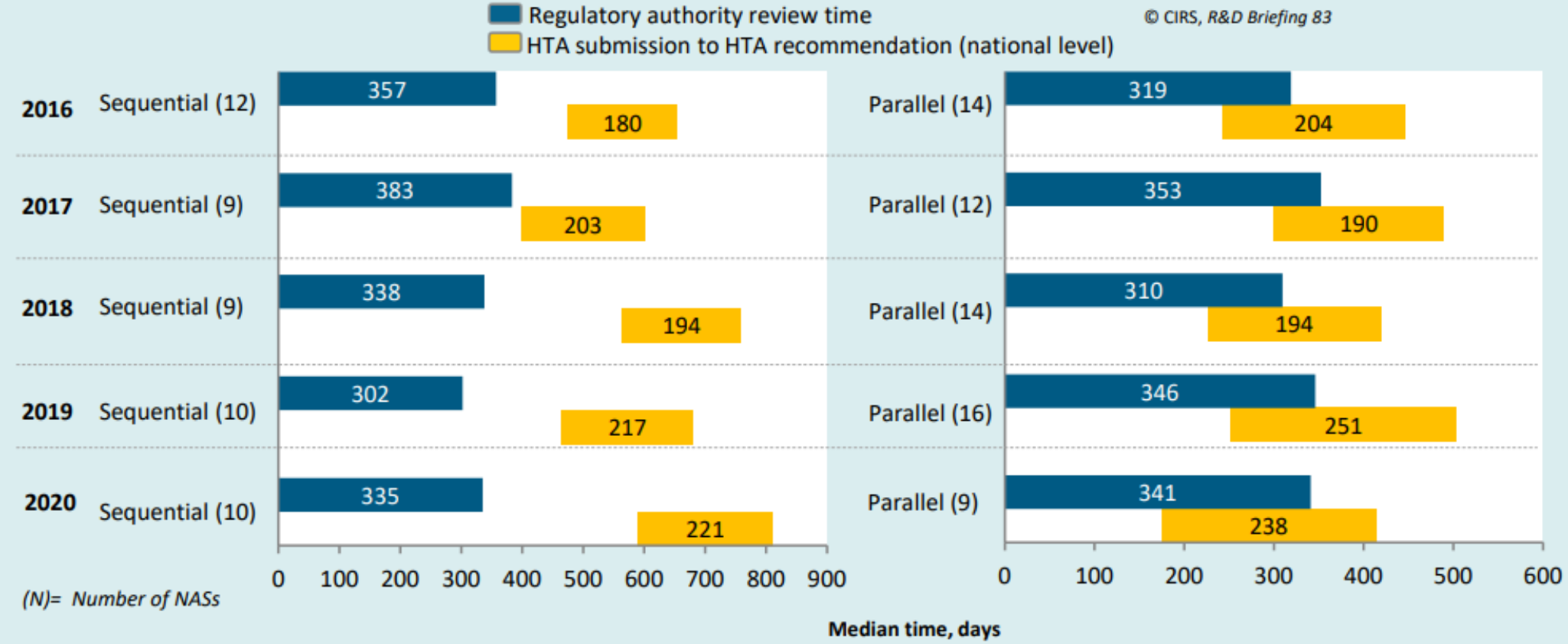
HTA/OU Completed
- Blood plasma (ES)
- Plaque psoriasis (ES & utilization study)
- Rheumatoid arthritis (utilization study)

COVID-19
- COVID-19 Advice completed for Paxlovid & Evusheld

Reimbursement Reviews (5 Years)



Advantage of Pre-NOC Submission



Moving Forward

- Incorporating information related to DEI in reimbursement recommendations and drug related projects
  - identifying gaps in evidence for patient populations
- Extrapolating learnings from regulators – potential work sharing with HTA organizations, opportunities for future collaboration

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Pharmaceutical Review Reimbursement Updates

Amanda Allard

Director – Pharmaceutical Reviews

Enhancing Pre-submission Meetings

Current Issue

Meetings not always used optimally

CADTH Vision

Maximize value of pre-submission meetings

- Meaningful, two-way dialogue
- Sponsors understand process and requirements
- CADTH understands drug complexity
- All stakeholders avoid delays (e.g., screening issues)

Renewed Focus on CADTH Value-Add

Sustainability

- Increasing volume and complexity of reimbursement submissions necessitates change
- Focus effort on where CADTH adds value:
  - Appraisal and interpretation of key evidence
  - Consolidation and integration of stakeholder perspectives
  - Effectively communicating key information to stakeholders
    - Reports primarily used by the expert committees
    - Recommendations used by the drug programs

Sponsor Summary of Clinical Evidence

- New requirement effective for drugs targeting **April 2023** expert committee meetings:
  - received on or after Oct. 17, 2022 for oncology drugs
  - received on or after Oct. 31, 2022 for non-oncology drugs
- Applies to all standard and complex reviews
- Benefits:
  - CADTH - more efficient review process
  - Sponsor - standardized process to highlight key clinical evidence
    - Including addressing gaps in pivotal trial evidence

Revised Clinical Reports

- Clinical review reports will be revised to:
  - Reduce overall complexity and focus on key information
  - Make it easier for stakeholders to understand the appraisal and interpretation of evidence
  - Ease burden on industry when reviewing draft reports
- Considering adopting new format for evidence appraisal (further details to be communicated at later date)

Continuous Program Evaluation

- Committed to continuous improvement and ensuring that any changes are having the desired impact
- Evaluation of new process to ensure:
  - Submission filing times are not affected (e.g., pre-NOC filing)
  - Information needs of CADTH and the expert committees are met
  - The template has clear instructions for industry (e.g., no training)
- Will consider further harmonization with other HTAs
  - Efficiencies for all stakeholders through broad alignment

Agility

Enhanced Reconsideration Phase

- New process allowing new information in reconsideration phase
- Decision to allow new information will be made by CADTH, based on:
  1. Addresses an important evidence gap identified by committee
  2. Was not available during the review phase
  3. Committee concluded drug has potential to address a medical need
  4. Drug was reviewed via expedited HC pathway (e.g., priority review)
  5. Provided in a format that allows complete a review and appraisal
- **New information must be identified within the reconsideration request template when submitting the request**

Future-Ready Reimbursement

- Guidance for submitting RWE
- New methods for evidence appraisal in CADTH clinical reports
- Incorporating ethical considerations into complex reviews
- Time-limited recommendations
- Increased transparency initiatives
  - Providing clarity about evidence gaps
  - Guidance for redactions

Ahead of the Curve...

"CADTH will work closely with partners across Canada"

"We will anticipate the needs of decision-makers, help them understand the available evidence, identify key gaps in the existing evidence, and predict challenges with system readiness to implement the best solutions."

— CADTH 2022–2025 Strategic Plan

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Pharmaceutical Review Appropriate Use Updates

Peter Dyrda, Manager

Policy & Program Development

Vision for Appropriate Use

Fit for purpose evidence products

- New streamlined review processes

HTA: adoption to appropriate use

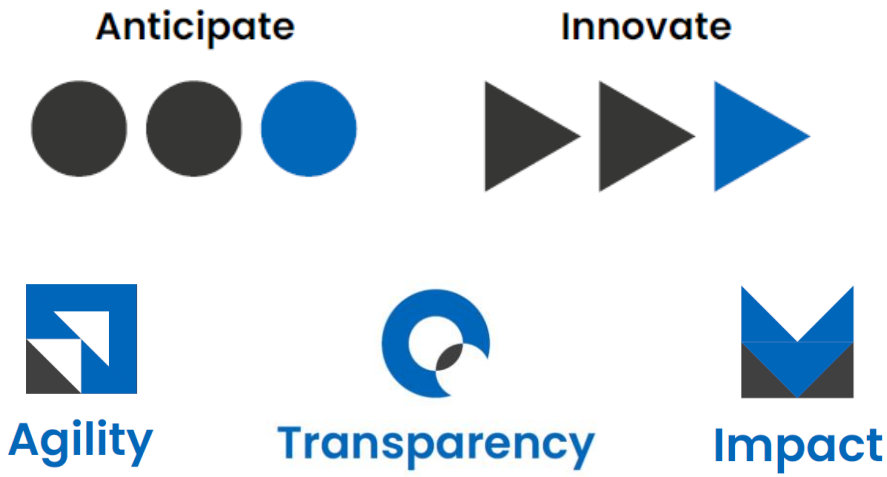
- Lifecycle reviews

Advice on system sustainability

- Formulary management initiatives

Initiatives from 2021–2022

- Implementation Advice Panels for COVID-19 Therapeutics
- Expanded Algorithms Process for Oncology Reviews



Initiatives for 2022-23

- Non-Sponsored Single Drug Review
- Streamlined Drug Class Review
- Implementation Advice Panels for Temporary Drug Shortages
- Utilization Analyses

Non-Sponsored Single Drug Reviews

Why?

Requests from beneficiaries/clinicians within public plans for access to drugs at or beyond exclusivity where evidence exists but where no previous HTA was conducted

What?

- Standard clinical review
- Economic analysis limited to cost comparison and BIA
- Expert Review via CDEC or pERC and recommendation issued
- 6-month review timeline

Agility

Transparency

Streamlined Drug Class Reviews

Why?

Standard therapeutic reviews deemed overly complex and time consuming for assessing certain therapeutic areas where robust evidence exists

What?

- Streamlined clinical review of therapeutic area
- Economic analysis limited to cost comparison and BIA
- Expert Review via CDEC or pERC and recommendation issued
- 6-month review timeline

Agility

Impact

Implementation Advice for Shortages

Why?

Jurisdiction initiated review of therapeutic alternatives for anticipated drug shortages

What?

- Streamlined clinical review of therapeutic alternatives
- Cost comparison
- Advice provided by CADTH is time-limited to the drug shortage
- Expected timeline of ~3 months

Agility

Impact

Information Session

Utilization Analyses

Therapeutic Review in Multiple Myeloma

Appropriate Use of Conventional Drugs in Arthritis

Old vs New Generation Biologics in Psoriasis

Initiatives for Beyond

- Fit for purpose reviews for pediatric drugs
- Addressing gaps within reassessment procedures
- Build capacity and collaborate on utilization analyses to advise decision makers on system sustainability


cadth