

Cost Recovery Annual Stakeholder Meeting

Welcome, we will start soon

Bienvenue, nous allons commencer bientôt



Cost Recovery Annual Stakeholder Meeting Human Drugs – Generics, OTCs, Biosimilars

FEBRUARY 24, 2022

TIME: 1:00 PM

VIA: Zoom

Traduction simultanée disponible en
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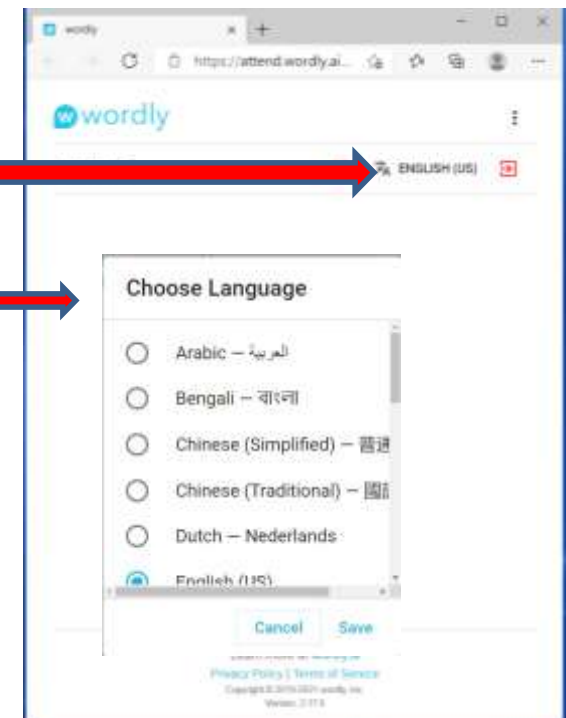
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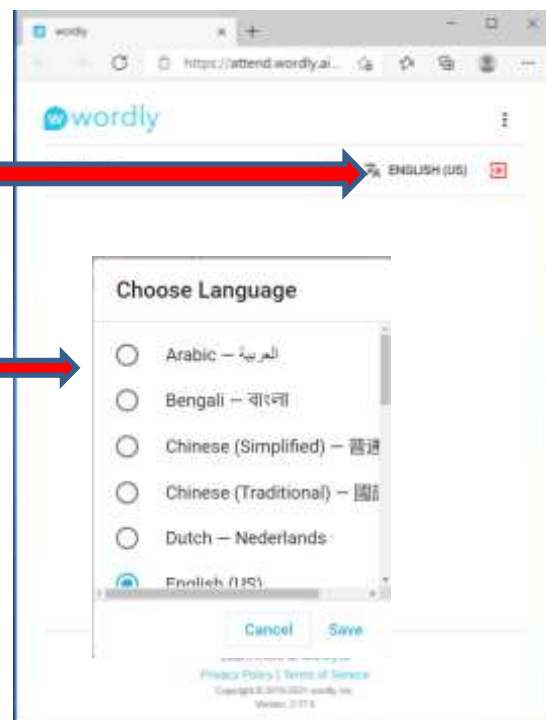
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Generics, OTCs, Biosimilars Cost Recovery Stakeholder Meeting Agenda

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OPENING REMARKS

2

IMPLEMENTATION AND PERFORMANCE RESULTS

First year of updated fees – costs, revenue, performance

3

BUSINESS IMPROVEMENTS

Industry Engagement

Horizontal initiatives

Breakout Sessions – Generics, OTC's, Biosimilars

Sector specific initiatives

Future initiatives

Post-Market, Establishment Licensing

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NEXT STEPS

5

CLOSING REMARKS

Generics, OTCs, Biosimilars Cost Recovery Stakeholder Meeting Agenda

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OPENING REMARKS

ETIENNE OUMETTE

DIRECTOR GENERAL

RESOURCE MANAGEMENT AND OPERATIONS DIRECTORATE

HEALTH PRODUCTS AND FOOD BRANCH

HEALTH CANADA

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Welcome to the Inaugural Cost Recovery Stakeholder Session

Purpose

- The general purpose of these meetings is to provide an opportunity to engage with all stakeholders annually to discuss issues related to cost recovery
- This meeting will be focussed on:
 - Results of the first year of implementing updated fees
 - Health Canada costs, revenue and performance, as per the Health Canada Report on Fees tabled in Parliament by the Minister of Health
 - Efforts to improve regulatory programs, processes and service delivery

Scope

- All product, site and licence holders, DIN holders, as well as industry associations have been invited to participate
- Program DGs are here to present their accomplishments and initiatives

This is not a consultation on revising fees, nor to discuss COVID-19 related initiatives

Context

- Effective April 1, 2020, the majority of fees with respect to drugs and medical devices under the *Financial Administration Act* were repealed and set under the authority of the *Food and Drugs Act*. These fees are now regulated under the *Fees in Respect of Drugs and Medical Devices Order*, which include new fee mitigation measures for small businesses and penalty provisions related to service standards.
- As per the *Service Fees Act* and the *Directive on Charging and Special Financial Authorities*, effective April 1, 2021, Health Canada implemented departmental and subordinate remission policies for fee regimes subject to the *Service Fees Act*. These policies grant remissions to fee-payers for missed service standards.
- Health Canada will continue to work towards continued transparency and accountability as it relates to fees.

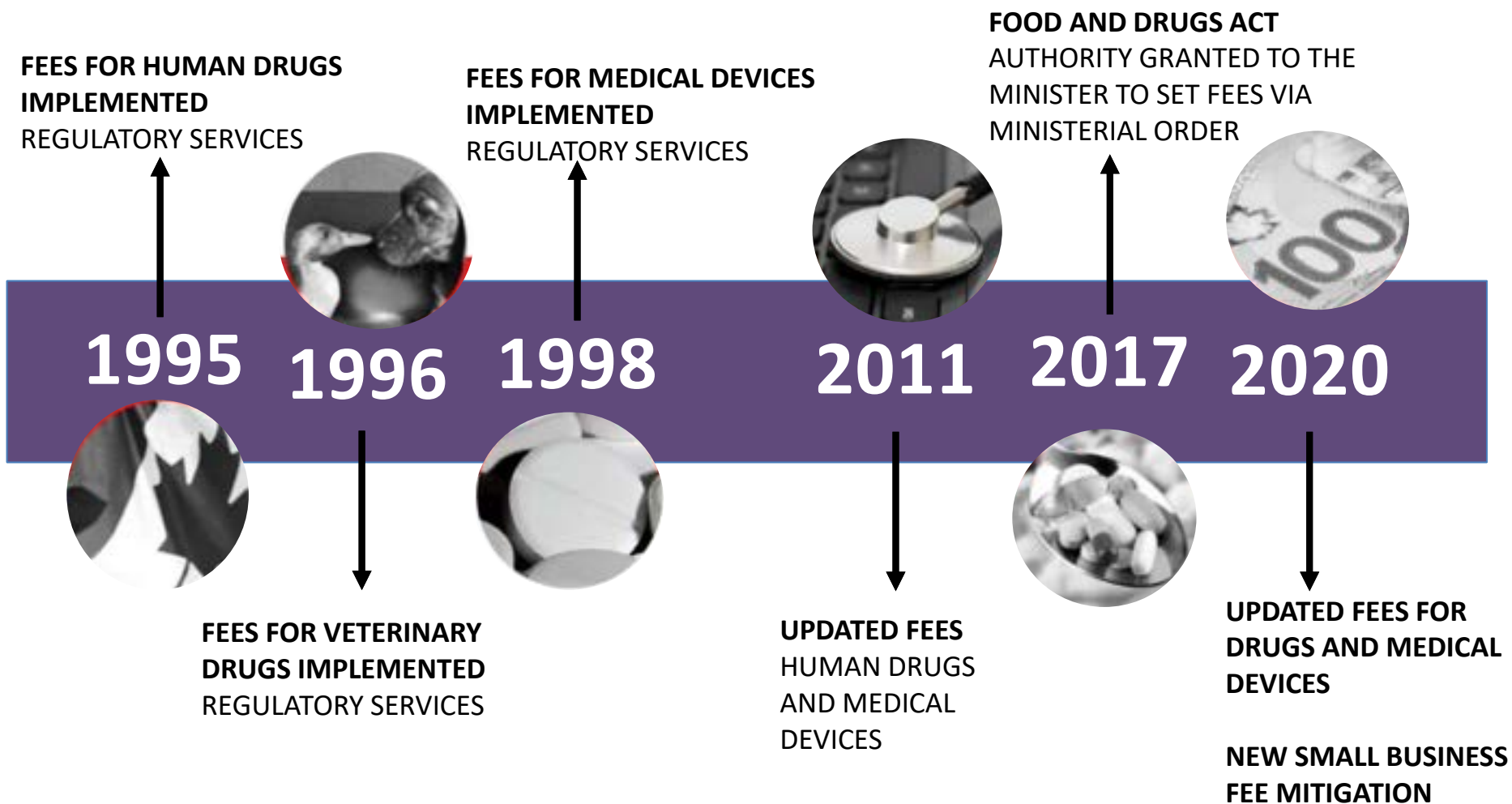


Context (cont.)

- Through collaboration and evidence-based decision-making, we will continue to advance key mandate priorities in order to maintain and improve the health and safety of all Canadians.
- Health Canada made a commitment to implement business improvements (BIs) for drugs and medical devices, and report to stakeholders the progress and future proposals.
- We will be presenting data on the cost recovery results for 2020-21, horizontal and program specific BIs completed, underway, and planned.



Timeline of Drug and Device Fees in Canada



Context - Global pandemic

- March 11, 2020 a pandemic was declared by the WHO.
 - Public health measures implemented across the globe defined a new reality for industry and regulators across the globe, almost overnight.
- Throughout 2020-21, Health Canada implemented many measures to help lead a whole-of-government response to the COVID-19 pandemic, including the approval of several COVID-19 related Ministerial Orders.
 - These Orders waived most fees for applications and were key to allowing Health Canada to expedite the regulatory review and approval of personal protective equipment, drugs and medical devices needed by Canadians during the pandemic.
- COVID-19 impacted Health Canada significantly and several of the planned BIs and resources, thus impacting the planned improvements for 2020-21, but despite this Performance Improved and BI Implementation proceeded effectively.
- 2020-2021 is seen, from a cost recovery perspective, as one of successful collaboration to build on, but not to benchmark on.



Generics, OTCs, Biosimilars Cost Recovery Stakeholder Meeting Agenda

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IMPLEMENTATION AND PERFORMANCE RESULTS

ALAIN LUMBROSO

DIRECTOR

STRATEGIC PLANNING AND ACCOUNTABILITY DIVISION

RESOURCE MANAGEMENT AND OPERATIONS DIRECTORATE

HEALTH PRODUCTS AND FOOD BRANCH

HEALTH CANADA

First year of updated fees – costs, revenue, performance

2020-21 Report on Fees – Drug and Medical Device Costs and Revenue

In December 2021, the Minister of Health tabled the Report on Fees in Parliament, as per the TBS Directive on Charging and Special Financial Authorities. The report has also been published to the Health Canada website ([2020-2021 Report on Fees](#))

Fee	2019/20			2020/21			
	Revenue	Cost	CR%	Revenue	Cost	CR%	Penalties
Drug Right to Sell Drugs	\$ 12,376,389	\$ 85,021,505	15%	\$ 21,093,308	\$ 73,709,077	29%	\$ -
Veterinary Drug Right to Sell Drugs	Merged with Drugs		NA	\$ 282,791	\$ 838,636	34%	\$ -
Fees for Right to Sell Licenced Class II,III,IV Medical Devices	\$ 8,559,329	\$ 26,802,633	32%	\$ 12,990,279	\$ 23,505,960	55%	\$ 1,429
Examination of a Submission - Drugs for Human Use	\$ 50,939,645	\$ 129,446,836	39%	\$ 77,265,889	\$ 153,080,486	50%	\$ 4,861
Examination of Medical Devices Licence Applications	\$ 5,613,398	\$ 23,779,103	24%	\$ 7,598,061	\$ 22,741,660	33%	\$ 3,704
Examination of a Submission - Drugs for Veterinary Use	\$ 817,043	\$ 10,109,721	8%	\$ 1,009,016	\$ 9,581,773	11%	\$ -
Certificate of Supplementary Protection Application	\$ 149,832	\$ 420,333	36%	\$ 210,780	\$ 245,591	86%	\$ -
Drug Master File	\$ 857,352	\$ 1,832,626	47%	\$ 926,890	\$ 1,364,478	68%	\$ -
Drug Establishment Licencing Fees	\$ 16,925,045	\$ 33,852,458	50%	\$ 17,510,606	\$ 34,542,183	51%	\$ -
Medical Devices Establishment Licencing Fees	\$ 9,455,621	\$ 12,264,929	77%	\$ 12,185,289	\$ 14,356,144	85%	\$ 134,258
Certificate of Pharmaceutical Product	\$ 263,554	\$ 291,892	90%	\$ 189,770	\$ 613,272	31%	\$ -
Total	\$ 105,957,208	\$ 323,822,036	33%	\$ 150,979,888	\$ 333,740,624	45%	\$ 144,252

2020-21 Costs and Revenue

Fees for Examination of a Submission - Drugs for Human Use

Revenue (\$)	Cost (\$)	Remissions (\$) (note 1)
77,265,889	153,080,486 50% Recovered	4,861

Fees for Right to Sell Drugs

Revenue (\$)	Cost (\$)	Remissions (\$)
21,093,308	73,709,077 29% Recovered	0

Drug Establishment Licensing Fees

Revenue (\$)	Cost (\$)	Remissions (\$)
17,510,606	34,542,183 51% Recovered	0

Total Program Cost Recovery

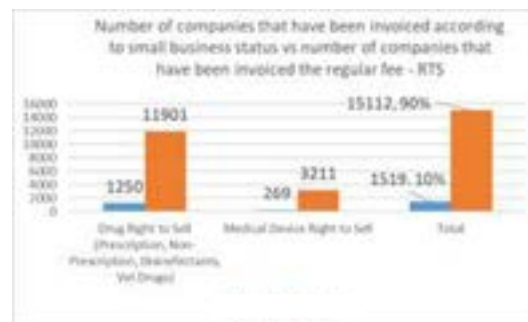
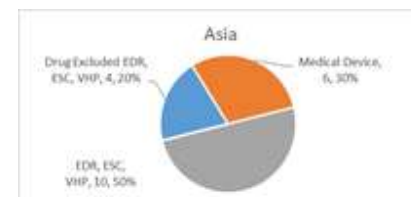
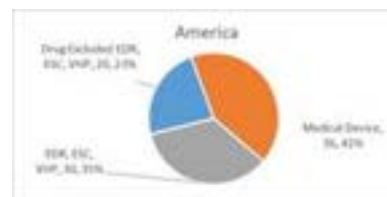
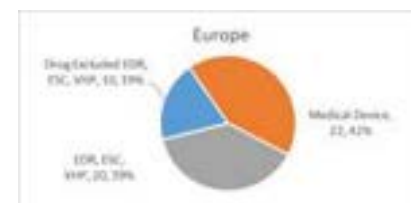
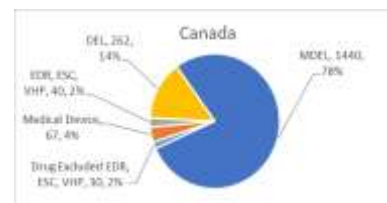
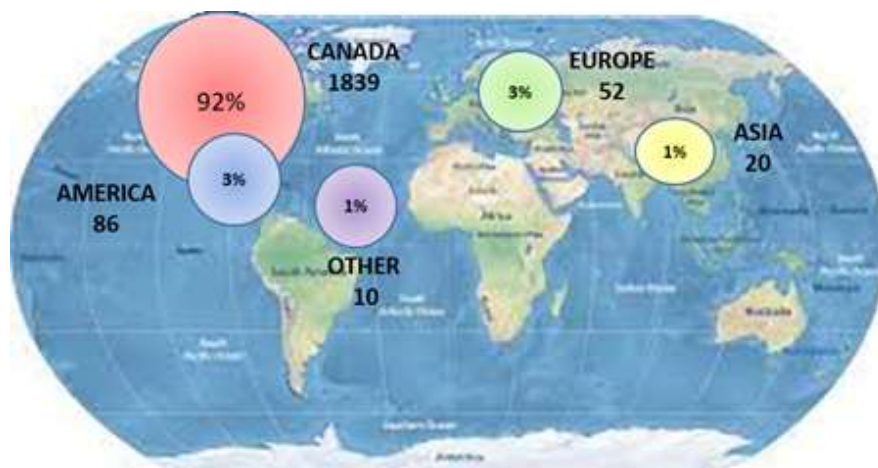
Revenue (\$)	Costs (\$)	Total % of Cost Recovered
\$ 115,869,803	\$ 261,331,746	44%

2020-21 Report on Fees – Performance Results

Service Standards - Pharmaceuticals		Old Fees		New Fees	
Fee Name	Submission Type	Service Standard - Review 1 (average time in calendar days)	Performance Result - Review 1 (average time in calendar days)	Service Standard - Review 1	Performance Result - Review 1 (number of submissions completed on time vs total)
New Active Substance	New Drug Submission	300	250	300	100.0%
Clinical/ Chemistry & Manufacturing	For drugs under Division 1 of the Food and Drug Regulations			210	n/a
	For drugs under Division 8 of the Food and Drug Regulations			300	100.0%
Clinical Only	For drugs under Division 1 of the Food and Drug Regulations			210	n/a
	For drugs under Division 8 of the Food and Drug Regulations			300	100.0%
Comparative Studies / Chemistry & Manufacturing	For drugs under Division 1 of the Food and Drug Regulations			210	100.0%
	For drugs under Division 8 of the Food and Drug Regulations			180	100.0%
Chemistry & Manufacturing	For drugs under Division 1 of the Food and Drug Regulations			210	100.0%
	For drugs under Division 8 of the Food and Drug Regulations			180	100.0%
Clinical or non-clinical data only, in support of safety updates to the labelling				120	100.0%
Labelling Only	New Drug Submission	60	53	120	100.0%
	Supplement to a New Drug Submission	60	52		
	Abbreviated New Drug Submission	60	43		
	Supplement to an Abbreviated New Drug Submission	60	45		
	Drug Identification Number Application - Pharmaceutical	180	165		
Labelling Only (Generic Drugs)				120	100.0%
Labelling Only (Disinfectants)				90	100.0%
Label Standard	Drug Identification Number Application - Pharmaceutical	45		60	100.0%
	Drug Identification Number Application – Disinfectant	45			
	Drug Identification Number Application – Category IV	45			
Administrative	Abbreviated New Drug Submission	45	23	45	99.6%
	New Drug Submission	45	37		
	Supplement to a New Drug Submission	45			
	Supplement to an Abbreviated New Drug Submission	45	33		
	Drug Identification Number Application - Pharmaceutical	45	25		
	Drug Identification Number Application – Disinfectant	45	27		
	Drug Identification Number Application – Category IV	45			

DRTS	Service Standard	Performance Result
Drugs Right to Sell	20 days to update Licence Listing database following receipt of a complete Annual Notification Package	100%
DEL	Service Standard	Performance Result
Application for new licence and annual review of licence	250 calendar days to issue a decision	100%

Small Business Update– 2020-2021



Human Drug Small Business Stats:

- # of Small Businesses registered - 460 (DEVAL and DEL)
- Avg Annual Gross Revenue - \$3,376,653
- Avg # of employees - 16
- Over 3500 emails were received and responded to from all sector stakeholders, many phone calls and video meetings held with small business applicants to help them navigate the process

Generics, OTCs, Biosimilars Cost Recovery Stakeholder Meeting Agenda

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BUSINESS IMPROVEMENTS – ALAIN LUMBROSO

Industry Engagement
Horizontal initiatives

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Business Improvements - Industry Engagement

In June 2019, Health Canada Assistant Deputy Ministers for Health Products and Foods Branch, Regulatory Operations and Enforcement Branch, and the Chief Financial Officer Branch sent a letter to a number of associations seeking feedback regarding ways in which the department could improve its fee-related regulatory activities and services.

The following associations provided feedback:

- BIOTECCanada
- Cosmetic Alliance Canada
- Canadian Animal Health Institute
- Canadian Consumer Speciality Products Association
- Canadian Generic Pharmaceutical Association
- Consumer Health Products Canada
- Innovative Medicines Canada
- MedTech Canada

Business Improvements - Industry Feedback

What we heard as primary areas of interest from associations:

- Enhancements to review process
- Increased international alignment / analyses
- Increased alignment with health technology assessors
- Increased transparency, especially related to costing
- Strengthened internal and external communication, IT systems
- Improved internal review coordination and process

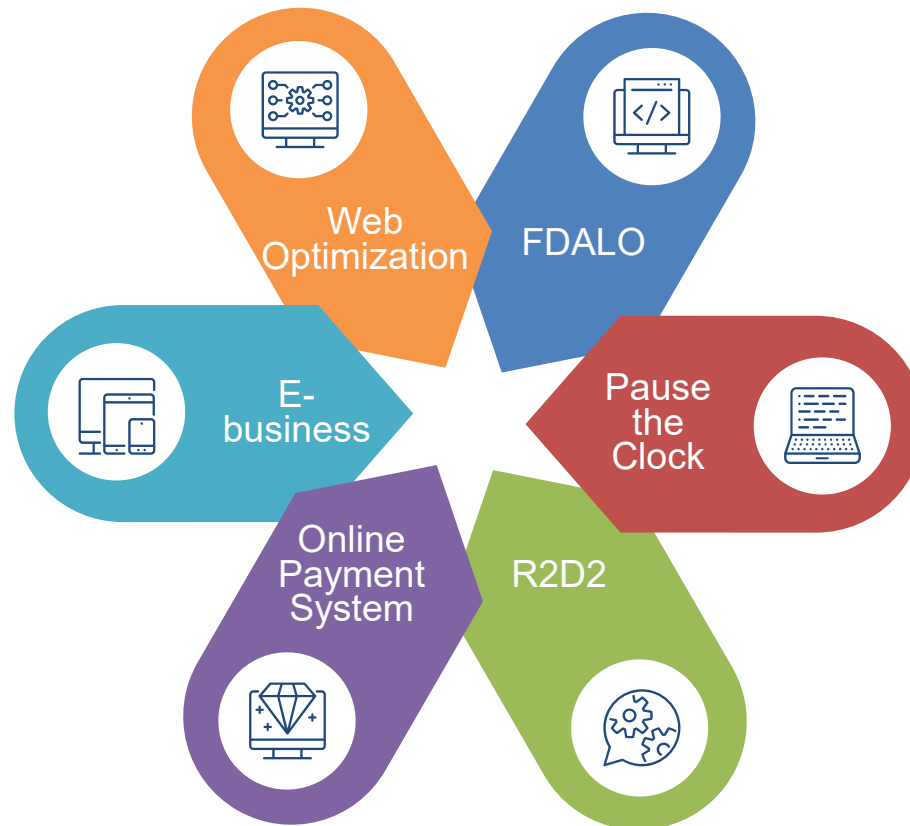


Human Drug Specific:

- Fee remission for low-volume products
- Sector specific fees
- DEL amendments
- DEL performance standards
- NACI alignment
- Sector specialization capacity
- Batching/grouping submissions

Business Improvements – Horizontal Achievements

Based on industry feedback, and internal issue identification, Health Canada has been making improvements in areas applicable to all sectors:



Health Canada's Regulatory Review of Drugs and Devices (R2D2)

Objective: A regulatory system that supports better access to therapeutic products based on healthcare system needs



Expanded collaboration with health partners

- Alignment of the Health Technology Assessment (CADTH and INESSS) Review with Health Canada Review
- Implementing a Mechanism for Early Parallel Scientific Advice
- Use of Foreign Reviews/Decisions
- International Collaboration and Work Sharing in Reviews



Enhanced Use of real world evidence

- Leveraging Data for Assessing Drug Safety and Effectiveness
- Strengthening the Use of Real World Evidence and Regulations for Medical Devices



More timely access to drugs and devices

- Expansion of Priority Review Pathways
- Improving Access to Biosimilars and Biologics
- Improving Access to Generic Drugs
- Building Better Access to Digital Health Technologies
- Pre-Submission Scientific Advice for Medical Devices
- Special Access Program (SAP) Renewal

Modern and flexible operations

Common Submission Intake
Appropriate Cost Recovery Framework
Public Release of Clinical Information

Generics, OTCs, Biosimilars Cost Recovery Stakeholder Meeting Agenda

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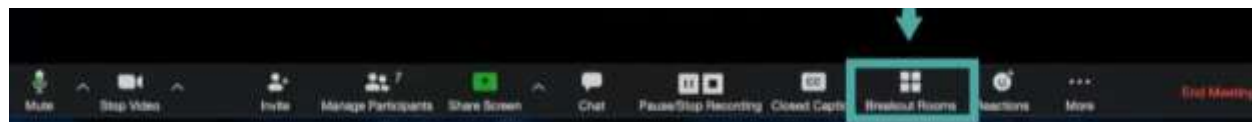
BUSINESS IMPROVEMENTS – Breakout Groups

GENERICS

NON-PRESRIPTION AND DISINFECTANTS

BIOSIMILARS

SELECT YOUR PREFERRED SESSION HERE



Generics, OTCs, Biosimilars Cost Recovery Stakeholder Meeting Agenda

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BUSINESS IMPROVEMENTS – POST-MARKET

KELLY ROBINSON
DIRECTOR GENERAL
MARKETED HEALTH PRODUCTS DIRECTORATE
HEALTH PRODUCTS AND FOOD BRANCH
HEALTH CANADA

Business Improvements – Post-Market Initiatives (Ongoing & Planned)

Good Review Practices

Internal review process improvements

Adverse Drug Reaction Reporting

Tools and resources to support adverse drug reaction reporting (e.g., CV Dashboard)

Real World Evidence

Real World Evidence public notice and principles document posted online



International Collaboration

International collaboration on RMP reviews (ACCESS, ORBIS)

Proactive Surveillance

Proactive surveillance program to detect and action false and misleading advertisements for COVID-19 related health products

Transparency

Increased transparency of risk minimization information

Guidance for Industry

Updating the 'Issuance of Health Product Risk Communications' guidance for industry

Generics, OTCs, Biosimilars Cost Recovery Stakeholder Meeting Agenda

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BUSINESS IMPROVEMENTS - COMPLIANCE & ENFORCEMENT, ESTABLISHMENT LICENCES

LINSEY HOLLETT

DIRECTOR GENERAL

HEALTH PRODUCT COMPLIANCE

REGULATORY OPERATIONS AND ENFORCEMENT BRANCH

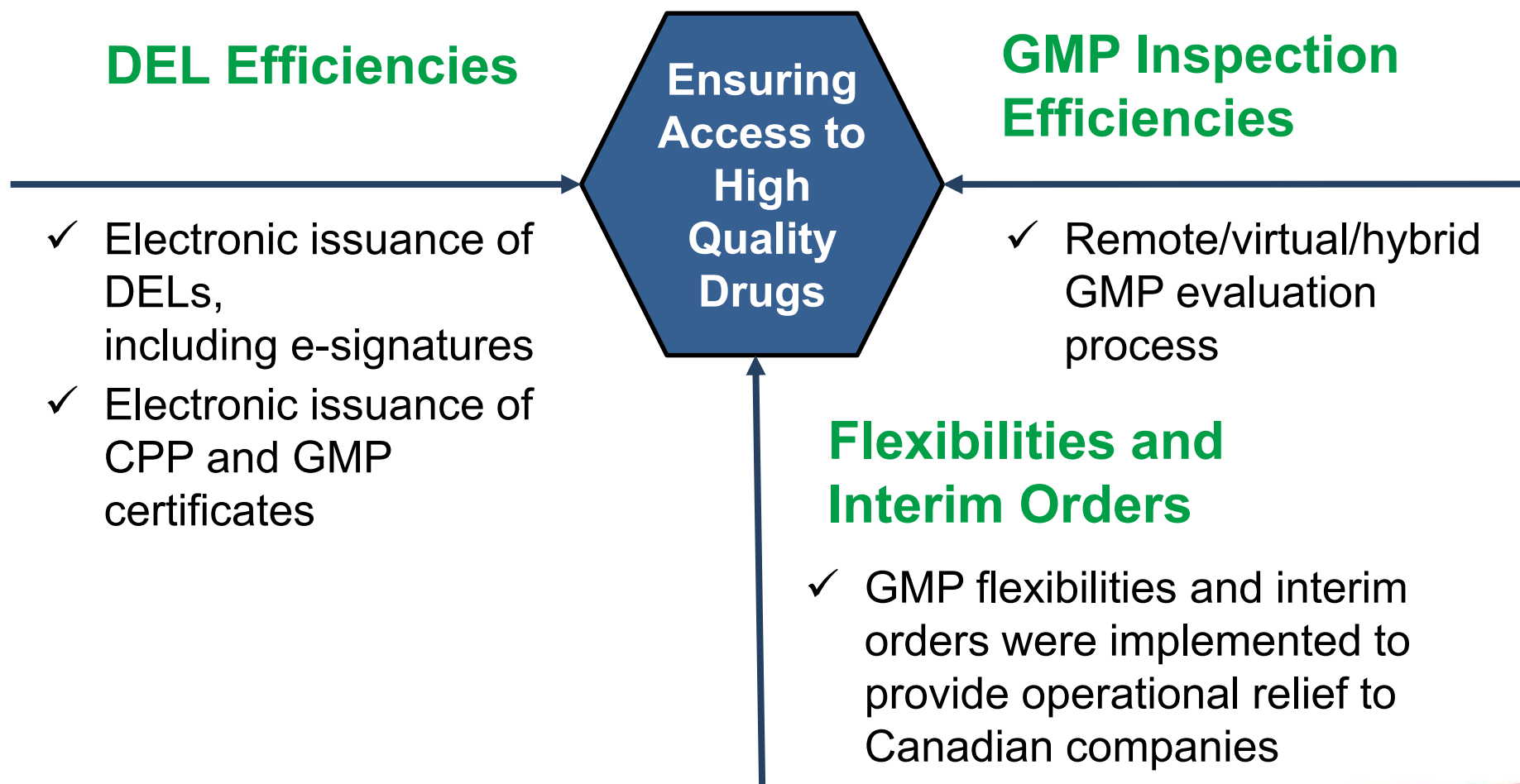
HEALTH CANADA

Cost Recovery for Drug Establishment Licensing

- Health Canada is working on optimizing its drug establishment licensing approach to enable quicker authorizations and faster access to drugs for Canadians.
- Implemented on April 1, 2020, fees are calculated based on the licensable activities, numbers of domestic and foreign buildings on their DEL.
- With increased fees, HC focused on delivering services within the established 250 days and committed to looking at finding further process efficiencies.

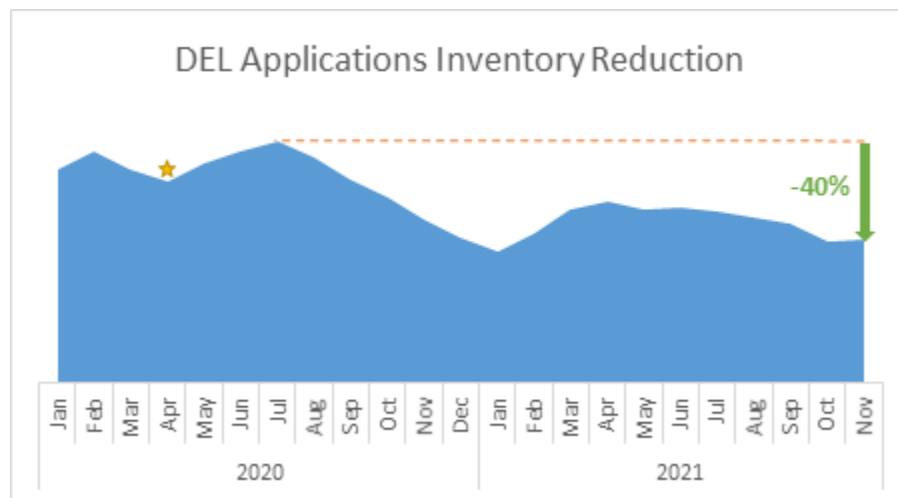
Activities on DEL	Fee as of April 1, 2020
Fabrication - sterile dosage form	\$41,626
Importation	\$27,359
Fabrication - non-sterile dosage form	\$27,000
Distribution	\$12,560
Wholesaling	\$4,937
Packaging/labelling	\$6,061
Testing	\$2,560
Building Outside Canada (each)	\$918

Response to the Pandemic



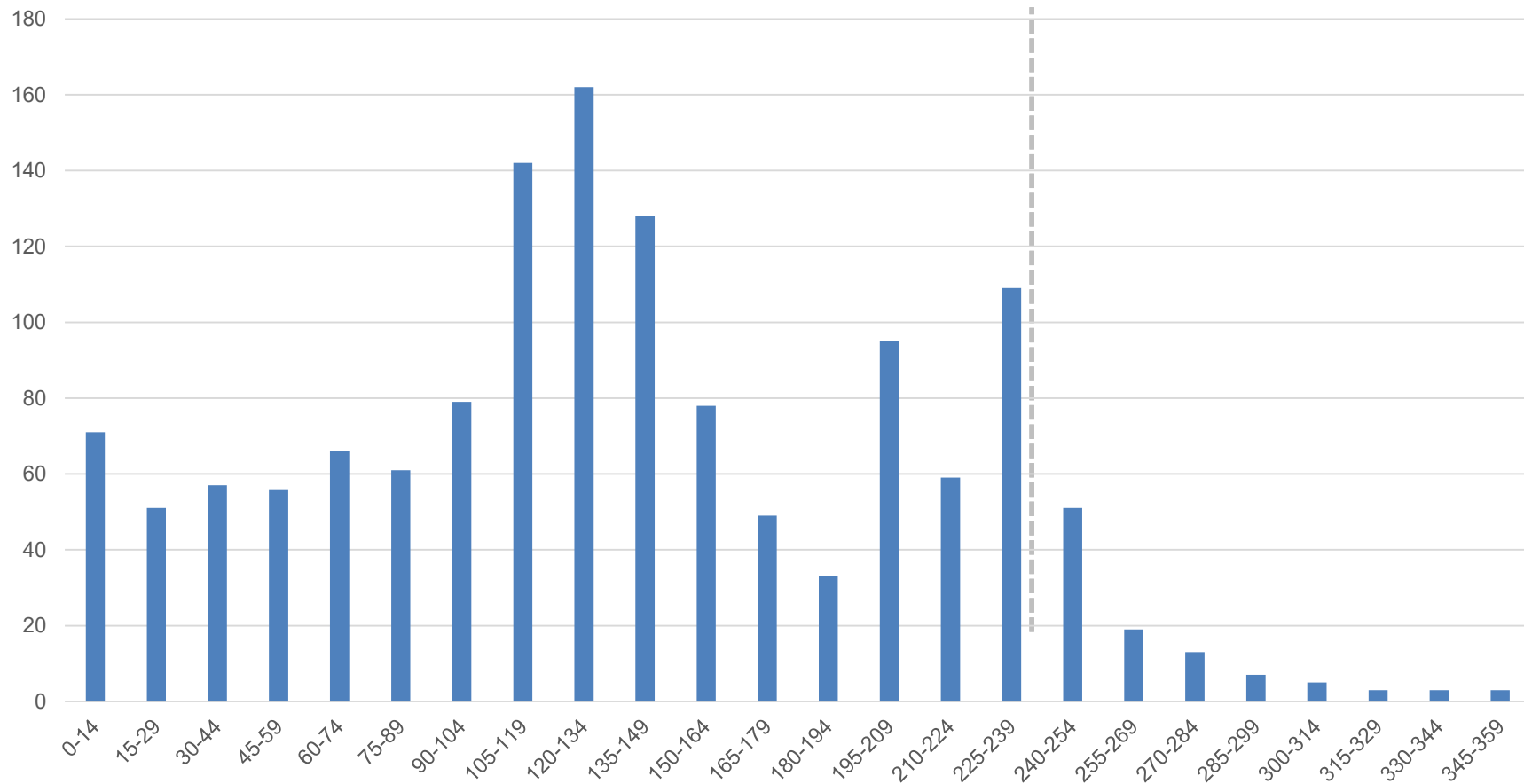
Service Standards

- In 2021-2022, HC issued **93% of DEL applications within the 250 day** service standard.
- The DEL applications **inventory has decreased by 40%** since April 2020.
- The total **average time for HC to issue DELs has reduced by 19%** and is averaging around 186 days in FY 20-21 and 150 days in FY 21-22.



Due to leaner, improved DEL application monitoring & processes

Distribution of Application Age in FY 2021-2022



Other work that may impact DEL services

To ensure that Canadians would continue to have timely access to drugs, including COVID-19 vaccines and therapies, Health Canada introduced:

- ✓ An [agile and expedited pathway for reviewing DEL applications](#) submitted in relation to COVID-19 drugs;
- ✓ Extending foreign building [New Evidence Required By \(NERBY\) dates](#);
- ✓ Accepting [alternative evidence to demonstrate GMP](#) compliance of foreign buildings on a case-by-case basis; and
- ✓ Where laboratory testing is required for identification purposes, but is not readily available, permitting the [application of a modified approach to the current unique identifier principles to confirm the identity](#) of the imported drugs.



Analysis is underway to assess COVID model post pandemic.

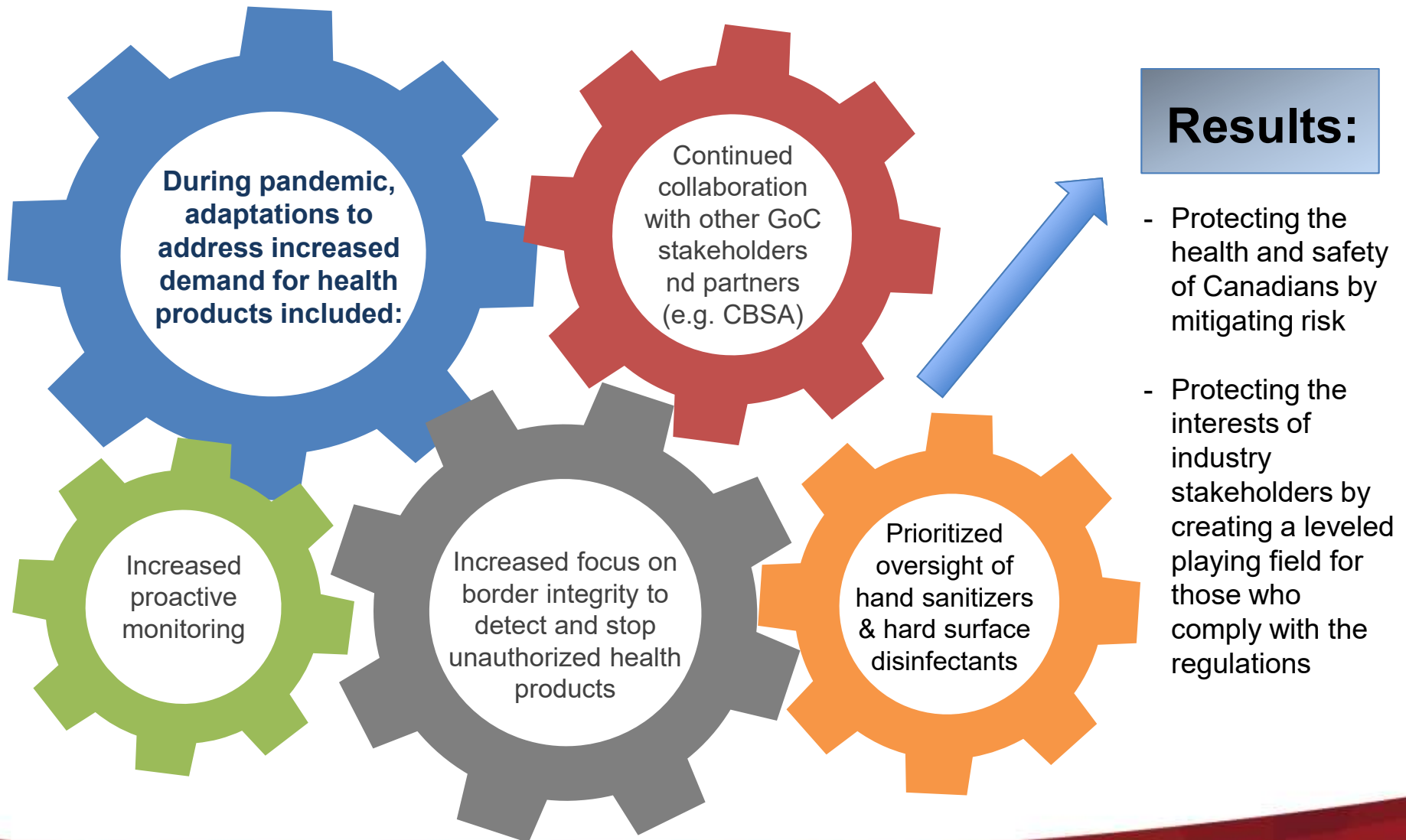
Post pandemic: Continuing to Improve & Modernize

- ❖ **Leverage experience during pandemic to solidify and lean out licensing pathways to optimize service delivery to the public**
 - Build on COVID practices to refine process post-pandemic
 - Assess service standards by activities to introduce granularity within scheme based on efforts needed and available evidence
 - Engage with stakeholders to validate efficiency gains and share metrics

- ❖ **Modernize entire drug establishment licensing continuum to reflect our reliance on trusted international partner inspections and efforts required**
 - Will reduce administrative burden on regulated parties through a more consistent and predictable licensing framework
 - Will enable more effective channelling of resources to improve service delivery while ensuring quality of the application review is not compromised



Business Improvements – Post-Market Compliance Verification, Border Operations and Labs



Generics, OTCs, Biosimilars Cost Recovery Stakeholder Meeting Agenda

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NEXT STEPS
ALAIN LUMBROSO

Regulatory Innovation Agenda for Health Products



Modernized
clinical trials for
drugs and
devices

To have better,
safer, and more
trials in Canada



A pathway for
Advanced
Therapeutic
Products

To ensure a
flexible
approach for
innovative
products that
do not fit within
the current
system



Agile licensing
for drugs and
devices

To make sure
regulations
align with the
nature and
lifecycle of
health products



Modernized
medical device
oversight

To make sure
there is
appropriate
oversight while
enabling
innovation



A better way of
communicating
with Canadians

To be the user-
friendly
authoritative
source for
information

Next Steps



Generics, OTC's, Biosimilars Cost Recovery Stakeholder Meeting Agenda

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CLOSING REMARKS
ALAIN LUMBROSO

Closing Remarks



Thank you for participating in the inaugural annual cost recovery stakeholder meeting.

A summary report of the meeting will be developed and shared in the coming weeks including a summary of comments and questions provided via Slido. In the meantime, please complete the post event survey.

<https://www.questionpro.com/t/AUqJ6ZquXR>

Looking forward to meeting with you again this fall.

ANNEX: Information sources

Departmental Plans and Priorities

<https://www.canada.ca/en/health-canada/corporate/transparency/corporate-management-reporting/report-plans-priorities.html>

Departmental Results Reports

<https://www.canada.ca/en/health-canada/corporate/transparency/corporate-management-reporting/departmental-performance-reports.html>

GC Infobase

<https://www.tbs-sct.gc.ca/ems-sgd/edb-bdd/index-eng.html#orgs/dept/127/infograph/intro>

Annual Drug Submission Performance reports available on request

Drug and Medical Device Highlights Reports

<https://www.canada.ca/en/health-canada/services/drugs-health-products/highlights-reports.html>

2020-2021 Report on Fees

<https://www.canada.ca/en/health-canada/corporate/about-health-canada/reports-publications/report-fees-2020-2021.html>

Cost Recovery Stakeholder Meeting OTCs and Disinfectants Breakout Session

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FEBRUARY 24, 2022

YOUR HEALTH AND SAFETY... OUR PRIORITY.



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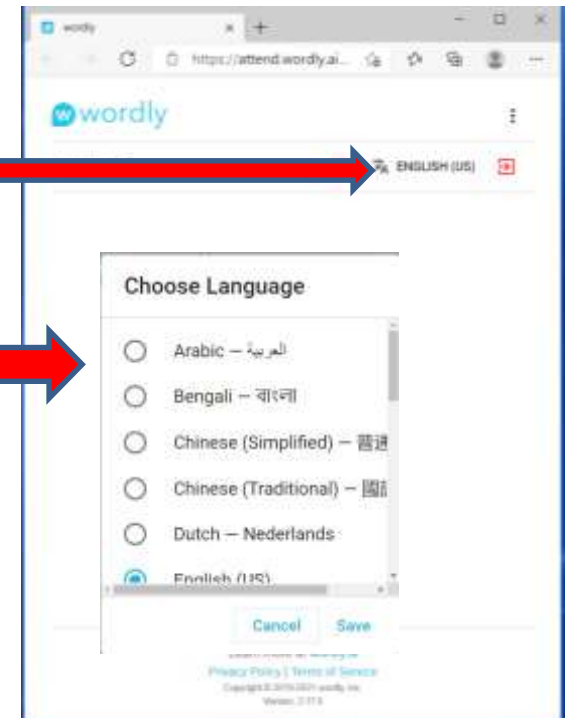
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Using Wordly

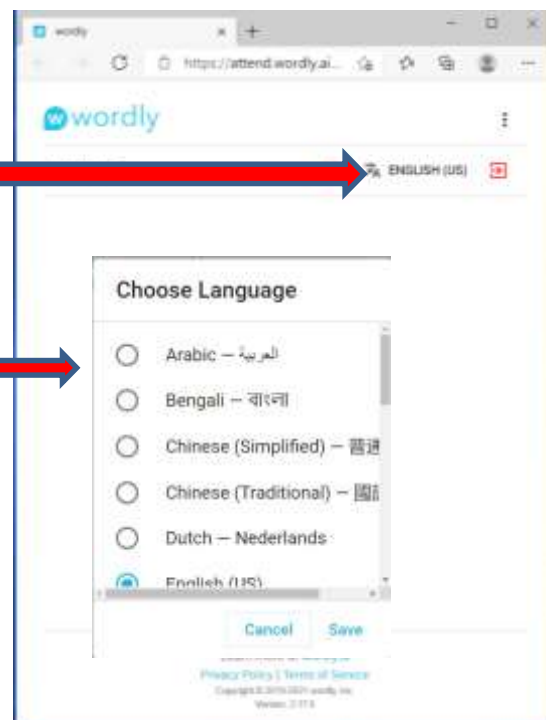
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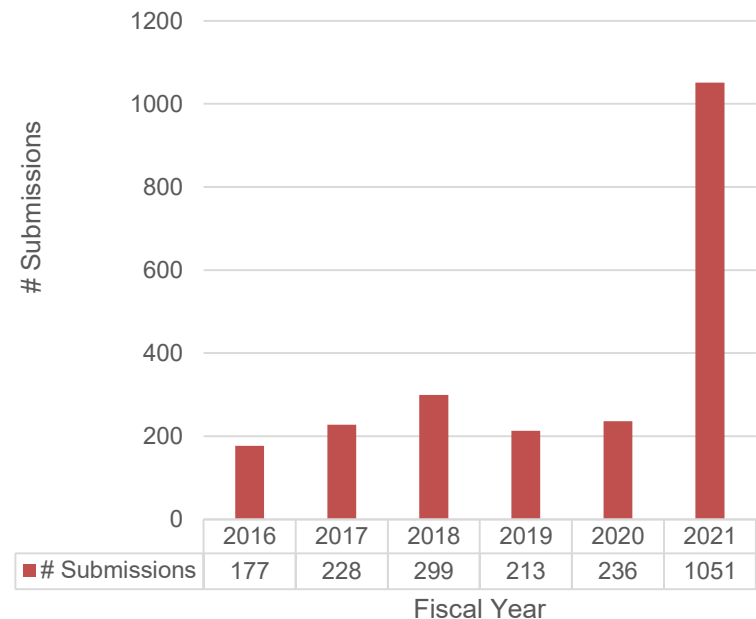
Outline

- COVID-19 and Disinfectants: Impacts, Response, and Lessons Learned
- Business Improvements:
 - 2021 Improvements
 - Current Initiatives
 - Future Initiatives
- Question Period

COVID-19: Flexible Response To Allow Exceptional Access to Disinfectants

- A number of interim measures were introduced to ensure sufficient supply of disinfectants for Canadians and to support the COVID-19 response:
 - **Prioritized review** (over new 430 disinfectants approved)
 - **Expedited internal service standards**
 - **Exceptional importation of products** (approximately 280 disinfectants imported via interim order)

COVID-19 impact on incoming disinfectant submissions



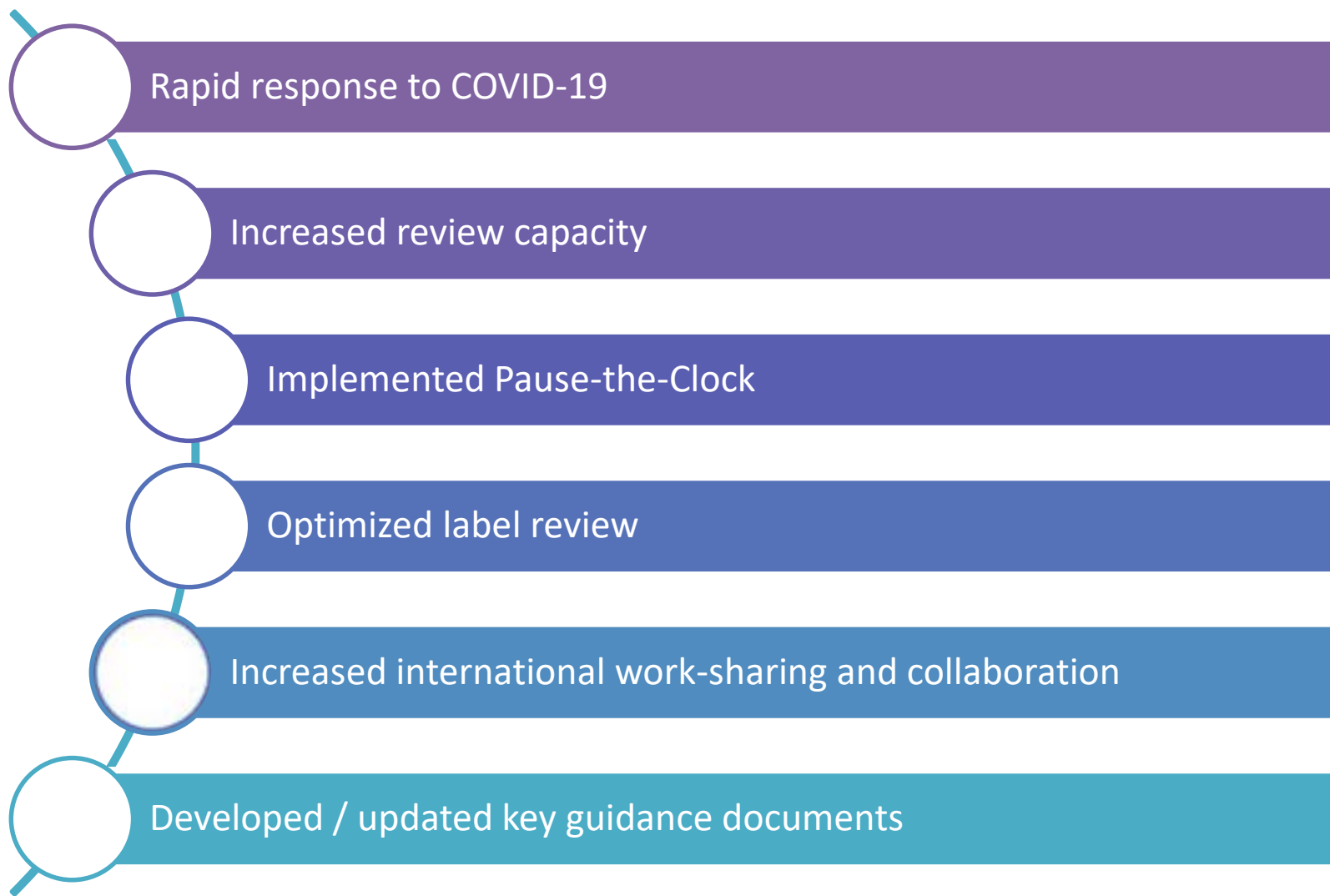
COVID-19: Flexible Response To Allow Exceptional Access to Disinfectants

- The pandemic was an exceptional circumstance, and now that the supply has returned to normal, the interim measures are no longer required to address supply issues for Canadians to access these products.
- Many interim measures are winding down and work is advancing on longer-term and predictable solutions through a regulatory proposal for biocides.
- The Department intends to bring forward a regulatory proposal to introduce flexibilities for biocides and place them under a single regulatory framework.
 - This will assure a biocides framework with proportional oversight and fees.

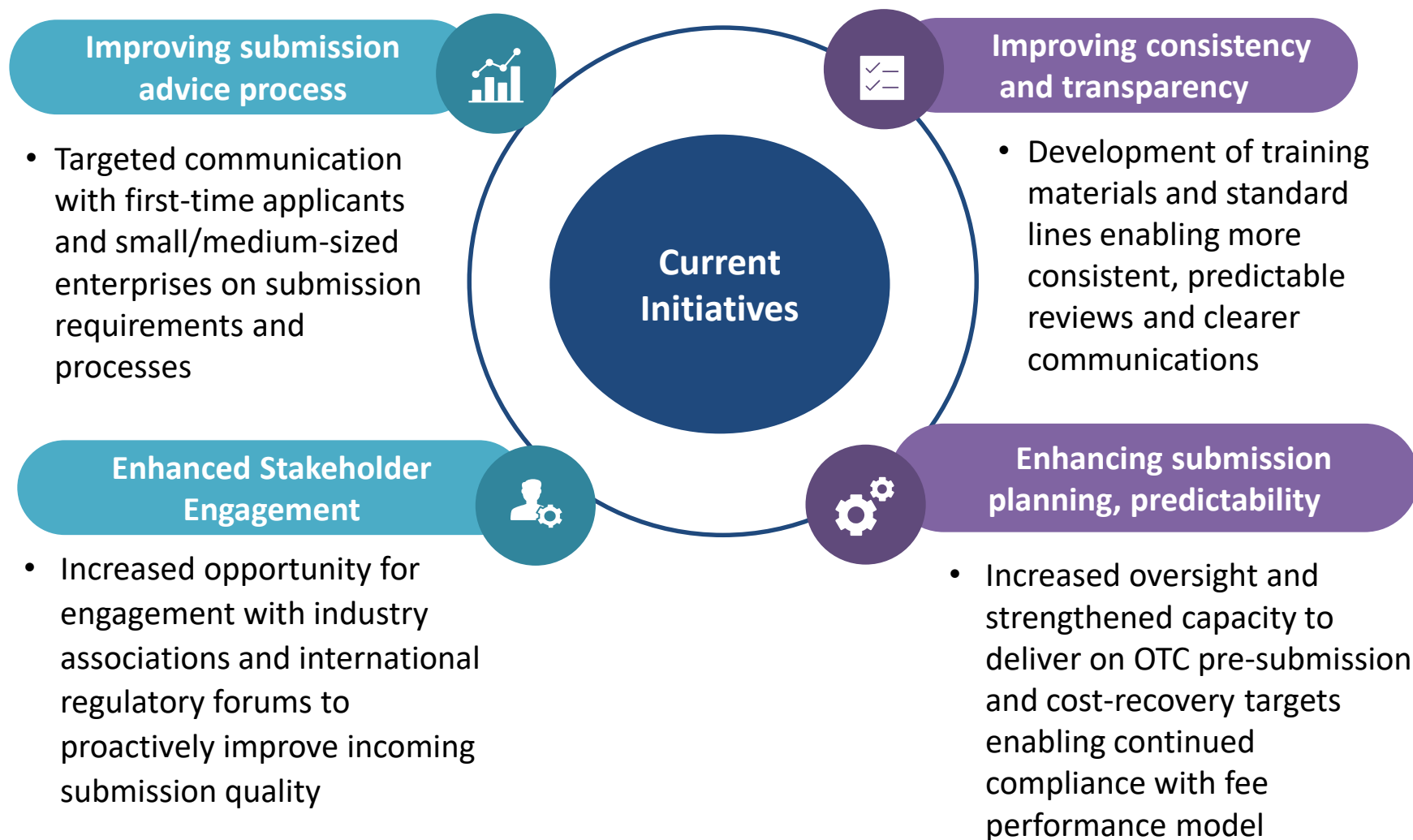
Lessons Learned from COVID-19: Disinfectants

- Pandemic highlighted existing challenges and reinforced the need for more flexible and tailored regulations:
 - **Increased need for innovative biocides**
 - **Disrupted supply chains** that created shortages for biocide products necessary for Canadians
 - **Increased need for greater international regulatory cooperation** to prevent future biocide shortages
 - Increased expectation from Canadians for **more transparency on regulatory decisions**

Business Improvements in 2021



Business Improvements: Current Initiatives



Business Improvements: Planned Initiatives

Biocides Framework

- A single streamlined framework for hard and soft surface biocides
- Requirements tailored to biocides
- Flexible post-market powers
- Use of foreign decisions pathway
- Revised user fees

Self-Care Framework

Simplified pathways for non-prescription drugs

- Risk-based approach to regulatory oversight, including expedited pathways for lower-risk products
- Revised user fees to align with regulatory changes
- In the interim, exploring non-regulatory options to advance Self-Care Framework principles, while work is underway on regulatory proposal
- Focus on measures that would reduce burden for industry

Q and A

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Cost Recovery Stakeholder Meeting Pharmaceutical (Generics) Sector Breakout Session

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February 24, 2022

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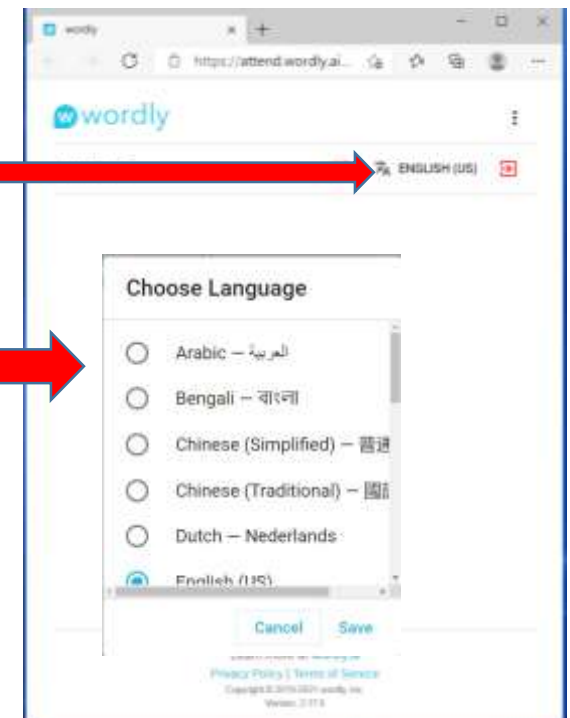
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Using Wordly

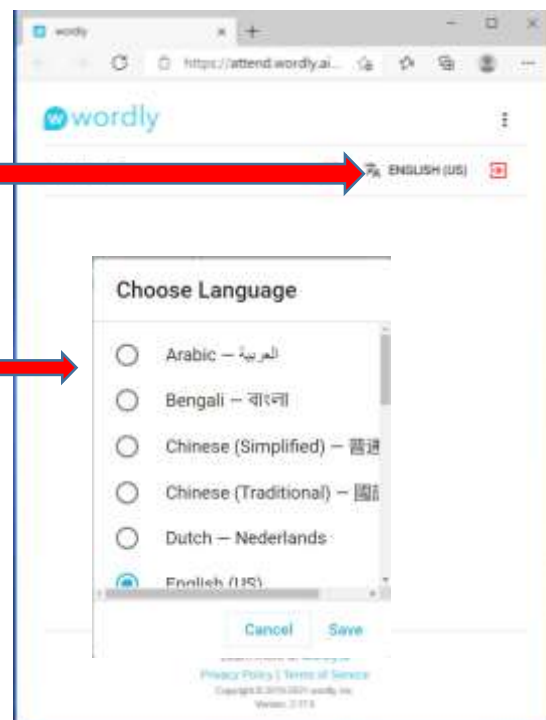
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Outline – Pharmaceuticals (Generics)

- Brief overview of:
 - Performance Results 2020-21 and 2021-22
 - Business Improvements
 - Industry Feedback
 - HPFB's Key Initiatives
- Q & A –via Slido

Fees for Examination of Cost-Recovered Submissions

Drugs for Human Use

Submission Class	Performance Standard (# of Days)	2020-21 Fee	2021-22 Fee
New Active Substance	300	\$400,288	\$437,884
Clinical/Chemistry and manufacturing data	210* 300**	\$204,197	\$224,691
Clinical or non-clinical data only	210* 300**	\$90,864	\$95,987
Comparative studies	210* 180**	\$53,836	\$55,737
Chemistry & Manufacturing	210* 180**	\$27,587	\$30,670
Safety Updates to Labelling	120	\$19,442	\$19,442
Labelling Only	120	\$3,816	\$4,328
Labelling Only (generic drugs)	120	\$2,010	\$2,006
Administrative Submission	45	\$432	\$540

Performance against Service Standards – Pharmaceutical Drug Decisions FY2020-21, FYTD 2021-22

Performance against service standards								
	FY 2020-21				FYTD 2021-22			
	Cost recovered**		Non-Cost recovered**		Cost recovered**		Non-Cost recovered**	
Submission Type*	% on time	Volume***	% on time	Volume***	% on time	Volume***	% on time	Volume***
NDS*	100%	97	100%	6	100%	70	100%	10
SNDS*	100%	407	90.9%	11	100%	423	100%	5
ANDS*	100%	260	99.0%	96	100%	187	100%	80
SANDS*	100%	538	100%	4	99.8%	447	100%	6
DINA*	100%	120	100%	7	100%	68	100%	5
Administrative	99.8%	485	100%	5	99.7%	347	100%	8

*Includes all fee lines (NAS, Clin/C&M, Comparative, C&M, Labelling, Labelling Generic, Safety label) except Administrative

**Cost recoverable includes Review 1 Iteration 1 cycles; Non-cost recoverable includes response to NONs & NODs

***Volume is the total number of submission decisions made in the fiscal year/fiscal year to date

Business Improvements - Industry Feedback

What we heard as primary areas of interest from associations -
Generics:



-  Enhancements to review process
-  Increased international alignment / analyses
-  Increased transparency, especially related to costing
-  Strengthened internal and external communication, IT systems



Key Business Improvements



Enhancements to Review Process

Introduced regulatory flexibilities in response to COVID-19 pandemic

- COVID-19 Response:
 - COVID-19 HPFB Task Force
 - Expedited *Interim Orders [IOs] Respecting*:
 - *the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*
 - *the Importation and Sale of Medical devices for Use in Relation to COVID-19*
 - *Clinical Trials for Medical Devices and Drugs Relating to COVID-19*
 - *Drug Shortages (Safeguarding the Drug Supply)*
 - *Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19*
 - Transition of COVID drugs approved under IOs (expired Sept 16, 2021) to approval under the amended *Food and Drug Regulations*
- Increasing use of pharmacometric analysis/modelling/simulation in reviews, especially to support pediatric, rare disease and COVID-19 indications

Key Business Improvements



Enhancements to Review Process

- Other Regulatory and Policy Instruments (some implemented as part of COVID-19 regulatory response):
 - Agile Licensing Framework
 - Rolling Submissions
 - Terms & Conditions
 - Risk Management Plans [RMPs]
 - Pause-the-Clock Policy – implemented April 1, 2020
 - Optimizing Use of Real-World Evidence in Decision-Making
 - Modernizing Clinical Trials Regulatory Framework
 - Pursuing pathways for:
 - Advanced Therapeutic Products
 - Use of Foreign Decisions
 - Modernizing sections of the *Food and Drug Regulations* and some policies to reflect Health Canada's current thinking and evolving science:
 - Updating the requirements for labelling the standard for certain drugs
 - Updating requirements for certain drugs that claim a manufacturer's standard
 - Publication of a joint notice on collaboration between the Competition Bureau and HPFB (January 2022)

Key Business Improvements



Enhancements to Review Process

Improving predictability & transparency of the review process

- Continued development of approaches for complex generic products and product specific discussions
- Updating the Post-Notice of Compliance (Quality) Guidance Document
- Review Planning Project, focus on:
 - More consistently establishing, adhering to review plans
 - Updating tools for more efficient submission tracking and management
 - More consistently communicating milestones to sponsors
- Developing, renewing and updating Guidance for Industry and internal SOPs

Key Business Improvements



Enhancements to Review Process

Ensuring activities are efficient, use resources optimally, meet client expectations

- Implementing a Quality Management System in TPD:
 - Phase 1: ANDS and SAP authorizations
 - Additional phases to follow
- Other Improvement projects under way:
 - Clinical trial application process
 - Pre-submission advice
 - ANDS review process
 - Executive Summary preparation
 - New reviewer orientation

Key Business Improvements



Increased International Alignment / Analyses

- International Council on Harmonization [ICH]
 - Q12 Technical and Regulatory Considerations for Pharmaceutical Lifecycle Management
 - E8 General Considerations on Clinical Trials
 - M13 Bioequivalence for Immediate-Release Solid Oral Dosage Forms
 - M10 Bioanalytical Method Validation
 - M9 Biopharmaceutics Classification System (BCS) Based Biowaivers
 - Quality Discussion Group and Generics Discussion Group
- International Work-Sharing/ Joint Reviews
 - Access Consortium
 - Project ORBIS
 - EMA Open
- Chairing the Nitrosamines International Strategic Group (NISG) and the Technical Working Group (NITWG)
 - Information sharing and alignment on expectations for control of nitrosamines

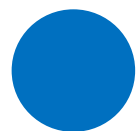
Key Business Improvements



Increased Transparency – Cost Recovery

- Updates at Bilateral Association Meetings
- Health Canada Annual Report on Fees to Parliament
- Annual Drug Submission Performance Reports
- Health Products Highlights Reports
- GC Infobase
- Departmental Results Report

Key Business Improvements



Strengthened Communications through IT enhancements

- Ongoing HFPB IP projects, including:
 - Electronic SAP system to enable clients to submit requests and review decisions electronically via mobile devices
 - XML standard for Product Monographs
- Continued facilitation of remote/ alternative models of work and collaboration with stakeholders

Q and A

Please use Sli.do to post questions



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Cost Recovery Stakeholder Meeting Biosimilars Breakout Session

February 24, 2022

Please use Sli.do to post questions



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Utilisation de Wordly

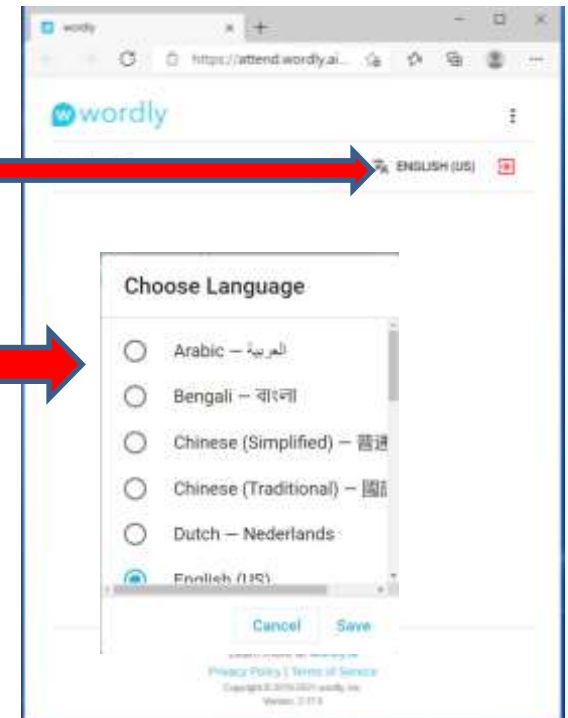
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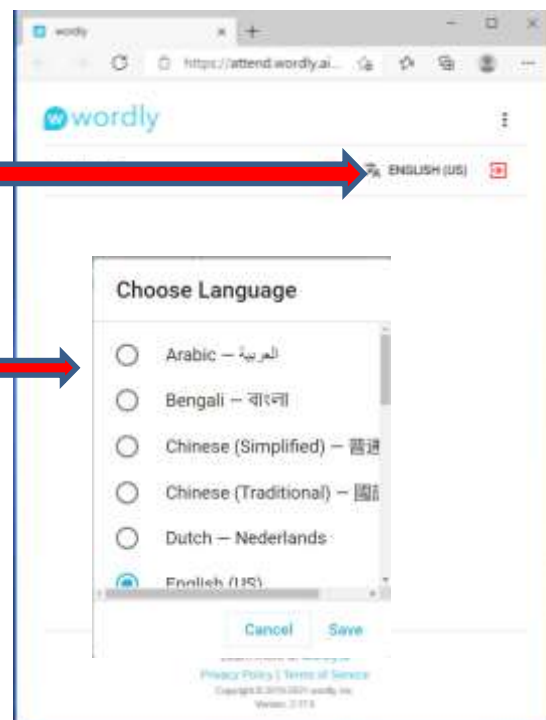
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Outline - Session 3 - Biosimilars

Brief overview of:

- Fall Fees & Performance Report 2020-21
- COVID-19 - Performance metrics
- Key Business Improvements
- Q & A

Fall Fees & Performance Report: 2020-21

Fees for Examination of a Cost-Recovered Submission – Drugs for Human Use

Submission Class	Performance Standard (# of Days)	BRDD Performance Results 2020-21	2020-21 Fee	2021-22 Fee
Clinical/Chemistry and manufacturing data	300**	100%	\$204,197	\$224,691
Clinical data only	300**	100%	\$90,864	\$95,987
Chemistry & Manufacturing	180**	100%	\$27,587	\$30,670
Safety Updates to Labelling	120	100%	\$19,442	\$19,442
Labelling Only	120	100%	\$3,816	\$4,328
Administrative Submission	45	100%	\$432	\$540

BRDD COVID-19 Performance Metrics

March 1, 2020 to February 24, 2022

284 COVID-19 AUTHORIZATIONS

8 IO
94 IO amendments

6 NDS
5 SNDS
14 NCs

53 CTAs Authorized
104 CTA-As Authorized

100% met targets

Business Improvements - Industry Feedback

What we heard as primary areas of interest from associations -
Innovators and Biologics:



-  Enhancements to review process
-  Increased international alignment
-  Increased alignment with health technology assessors
-  Increased transparency
-  Strengthened internal and external communication, IT systems
-  Improved internal review coordination and process



COVID-19 Related Business Improvements

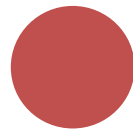


Enhancements to Review Process –

Introduced regulatory flexibilities in response to COVID-19 pandemic

- COVID-19 Response
 - COVID-19 HPFB Task Force
 - Expedited *Interim Orders (IOs) Respecting:*
 - *the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 (ISAD IO)*
 - *the Importation and Sale of Medical Devices for Use in Relation to COVID-19*
 - *Clinical Trials for Medical Devices and Drugs Relating to COVID-19*
 - *Drug Shortages (Safeguarding the Drug Supply)*
 - *Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19*
 - Transition of COVID drugs approved under ISAD IO (expired Sept 16, 2021) to approval under the amended *Food and Drug Regulations*

COVID-19 Related Business Improvements



Enhancements to Review Process –

Introduced regulatory flexibilities, taking lessons learned from the COVID-19

- Expedited clinical trials (14 day target) and prioritized market submission reviews for COVID-19, with no fees charged
 - Flexible submission requirements, rolling submissions and use of Terms and Conditions
 - Management of clinical trials during the COVID-19 pandemic: Notice to clinical trial sponsors
- Lessons learned to be taken forward under regulatory innovation, including
 - Terms and conditions
 - Mandatory risk management plans
 - Modernizing requirements for biologic drugs
 - Clinical trial framework renewal

Key Business Improvements



Enhancements to Review Process –

Introduced new measures under R2D2 and regulatory innovation

- Pause-the-Clock Policy – implemented April 1st, 2020
- Clarified Requirements for Real-World Evidence
- Advanced Therapeutic Products Pathway

Key Business Improvements



Enhancements to Review Process –

Improving predictability & transparency of the review process

- Biosimilars extension of indications
- Nitrosamines impurities in medications – Communications
 - Overview, Affected Medications List, Stakeholder Webinar and Test Methods
- Pediatric Drug Action Plan
 - Innovative strategy to increase access to safe and effective medicines for children in Canada
- SGBA+ Action Plan
 - To enhance considerations for the inclusion of diverse subpopulations in drug development and clinical trials

Key Business Improvements



Increased International alignment

Work-sharing arrangements / Collaboration

- International Work-Sharing / Joint Reviews
 - ACCESS Consortium-inviting expression of interest for work-sharing between regulatory authorities for the review of biosimilars
 - Project ORBIS
- International Pharmaceutical Regulators Programme (IPRP) Biosimilars WG
 - To enhance information sharing between international jurisdictions
 - US-FDA Chair & Membership from more than 30 international regulatory authorities
 - Primer on biosimilar-related regulatory topics for reviewers being finalized

Key Business Improvements



Increased International alignment /

Work-sharing arrangements / Collaboration

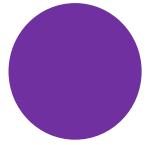
- WHO Guidelines on evaluation of Biosimilars
 - Health Canada collaborated on WHO biosimilar guidelines drafting group, participating on revisions to guidelines
 - *Guidelines on evaluation of similar biological products* (Consultation closed in January 2022)
 - Timeline for finalization of revised guidelines remains to be confirmed
- International Work Sharing / Joint Reviews
 - Q12 Technical and Regulatory Considerations for Pharmaceutical Lifecycle Management
 - E8 General Considerations on Clinical Trials
 - M10 Bioanalytical Method Validation

Key Business Improvements

Increased alignment with Health Technology Assessors (HTAs)

- CADTH – Canadian Agency for Drugs and Technologies in Health
 - Biosimilars no longer reviewed as of June 2019
 - Absence of CADTH Biosimilar review will not impact when pCPA negotiations initiated
 - pCPA has simplified their process that allows jurisdictions to cover biosimilars instead of the reference biologic without the CADTH Review
- INESSS – Institut national d'excellence en santé et en services sociaux
 - Listing and coverage of biosimilars by the Québec public drug plan will continue to be contingent on the INESSS recommendation

Key Business Improvements



Increased Transparency

- Health Canada cost-related communications
 - Annual Drug Submission Performance Reports
 - Drug and Medical Device Highlights Reports
 - GC Infobase
 - Bilateral Association Meetings (upon request for updates)
- Biosimilars Stakeholder Education Plan
 - Raise awareness on the regulatory market authorization process for Biosimilar products in Canada
 - [Consultation: Handbook for healthcare professionals on biosimilar biologic drugs - Canada.ca](#) (Consultation closes on April 17, 2022)
 - Infographic for patients

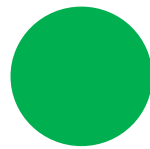
Key Business Improvements



Increased Transparency

- Massive Open Online Course [MOOC] for HCPs and patients/caregivers
 - Being developed by Ontario Health & University of Toronto (Leslie Dan Faculty of Pharmacy)
 - Curriculum-based, accredited, online educational module
 - One module targets patients/caregivers while other targets healthcare professionals
 - Health Canada providing input on the regulatory approval process for biosimilars for both modules
 - Further details available at [Foundations in Biosimilars and Biologics \(edX\) | MOOC List \(mooc-list.com\)](#)

Key Business Improvements



Strengthened internal and external communications through IT enhancements

- Streamlined Communications
 - MS Teams (M365) Project Management features
- Continued facilitation of 'remote' / 'alternative' models of work
- Government of Canada Science Network
 - A high-speed optical-fiber network
 - Direct method-transfer from research labs to lot-release labs
 - Lot-release, testing and quality assessment
- BRDD Laboratories Electronic Transition
 - Transition to fully electronic records
 - LIMS software environment

Key Business Improvements



Improved internal review coordination and process

- Risk-Based Consistency Testing Determination Tool
 - Submission prioritization
 - Guide on analytical methods to ensure consistency in application
- Streamlining Review and Operations Practices
- Development of useful tools and templates
 - QMS Audits
- Lot Release Testing
 - Internal audit & evaluation to enhance efficiencies in quality processes

Key Business Improvements

Improved internal review coordination and process

- Project Management
 - Communicate early on pre-established milestones for submission review
 - Pre-submission meetings
 - Advanced Feedback Template (Implemented on Mar 17, 2020)
- BRDD Research Labs
 - Support decision-making and solve regulatory issues at both national and international levels
 - Scientific research/ Knowledge transfer/ Technical expertise
 - Develop regulatory tools
 - Collaborative studies (WHO, NIBSC, EDQM)
 - Protein NMR Research
 - Glycobiology Research

Thank You!

Questions?

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