Health Canada Santé Canada

Canada

COVID-19 Response:

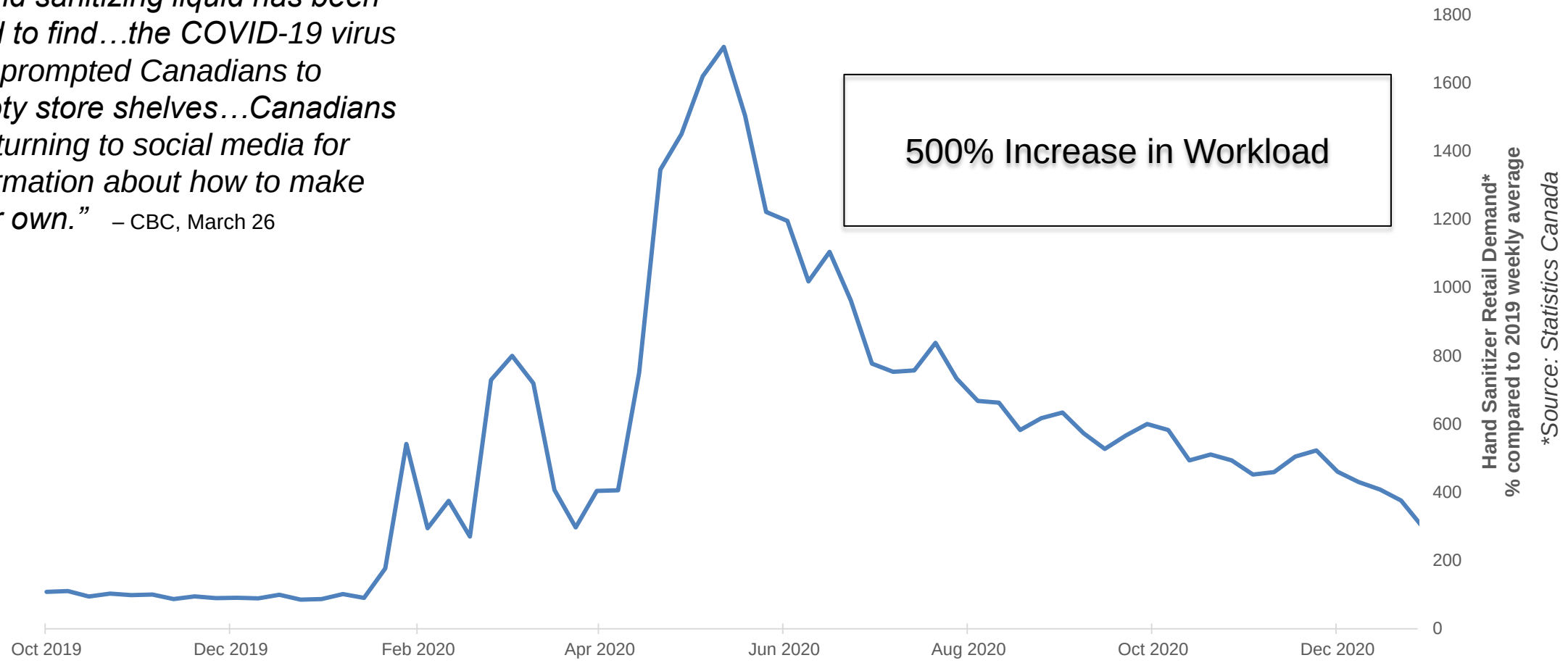
Natural and Non-prescription Health Products Directorate (NNHPD)

March 10, 2021

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Unprecedented consumer demand for hand sanitizers

"Hand sanitizing liquid has been hard to find…the COVID-19 virus has prompted Canadians to empty store shelves…Canadians are turning to social media for information about how to make their own." – CBC, March 26

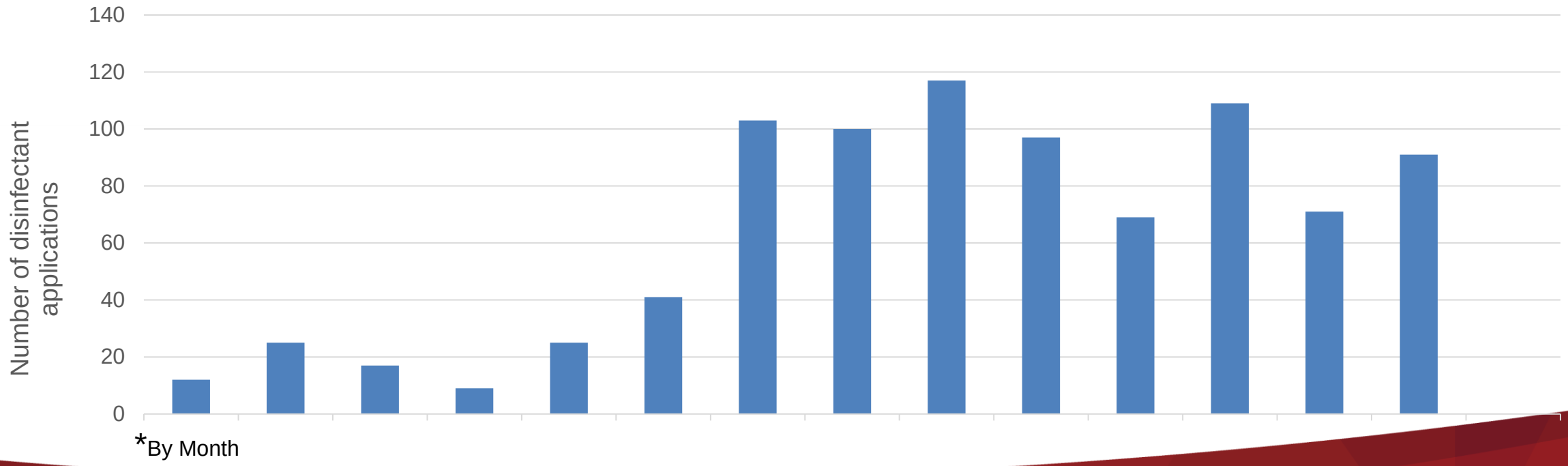


Unprecedented demand for Disinfectants

- According to industry, the increased volume of applications is expected to continue for the next 3 years

Since April, the number of total disinfectant applications is 500% higher than the pre-COVID average

Demand for disinfectant wipes estimated at approximately 1.2 billion wipes per month in Canada over the next year.



NNHPD's response to increased demand for disinfectants and hand sanitizers

Flexible Approaches

- 30+ interim measures introduced over 30 days, a response noted as exceptional by the OAG
- Expedited licensing put in place: 24-hour for hand sanitizers (vs. 60 days); 15-52 days for disinfectants (vs. 135-255 days)
- Exceptional temporary importation pathways implemented to increase supply
- 24/7 shift work put in place to respond to demand
- Streamlined systems and processes for faster service standards
- OAG audit concluded that COVID-19 response for hand sanitizers was sound

Partnerships

- New partnerships model (e.g., facilitator for Hand Sanitizer Manufacturing Exchange**)**
- Coordination across public service (e.g., ISED, NRC, CRA, PSPC, AAFC, etc.)
- Heightened collaboration with PTs, Poison Control Centres and international regulatory counterparts

Focus on Communications

- 25,000+ inquiries since March + daily web updates
- 8 of Health Canada's 10 most visited web pages from Mar-Sept relate to hand sanitizers and disinfectants
- 12+ guidance documents developed, consulted on and published

New Challenges Faced

Finances

- $893K spent on overtime to date
- 2000 hours of overtime banked to date
- One of the highest in Health Canada

Internal Pressure with Workload

- Challenges meeting service standards for product and site applications
  - Difficulty meeting cost recovery timelines
  - Accrued a NHP Class III backlog
  - 2000 temporary site licences will need to be revisited
  - Site license renewals delayed
- Major regulatory proposals delayed as staff re-allocated to COVID-19 work
  - NHP labelling; simplified market access for OTCs, Biocides framework

People

- Hired 37 term FTEs
- 49 FTEs were lent from other branches or departments

External Pressures from Stakeholders

- Inexperienced players
- Insufficient supply of ingredients and materials led to:
  - Non-traditional packaging (water bottles, pouches)
  - Non-traditional ingredients (technical-grade ethanol)
- Post-market oversight: 1,200+ product complaints, 123 recalls, and 49 cases of false/misleading advertising

Returning to Priorities

- Many priorities were affected by the COVID-19 pandemic as the response required a significant investment, which included:
  - Our policy team was converted to COVID-19 response
  - Operational experts were dedicated to TGE analysis/task force
  - 24 hour, 7 day a week licensing
    - Expedited service standards
  - Profiled non-COVID reviewers to support hand sanitizer and disinfectant reviews

- Moving into October/November 2020, resources began to transition back (gradually) to other priorities

- What are those priorities?
  - Backlog
  - Systems
  - Biocides Regulatory Changes
  - Improved Labelling for NHPs
  - Maintaining COVID-19 response
    - Reversion to normal service standards

Backlog

- For non-prescription drugs, we **continued to meet all service standards related to cost recovery** while expediting review timelines for disinfectants
  - This included 6 fold investment in the disinfectants team to meet service standards

- For NHPs, backlogs were an impact of the response
  - Class I and II backlogs have already been eliminated
  - Class III backlog is in the process of being addressed

Systems

- Planned **systems modernizations continued** to be implemented through response, including:
  - Successful roll-out of new automated product licence application web forms in June 2020
  - Completed phase out of paper applications – application process now fully electronic
  - Introduced a web-based site licence application system in Nov 2020 (replacing the former paper-based system)

Biocides Regulatory Structure

- NNHPD is working to establish a new regulatory structure for biocides.
- This structure will be separate from the requirements for other drugs
- The requirements will be standalone and not a part of Part C of the FDR
- The key features will include:
  - Standalone structure transferring soft-surface sanitizers from PCPA
  - Requirements that are tailored to biocides
  - A section related to the Use of Foreign Decisions (UFD)
- Timing is still being determined for a publication in CG I
  - Stakeholders will be engaged throughout the development

Improved Labelling for NHPs

- The need for improved NHP labelling was further emphasized during the pandemic
- NNHPD reinitiated consultation on the proposal in winter 2020/21
  - Focus was on homeopathic labelling
- Following the publication of the Forward Regulatory Plan, the regulatory proposal will be published in CGI this Spring, 2021
- Additional consultations on guidance will be held this April, 2021

Continued Response

- From a policy perspective, there are still significant challenges faced to support the response

- This includes, but is not limited to:
  - Decisions on TGE use
  - Interim orders (IO) for COVID response (e.g., exceptional importation IO)
  - Site license renewals
    - Compounded by the number of temporary COVID-19 site license
  - Applications for disinfectants continue to be higher than historic precedence
  - Innovative products

- Investment will be needed for the next couple of years to maintain support

THANK-YOU