LC AC
Long COVID Action
CANADA
Patient-led. Evidence-informed. Focused on action.

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2 November 2026

The Honourable Marjorie Michel, P.C., M.P.
Minister of Health, Government of Canada
House of Commons, Ottawa, ON K1A 0A6

CC: Parliamentary Secretary to the Minister of Health; Standing Committee on Health (HESA); and Health Canada Special Access Program (SAP) [4].

Re: Federal action on Canadian access pathways, Special Access Program policies, and clinical trial support for ensitrelvir (Xocova / Zokovea) and Long COVID therapeutics

Dear Minister Michel,

I am writing as a constituent living in Hamilton, Ontario who has lived with Long COVID since early 2020—for more than six years—and as the founder of Long COVID Action Canada (LCAC), an emerging patient-led initiative advocating for evidence-informed federal action on Long COVID research, care, and support.

> Our immediate request is for Health Canada to clarify three specific federal responsibilities regarding oral SARS-CoV-2 antivirals—specifically ensitrelvir fumaric acid (Xocova / Zokovea): **(1) how Health Canada is engaging with international manufacturers to encourage Canadian regulatory filings for post-exposure prophylaxis and acute treatment, (2) the policy governing Health Canada's Special Access Program (SAP) when manufacturer supply is discretionary, and (3) how federal research investments (CIHR) are supporting Canadian clinical trials investigating novel antivirals in established Long COVID?**

This inquiry parallels LCAC's formal inquiries sent directly to Shionogi Canada Inc. and Shionogi & Co., Ltd. Global Headquarters in Osaka [2, 10]. Millions of Canadians remain impacted by long-term COVID-19 symptoms, and households containing immunocompromised individuals face persistent vulnerability. We seek transparent federal leadership on the regulatory and clinical research pathways that determine Canadian access to emerging medical countermeasures.

CANADIAN REGULATORY STATUS AND ACCESS GAPS

Ensitrelvir is a selective oral inhibitor of the SARS-CoV-2 3CL main protease developed by Hokkaido University and Shionogi [2]. In May 2026, the *New England Journal of Medicine* published results from the Phase 3 SCORPIO-PEP trial demonstrating that a five-day course of ensitrelvir initiated within 72 hours of household exposure reduced the risk of symptomatic COVID-19 by 67% compared with placebo (2.9% vs. 9.0%) [6]. Ensitrelvir subsequently received regulatory approval for post-exposure prophylaxis (PEP) in Japan (March 2026), the United States (as Xocova, June 2026), and the European Union (as Zokovea, September 2026), alongside Japan's full approval for acute infection treatment [2, 7].

Despite these approvals among our closest regulatory peers, ensitrelvir remains unavailable in Canada. As of 30 September 2026, Health Canada's public lists of New Drug Submissions Under Review (SUR) and Completed Submissions do not include ensitrelvir [3]. Canadians at elevated risk of severe outcomes or infection transmission currently have no approved oral post-exposure prophylaxis option, and patients unable to tolerate ritonavir-boosted nirmatrelvir (Paxlovid) due to severe drug-drug interactions have limited oral acute antiviral alternatives [9].

In the absence of commercial market authorization, Canadian practitioners occasionally turn to Health Canada's Special Access Program (SAP) for patients with serious or life-threatening conditions [4]. However, Health Canada authorization does not obligate a pharmaceutical manufacturer to supply the medication. In the case of ensitrelvir, Shionogi Canada Inc.'s published policy explicitly states that supply is not guaranteed pursuant to an SAP

authorization, citing factors such as inventory allocation [4]. Health Canada must clarify what guidance and support it provides to Canadian physicians navigating SAP for non-marketed antivirals.

CLINICAL RESEARCH INTO ESTABLISHED LONG COVID

LCAC maintains a rigorous distinction between acute prevention and evidence of therapeutic efficacy in established Long COVID. Trials of post-exposure prophylaxis (SCORPIO-PEP) and acute illness (SCORPIO-SR / SCORPIO-HR) do not evaluate patients who have remained sick for months or years [5, 6, 7]. The only registered clinical trial of ensitrelvir in established Long COVID to date—the UCSF PREVAIL-LC pilot study (NCT06161688)—enrolled only 40 participants for a five-day course and posted summary outcome estimates in April 2026 without statistical group comparisons [5]. A small pilot cannot establish whether treatment works.

Furthermore, following the publication of RECOVER-VITAL (NCT05595369)—which found no evidence of benefit from 15- or 25-day Paxlovid regimens across three Long COVID phenotypes—the scientific community recognizes that future trials must evaluate distinct biological hypotheses, such as tissue-based viral persistence, unboosted protease inhibitors, extended durations, or combination antiviral approaches [8, 9]. Shionogi & Co., Ltd. currently lists ensitrelvir as an active area of interest on its global Investigator-Initiated Research (IIR) portal, inviting external investigator proposals for study drug and funding [11]. Canada has world-class post-viral researchers, yet federal mechanisms to support Canadian clinical trialists in launching patient-partnered, multi-centre antiviral studies remain severely limited.

FOUR QUESTIONS FOR THE MINISTER OF HEALTH & HEALTH CANADA

1. **Encouraging Canadian Regulatory Filings:** Is Health Canada actively communicating with Shionogi Canada Inc. or its global parent to encourage New Drug Submissions for ensitrelvir for post-exposure prophylaxis and acute treatment, and what regulatory incentives exist to prevent Canadian review delays [2, 3]?
2. **Special Access Program (SAP) Clarity:** What criteria and operational guidance does Health Canada provide to Canadian physicians seeking emergency access to unapproved SARS-CoV-2 antivirals through SAP when usual therapies are contraindicated, and how does Health Canada coordinate with manufacturers to facilitate supply [4]?
3. **Federal Research Priorities for Long COVID Therapeutics:** How is Health Canada, through the Canadian Institutes of Health Research (CIHR) or the Office of the Chief Science Advisor, supporting clinical trials that evaluate antiviral and pharmacological interventions in Canadians with established Long COVID [5, 9]?
4. **Patient-Partnered Research & Meaningful Endpoints:** Will the federal government ensure that future publicly funded Long COVID clinical trials meaningfully involve patients with lived experience in trial design, safety monitoring, and outcomes that measure functional capacity and daily life rather than solely acute viral clearance [5]?

NEXT STEPS

Following the government's response to House of Commons petition e-7076, Canadians living with Long COVID need concrete commitments and transparent information. We look forward to receiving Health Canada's written response to these questions within 60 days, which will be published as part of LCAC's public campaign records.

Thank you for your dedication to protecting the health and wellbeing of all Canadians.

Sincerely,



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REFERENCES

1. Recipient & Federal Portfolio
Office of the Minister of Health, Health Canada, Government of Canada directory and parliamentary profile.
https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/minister-health.html

2. U.S., EU & Japan Regulatory Approvals for Ensitrelvir
FDA approval of Xocova for PEP (1 June 2026), EMA marketing authorization of Zokovea for PEP (18 September 2026), and Japan MHLW standard approvals for acute treatment and post-exposure prophylaxis.
https://www.shionogi.com/global/en/news/2026/06/20260601.html
https://www.ema.europa.eu/en/medicines/human/EPAR/zokovea

3. Canadian Regulatory Submissions Under Review
Health Canada Drug and Health Product Submissions Under Review (SUR): New drug submissions under review, current to 30 September 2026.
https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/submissions-under-review/new-drug-submissions-under-review.html

4. Health Canada Special Access Program & Manufacturer Supply
Health Canada guidance on the Special Access Program (SAP) for drugs and Shionogi Canada Inc.'s Clinical Trials and Special Access policy.
https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/drugs.html
https://www.shionogi.com/ca/en/innovation/science/clinical-trials-and-special-access.html

5. Established Long COVID Ensitrelvir Trial (PREVAIL-LC)
UCSF PREVAIL-LC pilot study registration and summary results (NCT06161688): 40 participants evaluated on 5-day ensitrelvir vs. placebo; active, not recruiting.
https://clinicaltrials.ucsf.edu/trial/NCT06161688
https://clinicaltrials.gov/study/NCT06161688

6. Phase 3 Post-Exposure Prophylaxis (SCORPIO-PEP)
Hayden FG, Shinkai M, et al. N Engl J Med. 2026;394(19):1905-1915: 67% reduction in symptomatic infection through Day 10 following household contact.
https://pubmed.ncbi.nlm.nih.gov/42127390/
https://www.shionogi.com/global/en/news/2026/05/20260514.html

7. Acute Outpatient Trials (SCORPIO-SR, SCORPIO-HR & ACTIV-2d)
Clinical virology and symptom resolution outcomes in mild-to-moderate COVID-19 outpatients.
https://actgnetwork.org/publications/in-activ-2d-a5407-ensitrelvir-reduces-nasopharyngeal-sars-cov-2-levels-but-does-not-shorten-time-to-symptom-resolution-in-outpatients-with-covid-19/

8. Post-Acute Sequelae Prevention (RESILIENCE Protocol)
Trial design studying the impact of early acute antiviral treatment on subsequent Post-COVID-19 Condition incidence.
https://longcovidaction.ca/ensitrelvir

9. RECOVER-VITAL Trial Benchmark & Paxlovid Comparison
Published results (31 August 2026, NCT05595369) evaluating 15- and 25-day nirmatrelvir-ritonavir in Long COVID, and comparison with unboosted 3CL protease inhibition.
https://pubmed.ncbi.nlm.nih.gov/42673984/
https://clinicaltrials.gov/study/NCT05595369

10. Parallel Manufacturer Inquiry & 11. Shionogi Investigator-Initiated Research (IIR)
LCAC Ensitrelvir Campaign records, Shionogi Canada Inc., and Shionogi & Co., Ltd. Global IIR Portal listing Ensitrelvir fumarate.
https://longcovidaction.ca/ensitrelvir
https://www.shionogi.com/global/en/innovation/randd/iir.html