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October 29, 2021

Re: **PrCLOZARIL® (clozapine) – COVID-19, updated Health Canada Guidance**

Dear Health Care Professionals:

Health Canada has requested that HLS Therapeutics Inc, notify Health Care Professionals of the following:

Since March 2020 the Canadian health care system has been managing various aspects related to the COVID-19 pandemic. These actions and related protective measures had a potential impact on the treatment of patients receiving PrCLOZARIL® (clozapine).

In response, Health Canada has issued guidance related to hematological monitoring for patients that are treated with CLOZARIL®. The previous guidance was issued July 8, 2021.

On September 29, 2021, Health Canada has confirmed their previous guidance:

Health Canada recognizes that challenges may still exist that hinder access to testing for some patients. As previously communicated, Health Canada recommends that, if possible, patients continue to have white blood cell (WBC) counts and absolute neutrophil counts (ANC)<sup>1</sup> testing as per their regular schedule for hematological monitoring. Health Care Providers should continue to use their best clinical judgment in weighing the benefits and risks of continuing treatment in the absence of hematological testing. Health Care Providers should also communicate with their patients regarding these judgments, including the associated risks.

Health Canada's assessment of the current situation is supportive of extending the current recommendations by an additional 12 months (i.e. until September 30, 2022). However, this recommendation is subject to change. Hematological testing requirements will continue to be reassessed by Health Canada as the COVID-19 pandemic evolves. It is anticipated that hematological testing requirements will eventually return to their usual status. You will be updated regarding any future changes to the requirements.

Health Canada provided further guidance to CSAN® to obtain additional data from Healthcare Professionals as per the following:

**Missing or delayed laboratory test:**

- The reason should continue to be properly documented and reported to Health Canada. Details should be provided regarding the process by which patient status changed to "missing or delayed test".
- If provided, Health Canada requests that any details on patient COVID-19 infection status at the time of hematological events also be reported.

The CSAN® program is pleased to advise that; in spite of the COVID-19 Pandemic, the majority of patients receiving CLOZARIL® are in compliance with their routine defined testing. The CSAN® Program has reported

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<sup>1</sup> The product monograph for Clozaril® was revised May 31, 2021, Eliminates the requirement for total WBC monitoring for the evaluation of clozapine-induced neutropenia, only ANC will be evaluated.

to Health Canada that the compliance measured week-over-week has been  $\geq 91\%$  each week since January 2020.

The CSAN® program is proud to be part of your health care team for over 30 years, and we continue to be here to support you. Should you need assistance, please contact your local CSAN® Nurse Educator, as noted below, or the CSAN® program (800) 267-2726.

Region	Nurse Educator	Phone Number
Ontario West	Christopher Komel	(416) 779-7158
Ontario East	Sue Swaine	(613) 720-1131
Ontario Ottawa	Sarah Marchand-Lacoursière	(514) 229-5776
Quebec West	Marie-France Sabourin	(514) 951-4703
Quebec East	Sophie Ferland	(418) 563-7938
Atlantic Region	Sophie Ferland	(418) 563-7938
West Coast	Moriah Tate	(780) 281-1332

Please note; the CSAN® Program is now using the **CSAN® Pronto®**, a point of care capillary testing program, to help simplify access to routine ANC monitoring for CLOZARIL® patients. For more information, please contact CSAN®.

The CSAN® Team along with all of HLS Therapeutics we would like to commend all Health Care Professionals for their dedicated efforts during this historical period.

Sincerely,



Jason A. Gross, Pharm.D.  
 Vice President, Scientific Affairs  
 HLS Therapeutics Inc.  
[www.hlstherapeutics.com](http://www.hlstherapeutics.com)

In accordance with the Therapeutic Products Directorate and the CLOZARIL® Product Monograph, CLOZARIL® is available only through a distribution system that ensures maintenance of a CLOZARIL®-specific national database. The switching of a patient from one brand of clozapine to another must not be done by a pharmacist unless he/she obtains a new, registry-specific patient registration form filled out by the prescribing physician.<sup>2</sup> For more information the product monograph may be accessed at [www.Clozaril.ca](http://www.Clozaril.ca).