CSAN® Clozaril Support and Assistance Network
Phone (800) 267-2726 **Fax** (800) 465-1312
CSAN@HLStherapeutics.com

March 23, 2020

As the COVID-19 virus is pressure testing the Canadian health care systems, we are encountering a growing number of situations where patients receiving PrCLOZARIL® (clozapine) are unable to get safely tested in a timely fashion for their white blood cell (WBC) counts and absolute neutrophil counts (ANC). This test is mandatory for them to be eligible for the renewal of their CLOZARIL® prescription, a required treatment, without which a patient's risk of relapse is almost certain.

We have had discussions with Health Canada, and they recognize that there are situations where patients receiving CLOZARIL® cannot be tested for their blood count within the required time. Here are their recommendations.

Health Canada has advised health care providers prescribing and/or dispensing CLOZARIL® to assess whether there are sufficient reasons for not performing these blood tests during this crisis, and use their clinical judgment to assess the benefits and risks of continuing treatment in the absence of laboratory testing. Health care providers should also share with their patients and explain the risks associated with it.

The risk of clozapine-induced agranulocytosis is approximately 0.7%, with approximately 88% of cases occurring during the first six months of treatment. This is a limited measure, only to assure continuity of care. The risk of undetected agranulocytosis could increase, and this also requires health care providers to inform their patients of the risks.

This change in requirement for blood testing will be reassessed in three months or sooner. It is expected that once the COVID-19 related pressures are over, the required blood testing requirements will go back to what they were prior to this situation.

Health Canada also noted that if there is a missing or delayed laboratory test, the reason should be properly documented, and further asked CSAN® to report compliance trends to it on a biweekly basis. Our CSAN® team will be taking an active process in helping identify and conduct reporting to Health Canada.

Please be aware that patients receiving CLOZARIL® who present with fever and other symptoms of infection should have WBC and ANC testing, so that clozapine-induced agranulocytosis can be ruled out. It is important to note that neutropenia can occur from viral diseases, developing during the first 1 to 2 days of illness and may persist for 3 to 8 days. Transient neutropenia may also result from virus- or endotoxemia-induced redistribution of neutrophils from the circulating to the marginal pool and would not be a reason to discontinue CLOZARIL® (clozapine).

The CSAN® team will help in monitoring for missing or late WBC/ANC testing, and will advise health care providers. We will also be available to assist in assuring continuity of supply for patients.

For more information the product monograph may be accessed at www.Clozaril.ca. CSAN® has been supporting the safe and effective use of CLOZARIL® for nearly 30 years, and we continue to be here to support you.

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Should you need assistance please contact your local CSAN® Nurse Educator, as noted below, or the CSAN® program at (800) 267-2726.

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

Sincerely,

Jason A. Gross, Pharm.D.
Vice President, Scientific Affairs
HLS Therapeutics Inc.
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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.[1]

Reference: Health Canada. Press release, monitoring of patients taking clozapine. http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/ hc-sc/2004/14249a-eng.php, accessed November 27, 2017