Health Canada Santé Canada

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March 26, 2020

20-104505-417

Dear Perry Esler
Executive Director, Jesse's Journey;
Barbara Stead-Coyle
Chief Executive Officer, Muscular Dystrophy Canada;
Marie-Catherine Du Berger
President & Co-founder, La Force DMD; and
Edward Worsfold
Co-founder and Chair, Stand for Duchenne Canada

Thank you for your correspondence of February 28, 2020 regarding access to deflazacort for Duchenne Muscular Dystrophy (Duchenne). I appreciate this opportunity to provide clarification and information to you on the options that may be available for access to treatments in Canada.

Health Canada recognizes the importance of patients having access to therapies that may help treat, or in some cases cure, their serious or life-threatening conditions. In some circumstances, non-marketed drugs, such as deflazacort, may be requested via the Special Access Program (SAP). All requests must be initiated by a practitioner and considered on a case-by-case basis. The SAP considers requests from health care practitioners as they would be the ones responsible for the treatment decisions for their patients. Moreover, practitioners have the role and responsibility for clearly explaining the harms and benefits of the drug to their patients, and for monitoring and reporting the results, including any adverse reactions, to the SAP.

The decision to seek market authorization of a drug is at the discretion of the manufacturer. Although Health Canada would welcome and encourage manufacturers to bring their treatments to Canada to benefit the health and safety of all Canadians, Health Canada cannot compel a manufacturer to supply or market a drug in Canada.

Health Canada also cannot compel the manufacturer of an unauthorised drug, such as deflazacort, to have their drug available on any continuous basis. Health Canada is very aware and concerned that manufacturers may experience drug-shortages of an unauthorized drug that may affect Canadians. Although there are some options to

mitigate and resolve drug-shortages of products that are on the Canadian market, those same mechanisms are not always applicable for the prevention or mitigation of drug-shortages for non-marketed products, such as deflazacort. After considering the totality of the data available to us regarding repeated shortages of deflazacort over the past, we have concluded that pre-positioning will not solve disruption of drug supply.

Health Canada continues to encourage manufacturers to bring their products to market and submit a new drug submission that may benefit and ensure a more predictable supply of the therapy for Canadians.

I would like to thank you for taking the time to write to us, and I hope that this information is helpful.

Sincerely,

Carole Légaré, MD
Director, Office of Clinical Trials
Therapeutic Products Directorate