Table of Contents

Health Canada
Santé Canada

Health Products and Food Branch
Direction générale des produits de santé et des aliments

Biologic and Radiopharmaceutical Drugs Directorate
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March 29, 2021

Dossier ID: HC6-024-E248651
Control #: 250728

INTERIM ORDER AUTHORIZATION AMENDMENT– TERMS AND CONDITIONS

Health Canada is aware of the increasing number of reports of rare thrombotic events with thrombocytopenia that have been reported following immunization with the COVISHIELD (ChAdOx1-S [recombinant]). Health Canada is also aware of a proposed mechanism of action, which provides support for biological plausibility of an association between the vaccine and these events. As a result, Health Canada is considering whether additional action is required related to the recommended uses of the vaccine to mitigate these risks. To determine whether additional risk mitigation measures are needed, Health Canada is requesting that Verity Pharmaceuticals Inc. provide additional information to support the ongoing use of COVISHIELD (ChAdOx1-S [recombinant]) as is currently indicated in Canada.

In accordance with section 10 of the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to Covid-19*, the following Terms and Conditions are imposed on the authorization issued in respect of COVISHIELD (ChAdOx1-S [recombinant]):

RISK MANAGEMENT PLAN:

1. Verity Pharmaceuticals Inc. will provide by April 5, 2021, an assessment of the benefits and the risks, stratified by sex and age, for the use of the COVID-19 vaccine in the current Canadian context, taking into consideration disease projections and the epidemiology of circulating variants, and post-market reports of rare thrombotic events, including those associated with thrombocytopenia.

2. Verity Pharmaceuticals Inc. will provide an analysis, by March 31, 2021, of the proposed or alternate mechanisms of development of thrombotic events with thrombocytopenia considering available case reports and data.

3. Verity Pharmaceuticals Inc. will propose additional pharmacovigilance activities, including in the Canadian context, for those individuals who receive(d) the vaccine, to be submitted by March 31, 2021.

4. Verity Pharmaceuticals Inc. will provide an assessment of the need for and propose any additional risk minimization measures that could be applied in the Canadian context, to be submitted by March 31, 2021.

The information above is to be reflected in the revised Risk Management Plan, requested on March 26, 2021, for submission by April 8, 2021. Health Canada wishes to remind Verity Pharmaceuticals Inc. of the requirement to notify Health Canada without delay of any international regulatory actions taken in relation to this or any other issue, as per Section C.01.050 of the Food and Drug Regulations.

Canada

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April 6, 2021

Dossier ID: HC6-024-E248651
Control #: 250728

INTERIM ORDER AUTHORIZATION AMENDMENT– TERMS AND CONDITIONS

Further to the request received April 5, 2021 and the follow up correspondence, Health Canada is amending the Terms and Conditions issued March 29, 2021. This amendment provides an extension for Verity Pharmaceuticals Inc. to provide a complete response to Term #1 issued March 29, 2021 no later than April 7, 2021, taking into account the global updates to COVISHIELD (ChAdOx1-S [recombinant]).

In accordance with section 10 of the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to Covid-19*, the following Terms and Conditions are imposed on the authorization issued in respect of COVISHIELD (ChAdOx1-S [recombinant]):

RISK MANAGEMENT PLAN:

1. Verity Pharmaceuticals Inc. will provide by April 7, 2021, an assessment of the benefits and the risks, stratified by sex and age, for the use of the COVID-19 vaccine in the current Canadian context, taking into consideration disease projections and the epidemiology of circulating variants, and post-market reports of rare thrombotic events, including those associated with thrombocytopenia.

Health Canada wishes to remind Verity Pharmaceuticals Inc. of the requirement to notify Health Canada without delay of any international regulatory actions taken in relation to this or any other issue, as per Section C.01.050 of the Food and Drug Regulations.

Canada