Health Canada / Santé Canada

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

INTERIM ORDER– TERMS AND CONDITIONS
Company: Hoffmann-La Roche Limited
Product: casirivimab and imdevimab
Dossier ID: HC6-024-E246889

Background:

The Interim Order allows the Minister to impose or amend terms and conditions, and request additional information, in relation to a COVID-19 drug submission, authorization, or establishment licence, at any time while it is in effect. In light of the severity of the COVID-19 pandemic, this allows the Minister to act quickly to gather important safety information or mitigate risk in a timely manner.

Depending on the requirement, terms and conditions can be ongoing (e.g., require a monthly report), have a defined time (e.g., a report is due to Health Canada on a specific day) or are to be completed once the data is available (e.g., a clinical trial is completed).

The status of the Terms and Conditions will be updated on a regular basis.

Status as of June 9, 2021:

Total Number: *9*

Ongoing/pending: *9*

Closed: *0*

Table: Terms and Conditions

	Terms and Conditions	**Issued**	**Status**
1	Provide a complete reporting of the clinical study with protocol number R10933-10987-COV-2067, titled: *A master protocol assessing the safety, tolerability, and efficacy of anti-spike (S) SARS-CoV-2 monoclonal antibodies for the treatment of ambulatory patients with COVID-19.* The complete report(s) should provide the final analyses of efficacy and safety from all phases and cohorts including, but not limited to, patients at high-risk of hospitalization or death, pediatric patients, and pregnant women. The submission of this information should include complete Clinical Study Reports and associated documentation in accordance with the relevant ICH guidelines (e.g., ICH E3, ICH M4).	June 9, 2021	Pending availability of data

	Terms and Conditions	Issued	Status
2	Provide regular updates to Health Canada regarding the activity and/or clinical efficacy/effectiveness of casirivimab and imdevimab against the current and future Variants of Concern and Variants of Interest identified by the World Health Organization (WHO). The WHO lists Variants of Concern and Variants of Interest in its weekly epidemiological update on COVID-19, which can be accessed on its website: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports.	June 9, 2021	Pending availability of data
3	Provide updates on global regulatory strategies, including anticipated timelines, for conditional and full marketing authorization applications at least twice per year.	June 9, 2021	Ongoing
4	Notify the Biologic and Radiopharmaceutical Drugs Directorate (BRDD) of any out-of-specification or out-of-trend results during long-term stability testing studies.	June 9, 2021	Ongoing
5	Submit an EU/Core Risk Management Plan and the Canadian RMP no later than July 31, 2021. The RMP format should follow the guidance (Guidance Document Submission of Risk Management Plans and Follow-Up Commitments) and should include the following in the context of the COVID-19 drugs submitted for authorization under the IO: a. A safety specification that details the identified risks, potential risks, and missing information for the product, with a focus on risks in COVID-19 patients. b. A pharmacovigilance plan that details specific measures to be taken to identify and report safety issues in COVID-19 patients, including adverse reaction reporting, periodic reporting, and ongoing/planned studies. c. A risk minimization plan, if applicable, to manage risks that may require additional measures beyond those considered standard (for instance, labelling).	June 9, 2021	Expected July 31, 2021
6	After authorization and commencing July 1 2021, Hoffmann-La Roche Limited is required to submit monthly safety reports for the period of the IO authorization, unless otherwise determined by Health Canada.	June 9, 2021	Ongoing
7	Hoffmann-La Roche Limited to submit final snapshots of all components of the electronic platform (linked to on the foreign and Canadian specific labels), containing Canadian-specific labelling information for casirivimab and imdevimab in French and English for Health Canada's review and records, prior to launch of the electronic platform and for each subsequent update.	June 9, 2021	Pending
8	Hoffmann-La Roche Limited to develop and distribute a Health Product Risk Communication (HPRC), in French and English, with Health Canada approval and endorsement, to inform healthcare professionals about the authorization of the casirivimab and imdevimab under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19* with global labels for the initial supply, to expedite access of the drug in the context of the pandemic.	June 9, 2021	Pending

	Terms and Conditions	Issued	Status
	a. The letter should direct healthcare professionals to the electronic platform where they can find information about Canadian-specific labelling in both official languages and should be issued prior to and alongside the distribution of the casirivimab and imdevimab until such a time that Canadian specific labelling is implemented. b. The letter should include an alternative method for the health care professionals to obtain a paper copy of the Product Monograph by mail or fax from Hoffmann-La Roche Limited, if they cannot access the internet.		
9	Hoffmann-La Roche Limited to implement Canadian-specific bilingual labelling for casirivimab and imdevimab once supplies are transitioned to Canadian dedicated supplies. Health Canada should be kept informed of estimated timelines and proposed strategies concerning the implementation of Canadian-specific bilingual labels. a. During the period prior to implementation of the Canadian-specific bilingual labeling, approved mock-ups of the proposed Canadian labels should be made available to healthcare professionals as reference.	June 9, 2021	Pending