Health Canada | Santé Canada

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

TERMS AND CONDITIONS

Company: Moderna Biopharma Canada Corporation

Product: Spikevax XBB.1.5 (andusomeran)

Dossier ID: HC6-024-E275936

Background:

The Food and Drug Regulations allows the Minister to impose or amend terms and conditions, and request additional information, in relation to a COVID-19 drug submission, Drug Identification Number (DIN), 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 September 12, 2023:

Total Number: 9

Ongoing: 9

Closed: N/A

Table: Terms and Conditions

	Terms and Conditions	Issued	Status
1	Pertaining to Study mRNA-1273-P205 Part J provide the following interim analyses regarding primary and exploratory endpoints, as soon as the data become available as a Supplement to a New Drug Submission (SNDS) Level II, such as: a. Antibody response of mRNA-1273.815 (50 µg) and mRNA-1273.231(50 µg) against SARS-CoV-2 Omicron BA.4/BA.5, BQ.1.1, and XBB.1.5 subvariants by GMT, geometric mean fold rise (GMFR), and SRR at Day 29, b. Unsolicited AEs during the 28-day follow-up period after injection SAEs, MAAEs, AEs leading to withdrawal, and AESI from Day 1 to Day 181 (End of Study).	September 11, 2023	Ongoing

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	c. All exploratory endpoints data.		
2	Provide the final Clinical Study Report for Study mRNA-1273-P205 Part J mentioned above, when available.	September 11, 2023	Ongoing
3	Pertaining to Study mRNA-1273-P203 Part 3 intended to infer effectiveness of the 50 µg mRNA-1273.222 vaccine in the PPIS-Pos immunogenicity subset: a. Provide the data obtained from the pre-specified endpoints according to Protocol Amendment 6 as soon as the data become available as a Supplement to a New Drug Submission (SNDS) Level II.	September 11, 2023	Ongoing
4	Provide the final Clinical Study Report for parts of Study mRNA-1273-P203 Part 3 mentioned above, when available.	September 11, 2023	Ongoing
5	Moderna Biopharma Canada Corporation is required to submit Periodic Safety Update Reports (PSURs)/Periodic Benefit Risk Evaluation Reports (PBRERs) every 6 months for Spikevax XBB.1.5, unless otherwise determined by Health Canada.	September 11, 2023	Ongoing
6	Moderna Biopharma Canada Corporation is required to submit an updated core RMP with the Canadian Addendum in a timely manner if a safety issue is identified that requires immediate regulatory action or as requested by Health Canada. The RMP format should follow the guidance (Guidance Document Submission of Risk Management Plans and Follow-Up Commitments) and should include the following: a. A safety specification that details the identified risks, potential risks, and missing information for Spikevax XBB.1.5; 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; and c. A risk minimization plan, if applicable, to manage risks that may require additional measures beyond those considered standard.	September 11, 2023	Ongoing
7	Moderna Biopharma Canada Corporation to provide a summary of the changes made to the website for Health Canada's review with each update. a. Moderna Biopharma Canada Corporation to attest that the content of the website is consistent with the approved Canadian-specific labelling information for Spikevax XBB.1.5 (andusomeran mRNA vaccine) in French and English. The website content related to the appropriate storage & handling and preparation & administration of Spikevax XBB.1.5 (andusomeran mRNA vaccine) should be aligned with information in the Product Monograph.	September 11, 2023	Ongoing
8	Moderna Biopharma Canada Corporation is requested to develop and distribute a company-led customer communication, in English and French, should a decision be made to import non-Canadian labelled supplies for Canadian sites. The customer communication should aim to inform healthcare professionals that Moderna Biopharma Canada Corporation will delay the implementation of Canadian-specific inner/outer labels following	September 11, 2023	Ongoing

	Terms and Conditions	Issued	Status
	NDS approval for Spikevax XBB.1.5 (andusomeran mRNA vaccine), and that interim inner/outer labels will be used for the short term. Please note the following: a. Moderna Biopharma Canada Corporation should consider including images and texts of these labels in the customer communication and clearly outline all deviations from Canadian requirements; b. The customer communication should direct healthcare professionals to the electronic platform where they can find information about the approved Canadian-specific labelling in both official languages c. The customer communication should not resemble a Health Canada-endorsed Health Product Risk Communication and should not reflect a red banner at the top of the document. A company led risk communication may take the form of a letter carrying the company letterhead, for example. The company-led customer communication does not require review by Health Canada; however, Moderna Biopharma Canada Corporation is welcome to seek courtesy feedback from BRDD. Moderna Biopharma Canada Corporation is expected to exercise due discretion to ensure prompt finalization and dissemination of the customer communication. Please provide a copy of the final, signed customer communication in English and French via eCTD once available.		
9	Moderna Biopharma Canada Corporation to commit to developing Canadian specific bilingual labelling for Spikevax XBB.1.5 (andusomeran mRNA vaccine) Drug Identification Number (DIN) currently marketed in Canada, to be submitted in Q1 of 2024, and implementing such labelling once supplies are transitioned to Canadian dedicated supplies. Health Canada should be kept informed of estimated timelines and proposed strategies concerning the development and implementation of Canadian-specific bilingual labels. During the period prior to implementation of the Canadian-specific bilingual labeling, Canadian reference labels should be made available to healthcare professionals.	September 11, 2023	Ongoing