Health Canada / Santé Canada

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

TERMS AND CONDITIONS

Company: ModernaTx Inc.

Product: Spikevax (elasomeran mRNA vaccine)

Dossier ID: HC6-024-E252733

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 November 12, 2021:

Total Number: 17

Ongoing/pending: 17

Closed: 0

Table: Terms and Conditions

	Terms and Conditions	Issued	Status
1	For the indication in adults 18 years of age and older, provide full study report including safety, efficacy and immunogenicity, when available.	September 16, 2021	Pending availability of data
2	For the indication in adults 18 years of age and older, provide a safety update for subjects in the Phase 3 study (mRNA-1273-P301) at the 6-month safety follow up when available for at least 3000 vaccinated subjects as well as for available and relevant data from placebo subjects.	September 16, 2021	Pending availability of data
3	For the indication in adults 18 years of age and older, to fill data gaps, for various sub-populations for example, provide results, when available, of all ongoing studies, or studies to come, conducted with the vaccine.	September 16, 2021	Pending availability of data

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4	For the indication in individuals 12 to 17 years of age, provide safety data for all adolescents 12 through 17 years of age in study P203, 6 months after Dose 2, when the data become available.	September 16, 2021	Pending availability of data
5	For the indication in individuals 12 to 17 years of age, provide the report for Study P203 including safety, efficacy and immunogenicity data up to 1 year after Dose 2 in adolescents 12 through 17 years of age, when the study is completed.	September 16, 2021	Pending availability of data
6	Provide an updated Certified Product Information Document (CPID) that includes the facilities by December 31, 2021.	September 16, 2021	Expected by December 31, 2021
7	Provide final reports for ongoing drug substance (DS) and drug product (DP) PPQ activities at all manufacturing sites/scales as they become available.	September 16, 2021	Ongoing
8	In addition to the requirements under the *Food and Drug Regulations*, ModernaTX, Inc. commits to the following: ModernaTX, Inc. is required to: a. Treat adverse reactions associated with SPIKEVAX as priority and submit the corresponding reports to Health Canada without delay;	September 16, 2021	Ongoing
9	In addition to the requirements under the *Food and Drug Regulations*, ModernaTX, Inc. commits to the following: ModernaTX, Inc. is required to submit monthly safety reports, unless otherwise determined by Health Canada. The monthly safety reports should be submitted within 15 days after the last day of a month, beginning after the first full calendar month after authorization. These reports should contain the following: a. Interval and cumulative number of reports (serious and non-serious), overall and by age groups and in special populations (e.g. pregnant women); b. Interval and cumulative number of reports; c. Total number of adverse event reports in Canada and Globally; d. Exposure data stratified by country, including any available data on age groups, race, ethnicity, on indigenous populations and remote communities; e. Changes to reference safety information in the interval; f. Ongoing and closed signals in the interval; g. Updated list of adverse events of special interest including the Safety Platform for Emergency Vaccines (SPEAC) list and Risk Management Plan (RMP) safety concerns (including the additional missing information): reports – numbers and relevant cases, time-to-onset and observed/expected analyses including causality assessment; h. Fatal reports – numbers and relevant cases, including observed/expected analyses; i. Vaccination failure / lack of efficacy (including confirmed and suspected cases) reports and vaccination errors (categories according to preferred terms); j. Potential interaction with other vaccines/concomitant treatments-number and relevant cases;	September 16, 2021	Ongoing

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	k. Summary outcomes of some of the routine pharmacovigilance activities (as presented in the EU RMP Part III and applied in the Canadian context) should be included for the purpose of rapid signal detection and communication activities. Summary of all ongoing registries and studies should be included in the six-month scheduled Periodic Benefit-Risk Evaluation Reports (PBRERs), unless a safety signal is identified that requires immediate regulatory action.; and l. Overall risk/benefit consideration		
10	In addition to the requirements under the *Food and Drug Regulations*, ModernaTX, Inc. commits to the following: ModernaTX, Inc. is required to provide an updated Core RMP and Canadian Addendum in a timely manner if a signal of safety issue is observed in post-authorization surveillance. 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 the SPIKEVAX; 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 (for instance, labelling)	September 16, 2021	Ongoing
11	ModernaTX, Inc. to submit final snapshots of all components of the electronic platform (linked to on the any foreign or Canadian specific labels), containing the approved Canadian-specific labelling information for SPIKEVAX in French and English for Health Canada's review and records, prior to launch of the electronic platform, and for each subsequent update.	September 16, 2021	Ongoing
12	ModernaTX, Inc. is requested to develop and distribute a Health Product Risk Communication (HPRC), in French and English, should a decision be made to import, for Canadian sites, non-Canadian labelled supplies. In this case the HPRC would need to be developed with Health Canada approval and endorsement, to inform healthcare professionals that ModernaTX, Inc. will delay implementation of Canadian-specific inner/outer labels following NDS-CV approval for SPIKEVAX, and that interim non-Canadian inner/outer labels will be used for the short term. Please note the following: a. ModernaTX, Inc. should include images and texts of these labels in the HPRC and clearly outline all deviations from Canadian requirements b. The HPRC 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 HPRC should include an alternative method for the health care professionals to obtain a paper copy of the HPRC and/or Product Monograph by mail or fax from ModernaTX, Inc., if they cannot access the internet	September 16, 2021	Pending

	Terms and Conditions	Issued	Status
	Finally, ModernaTX, Inc. should devise an appropriate dissemination strategy to ensure the HPRC reaches the intended audience in a timely manner.		
13	ModernaTX, Inc. to commit to developing Canadian specific bilingual labelling for SPIKEVAX, to be submitted in Q1 of 2022, 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. a. During the period prior to implementation of the Canadian-specific bilingual labeling, Canadian reference labels should be made available to healthcare professionals.	September 16, 2021	Expected by Q1 2022
14	Provide immunogenicity and safety data for 6 months following the administration of the booster dose from Study P201, when the data become available.	November 12, 2021	Pending availability of data
15	Provide immunogenicity and safety data for 12 months following the administration of the booster dose from Study P201, when the data become available.	November 12, 2021	Pending availability of data
16	Provide the results from the planned Study P301 Part C, in which a subset of Phase 3 participants will receive a 50 µg booster dose, when the data become available.	November 12, 2021	Pending availability of data
17	ModernaTX, Inc. is required to submit an updated Core Risk Management Plan (RMP) in conjunction with the Canadian Addendum by December 10, 2021 to address any safety concerns, pharmacovigilance and risk minimization measures related to the use of a booster dose of Spikevax in Canada.	November 12, 2021	Expected by December 10, 2021