Health Canada / Santé Canada

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

TERMS AND CONDITIONS
Company: BioNTech Manufacturing GmbH
Product: Comirnaty Omicron XBB.1.5
(COVID-19 mRNA Vaccine, Monovalent [Omicron XBB.1.5])
Dossier ID: HC6-024-E276302

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 28, 2023:

Total Number: 15

Ongoing/pending: 15

Closed: 0

Table: Terms and Conditions

	Terms and Conditions	Issued	Status
1	Provide interim analyses at 1 month of the immunogenicity and safety data from **Study C4591048 Substudy A, Phase 1** pertaining to the primary, secondary, and exploratory immunogenicity and safety objectives, estimands and endpoints (following the administration of the XBB formulation [Dose 4]) as soon as it becomes available as a Supplement to a New Drug Submission (SNDS)/Level II – Supplement.	September 28, 2023	Ongoing
2	Provide interim analyses at 1 month of the immunogenicity and safety data from **Study C4591048 Substudy A, Phase 2/3** pertaining to the primary, secondary, and exploratory immunogenicity and safety objectives, estimands and endpoints (following the administration of the XBB formulation) as soon as it becomes	September 28, 2023	Ongoing

	Terms and Conditions	Issued	Status
	available as a Supplement to a New Drug Submission (SNDS)/Level II – Supplement.		
3	Provide interim analyses at 6 months of the safety data from **Study C4591048 Substudy A**, **Phase 1** pertaining to the primary, secondary, and exploratory safety objectives, estimands and endpoints (following the administration of the XBB formulation) as soon as it becomes available as a Supplement to a New Drug Submission (SNDS)/ Level II – Supplement.	September 28, 2023	Ongoing
4	Provide final analyses at 6 months of the safety data from **Study C4591048 Substudy A**, **Phase 2/3** pertaining to the primary, secondary, and exploratory safety objectives, estimands and endpoints (following the administration of the XBB formulation) as soon as it becomes available as a Supplement to a New Drug Submission (SNDS)/ Level II – Supplement.	September 28, 2023	Ongoing
5	Provide interim analyses at 1 month of the safety and immunogenicity data from **Study C4591048 Substudy E,** pertaining to the primary, secondary, and exploratory safety and immunogenicity objectives, estimands and endpoints (following the administration of the XBB formulation) as soon as it becomes available as a Supplement to a New Drug Submission (SNDS)/ Level II – Supplement.	September 28, 2023	Ongoing
6	Provide final analyses at 6 months of the safety data from **Study C4591048 Substudy E**, pertaining to the primary, secondary, and exploratory safety and immunogenicity objectives, estimands and endpoints (following the administration of the XBB formulation) as soon as it becomes available as a Supplement to a New Drug Submission (SNDS)/ Level II – Supplement.	September 28, 2023	Ongoing
7	Provide interim analyses at 1 month of the immunogenicity and safety data from **Study C4591054 Substudy A**, pertaining to the primary, and exploratory immunogenicity and safety objectives, estimands and endpoints (following the administration of the XBB formulation) as soon as it becomes available as a Supplement to a New Drug Submission (SNDS)/Level II – Supplement.	September 28, 2023	Ongoing
8	Provide final analyses at 6 months of the safety and immunogenicity data from **Study C4591054 Substudy A** pertaining to the primary, and exploratory immunogenicity and safety objectives, estimands and endpoints (following the administration of the XBB formulation) as soon as it becomes available as a Supplement to a New Drug Submission (SNDS)/ Level II – Supplement.	September 28, 2023	Ongoing
9	Provide interim analyses at 1 month of the immunogenicity and safety data from **Study C4591054 Substudy B**, pertaining to the primary, and exploratory immunogenicity and safety objectives, estimands and endpoints (following the administration of the XBB formulation) as soon as it becomes available as a Supplement to a New Drug Submission (SNDS)/Level II – Supplement.	September 28, 2023	Ongoing

	Terms and Conditions	Issued	Status
10	Provide final analyses at 6 months of the safety and immunogenicity data from **Study C4591054 Substudy B,** pertaining to the primary, and exploratory immunogenicity and safety objectives, estimands and endpoints (following the administration of the XBB formulation) as soon as it becomes available as a Supplement to a New Drug Submission (SNDS)/ Level II – Supplement.	September 28, 2023	Ongoing
11	BioNTech Manufacturing GmbH is required to submit Periodic Safety Update Reports (PSURs)/Periodic Benefit Risk Evaluation Reports (PBRERs) every 6 months for Comirnaty Omicron XBB.1.5 [COVID-19 mRNA vaccine, Monovalent (Omicron XBB.1.5)], unless otherwise determined by Health Canada.	September 28, 2023	Ongoing
12	BioNTech Manufacturing GmbH is required to submit an updated core Risk Management Plan (RMP) with the Canadian Addendum in a timely manner 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 Comirnaty Omicron XBB.1.5 [COVID-19 mRNA vaccine, Monovalent (Omicron 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 28, 2023	Ongoing
13	**BioNTech Manufacturing GmbH** to provide a summary of the changes made to the website for Health Canada's review with each update. a. **BioNTech Manufacturing GmbH** to attest that the content of the website (CVDVaccine.ca) is consistent with the approved Canadian-specific labelling information for Comirnaty Omicron XBB.1.5 in French and English. The website content related to the appropriate storage & handling and preparation & administration of Comirnaty Omicron XBB.1.5 should be aligned with information in the Product Monograph. b. For revisions to the website design and layout related to updates to the indication, use or presentation of the vaccine, **BioNTech Manufacturing GmbH** commits to providing final screenshots of relevant components of the electronic platform (linked to any foreign or Canadian specific Comirnaty Omicron XBB.1.5 labels dispensed in Canada), containing the approved Canadian-specific	September 28, 2023	Ongoing

	Terms and Conditions	Issued	Status
	labelling information for Comirnaty Omicron XBB.1.5 in French and English for Health Canada's records, following review and approval by Pharmaceutical Advertising Advisory Board (PAAB).		
14	**BioNTech Manufacturing GmbH** 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 BioNTech Manufacturing GmbH and Pfizer Canada ULC will delay the implementation of Canadian-specific inner/outer labels following NDS-CV approval for Comirnaty Omicron XBB.1.5, and that interim inner/outer labels will be used for the short term. Please note the following: a. BioNTech Manufacturing GmbH 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, BioNTech Manufacturing GmbH is welcome to seek courtesy feedback from BRDD. BioNTech Manufacturing GmbH 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.	September 28, 2023	Ongoing
15	**BioNTech Manufacturing GmbH** to commit to developing Canadian specific bilingual labelling for Comirnaty Omicron XBB.1.5 presentations Drug Identification Numbers (DINs) 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 28, 2023	Ongoing