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 Original/Omicron BA.1
[COVID-19 mRNA Vaccine (nucleoside modified), Bivalent [Original and Omicron (B.1.1.529) Variant])
Dossier ID: HC6-024-E266189

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 October 21, 2022:

Table: Terms and Conditions

	Terms and Conditions	Issued	Status
1	Provide immunogenicity and safety data after the second booster (fourth) dose in subjects 55 years of age and older from Study C4591031 Phase 3 Substudy E. Please submit the final analysis, when the data become available.	October 21, 2022	Ongoing
2	Provide immunogenicity and safety data after the second booster (fourth) dose in subjects 18 to 54 years of age from Study C4591031 Phase 3 Substudy D. Please submit the final analysis, when the data become available.	October 21, 2022	Ongoing
3	Provide immunogenicity and safety data after the first booster (third) dose of Comirnaty for subjects 12 to 17 years of age from Study C4591031 Phase 3 Substudy C. Please include interim (1 and 6 months) and final analysis, when the data become available.	October 21, 2022	Ongoing

4	Provide safety data after the first booster (third) dose of Comirnaty for subjects 12 to 17 years of age from Study C4591031 Phase 3 Substudy B. Please submit the final analysis, when the data become available.	October 21, 2022	Ongoing
5	Provide updates for ongoing stability studies of the BNT162b2 Omicron BA.4/BA.5 mRNA drug substance. Data for each study can be submitted after the 12 month time-point and at completion.	October 21, 2022	Ongoing
6	Provide updates for ongoing stability studies of the BNT162b2 Bivalent (Original & Omicron BA.4/BA.5) drug product. Data for each study can be submitted after the 12 month time-point and at completion.	October 21, 2022	Ongoing
7	Provide a Certified Product Information Document (CPID).	October 21, 2022	Ongoing
8	Pfizer/BioNTech Manufacturing GmbH is required to treat adverse reactions associated with Comirnaty Original/Omicron BA.1 (COVID-19 mRNA Vaccine (nucleoside modified), Bivalent [Original and Omicron (B.1.1.529)] Variant) as priority and submit the corresponding reports to Health Canada without delay.	October 21, 2022	Ongoing
9	Pfizer/BioNTech Manufacturing GmbH is required to submit Periodic Safety Update Reports (PSURs)/Periodic Benefit Risk Evaluation Reports (PBRERs) every 6 months for Comirnaty Original/Omicron BA.1 (COVID-19 mRNA Vaccine (nucleoside modified), Bivalent [Original and Omicron (B.1.1.529)] Variant), unless otherwise determined by Health Canada. The core PSUR/PBRER format should follow international guidance for COVID-19 vaccines.	October 21, 2022	Ongoing
10	Pfizer/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 Original/Omicron BA.1 (COVID-19 mRNA Vaccine (nucleoside modified), Bivalent [Original and Omicron (B.1.1.529)] Variant); 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	October 21, 2022	Ongoing

	c. A risk minimization plan, if applicable, to manage risks that may require additional measures beyond those considered standard (for instance, labelling).		
11	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 Original/Omicron BA.1 in French and English. The website content related to the appropriate storage & handling and preparation & administration of Comirnaty Original/Omicron BA.1 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 Original/Omicron BA.1 labels dispensed in Canada), containing the approved Canadian-specific labelling information for Comirnaty Original/Omicron BA.1 in French and English for Health Canada's records, following review and approval by Pharmaceutical Advertising Advisory Board (PAAB)	October 21, 2022	Ongoing
12	BioNTech Manufacturing GmbH are 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 BioNTech Manufacturing GmbH and Pfizer Canada ULC will delay implementation of Canadian-specific inner/outer labels following NDS-CV approval for Comirnaty Original/Omicron BA.1, and that interim non-Canadian inner/outer labels will be used for the short term. Please note the following:	October 21, 2022	Ongoing

	a. BioNTech Manufacturing GmbH 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 BioNTech Manufacturing GmbH, if they cannot access the internet. d. BioNTech Manufacturing GmbH should devise an appropriate dissemination strategy to ensure the HPRC reaches the intended audience in a timely manner.		
13	BioNTech Manufacturing GmbH to commit to developing Canadian specific bilingual labelling for Comirnaty Original/Omicron BA.1 presentations Drug Identification Numbers (DINs) marketed in Canada 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.	October 21, 2022	Ongoing