Health Canada / Santé Canada

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

TERMS AND CONDITIONS

Company: Janssen Inc.

Product: JCOVDEN (AD26.COV2.S [recombinant])

Dossier ID: HC6-024- E252734

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 April 4, 2023:

Table: Terms and Conditions

	Terms and Conditions	Issued	Status
1	Provide data and updated clinical study reports on vaccine efficacy, safety and immunogenicity from Study COV3001, as soon as they are available.	November 23, 2021	Closed
2	Provide safety updates for participants in Study COV3001 when 6-month data that is representative of the overall trial population is available, which includes elderly participants.	November 23, 2021	Closed
3	Provide a discussion describing how Janssen intends to monitor long-term efficacy and safety once Study COV3001 is unblinded and the placebo group is administered the vaccine.	November 23, 2021	Closed

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4	Provide updated clinical study reports on vaccine efficacy, safety and immunogenicity from Studies COV2001, COV1002, and COV1001, as soon as they are available.	November 23, 2021	Closed
5	Provide the results of the coagulopathy assessments in Study COV2001 as soon as they are available.	November 23, 2021	Closed
6	Provide updated clinical study reports on vaccine efficacy, safety and immunogenicity from Study 3009, as soon as they are available.	November 23, 2021	Closed
7	Provide data regarding protection against variants of concerns, including new or emerging variants when available, if their clinical presentation and/or epidemiological distribution warrants it.	November 23, 2021	Ongoing
8	Provide complete reports for ongoing process qualification and comparability studies as soon as the data become available.	November 23, 2021	Ongoing
9	Provide complete stability data for Drug Substance (DS) and Drug Product (DP), and verify and/or confirm that the currently proposed release and stability specifications for DS and DP, especially the potency specifications, are still appropriate based on accumulated and updated product release and stability data.	November 23, 2021	Ongoing
10	Provide yearly Batch Disposition Reports for the specified site for the years of 2021 and 2022. The reports should include information for major deviations, and the reasons for rejected batches, if there were any.	November 23, 2021	Ongoing
11	Janssen Inc. is required to treat adverse reactions associated with the Janssen COVID-19 Vaccine as priority and submit the corresponding reports to Health Canada without delay.	November 23, 2021	Ongoing
12	Janssen Inc. is required to submit bi-monthly safety reports, unless otherwise determined by Health Canada. The bi-monthly safety reports should be submitted within 15 days after the last day of every second 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 per High Lever Term (HLT) and System Organ Class (SOC); c. Number of reports in Canada and Global; d. Exposure data, stratified by country, age groups, race and ethnicity; e. Changes to reference safety information in the interval; f. Ongoing and closed signals in the interval;	November 23, 2021	Closed

	Terms and Conditions	Issued	Status
	g. Updated list of adverse events of special interest including the Safety Platform for Emergency Vaccines list and 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) and errors-number relevant cases; j. Potential interaction with other vaccines/concomitant treatments-number and relevant cases; 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 studies can be included in the first six-month scheduled PBRER, unless a safety signal is identified that requires immediate regulatory action; and l. Overall risk/benefit consideration.		
13	Janssen Inc. 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 important identified risks, important potential risks, and missing information for Janssen COVID-19 Vaccine; 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).	November 23, 2021	Ongoing
14	Janssen 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 Janssen Inc. will delay implementation of Canadian-specific inner/outer labels following NDS-CV approval for Janssen COVID-19 Vaccine, and that interim non Canadian inner/outer labels will be used for the short term. Please note the following:	November 23, 2021	Closed

	Terms and Conditions	Issued	Status
	a. Janssen 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; and 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 Janssen Inc., if they cannot access the internet. Finally, Janssen Inc. should devise an appropriate dissemination strategy to ensure the HPRC reaches the intended audience in a timely manner.		
15	Janssen 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 Janssen COVID-19 Vaccine in French and English for Health Canada's review and records, prior to launch of the electronic platform, and for each subsequent update.	November 23, 2021	Ongoing
16	Janssen Inc. to commit to revising all inner and outer labels for Janssen COVID-19 Vaccine to include the printed expiry date information at a point when the global supply and pandemic situation will allow.	November 23, 2021	Ongoing
17	Janssen Inc. is required to submit Periodic Safety Update Reports (PSURs)/Periodic Benefit Risk Evaluation Reports (PBRERs) every 6 months, unless otherwise determined by Health Canada. The core PSUR/PBRER format should follow international guidance for COVID-19 vaccines.	March 17, 2022	Ongoing
18	Janssen Inc. to commit to implementing Canadian specific bilingual labelling by June 2023, for JCOVDEN, 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.	August 5, 2022	Ongoing
19	Janssen Inc. 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 Janssen Inc. will delay the implementation of Canadian-specific inner/outer labels following NDS-CV approval for Jcovden (AD26.COV2.S [recombinant]), and that interim inner/outer labels will be used for the short term. Please note the following: a. Janssen Inc. 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-	April 4, 2023	Ongoing

	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, Janssen Inc. is welcome to seek courtesy feedback from BRDD. Janssen Inc. 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.		