Health Canada | Santé Canada

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

INTERIM ORDER– TERMS AND CONDITIONS
Company: Janssen Inc.
Product: Janssen Vaccine (AD26.COV2.S)
Dossier ID: HC6-024-E244995

Background:

The Interim Order allows the Minister to impose or amend terms and conditions, and request additional information, in relation to a COVID-19 drug submission, authorization, 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 22, 2021:

Total Number: *25*

Ongoing/pending: *22*

Closed: *3*

Table: Terms and Conditions

	Terms and Conditions	Issued	Status
1	Provide updated clinical study reports on vaccine efficacy, safety and immunogenicity from StudyCOV3001, as soon as they are available.	March 5, 2021	Pending availability of data
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.	March 5, 2021	Expected Q2 2021
3	Provide a discussion describing how Janssen Inc. intends to monitor long-term efficacy and safety once Study COV3001 is unblinded and the placebo group is administered the vaccine.	March 5, 2021	Pending availability of data

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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.	March 5, 2021	Pending availability of data
5	Provide the results of the coagulopathy assessments in Study COV2001 as soon as they are available.	March 5, 2021	Expected Q2 2021
6	Provide updated clinical study reports on vaccine efficacy, safety and immunogenicity from Study 3009, as soon as they are available.	March 5, 2021	Pending availability of data
7	Provide a list and brief descriptions of all clinical trials currently underway.	March 5, 2021	Pending
8	Provide data regarding protection against variants of concerns (e.g. B.1.1.7, B.1.351 (501Y.V2), P1), including new or emerging variants (e.g., CAL.20C (L452R), B.1.525, A.23.1) when available, if their clinical presentation and/or epidemiological distribution warrants it.	March 5, 2021	Pending availability of data
9	All lots to be sold in Canada should comply with the approved specifications for drug substance (DS) and drug product (DP). A Lot Release Protocol should be submitted to BRDD for each lot to be distributed in Canada, the Sponsor requires a lot release letter from BRDD prior to distribution in the Canadian market. A summary of batch disposition should be submitted on a biannual basis from the facilities approved to supply Canada. The summary should include all DS and DP lots produced, failed, or aborted and a brief description of the issue(s) where this is relevant. Health Canada may revisit this requirement at any time based on the risk profile of the product. The email address where this information should be sent will be provided to the Sponsor in an additional correspondence.	March 5, 2021 Updated May 13, 2021	Ongoing
10	Post-authorization the following information should be submitted as soon as it is available: • Updates on process validations at full commercial scale including all additional PPQ batches, comparability data for all facilities included in authorization and in subsequent amendments. • Comparability of different sites including characterization of DS and DP and enrollment instability studies. • Updates on all assay validation studies completed post-authorization, including assay performance and comparability of all laboratory testing sites. Please note, all analytical assays must be validated prior to New Drug Submission. • Any critical changes to the manufacturing process, the specifications for critical quality attributes or to the key analytical assays should be submitted promptly as amendments to the authorization. • Provide all information available to any new facilities relevant to the Canadian supply chain when available.	March 5, 2021	Ongoing
11	Provide stability information in a timely manner to support extension of the expiry date. Once approved, relevant databases should be updated with the new expiry date.	March 5, 2021	Ongoing
12	Provide notification of changes in GMP status for any of the facilities included in the authorization as well as any new facilities relevant to the Canadian supply chain when available.	March 5, 2021	Ongoing

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13	As per the Interim Order authorized drugs, Janssen Inc. will: • Treat adverse reactions associated with Janssen COVID-19 Vaccine as priority and submit the corresponding reports to Health Canada without delay; and • Identify in the report that the Janssen COVID-19 Vaccine is a Janssen Inc. product authorized under the Interim Order.	March 5, 2021	Ongoing
14	Janssen Inc. is required to provide, prior to distribution, patient information cards to support traceability, where required, which will include elements such as manufacturer name, name of vaccinee, space for recording date of administration, and associated batch/lot numbers, and information on how to report any adverse events.	March 5, 2021	Closed
15	Janssen Inc. is required to submit monthly safety reports for the period of the Interim Order authorization, 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: • Interval and cumulative number of reports (serious and non-serious), overall and by age groups and in special populations (e.g. pregnant women); • Interval and cumulative number of reports; • Total number of adverse event reports in Canada and Globally; • Exposure data stratified by country, including any available data on age groups, race, ethnicity, on frail elderly, patients with chronic illness, immunocompromised and on indigenous populations and remote communities; • Changes to reference safety information in the interval; • Ongoing and closed signals in the interval; • List of adverse events of special interest and RMP safety concerns (including the additional missing information): reports–numbers and relevant cases, including time-to-onset and observed/expected analyses; • Fatal reports–numbers and relevant cases (causality assessment); • Vaccination failure / lack of efficacy (including definition of confirmed and suspected cases) reports and vaccination errors (categories according to preferred terms); • Potential interaction with other vaccines/concomitant treatments-number and relevant cases; • Summary outcomes of some of the routine pharmacovigilance activities (as presented in the Core 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 PBRERs, unless a safety signal is identified that requires immediate regulatory action; and • Overall risk/benefit assessment.	March 5, 2021	Ongoing
16	Janssen Inc. is required to: a) Provide a Canadian Addendum to the Core Risk Management Plan (RMP) by March 31, 2021. This Canadian addendum should follow Health Canada	March 5, 2021	Received and

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	guidance (1. Guidance Document Submission of Risk Management Plans and Follow-Up Commitments; 2. Guidance for market authorization requirements for COVID-19 vaccines; 3. Notice of clarification to drug manufacturers and sponsors: Canadian specific considerations in risk management plans)and include the following: i. In addition to the important potential risks in the Core RMP, the following should be included: • Anaphylaxis • Venous thromboembolism ii. In addition to the missing information in the Core RMP, the following should be included: • Use in pediatric <18 years of age • Long-term safety and effectiveness The pharmacovigilance and risk minimization activities should be included for the above important potential risks and missing information. iii. A description of the planned pharmacovigilance activities for monitoring of use in pregnant and breastfeeding women in Canada (e.g., inclusion of Canadian women in the pregnancy registry).		review underway
17	b. 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 in the context of the COVID-19 drugs submitted for authorization under the Interim Order: • a safety specification that details the identified risks, potential risks, and missing information for the Janssen COVID-19 Vaccine; • 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 • a risk minimization plan, if applicable, to manage risks that may require • additional measures beyond those considered routine (for instance, labelling).	March 5, 2021	Ongoing
18	Janssen Inc. to submit final snapshots of all components of the electronic platform (linked to on the global labels), containing 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.	March 5, 2021	Ongoing
19	Janssen Inc. to develop and distribute a Health Product Risk Communication (HPRC) in French and English, with Health Canada approval and endorsement, to inform healthcare professionals about the authorization of the Janssen COVID-19 Vaccine under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19with global English-only vial and carton labels, to expedite global access of the drug in the context of the pandemic. • The letter should direct healthcare professionals to the electronic platform where they can find information about Canadian-specific	March 5, 2021	Closed

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	labelling and expiry date information in both official languages and should be issued prior to and alongside the distribution of the vaccine. • The letter should specify when the Canadian-specific labels will be implemented.		
20	Janssen Inc.to commit to developing Canadian-specific bilingual labelling for Janssen COVID-19Vaccine and implementing such labelling at a point when the global supply and pandemic situation will allow. 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, interim Canadian reference labels should be made available to healthcare professionals as reference.	March 5, 2021	Ongoing
21	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.	March 5, 2021	Ongoing
22	Provide a deviation summary report for all Ad26.COV2.S lots manufactured at the site, including lot identifier, details of the deviation, corrective and preventive action implemented as a result of deviation, and final lot disposition.	April 23, 2021	Ongoing
23	Commit to notify BRDD of any critical deviations involving manufacturing suites used to manufacture vaccine supplied to Canada.	April 23, 2021	Ongoing
24	Commit to provide the outstanding CMC packages as indicated in the information submitted (sequence 0040).	April 23, 2021	Ongoing
25	Janssen Inc. to develop and distribute, prior to product availability in Canada, a Health Product Risk Communication (HPRC) in French and English, with Health Canada approval and endorsement, to inform healthcare professionals about the authorization of the Janssen COVID-19 Vaccine under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19* with foreign English-only vial and carton labels, to expedite global access of the drug in the context of the pandemic. a) The letter should instruct healthcare professionals how to access all relevant labelling information including the expiry date for all label types. i. In the case of online expiry dating, the letter should direct healthcare professionals to the electronic platform where they can find information about Canadian-specific labelling and expiry date information in both official languages and should be issued prior to and alongside the distribution of the vaccine. b. The letter should clearly state relevant differences between label types including the method of recording date and time on the vial label. c. The letter should specify when the Canadian-specific labels will be implemented.	April 23, 2021	Closed