

Federal Office of Public Health
Schwarzenburgstrasse 157
3003 Bern, Switzerland

Swiss Armed Forces Pharmacy
Worbentalstrasse 36
3063 Ittigen, Switzerland

11 October 2022

RE: Bavarian Nordic A/S' supply of JYNNEOS® to Federal Office of Public Health and Swiss Armed Forces Pharmacy

1. Reference is made to recent contacts established between the Swiss Confederation represented by the Federal Office of Public Health with offices at Schwarzenburgstrasse 157, 3003 Bern, Switzerland and the Swiss Armed Forces Pharmacy with offices at Worbentalstrasse 36, 3063 Ittigen, Switzerland (hereinafter referred to as "Purchaser") and [REDACTED] Bavarian Nordic A/S regarding sales and delivery to Purchaser of Bavarian Nordic A/S' (hereinafter referred to as "BN") smallpox and monkeypox vaccine, "JYNNEOS®" (hereinafter referred to as "JYNNEOS®"). Purchaser and BN are sometimes referred to individually as a "Party" and collectively as the "Parties".
2. The purpose of this Letter (hereinafter referred to as the "Agreement") is to set out the following terms and conditions under which BN is willing to sell and Purchaser is willing to purchase JYNNEOS®.
3. On the basis of this Agreement Purchaser hereby orders and purchases 100'000 doses (0.5 ml vials) of JYNNEOS® with a production date of minimum June 2022 and minimum shelf life of 66% of the approved shelf life according to Schedule 1, Table 1. BN currently has JYNNEOS® product available. JYNNEOS®, was approved by the USA FDA on 24-September-2019 (BLA #125678). JYNNEOS® is indicated for the prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection. The product including the information on the label is in compliance with the US regulatory requirements.
4. The total purchase price, incl. transportation costs, is EUR 11'000'000 (excl. VAT), where Purchaser buys 100'000 doses at a price of EUR 110 per dose.

BN shall submit invoices to Purchaser for every delivery, which must be paid no later than 30 calendar days upon receipt. Invoices shall be provided electronically in accordance with the requirements of the Swiss federal administration applicable to e-bills and PDF invoices via e-mail, as available at <https://www.e-rechnung.admin.ch/e/index.php> and the invoices should be sent to the following address:

Verteidigung
c/o Kreditoren VBS
Postfach 3003 Bern
pdf-rechnung-verteidigung.astab@vtg.admin.ch

5. Delivery shall occur pursuant to the Delivery Schedule attached in Schedule 2 and is to be made DAP Incoterms 2020 to:

armasuisse, Transport and Customs
c/o Logistikbasis der Armee LBA
Militärbetriebe
Aussenstelle Burgdorf
Militärstrasse 34
CH-3400 Burgdorf
Switzerland

Title to the Product and risk of loss or damage shall transfer to Purchaser upon unloading of the Product at delivery point. The process of unloading is recorded in the separate quality agreement. Shipment shall not occur with postal service.

At least 48 hours before shipment of the goods, the supplier shall notify armasuisse by e-mail to transport-Zoll@armasuisse.ch and aapotqscovid.lba@vtg.admin.ch:

- Commercial/customs invoice showing order number, customs tariff number, origin of goods
- Packing details as weight, dimensions, marks etc.
- Customs Export accompanying document (MRN)
- Movement certificate EUR 1 or declaration of origin on invoice if applicable
- For shipments sent by courier indicate tracking number
- For goods delivered by truck mention transportation date, forwarder and point of border crossing
- For goods shipped by Airfreight please advise HAWB Number and freight forwarder.

BN shall assure freight forwarder contacts Purchaser beforehand for customs clearance at the addresses stated in Sect. 24.

BN is responsible to procure at his own expenses any export licences which may be needed to export the ordered products. Dangerous goods must be packed according to ADR / IATA regulations.

6. Purchaser shall be responsible, at its own cost and expense, for obtaining and/or issuing as the case may be, any and all permits, approvals and documentation required for JYNNEOS® to be dispatched from BN to Purchaser and for the fulfilment of any legal requirements in Switzerland and Liechtenstein pertaining to this Agreement.
7. Purchaser, including any of its representatives, shall not sell, re-sell, transfer or otherwise make available JYNNEOS® to anyone outside Switzerland and Liechtenstein without the prior written consent of BN, such consent to be given at BN's sole discretion only. However, Purchaser may donate some or all of the Vaccines for humanitarian aid only with the prior written consent of BN, such consent to be given at BN's sole discretion, and only if Purchaser is not in breach of this Agreement and Purchaser has paid to BN the full price for JYNNEOS® that Purchaser intends to donate.
8. The Food and Drug Administration (FDA) has granted marketing authorization for JYNNEOS® on the basis of its decision of 24 September 2019 (BLA #125678). Information about the characteristics of JYNNEOS® etc. can be found in the Full Prescribing Information (US package insert) of JYNNEOS®, as updated from time to time, which is publicly available on the FDA's website <https://www.fda.gov/vaccines-blood-biologics/jynneos>. This summary reflects BN's recommendations as to how JYNNEOS® is to be used, how JYNNEOS® works, which criteria recipients should meet to be eligible to receive JYNNEOS®, a summary of clinical data generated in so far relevant for general use of JYNNEOS®, risks associated with the use of JYNNEOS® and such other product

information, which BN may deem relevant. However, JYNNEOS® is an unlicensed medicinal product in Switzerland and Liechtenstein, neither for smallpox nor for the protection against monkeypox virus (this indication is currently approved in the United States, European Union and Canada). Furthermore, reference is made to the special characteristics and specifications applicable to the Product set out in the **Schedule 1: Summary Information to support Request for Supply of JYNNEOS® outside US**. Purchaser, therefore, acknowledges that the JYNNEOS® doses supplied under this Agreement are not licensed for use in Switzerland and Liechtenstein for any purpose. Consequently, any administration, use, distribution and/or handling of JYNNEOS® supplied under this Agreement whatsoever is subject to Purchaser assuming any and all liability related thereto without recourse to BN.

9. BN will submit an application for marketing authorization for JYNNEOS® to Swissmedic within 3 months following the signature of this agreement.
BN warrants to Purchaser that, upon delivery of Product, such Product will (a) conform to the specifications for such Product as set forth in Schedule 1 as updated from time to time, (b) have been manufactured in accordance with current good manufacturing practice (cGMP) as defined under applicable laws and (c) comply with the applicable Regulatory Approval once granted for such Product in the Territory, (Product satisfying clauses (a)-(c) hereof, "Conforming Product"). Any claims by Purchaser that Product fails to meet this warranty set forth in this Section must be made by Purchaser within thirty (30) days of delivery of the Product (or in the case of any Latent Defect, within thirty (30) days after discovery by Purchaser).
10. If the JYNNEOS® delivered to Purchaser is not a Conforming Product at the time of delivery, BN shall as soon as reasonably possible but no later than within thirty days replace such JYNNEOS® by delivering new dosages of JYNNEOS® to Purchaser. BN shall have no other liability, obligation or responsibility whatsoever towards Purchaser and Purchaser shall have no other remedy, claims or rights against BN in the event the delivered Product to Purchaser is not a Conforming Product.

In case BN anticipates that any delivery schedule of a shipment cannot be met, BN shall immediately notify Purchaser and a new schedule shall be agreed in good faith by both parties in writing. In the event that the delivery has not occurred within 3 months according to Schedule 2 (Delivery Schedule for JYNNEOS®) (or any extension thereof, as may mutually be agreed upon in writing by the Parties), Purchaser may, by written notice, terminate this Agreement and in such case shall not incur any liability due to such termination.

11. Any safety relevant information as defined per national reporting requirements, and any import licence provisions granted, shall be forwarded from the Swiss Armed Forces Pharmacy to BN when taken notice of and be reported as per local reporting requirements by BN. BN undertakes to comply with the pharmacovigilance obligations in Switzerland for JYNNEOS®. For this purpose, a pharmacovigilance agreement ("Safety Data Exchange Agreement") shall be concluded between BN and the Swiss branch of BN within thirty (30) days following the signature of this agreement.
12. Except for losses directly caused by intentional or grossly negligent non-cGMP or non-cGDP compliant manufacture and/or distribution, or Wilful Misconduct, liability of BN under this Agreement shall not exceed the amount effectively paid by Purchaser to BN under this Agreement.
13. Any information disclosed or provided by a Party under this Agreement must be kept strictly confidential by the other Party and shall only be used for purposes of this Agreement. Such Information must not be reproduced, copied, given or in any manner disclosed by a Party to any third parties except as required by law (e.g. Swiss Transparency Act, BÖB etc.) or to respond to a regulatory request or with the prior approval in writing of the other Party. Any such disclosures must be limited to the exact

minimum required by law or regulatory request. If Purchaser makes any announcements related to this Agreement or any circumstances related to this Agreement, Purchaser must in such announcement acknowledge BN as the supplier of JYNNEOS® to Purchaser, as further coordinated and agreed upon between the parties. Moreover, as BN is listed on the Nasdaq Copenhagen stock exchange BN shall therefore be entitled to make stock exchange announcements about this Agreement disclosing certain information from this Agreement.

14. Purchaser shall during the Term of the Agreement have the right of inspection in relation to all information under the control of BN relating to its performance of this Agreement, which right may also be exercisable by any governmental or regulatory body which has a right and need to know such information under applicable law (such third party being referred to as "Control Organs"). BN will grant such Control Organs reasonable access during business hours, on receipt of at least ten (10) days' notice to such reasonable information and/or files relating to the subject matter of the Agreement and the contractual relationship between Purchaser and BN as well as be available for questions. Such Control Organs shall be legally bound to keep any such information and/or files confidential.
15. The Federal Office of Public Health and the Swiss Armed Forces Pharmacy as well as the Swiss Federal Audit Office (Eidg. Finanzkontrolle) have an audit right of invoices with regard to the actual deliveries of Product that is provided by the laws applicable to the FOPH and/or the Swiss Armed Forces Pharmacy as well as the Swiss Federal Audit Office. The FOPH and the Swiss Armed Forces Pharmacy may delegate these rights to third parties that support them in fulfilling their duties as state authorities related to this Agreement and that are no direct or indirect competitors of Supplier. Supplier undertakes to grant to the entitled controlling bodies indicated access to all records that are subject of the Audit Right, and to be available to provide information. Auditors shall be bound to the same confidentiality requirements of other Recipients.
16. In the event of any controversy arising out of or relating to any provision of this Agreement or the breach thereof, the parties shall try to settle the controversy amicably between them. Should they fail to agree, the matter in dispute, whether arising before or after the termination of this Agreement, shall be settled by binding arbitration to be conducted in the English language before the ICC International Court of Arbitration Switzerland, Zurich ("ICC") under the Rules of Procedure of ICC in force on the day upon which arbitration proceedings are commenced. The arbitration shall take place in Zurich, Switzerland. Any such arbitration shall be heard by a sole arbitrator appointed by the ICC. The arbitrator shall be required to deliver a written report of the arbitrator's findings. Awards granted by the arbitrator may be enforced by any court of competent jurisdiction.
17. This Agreement and the validity thereof shall be governed by and construed in accordance with the substantive laws of Switzerland to the exclusion of any rule that would refer the subject matter to another jurisdiction.
18. To the extent that Purchaser /the Swiss government may be entitled to claim for itself immunity in respect of its obligations under or in relation to this Agreement from claims, service of process, suit, judgment, execution or legal process or to the extent that in any such jurisdiction there may be attributed to it such immunity Purchaser/the government hereby irrevocably agrees not to claim and hereby irrevocably waives such immunity.
19. This Agreement shall enter into force on 11 October 2022 and shall remain in force until delivery of the Product.
20. Notwithstanding the foregoing this Agreement may be terminated by either party:

- a. in case a material breach of this Agreement has not been cured by the defaulting party within 60 days after receipt of written notice by the other party.
 - b. in the event of liquidation, bankruptcy or an assignment of the benefit of creditors or of a declaration of insolvency of the other party.
21. Termination of this Agreement under the foregoing section does not relieve a party of its obligations accrued prior to termination. Sections 6, 7, 8, 9, 10, 11, 12, 13, 15, 16, 17 and 18 of this Agreement shall survive any termination, expiration or completion of this Agreement.
22. The roles and responsibilities regarding quality assurance will be defined in a separate quality agreement between BN and the Swiss Armed Forces Pharmacy under the Lead of BN.
23. The Parties represent and warrant that, beyond the mutual consideration set forth in this Agreement, neither they nor their agents have provided or requested, or will provide or request, any additional incentive or benefit to or from the other Party or its agents to induce either Party to enter this Agreement or perform any part of this Agreement. BN has not made, and will not make, in the performance of this Agreement directly or indirectly any payment, offer, promise, or authorization of payment of money or anything of value to a Government official, political party, candidate for political office, or any other Person, and has not sought and will not seek improperly or corruptly to influence any Government official, political party, candidate for political office, or any other Person, in order to gain an improper business advantage. (c) The Parties will comply with applicable economic sanctions, import, and export control Laws in the performance of this Agreement.
24. Any notice required to be given hereunder shall be in writing and deemed to have been sufficiently given, (a) when delivered in person, (b) on the next Business Day after mailing by overnight courier service, or, where overnight courier service is unavailable, by other expedited delivery provided by a recognized express courier, or (c) when delivered via e-mail, provided the original is delivered via one of the preceding methods on or prior to the fifth (5th) Business Day after transmission of the e-mail, to the addresses specified below. Each notice shall specify the name and date of and Parties to this Agreement.

If to Purchaser:

Federal Office of Public Health, Schwarzenburgstrasse 157, 3003 Bern, Switzerland

Attn: Competence Centre Security of Supply

Email: HMR_COVID@bag.admin.ch.

and

The Swiss Armed Forces Pharmacy, Worblentalstrasse 36, 3063 Ittigen, Switzerland

Attn: Quality Assurance

Email: aapotqscovid.lba@vtg.admin.ch.

If to BN:

Bavarian Nordic A/S, Philip Heymans Alle 3, DK-2900 Hellerup, Denmark

Attn: Legal Department

Email: legal@bavarian-nordic.com

25. If Purchaser accepts the abovementioned terms and conditions for supply of JYNNEOS® I kindly ask of you to ensure that the duly authorised representatives of Purchaser sign the enclosed copy of this Agreement and returns it to me.

Best Regards,

[Redacted signature]

[Redacted name]

Bavarian Nordic A/S

For and on behalf of Purchaser we hereby accept the above terms and conditions:

Federal Office of Public Health

[Redacted signature]
[Redacted name]
[Redacted address]
[Redacted phone]
[Redacted email]
[Redacted website]
[Redacted fax]

[Redacted signature]
[Redacted name]
[Redacted address]
[Redacted phone]
[Redacted email]
[Redacted website]
[Redacted fax]

Swiss Armed Forces Pharmacy
Logistikbasis der Armee

[Redacted signature]
[Redacted name]
[Redacted address]
[Redacted phone]
[Redacted email]
[Redacted website]
[Redacted fax]

[Redacted signature]
[Redacted name]
[Redacted address]
[Redacted phone]
[Redacted email]
[Redacted website]
[Redacted fax]
13.10.2022

| **Schedule 1 - Summary Information to support Request for Supply of JYNNEOS® outside US**

Schedule 2 - Delivery Schedule for JYNNEOS®

20 000 doses - no later than 31 October 2022
20 000 doses - no later than 31 December 2022
60 000 doses - no later than 31 March 2023

Summary Information to support Request for supply of JYNNEOS outside US

19 Aug 2022

JYNNEOS

Suspension for injection

Smallpox Vaccine

BLA 125678

1 Introduction

Due to escalation of the Monkeypox situation in May 2022 followed by the WHO declaration of “Public Health Emergency of International Concern” of July 2022 several competent health authorities has requested access to Bavarian Nordic (BN) smallpox and monkeypox vaccine. Current available batches produced for US will be used to fulfill the urgent request for supply outside US. [REDACTED]

The batches have been produced with a US label and indication. The product is registered under the name JYNNEOS®.

Full overview of approved DP shelf life is provided in the following table.

Table 1 Overview of approved DP Shelf Life in US

Storage Temperature	Market	Approved Shelf Life
-20°C ± 5°C	US	3 years
-50°C ± 10°C	US	5 years

In addition, a study was conducted to support short term storage at other temperatures. The data support a label claim for short term storage of LF MVA-BN DP at 5°C for 24 weeks within the approved shelf life period of 5 years when the drug product was previously stored at -50°C. The storage period at 5°C should not exceed the expiry date for storage at -50°C.

It should be noted that the drug product labelling only includes information for storage at -20°C. Information on expiration conditions for storage at -50°C is captured in a memorandum. The label claim for short term storage at 5°C for 24 weeks within the shelf life period of drug product stored at -50°C will thus not appear on the leaflet but is handled in the separate memorandum, as recommended by FDA.

Shipment

Shipment of DP will be performed at ≤-15°C.

1.1 Indication

An overview of the current indications is provided in the following table.

Table 2 Indication

JYNNEOS – US BRAND NAME
Prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection.

JYNNEOS – US BRAND NAME
Indication approved September 2019

Table 3 Indication

IMVANEX – EU BRAND NAME
Active immunisation against smallpox, monkeypox and disease caused by vaccinia virus in adults (see sections 4.4 and 5.1). The use of this vaccine should be in accordance with official recommendations
Indication approved July 2022 (EU)

2 Exemptions

Exemptions to be addressed

- Exemption for delivering with US JYNNEOS label
- Exemption of OMCL release testing, release based on CoA

QUALITY ASSURANCE AGREEMENT between

(1) ARMEEAPOTHEKE ("Contract Acceptor")

Worblentalstrasse 36,
CH-3063 Ittigen,
Switzerland

(2) Bavarian Nordic A / S ("Contract Giver")

Philip Heymans Alle 3,
DK-2900 Hellerup,
Denmark

SIGNED

On behalf of Armeeapotheke	[Redacted]	Date [Redacted] info: admin.ch/esignature validator.ch
On behalf of Armeeapotheke	[Redacted]	Date [Redacted]
On behalf of Bavarian Nordic A/S	[Redacted]	Date DocuSigned by: [Redacted] Signer Name: [Redacted] Signing Reason: I approve this document Signing Time: 24-Oct-2022 10:27 CEST
On behalf of Bavarian Nordic A/S	[Redacted]	Date: E8BED5406D624EE483DBD9F6C3AD9781 DocuSigned by: [Redacted] Signer Name: [Redacted] Signing Reason: I approve this document Signing Time: 24-Oct-2022 10:41 CEST 3F439FAD541E499595D3CC37EC55D2CB

1 Introduction

Unless otherwise specifically provided in this QA Agreement, the following terms shall have the following meanings:

- Applicable Laws and Regulations** with respect to JYNNEOS® the rules, regulations, guidances, guidelines and requirements of EU in effect from time to time applicable to the handling of such Product in Switzerland including applicable cGMP principles and GDPs.
- Good Distribution Practice or "GDP"** means the laws, regulations, practices, guidelines, guidance's, pharmaceutical industry standards and requirements in force from time to time during the term of this Agreement that apply to the warehousing of each Product in Territory. Key Directive is 2001/83/EC as amended and Guidelines on Good Distribution Practice of Medicinal Products for Human Use (2013/C 343/01).
- Importation and Import** means importation of finished goods into Switzerland.
- Contract Acceptor Procedures** means Contract Acceptors' s written standard operating procedures in full compliance with Applicable Laws and Regulations.
- Parties** **Contract Giver** (Bavarian Nordic A / S) and Contract Acceptor (Swiss Armed Forces Pharmacy)
- Product** means the Monkeypox and Smallpox Vaccine (JYNNEOS®) in finished, labelled and packaged form for human as stipulated in the vaccine supply contract.
- Regulatory Approvals** means all licences, permissions and authorisations that are necessary for the manufacture, import, warehousing, storage and handling, distribution and marketing of each Product (For delivery of not licensed product according to the vaccine supply contract).
- Responsible Person (RP) "Fachtechnisch verantwortliche Person"** means a Person at the disposal of the license holders as defined in the Swiss Law on Therapeutic products and the ordinances for delivery of not licensed product according to the vaccine supply contract, release by BN A/S QP.

2 Purpose and Scope

The purpose of this QA Agreement is to define and establish the obligations and responsibilities of Contract Giver and Contract Acceptor relating to the quality assurance requirements of the Swiss Market Release, of the delivery and reception of Product and of any Recall.

- 2.1 This Quality Assurance Agreement shall come into effect on the date of last signature and shall remain in force for all Deliveries for batches that are stored at the Contract Acceptor warehouse directly after importation into Switzerland.
- 2.2 The Parties shall obtain and maintain all applicable Regulatory Approvals required by Applicable Laws and Regulations in order to Import, Store and Handle and Distribute the Vaccine in accordance with this Quality Assurance Agreement.
- 2.3 The Contract Giver is the Marketing Authorization Holder for the Vaccine. He shall support the Contract Acceptor in the fulfilment of his legal duties vis-à-vis the authorities by providing the Contract Acceptor with the necessary information and documentation listed below:
 - Commercial/customs invoice showing order number, customs tariff number, origin of goods
 - Packing details as weight, dimensions, marks etc.
 - Customs Export accompanying document (MRN)
 - Movement certificate EUR 1 or declaration of origin on invoice if applicable
 - For shipments sent by courier indicate tracking number
 - For goods delivered by truck mention transportation date, forwarder and point of border crossing
 - For goods shipped by Airfreight please advise HAWB Number and freight forwarder.
 - For each batch: Test Report from Paul Ehrlich Institute
 - Certificate of Analysis (CoA)
 - For each Delivery: Temperature logger data covering the temperature course of the entire transport.
- 2.4 The Contract Acceptor shall conduct all Product and People related activities in compliance with all applicable Laws and Regulations in special the "Good Distribution Practice" guidelines and according to dedicated local SOPs.
- 2.5 All facilities and equipment must be in compliance with all applicable Laws and Regulation, especially the GDP guidelines including qualification and validation procedures, but also relevant safety guidelines.

3 Goods Receipt Process

- 3.1 Contract Giver should provide the Contract Acceptor with the necessary safety information of any hazardous material including storage and transport requirements.
- 3.2 Contract Acceptor and Contract Giver shall agree upon delivery time as well as upon the delivered quantity of Product before each shipment.

- 3.3 Contract Giver will provide a shipping notice in advance that include all required information to run Goods Receipt process at Contract Acceptor. E.g. quantity of product, batch number, release documentation, expiry date and number of seal at the least.
- 3.4 Contract Giver shall deliver Product to Contract Acceptor under the specified transport conditions to the agreed upon delivery place with accompanying documentation showing identity and quantity of the Product.
- 3.5 An employee from the Contract Acceptor and the driver (together!) should directly before unloading:
 - 3.5.1 open the seal of truck of container
 - 3.5.2 compare the number of the seal with the one on the shipping documentation
 - 3.5.3 sign the shipping documentation
- 3.6 In case of an anomaly (already broken seal, seal number does not match.), Contract Acceptor should:
 - 3.6.1 Take photos inside and outside of the truck and/or container
 - 3.6.2 Unload the goods, keep the Goods in question separated (stored at -20°C)
 - 3.6.3 Inform Contract Giver RP immediately by telephone and within 24 hours in writing.
- 3.7 After unloading, the Contract Acceptor shall perform receipt checks according to internal written procedures that includes:
 - 3.7.1 Condition of the shipment (Humidity, moisture, dirt, damage)
 - 3.7.2 Number of pallets and/or boxes unloaded match to document
- 3.8 Each thermal shipper has reusable GPS enabled monitoring device to ensure end-to-end distribution within required temperatures. Remove and switch off immediately temperature monitors attached to the delivery. Instructions will be provided. Check the alarm signal of data logger. A report will be sent automatically by e-mail upon delivery that will provide information on the temperature monitoring during transit.
- 3.9 All Temperature monitors must be handled according to instruction of Contract Giver.
- 3.10 Proof actual delivery by comparing at least the following elements between physical shipment and shipping documentation (Product Code, Batch number, Quantity and Expiry date).

Each position has to be marked on the document.

In the event of any of discrepancy, or deviations Contract Acceptor will quarantine the Product/Products and consult immediately Contract Giver RP.
- 3.11 Any Product container suspected of being tampered with must be physically segregated and reported to Contract Giver RP within 24 hours.
- 3.12 All received products must be stored in the warehouse under a quarantined status (Not released for sale).
- 3.13 The Goods In receive shall be registered in the IT (SAP) system of the contract Acceptor latest 24 hours after unloading.

4 Quality Evaluation and Release Process

- 4.1 The Contract Giver will keep color photographs of printed packaging components according to Technical Interpretation I-SMI.TI.03e Retention Samples of each batch.
- 4.2 Contract Acceptor will complete a Checklist for each received batch. The checklist requires information about condition, component codes of packaging material.
- 4.3 Contract Giver RP will verify and decide, if the batch can be released or not and communicate the decision via email together with the contract givers release checklist.
- 4.4 The Contract Acceptor RP or defined and trained deputy releases the products (change the status in SAP system) based on the written confirmation from the Contract Giver RP.

5 Product Recall

- 5.1 Contract Giver shall have the responsibility for any communication with Regulatory Authorities regarding a recall.
- 5.2 In the event that a Major Quality Incident originates at Contract Giver which leads to a recall decision, Contract Giver shall notify Contract Acceptor immediately of such decision. Contract Giver shall communicate the official recall instruction to Contract Acceptor when customers are instructed to return Product to Contract Acceptor.
- 5.3 Contract Acceptor shall cooperate with Contract Giver in conducting any recall.
- 5.4 In the event of a recall, Contract Acceptor shall ensure that all recalled Product at Contract Acceptor, or supplied from Contract Acceptor, are reconciled and shall provide Contract Giver with all requested information regarding the Storage and Handling of recalled material. Contract Acceptor shall ensure that recalled material under Contract Acceptor control is secured upon receipt and is subsequently destroyed if required or otherwise handled in accordance with Contract Giver Instructions.

Quality Agreement History Page

Brief description of revisions	Version Number	Effective Date
New version	1.0	Date of last signature

Safety Data Exchange Agreement

BETWEEN

Bavarian Nordic Switzerland AG

AND

**Swiss Armed Forces Pharmacy
Version 1.0**

1 Introduction

This Safety Data Exchange Agreement (SDEA) is made and entered into by and between:

(1) Bavarian Nordic Switzerland AG (CHE-259.519.429), with registered office at Grafenauweg 8, CH-6300 Zug, Switzerland (hereinafter referred to as "Bavarian Nordic"); a fully owned subsidiary of Bavarian Nordic A/S registered with the Danish Business Authority under CVR-no: 16271187, with registered offices at Philip Heymans Alle 3, 2900 Hellerup, Denmark.

and

(2) Swiss Armed Forces Pharmacy, Worblentalstrasse 36, 3063 Ittigen, (hereinafter referred to as "Swiss Armed Forces Pharmacy");

Bavarian Nordic and Swiss Armed Forces Pharmacy may be referred to herein individually as a "Party" and collectively as the "Parties".

The purpose of the SDEA is to describe the procedures for exchange of safety data to be followed by Swiss Armed Forces Pharmacy.

The Products and the Territory are detailed below.

Product(s) / Active Ingredient(s)	Territory
Jynneos/ Modified Vaccinia Ankara – Bavarian Nordic Live virus	Switzerland

The SDEA is based upon and is supplementary to the separate Supply Agreement (Master Agreement) from 11-Oct-2022 entered into between the Parties of the present agreement and the Federal Office of Public Health.

2 Responsibilities

Swiss Armed Forces Pharmacy shall forward any potential safety information (defined as: any suspected adverse drug reactions (ADRs) and adverse events, suspected transmission of an infectious agent, lack of effect, abuse, misuse, medication error, overdose, off-label use, all the latter special scenarios refer to whether or not associated with adverse event, same for use of product during pregnancy or breastfeeding with or without any associated adverse event, product quality complaints (PQCs) associated with potentially safety relevant information, any suspected counterfeit product, unexpected positive effects, occupational exposure), via email to Bavarian Nordic drug.safety@bavarian-nordic.com within 3 calendar days of initial knowledge.

Swiss Armed Forces Pharmacy shall forward any potential PQC defined as any deviation of the pharmaceutical properties listed in the package insert or summary of product characteristics, e.g. in view of colour, smell, liquidity, taste, solubility, miscibility or filling-grade and every impairment of the packaging, outer or inner envelopment or package-insert and any malfunction, (suspect) counterfeit medicines to quality.complaints@bavarian-nordic.com within 3 calendar days of initial knowledge.

Swiss Armed Forces Pharmacy shall forward any Medical Information Inquiry (MIE) to medical.information_eu@bavarian-nordic.com within 3 calendar days of initial knowledge.

Bavarian Nordic Switzerland AG is responsible for the further follow-up of the obligations arising from the regulations on the handling and reporting to Swissmedic of adverse reactions and other safety information.

3 Miscellaneous

3.1 Data Privacy

To the extent required under applicable laws, each Party warrants to the other that its activities and obligations under this SDEA will comply with Data Protection and Privacy legislation applicable to its activities within the Swiss territory.

3.2 Language of Communication

Both Parties will use English to communicate under this SDEA. However, potential safety information, potential PQC and MIE received by Swiss Armed Forces Pharmacy will be transmitted in the language of receipt, without any translation and processing, except for anonymisation (initials, gender and age), if applicable.

3.3 Applicable Law

Each Party shall comply with applicable law and regulations.

4 Duration and Term of the Agreement

Any amendment to the SDEA, except changes to contact information, requires signatures from both Bavarian Nordic and Swiss Armed Forces Pharmacy.

The SDEA will be reviewed no less than every two years by both Parties or within one month of the product authorization status change.

Any of the Parties may terminate the SDEA with a written termination notice delivered to the other Party. The termination period shall be one (1) month and shall commence on the first day of the month following the termination notice delivery to the other Party.

The SDEA shall expire automatically upon expiry or termination of the Master Agreement between Bavarian Nordic, the Federal Office of Public Health and Swiss Armed Forces Pharmacy.

5 Governing law and jurisdiction

This SDEA shall be governed by Applicable Swiss Law (both parties being located in Switzerland).

6 Signatures

This SDEA shall become effective upon the date of the last signature of any Party hereto.

Bavarian Nordic Switzerland AG

Name: [Redacted]

Date: 17-Nov-2022 | 13:34 CET

Job position: [Redacted]

Signature: [Redacted]

DocuSigned by:
[Redacted]
Signer Name: [Redacted]
Signing Reason: I approve this document
Signing Time: 17-Nov-2022 | 13:34 CET
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Bavarian Nordic A/S EU QPPV

Name: [Redacted]

Date: 17-Nov-2022 | 17:16 CET

Job position: [Redacted]

Signature: [Redacted]

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[Redacted]
Signer Name: [Redacted]
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Swiss Armed Forces Pharmacy

Name:

Date:

Job position:

Signature:

Swiss Armed Forces Pharmacy

Name:

Date:

Job position:

Signature:

Swiss Armed Forces Pharmacy

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Version 2.0

Name:

Date:

Job position:

Signature:

7 Appendix 2: Contact Details

Bavarian Nordic	
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Swiss LPPV	Name: [REDACTED] Address: [REDACTED] [REDACTED] CH-8620 Wetzikon Switzerland Phone: [REDACTED] Email: [REDACTED]
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Safety data, MIE and PQC transmission email address	drug.safety@bavarian-nordic.com for safety relevant information medical.information_eu@bavarian-nordic.com for MIEs quality.complaints@bavarian-nordic.com for PQCs

Swiss Armed Forces Pharmacy	
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Safety data, MIE and PQC transmission email address	pharmacovigilance.lba@vtg.admin.ch (for Safety data; MIE) aapotqscovid.lba@vtg.admin.ch (for PQC)

Any changes have to be communicated in writing within seven (7) calendar days and date of the change has to be stated. Apart from update of contact details, any change requires signatures of both Parties.