14 September 2022

Direct Healthcare Professional Communication

Letter to GB/UK Healthcare professionals about the differences between IMVANEX® brand (licensed in GB/UK) and JYNNEOS® brand (licensed in US) of *Live Modified Vaccinia Virus Ankara*

Dear Healthcare Professional,

This letter explains

- the regulatory conditions under which JYNNEOS® vaccine has been approved for use in the current program for NHS management of monkeypox,
- the shelf-life and storage conditions approved for the vaccine by MHRA,
- the differences between the regulatory approvals in the UK and in the US.

Please ensure all relevant staff are made aware of the content of this letter.

In the context of the current outbreak of monkeypox, the UKHSA has implemented a programme that includes the use of a vaccine developed by Bavarian Nordic.

Bavarian Nordic has a licensed vaccine containing *Live Modified Vaccinia Virus Ankara* (MVA-BN) to prevent disease due to an infection with smallpox. This vaccine has also shown to be able to prevent monkeypox and other orthopox diseases. The MVA-BN vaccine is licensed in UK, EU, US and Canada but no stock of the UK-licensed Imvanex product is immediately available.

In view of the urgency of the need to manage the monkeypox outbreak, Batch-Specific Variations for batch FDP00012 and FDP00072 have been granted by MHRA to allow importation of the Food and Drug Administration (FDA)-licensed JYNNEOS® brand of the MVA-BN vaccine in the US.

The conditions of regulatory approval by MHRA vary slightly from those of the FDA for the US market.

Table illustrating the major differences between the two vaccine registrations:

EU/UK	US	Explanation/ Justification
IMVANEX®	JYNNEOS®	Different brand names in each region
Live Modified Vaccinia Virus Ankara	Live Modified Vaccinia Virus Ankara	The vaccine is comparable and was made under similar manufacturing conditions.
Active immunisation against smallpox, monkeypox and disease caused by vaccinia virus in adults.	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® approval includes a monkeypox indication. For IMVANEX® the extension of indication including monkeypox was granted by MHRA in Sep 2022. Batch-specific variation for JYNNEOS® granted for import to UK market summer/autumn 2022.
Store in a freezer -20°C (±5°C) or -50°C (±10°C) or -80°C (±10°C)	Store frozen: - 25°C to -15°C (-13°F to +5°F) or - 50°C ± 10°C	Labelled storage condition for JYNNEOS® is at -20°C (±5°C), however JYNNEOS® can be also stored at -50°C (±10°C) and -80°C (±10°C).
A two-year shelf life for the product stored at -20°C ± 5°C A five-year shelf life for the product stored at -50°C ± 10°C A five-year shelf life for the product stored at -80°C ± 10°C	A three-year shelf life for the product stored at -20°C ± 5°C A five-year shelf life for the product stored at -50°C ± 10°C NA shelf life for the product stored at -80°C ± 10°C	Project to harmonise storage conditions and shelf life across all markets is ongoing. Labelled expiry date is set based on a shelf life of 3years at -20°C (±5°C) as approved by US.

As part of the batch-specific variation, MHRA has accepted additional stability data that support the three-year shelf-life for JYNNEOS® when stored at -20°C ± 5°C, as also approved by the FDA.

In addition, MHRA has also approved for JYNNEOS® a shelf-life of 8 weeks starting from the time of thawing and transfer from –20°C storage to the refrigerator at 2-8°C in line with the UK/EU approval, whereas FDA approval for the US market only allow a holding time of 12 hours at 2-8°C.

Healthcare professionals are asked to provide JYNNEOS® package insert included in the outer packaging to patients receiving a vaccine. The UK Patient Information Leaflet for IMVANEX® is also available for patients to read on the MHRA website (*https://products.mhra.gov.uk/search/?search=IMVANEX*).

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions (ADRs) to the Yellow Card Scheme electronically. Please report via the website www.mhra.gov.uk/yellowcard, by the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free 9am – 5pm Monday to Friday.

The QR code can be used for quick and easy access to the Yellow Card reporting site.

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When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a vaccine, please provide the brand name (or product licence number and manufacturer), and the specific batch-number.

Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card Scheme.

We remain available for any further questions about this vaccine. Please use medical.information_EU@bavarian-nordic.com to send us your questions,

Best regards,

Bernard Hoet, MD
VP Head of Medical Strategy
Bavarian Nordic