Moderna Biotech Spain S.L.
Calle Monte Esquinza 30, 28010 Madrid
Spain

15 October 2021

Direct Healthcare Professional Communication

Spikevax▼ (also known as COVID-19 Vaccine Moderna): Potential mismatch between printed Patient Information Leaflets (PILs) and vial labels and cartons as Moderna makes the tradename transition

Dear Healthcare Professional,

MODERNA BIOTECH SPAIN, S.L. in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

- Moderna is in the process of updating the product's invented name on the vial label and carton from the previously used common name "COVID-19 Vaccine Moderna" to the newly approved invented name "Spikevax".

- The manufacturing of the new packaging materials started as of 6th of September 2021. Batch release of product occurring after 31st of October 2021 is expected to have the "Spikevax" name on the pack.

- In this interim period, there may be a mismatch between printed PILs with the "Spikevax" name (which are shipped directly to vaccination sites and are printed separately) and vial labels and cartons (labeled as "COVID-19 Vaccine Moderna") as Moderna makes the transition.

- Please note that both vial labels and cartons bearing the names "COVID-19 Vaccine Moderna" and "Spikevax" may be present at vaccination sites during transition in supply.

There are only two **actions we ask NHS Healthcare professional to take**

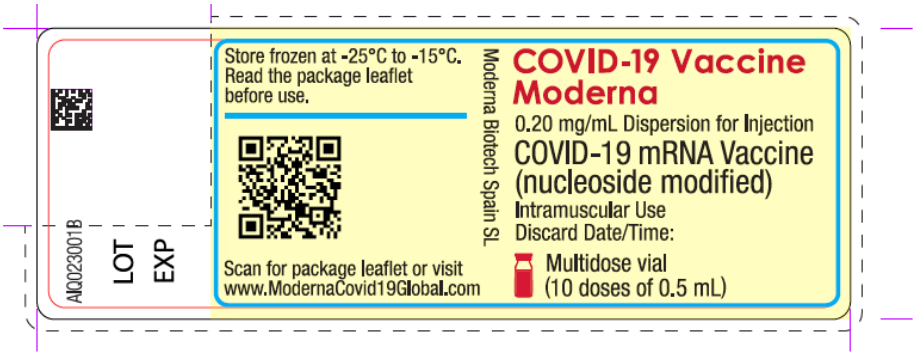
1. Once local supplies of the unbranded Patient Information Leaflet are exhausted, ensure the Spikevax Patient Information Leaflet supplied with your order is provided to the vaccine recipients, irrespective of whether they are receiving COVID-19 Vaccine Moderna or its branded equivalent Spikevax.

2. Where necessary, reassure vaccine recipients that they are receiving the correct vaccine and that it is the same vaccine previously known as COVID-19 Vaccine Moderna.

The only change to our COVID-19 vaccine is the change of name to Spikevax. Spikevax is identical in every respect to the COVID-19 Vaccine Moderna previously supplied by Moderna.

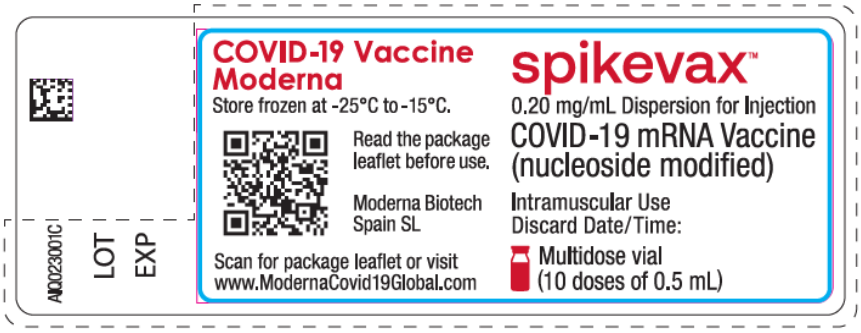
Please see the labeling examples below for more details.

Vial Label Example (prior to tradename adoption):

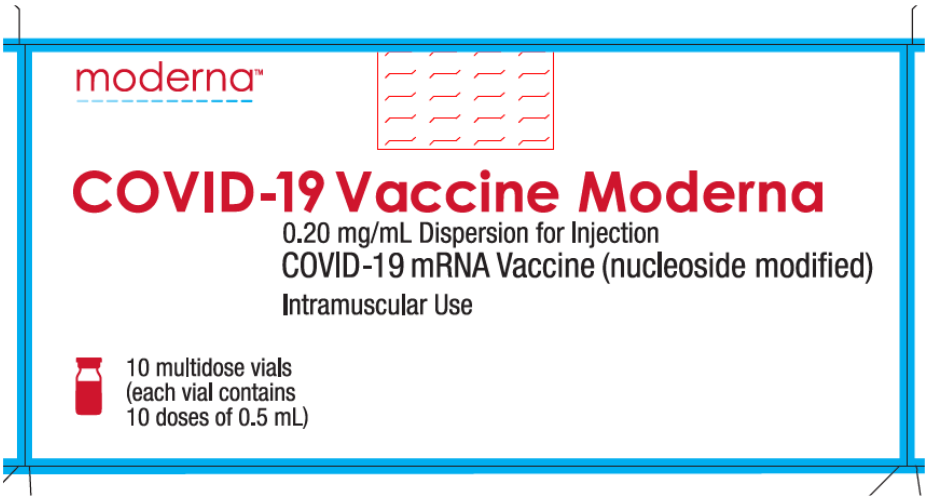


Please note: the vial label is not really yellow; this color signifies the varnished area rather than a printed color.

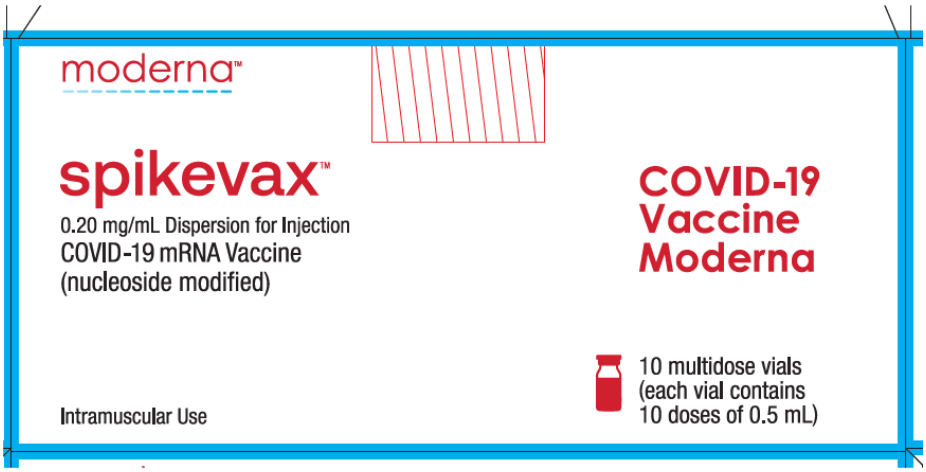
Vial Label Example (with Spikevax tradename):



Carton Front Panel Example (prior to tradename adoption):



Carton Front Panel Example (with Spikevax tradename):



Spikevax has been approved in the UK under conditional marketing authorisation for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older. It was previously available as COVID-19 Vaccine Moderna, following approval by the MHRA on 8 January 2021.

Call for reporting

Healthcare professionals and patients are asked to report any suspected adverse reactions associated with the use of COVID-19 vaccines to the Coronavirus Yellow Card reporting site at https://coronavirus-yellowcard.mhra.gov.uk/ or Yellow Card App.

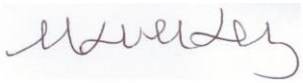
When reporting, please provide as much information as possible, including vaccine brand name and batch number, vaccination date, previously received doses, onset and description of the reaction, and information about medical history and any concomitant medication.

Other suspected adverse drug reactions (ADRs) should be reported via to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, 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 effect can also be reported by calling 0800 731 6789 for free.

MARKETING AUTHORISATION HOLDER
MODERNA BIOTECH SPAIN, S.L.
Calle Monte Esquinza 3028010
Madrid
Spain
medinfo@modernatx.com
https://www.modernacovid19global.com/

Contact Moderna
8am-5pm GMT – Mon – Fri
08000857562
Email: EMEAMedinfo@modernatx.com



Matthew Lumley MBBS PhD MRCP MFPM
Senior Medical Director | Moderna Inc.