Importation of Moderna COVID-19 Vaccine with either 10 or up to 15 Doses per Vial and English-only Vial and Carton Labels (US-Labelled Supply)

10/09/2021

Audience

Healthcare professionals including infectious disease physicians, pharmacists, family physicians, public health officials, nurses and nurse practitioners, and healthcare professionals at identified points of use.

Zuellig Pharma is distributing COVID-19 Vaccine Moderna doses directly to vaccination locations where administration of the vaccine will occur, as outlined by provincial and territorial governments and public health authorities.

Key messages

- **Further to the May 05, 2021 Conditional Approval of the COVID-19 Vaccine Moderna, ModernaTx, Inc. is providing US-labelled vaccine supplies with English-only vial and carton labels (see Appendix A) in order to expedite the distribution of the vaccine in the Philippines.**
- **Moderna COVID-19 Vaccine with US labels is the same as the Food and Drug Administration Philippines authorized COVID-19 Vaccine Moderna in all aspects (i.e., formulation, strength, route of administration).**
- **Healthcare professionals are advised that:**
    - **The US-labelled supply may be additionally offered in an 8 mL vial fill containing 15 of 0.5 mL each. This is different from the Food and Drug Administration Philippines authorized product which comes in vials containing 10 doses of 0.5 mL each.**
    - **Information regarding the vaccine name, description of pharmaceutical form, volume of vial fill and storage conditions are different on the US labels. Continue to reference the Food and Drug Administration Philippines approved labelling for all product**

information for use in the Philippines.

- **The expiration date is not printed on the US vial and carton labels. Healthcare professionals must verify the expiration date prior to vaccination. The expiration date for the corresponding lots can be found on this website. Please follow the instruction to retrieve the expiration date.**

What is the issue

COVID-19 Vaccine Moderna was authorized for use in accordance with Food and Drug Administration Philippines regulation. As an extraordinary measure to provide access to vaccine supplies in the context of the global pandemic, Moderna is providing US-labelled vaccine supply on a temporary basis.

The US-labelled vaccine, named 'Moderna COVID-19 Vaccine', can be supplied in a carton of 10 multiple-dose vials with either 6.3 mL fill volume (10 doses) or 8 mL fill volume (15 doses).

Products affected

U.S. Vaccine Name	Dosage Form, Strength, and Route of Administration	Country of Origin and Identifying Code	Manufacturer	Importer and Supplier in the Philippines
Moderna COVID-19 Vaccine	Suspension for Intramuscular Injection 10 multiple-dose vials (each vial contains maximum of 10 doses of 0.5 mL) Or 10 multiple-dose vials (each vial contains maximum of 15 doses of 0.5 mL)	USA NDC 80777-273-15 (vial) NDC 80777-273-98 (carton)	Moderna US, Inc.	Zuellig Pharma

Expiration Date of Moderna COVID-19 Vaccine manufactured in US
The expiry date is not printed on the vial and carton labels (see Appendix A). To find the expiration date for Moderna COVID-19 Vaccine lots manufactured in US, please click on the following link and follow the instruction:

https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup#vialLookUpTool

Background information
COVID-19 Vaccine Moderna is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older.

As an extraordinary measure to provide access to vaccine supplies in the context of the global pandemic, Food and Drug Administration Philippines has authorized the importation and sale of US-labelled Moderna COVID-19 Vaccine with vial and carton labels that are in English-only. The availability of US-labelled Moderna vaccine will be offered on an exceptional basis.

Information regarding the vaccine name, description of pharmaceutical form, volume of vial fill and storage conditions are different on the US labels. Continue to reference the Food and Drug Administration Philippines approved labelling for all product information for use in the Philippines.

Food and Drug Administration Philippines has approved the following interim US-labelled Moderna COVID-19 Vaccine Product Presentation:

- Carton of 10 multiple-dose vials with 8 mL fill volume.
    - Each vial contains 15 doses (0.5 mL).
- Carton of 10 multiple-dose vials with 6.3 mL fill volume.
    - Each vial contains 10 doses (0.5 mL).

The US Moderna COVID-19 Vaccine with English-only labels is the same as the Food and Drug Administration Philippines authorized COVID-19 Vaccine Moderna in all aspects (i.e., formulation, strength, route of administration) and should be used in the Philippines for the same indication and per the same vaccination schedule.

Information for healthcare professionals
Healthcare professionals should be aware that there are no changes to the product.

The indication, dosage, route of administration, strength, formulation, and non-medicinal ingredients in the US-labelled product are the same as the current Food and Drug Administration Philippines authorized COVID-19 Vaccine Moderna.

Healthcare professionals are advised that:

- The US-labelled Moderna COVID-19 Vaccine has a different carton and vial label. Continue to reference the Food and Drug Administration Philippines approved product information for use in the Philippines.
- The expiry date is not printed on the vial and carton labels (see Appendix A). **The expiration date for the corresponding lots can be found on this website. Please follow the instruction to retrieve the expiration date.**
- There are no changes to the dosage and administration, other than the total number of doses per vial (8 mL)
- There are no changes to the storage, stability and disposal of the vaccine. The US-labelled Moderna COVID-19 Vaccine should be stored and discarded in accordance with the Food and Drug Administration Philippines approved information.

Report health or safety concerns

Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any serious or unexpected side effects in patients receiving COVID-19 Vaccine Moderna should be reported to your local Health Unit.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the FDA at (02) 8809 5596 or report online to https://www.fda.gov.ph/covid-19-vaccine-report-a-side-effect.

Original signed by

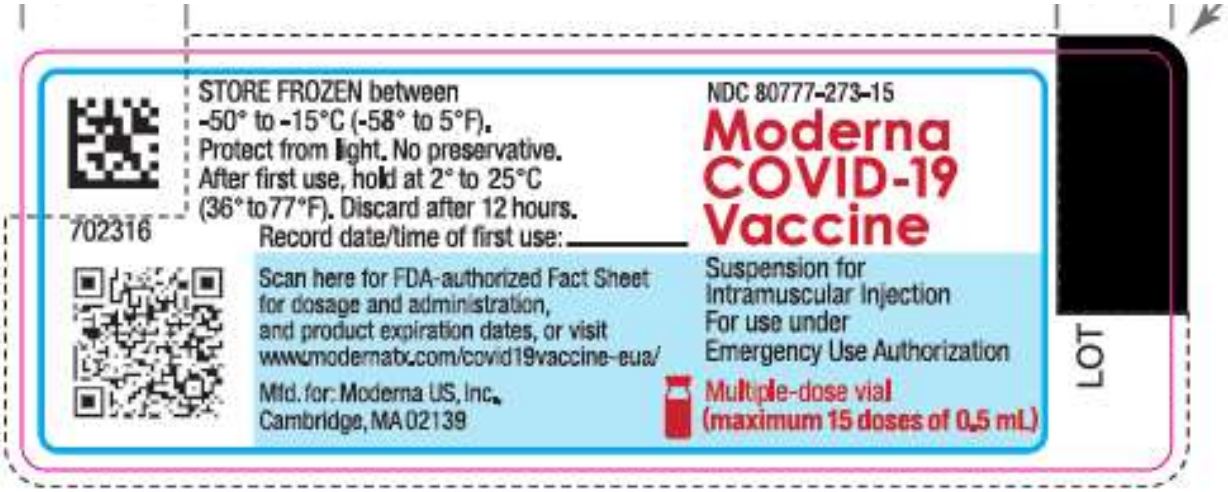
Paolo Dametto

Digitally signed by Paolo Dametto
Date: 2021.09.10 18:08:49 +02'00'

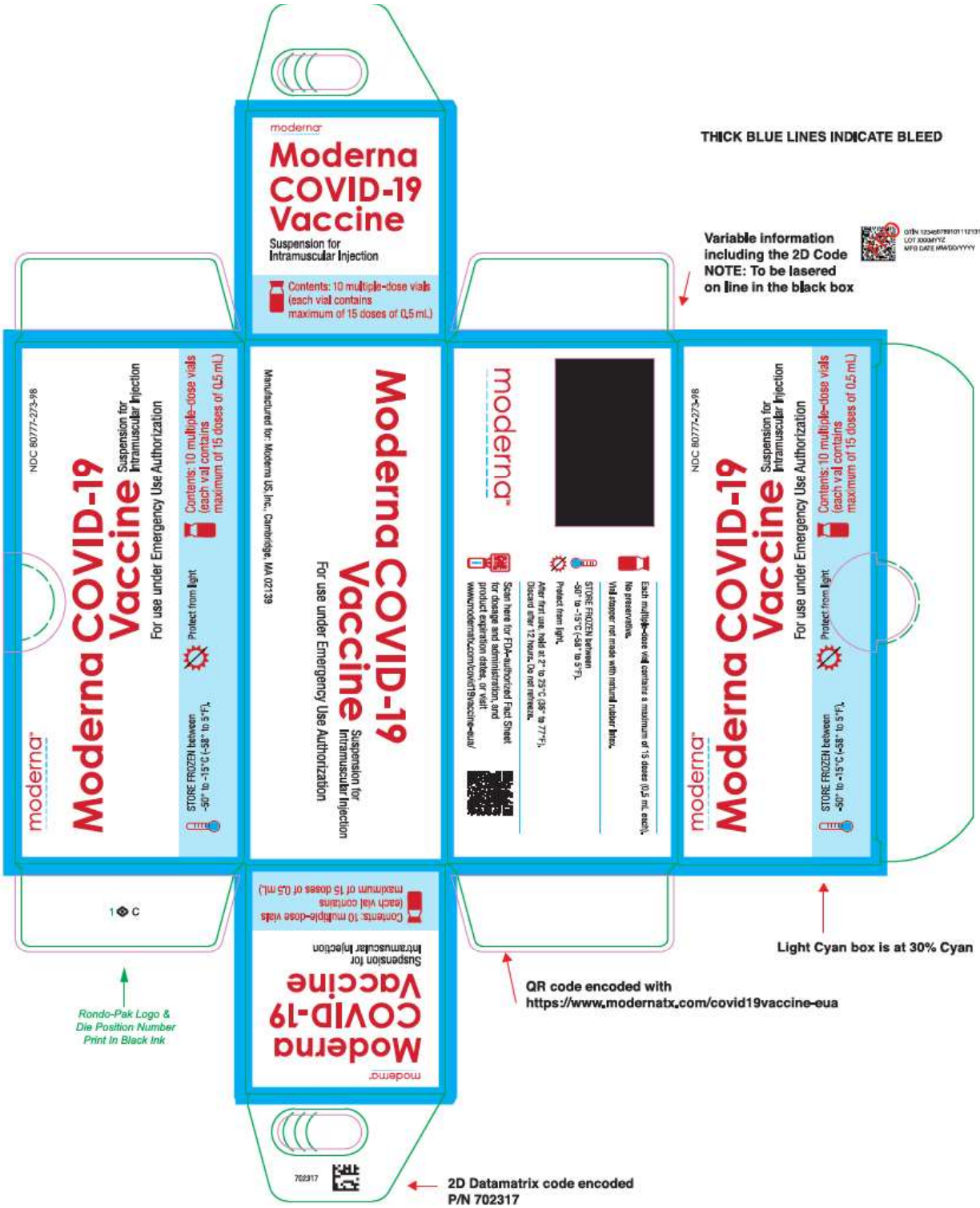
Paolo Dametto, PhD
Sr. Manager – International Regulatory Affairs
Moderna Switzerland GmbH

Appendix A – Vial and Carton Labels for Moderna COVID-19 Vaccine with English-only Labelling (US-labelled supply)

U.S. VIAL LABEL



U.S. CARTON LABEL


THICK BLUE LINES INDICATE BLEED
Variable information including the 2D Code
NOTE: To be lasered on line in the black box
moderna
Moderna COVID-19 Vaccine
Suspension for Intramuscular Injection
Contents: 10 multiple-dose vials (each vial contains maximum of 15 doses of 0.5 mL)
NDC 80777-273-98
For use under Emergency Use Authorization
Protect from light
STORE FROZEN between -50° to -15°C (-58° to 5°F).
Manufactured for: Moderna US, Inc., Cambridge, MA 02139
Each multiple-dose vial contains a maximum of 15 doses (0.5 mL each).
No preservative.
Vial stopper not made with natural rubber latex.
After first use, hold at 2° to 25°C (36° to 77°F).
Discard after 12 hours. Do not refreeze.
Scan here for FDA-authorized Fact Sheet for dosage and administration, and product expiration dates, or visit: www.modernatx.com/covid19vaccine-eua/
Light Cyan box is at 30% Cyan
QR code encoded with https://www.modernatx.com/covid19vaccine-eua
Rondo-Pak Logo & Die Position Number Print In Black Ink
2D Datamatrix code encoded P/N 702317
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