To: QP-RIVM[1.2e @rivm.nl]; batchreview[5.1.2e @rivm.nl]; 5.1.2e [5.1.2e @rivm.nl]
Cc: 5.1.2e [5.1.2e @modernatx.com]; 5.1.2e [5.1.2e @live.com]; Moderna Vaccine Information[5.1.2e @modernatx.com]
From: 5.1.2e
Sent: Fri 1/8/2021 12:17:04 PM
Subject: Moderna-The Netherlands: Finalizing vaccine delivery details
Received: Fri 1/8/2021 12:17:05 PM

Dear 5.1.2e

As agreed today during our call with the Netherland team, we are providing you with a summary of the release related activities we will be performing with your collaboration and the list of related documentation. Do not hesitate to contact us if you have any questions.

Note: Any additional document requested in addition to the ones described above may lead to some delays in the shipment of goods to your country (originally planned for Monday January 11th).

1. Overview of the different release steps:

- Finished Product is manufactured at Rovi in Spain, where EU batch certification is performed and retention samples stored
- The product is shipped from Spain to Belgium, where is it stored at the central warehouse of our partner Kuehne + Nagel
- The product is released by the Moderna EU Responsible Person for further distribution to your country
- The product is shipped to your country and delivered to the defined handover point.
- Country incoming goods check documentation is sent to Moderna
- You will release the product for in Country distribution.

2. Documentation you will receive from Moderna when the product is shipped to your country:

- Manufacturing site (Rovi) CoA and CoC (including EU Batch certificate and list of critical and major deviations)
- OMCL certificate
- Moderna CoC

3. Documentation you will need to send to Moderna QA as soon as possible after receiving the product:

- Confirmation that the goods have been received in good physical condition
- Incoming checks for the labeled identity (product name, batch number, quantity) of the material, as well as seal checks.
- Filled receiving site part of the Transport data logger tracking form
- Read outs of the temperature data including immediate notification of any excursions.
- After you have released the product, please send us a confirmation that it was released, including an evidence (E.g. local batch certificate)

Any discrepancy in the incoming checks at the Country should be notified to Moderna QA in Basel within 24 hours of goods receipt.
Note: in case no discrepancy is detected, the final release will be performed at Moderna based on the documents listed in 3), with no further communication to you and you may go ahead with your local release activities. Only in case of discrepancy at incoming goods check will we be further communicating on this batch with you.

4. Pandemic customer qualification concept

- The need for a full GDP qualification of the country distributor has been waived to allow us to ensure the first deliveries to all member states according to the planned schedule.
- We are open to establishing a Quality Agreement with you, should you need it, once the routine supply and release processes have reached a steady state.

Your primary Moderna QA contacts are:

- 5.1.2e 5.1.2e
- 5.1.2e
- 5.1.2e 5.1.2e

The release documentation will be sent to you by 5.1.2e via the following email address: 5.1.2e @modernatx.com. Incoming goods check documentation should be sent back to the same email address.

We are looking forward to sending you the first mRNA-1273 Covid-19 Vaccine delivery.
Kind regards

5.1.2e

5.1.2e

VP, International Quality
Moderna Switzerland GmbH
5.1.2e @modernatx.com
Cell: 5.1.2e

Please consider the environment before printing this email