EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

SANTE.DDG1.B.5[redacted]2020)8857821

BTO : Meeting with Pfizer/BioNTec on Moday 21 December 2020 - request for MIF response waiver

The company explained that normal process requires that the MAH submits the Marketing Information form and other supporting documentation to the Member State Competent Authority to inform them that the MAH is placing the batch on the market. The MAH has to wait up to 7 days pending any response from the Competent Authority in the Member State. If no response received, the MAH can then place the product on the market for distribution.

[redacted]

in parallel to shipment of the batches to the Member States in but **requested a waiver regarding the waiting for a response by MS in order to avoid delays in delivery**. The maximum time they could wait for a response by MS is up to 2 hours. The request for the waiver in the waiting time for a response is only for the period of Christmas and New year. Further updates on the MIF process timing will be agreed with the EC in middle of January.

- ✓ Company to send email following call confirming the above.

- ✓ EC to send an email informing MS on the waiver request with the above information including the duration for the holiday period. For any MS not agreeing with the waiver they can contact the company directly to make appropriate arrangments. In January there will be revision of when the normal process can resume.

[redacted] asked about the request by some authorities on pictures of batches. EC is not aware but considered this may be possibly due to serialisation omission.

END

Participants: [redacted]

EC: [redacted]