From: (SANTE)
Sent: jeudi 9 avril 2020 12:38
To: NEOCLEOUS Olympia (CAB-KYRIAKIDES); OJALA Annukka (CAB-KYRIAKIDES)
Cc: RYS Andrzej Jan (SANTE); SEYCHELL Martin (SANTE); (SANTE); JUELICHER Sabine (SANTE); (SANTE); SANTE); (SANTE); (SANTE); (SANTE); (SANTE); (SANTE); (SANTE); (SANTE); (SANTE); (SANTE); (SANTE); (SANTE)
Subject: BTO – meeting between Commissioner Kyriakides and Novartis, 7 April 2020

Follow Up Flag: Follow up
Due By: mardi 14 avril 2020 17:00
Flag Status: Flagged

Dear all,
With thanks to , please see read out of the meeting with Novartis.

BTO – meeting between Commissioner Kyriakides and Novartis, 7 April 2020
Participants: Commissioner Kyriakides, Annukka Ojala, Olympia Neocleous (CAB), (SANTE B5), Guido Rasi, Noel Wathion, (EMA)
Novartis: - EU Institutions Novartis, – Sandoz Head Europe, Public Affairs Sandoz Europe
The meeting took place via videoconference.

Summary – Commissioner Kyriakides informed about the Commission activities. Novartis/Sandoz informed of their activities to ensure business continuity, in particular maintaining supply of their medicines which are in demand for the treatment of COVID-19 patients. They raised concern that patients with other diseases or conditions, such as cancer, might not have surgery or treatment due to the demands caused by COVID-19. The Commissioner asked for more specific information on this issue.

Details of the discussion - Commissioner Kyriakides expressed appreciation for the regular updates from the industry associations. She informed that guidance on optimal and rational use of medicines would be published on 8 April. She noted the offer of a donation of hydroxychloroquine and asked if the data on its safety and efficacy was being collected.
Novartis indicated that the regular contacts with the Commissioners was important allowing updates on emerging issues. They thanked the Commissioner for the letter concerning critical medicines for treatment of COVID-19 in intensive care units (UCU) which helps to frame the follow up by the industry. They informed on the actions they had taken to ensure business continuity. They seek to combine security of supply, quality and a strong manufacturing base. All 10 EU production sites are fully operational. Their supply teams monitor the situation to avoid stockpiling, giving priority to products in low stock. Some medicines are at risk of shortage due to increased demand for treatment and stockpiling. They are assessing what contribution they can make to the supply of ICU medicines and the industry coordination activity initiated by Medicines for Europe. They noted the need for some

regulatory flexibility to allow the company to take certain actions. EMA informed that the flow of information on supply and demand is important and that all companies are asked to identify a contact person for the exchange of this information. Regarding regulatory flexibility, a Q&A had been prepared.

Novartis informed that they are planning the investigation of potential treatments for COVID-19. Clinical trials have started with some medicines but it will take time to collect the evidence. They are looking to participate in international clinical trials. Regarding the donation of hydroxychloroquine, they are investigating the systematic allocation and the possibility of having compassionate use programmes for their medicines in clinical trials.

Novartis indicated that they had received reports that operations or treatment are not taking place for patients with other diseases and conditions. The Commissioner ask for more details.

The Commissioner suggested another meeting in 3-4 weeks for an update on shortages, ICU medicines and care for other patient groups (oncology).
END