From: SANTE PHARMACEUTICALS B5
To: [redacted]
Cc: SANTE PHARMACEUTICALS B5
Subject: RE: Remdesivir for European Commission
Date: vendredi 17 juillet 2020 11:58:12
Attachments: image001.png

Dear [redacted]

With reference to your correspondence of 6 July 2020, I would like to inform you that a medicinal product can be placed on the European Union market only after a marketing authorisation has been granted in accordance with the pharmaceutical legislation[1] either by the competent authority of an EU Member State for its own territory (national authorisation) or by the European Commission for the entire EU (EU authorisation).

The European Commission granted a conditional marketing authorisation for the Veklury (remdesivir) on 3 July 2020. According to the EU pharmaceutical legislation, once the medicinal product is placed on the market in a Member State, the marketing authorisation holder is responsible for the supply process.

It should be also noted that a company can only market a generic medicine in Europe once the 10-year period of marketing protection (of which 8-year period of data protection) for the original medicine has expired.

We thank you for your offer, however at this point and time we do not need to reserve any supply.

Yours sincerely,

Unit "Medicines: policy, authorisation and monitoring"

European Commission
DG Health and Food Safety

From: [redacted]
Sent: Monday, July 6, 2020 7:27 PM
To: SANTE CONSULT-B5
Subject: Remdesivir for European Commission

Good Afternoon:
Ik las een artikel waarin [redacted] werd genoemd over de lopende onderhandelingen tussen de Europese Commissie en Gilead Sciences om de voorziening van levensreddende Remdesivir veilig te stellen.

Ik begrijp de huidige situatie van het tekort, samen met de aankondiging van Gilead over de toewijzing van bijna al het aanbod voor de komende drie maanden Remdesivir aan de Verenigde Staten.

Wij vertegenwoordigen een van de grootste geneesmiddelen in Bangladesh met een

generieke Remdesivir voor gebruik en beschikbaarheid door EUA.

Laat het ons weten als we de Europese Commissie op dit moment kunnen helpen bij het toewijzen van de productie van Remdesivir.

Dank u

I read an article that mentioned [redacted], regarding the ongoing negotiations between European Commission and Gilead Sciences to secure the supply of life saving drug **Remdesivir**.
I understand the current situation of the shortage along with the Gilead's announcement on allocation of nearly all of its supply for the next three months of Remdesivir to the United States.
We represent one of the largest pharmaceuticals in Bangladesh that has a generic Remdesivir for EUA use and availability.

Please let us know if we can help European Commission allocate any of the production of Remdesivir at this time.

Thank you

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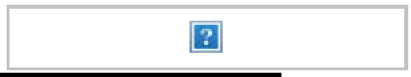

[redacted]

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[1] Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, as amended, Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, as amended.