From: SANTE PHARMACEUTICALS B5
To: [redacted]
[redacted] SANTE PHARMACEUTICALS B5
Subject: RE: Generic Remdesivir
Date: vendredi 17 juillet 2020 13:27:53
Attachments: image001.png

Dear [redacted],
With reference to your correspondence of 2 July 2020 addressed to Commissioner Kyriakides, which has been forwarded to us for reply.
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.
Yours sincerely,
Unit "Medicines: policy, authorisation and monitoring"
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European Commission
DG Health and Food Safety

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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.

Von: "[redacted]
Datum: Donnerstag, 2. Juli 2020 um 13:31:57
An: [redacted] (CAB-KYRIAKIDES)" [redacted]
Betreff: Generic Remdesivir
Dear Commissioner Stella Kyriakides and team:

I had read an article that mentioned the EU's efforts to secure Remdesivir since the U.S. had bought up all of Remdesivir supply from Gilead Sciences for the next three months.
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 the European Commision procure any of this supply.

Thanks,
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ProcureNet

[redacted]

Procuring Safety.
Hong Kong

[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.