Dear [Name],

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“

European Commission
DG Health and Food Safety

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Thanks,

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ProcureNet

Procuring Safety.
Hong Kong

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