From: SANTE PHARMACEUTICALS B5
To: [redacted]
Cc: SANTE PHARMACEUTICALS B5; DELEGATION BANGLADESH (EEAS)
Bcc: [redacted]
Subject: RE: Remdesivir Injection
Date: lundi 20 juillet 2020 09:10:00
Attachments: image002.png
image003.png

Dear [redacted]

With reference to your correspondence of 2 July 2020 addressed to the EC Delegation in Bangladesh. 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

[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.

From: [redacted]

Sent: 02 July 2020 14:06
To: DELEGATION BANGLADESH <xxxxxxxxxxxxxxxxxxxxx@xxxx.xxxxxx.xx >
Subject: Remdesivir Injection

Dear [redacted]

You may be aware that Beximco Pharmaceuticals Ltd. was the first company in the world to launch generic Remdesivir IV Injection under the brand name “Bemsivir” and since its launch on May 21, 2020 we have been providing this drug free of cost to all govt designated COVID-19 treating hospitals in the country. This reinforces our commitment to play our part in ensuring access to breakthrough therapy during this unprecedented pandemic. As a responsible Company, we will do our best to provide access to Remdesivir, making them highly affordable to critically ill patients around the world.

We are already exporting Remdesivir to several countries and to expand the supply of this drug to other countries who need them urgently, we are ramping up production to meet the growing demand. At this moment, after meeting our local requirements, we can supply around 50,000 vials (100 mg, lyophilized injectable vials) every month which is expected to rise to 100,000 vials within shortest possible time.

As we are receiving large number of requests from all over the world, it would be important for us to understand the need or requirement for Remdesivir from your end, which would be very helpful for our proper planning and allocation.

For your information, Beximco Pharma′s state-of-the-art manufacturing facilities are certified by global regulatory authorities of USA, Europe, Australia, Canada, GCC and Latin America, among others and the Company has a geographic footprint in more than 50 countries.

If you have any queries, please do not hesitate to contact me through Email.

Thanking you.

Yours sincerely,

[redacted] | Beximco Pharmaceuticals Ltd. | 19 Dhanmondi R/A, Road #7, Dhaka 1205 | Bangladesh
[redacted] |**Web** www.beximcopharma.com