

**Via Email to:**

CBG  
IGJ  
VWS  
RIVM

Date: August 5, 2020  
Subject: ESI and translation exemption  
Product: Veklury (remdesivir) 100 mg powder for concentrate for solution for infusion  
Veklury (remdesivir) 100 mg concentrate for solution for infusion  
MA number: EU/1/20/1459/001-002

Dear Sir/Madam,

On 3 July 2020, Veklury (remdesivir) 100 mg powder for concentrate for solution for infusion and 100 mg concentrate for solution for infusion were granted a conditional Marketing Authorisation (MA) for the treatment of coronavirus disease 2019 (COVID-19) in adults and adolescents (aged 12 years and older with body weight at least 40 kg) with pneumonia requiring supplemental oxygen.

Further to the grant of this conditional MA, the European Commission has announced on 29 July that an agreement has been reached between the Commission and Gilead to ensure that stocks of Veklury are delivered to the EU. Veklury will be supplied under the Emergency Supply Instrument (ESI) to EU Member States and the UK, with the coordination and support of the Commission.

Gilead Sciences Ireland UC (Gilead) submitted on 7 May 2020 a request for a full translation exemption to your attention as Veklury is going to be provided as an Irish only pack to all EU countries. In that context, Gilead had planned for an information letter to be sent to healthcare professionals (HCPs) to inform them on how to access to the product information in their local language(s), i.e. through a QR code and/or an URL address located on both the packaging and the leaflets, thereby allowing proper and safe administration of the product to patients.

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The patient information leaflet and healthcare provider leaflet in local language(s) and/or blue box where relevant, will still be accessible via the QR code and/or the URL address located on both Veklury's packaging and leaflets.



The patient information leaflet and healthcare provider leaflet in your local language are also attached to this letter.

We remain at your disposal whether you may need additional information.

Yours faithfully,

[Redacted signature block containing the text 5.1.2e]

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