WHO Prequalification Programme
WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

Veklury [1]

Remdesivir 100 mg powder for concentrate for solution for infusion

The innovator product Veklury was submitted by Gilead Sciences Ireland UC in 2022 to be considered for prequalification and subsequently accepted for the WHO list of prequalified medicinal products for the treatment of Coronavirus disease 2019 (Covid-19) on 25 April 2022.

WHO's recommended use (as per the WHO Therapeutics and COVID-19 living guideline[2]. is for

1. **Patients with non-severe COVID-19 at highest risk of hospitalization. Patients at highest risk of hospitalization would be e.g., older people, or those with immunodeficiencies and/or chronic diseases, further enhanced by lacking vaccination.**
2. **Patients with severe COVID-19, defined by oxygen saturation < 90% on room air, signs of pneumonia or signs of severe respiratory distress (in adults, accessory muscle use, inability to complete full sentences, respiratory rate > 30 breaths per minute; and, in children, very severe chest wall in-drawing, grunting, central cyanosis, or presence of any other general danger signs including inability to breastfeed or drink, lethargy, convulsions or reduced level of consciousness).**

Information on the site(s) involved in the manufacture of the product and the API is available at the products listing information: https://extranet.who.int/pqweb/medicine/4408

The "Procedure for prequalification of pharmaceutical products[3]"defines specific evaluation mechanisms for products approved by regulatory authorities, which apply similar stringent standards for quality, safety and efficacy as those required by WHO.

The prequalification of this product by the WHO Prequalification Team: Medicines (PQTm) is based on the approval by the European Medicines Agency (EMA: http://www.ema.europa.eu/ema/), in line with the "Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities"[4].

Veklury was given a conditional marketing authorisation (CMA)[5] in the European Union. The CMA was issued on 03 July 2020 and was switched to a full marketing authorisation on 8 August 2022.

[1] Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

[2] https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2022.3

[3] https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/prequalification/trs961-annex10-who-procedure-prequalification.pdf?sfvrsn=85029f47_2

[4] .https://gxp-academy.org/upload/iblock/4d6/4d60594fd319202b4d3e2ab825702c72.pdf

[5] https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/conditional-marketing-authorisation

Veklury was accepted for the WHO list of prequalified medicinal products for the treatment of Coronavirus disease 2019 (Covid-19) on 25 April 2022.

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Programme.
However, according to the SRA guideline WHO may request additional data when considered necessary for the safe use of the product in regions relevant for prequalified products and such information may be included in the WHOPAR as a separate piece of information. In order to safeguard product quality throughout its entire intended shelf-life, stability studies under the conditions defined for Climatic Zones IVb have been requested from the Applicant[6].

WHO PQTm considers the following storage condition appropriate for the product when distributed in regions with zone III, IVa and IVb climatic conditions, based on available stability information:

- Do not store above 30°C.
- The shelf-life at this storage condition is 36 months.

Based on the above, the WHOPAR for Veklury refers for parts 1, 3, 4, 5, 6 and 8 to the previously issued public assessment report as follows:

WHOPAR part		**Reference[7]**
Part 1	Summary for the Public	https://www.ema.europa.eu/en/documents/overview/veklury-epar-medicine-overview_en.pdf
Part 3	Package Leaflet	https://www.ema.europa.eu/documents/product-information/veklury-epar-product-information_en.pdf
Part 4	Summary of Product Characteristics	https://www.ema.europa.eu/documents/product-information/veklury-epar-product-information_en.pdf
Part 5	Labelling	https://www.ema.europa.eu/documents/product-information/veklury-epar-product-information_en.pdf
Part 6	Discussion	https://www.ema.europa.eu/documents/assessment-report/veklury-epar-public-assessment-report_en.pdf
Part 8	Steps taken following Authorization	https://www.ema.europa.eu/documents/procedural-steps-after/veklury-epar-procedural-steps-taken-scientific-information-after-authorisation_en.pdf

Parts 2 and 7 of Veklury are included here.

[6] https://extranet.who.int/pqweb/sites/default/files/documents/48%20Stability%20data%20SRA%20FPPs_March2016_newtempl.pdf

[7] https://www.ema.europa.eu/en/medicines/human/EPAR/veklury

Summary of Prequalification Status for Veklury:

Initial acceptance	**Date**	**Outcome**
Status on PQ list	25 April 2022	listed
Dossier Evaluation	April 2022	MR
PQ: prequalification MR: meets requirements		

The table represents the status of relevant completed activities only.