Paxlovid

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type IA_IN / EMA/VR/0000310079	B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.1 New certificate	06/11/2025	N/A		

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

	from an already approved manufacturer - Accepted				
Variation type IB / EMA/VR/0000307779	This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted	05/11/2025	N/A		

Variation type II / EMA/VR/0000262540	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted Update of sections 4.2 and 5.1 of the SmPC in order to include information on the treatment of patients with severe immunosuppression, based on the final efficacy, safety, and PK analyses from study C4671034 following CHMP outcome for procedure EMA/H/C/005973/P46. This is an Interventional Efficacy and Safety, Phase 2, Randomized, Double-Blind, 3-Arm Study to Investigate Nirmatrelvir/Ritonavir in Nonhospitalized Participants at Least 12 Years of Age With Symptomatic COVID-19 Who Are Immunocompromised.	02/10/2025	21/11/2025	SmPC	
Variation type II / EMA/VR/0000280843	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted Submission of the final report from study C4671042. This is an Interventional, Efficacy and Safety, Phase 2, Randomized, Double-Blind, 2-Arm Study to Investigate a Repeat 5-Day Course of Nirmatrelvir/Ritonavir	04/09/2025	N/A		

	Compared to Placebo/Ritonavir in Participants at Least 12 Years of Age With Rebound of COVID-19 Symptoms and Rapid Antigen Test Positivity.				
Article 61(3) / EMA/N/0000279022	- Notification acc. Article 61(3) - Accepted To update the website, accessible via the link approved as part of the initial conditional marketing authorisation for Paxlovid to reflect the transition to full marketing authorisation and the availability of country-specific packs, the website will be simplified, maintaining access for HCPs and patients to the latest approved SmPC and PIL via a direct link to the EMA website.	01/09/2025	N/A		
Variation type II / EMA/VR/0000249354	This was an application for a group of variations. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Submission of additional clinical and non-clinical studies, including BE-studies. - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Submission of additional clinical and non-clinical studies, including BE-studies. - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Submission of additional	25/04/2025	21/11/2025	SmPC	

	clinical and non-clinical studies, including BE-studies. - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Submission of additional clinical and non-clinical studies, including BE-studies. - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Submission of additional clinical and non-clinical studies, including BE-studies. - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Submission of additional clinical and non-clinical studies, including BE-studies. - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Submission of additional clinical and non-clinical studies, including BE-studies. - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Submission of additional clinical and non-clinical studies, including BE-studies. - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Submission of additional clinical and non-clinical studies, including BE-studies. - Accepted				

	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Submission of additional clinical and non-clinical studies, including BE-studies. - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted A grouped application comprised of 12 Type II Variations, as follows: 2 x (C.I.4): Update of section 5.1 of the SmPC in order to update information on antiviral activity, based on non-clinical pharmacology study reports. 10 x (C.I.13): Submission of 10 non-clinical studies in order to provide updated non-clinical data.				
Variation type IA_IN / EMA/VR/0000252236	This was an application for a group of variations.	14/02/2025	02/05/2025	Annex II and PL	

	A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.a The activities for which the manufacturer/importer is responsible include batch release - Accepted A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted				
PSUR / EMA/PSUR/0000257871	- -				Maintenance