Rukobia

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
II/0011	Update of section 5.1 of the SmPC in order to update cross-resistance information based on results from virology study aimed at further characterization of HIV-1 gp120 amino acid polymorphism E202. C.I.4 - Change(s) in the SPC, Labelling or PL due to	14/09/2023		SmPC	There was no evidence of cross-resistance to representative agents from other antiretroviral (ARV) classes. Temsavir retained wild-type activity against viruses resistant to the INSTI raltegravir; the NNRTIs rilpivirine and efavirenz; the NRTIs abacavir, lamivudine, tenofovir, zidovudine and the PIs atazanavir and darunavir. Additionally, abacavir,

[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).

	new quality, preclinical, clinical or pharmacovigilance data				tenofovir, efavirenz, rilpivirine, atazanavir, darunavir and raltegravir retained activity against site-directed mutant viruses with reduced temsavir susceptibility (S375M, M426L, or M426L plus M475I). No cross-resistance was observed between temsavir and maraviroc or enfuvirtide. Temsavir was active against viruses with resistance to enfuvirtide. Some CCR5-tropic, maraviroc-resistant, viruses showed reduced susceptibility to temsavir, however, there was no absolute correlation between maraviroc resistance and reduced sensitivity to temsavir. Maraviroc and enfuvirtide retained activity against clinical envelopes from the Phase IIa study (206267) that had reduced susceptibility to temsavir and contained S375H, M426L, or M426L plus M475I substitutions. Temsavir was active against several ibalizumab-resistant viruses. Ibalizumab retained activity against site-directed mutant viruses that had reduced susceptibility to temsavir (S375M, M426L, or M426L plus M475I). HIV-1 gp120 E202 was identified as a rare treatment-emergent substitution in BRIGHTE that can reduce susceptibility to temsavir, and, depending on the sequence context of the envelope, may also result in reduced susceptibility to ibalizumab. For more information, please refer to the Summary of Product Characteristics.
PSUSA/10911 /202302	Periodic Safety Update EU Single assessment - fostemsavir	31/08/2023	n/a		PRAC Recommendation - maintenance
PSUSA/10911 /202208	Periodic Safety Update EU Single assessment - fostemsavir	16/03/2023	n/a		PRAC Recommendation - maintenance

PSUSA/10911 /202202	Periodic Safety Update EU Single assessment - fostemsavir	01/09/2022	n/a		PRAC Recommendation - maintenance
IG/1531	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	19/08/2022	04/08/2023	SmPC and PL	
PSUSA/10911 /202108	Periodic Safety Update EU Single assessment - fostemsavir	10/03/2022	n/a		PRAC Recommendation - maintenance
IA/0005/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	15/10/2021	n/a		
IB/0003	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	05/07/2021	24/03/2022	SmPC and PL	
IB/0004	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	28/06/2021	n/a		
IB/0002	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	10/03/2021	24/03/2022	SmPC, Labelling and PL	