EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Vitekta

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
WS/0884	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	28/01/2016		SmPC and PL	
IG/0616	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP -	03/11/2015	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).

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	Replacement/addition of a site where batch control/testing takes place				
PSUSA/2577/ 201502	Periodic Safety Update EU Single assessment - ELVITEGRAVIR	10/09/2015	n/a		PRAC Recommendation - maintenance
IG/0600	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	18/08/2015	n/a		
IG/0599	B.I.c.2.b - Change in the specification parameters and/or limits of the immediate packaging of the AS - Addition of a new specification parameter to the specification with its corresponding test method	12/08/2015	n/a		
IG/0595	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	04/08/2015	n/a		
IB/0016	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	28/07/2015	n/a		
IG/0583	A.7 - Administrative change - Deletion of manufacturing sites	23/07/2015	n/a		
IB/0014/G	This was an application for a group of variations. C.I.11.a - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of	09/07/2015	n/a		

	wording agreed by the competent authority C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation				
PSUSA/2577/ 201408	Periodic Safety Update EU Single assessment - ELVITEGRAVIR	12/03/2015	n/a		PRAC Recommendation - maintenance
IG/0521	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	26/02/2015	11/02/2016	Annex II and PI	
II/0011	Submission of the final clinical study report for study GS-US-183-1004, a phase 1, multiple-dose study to evaluate the pharmacokinetics of cobicistat-boosted elvitegravir (EVG) in subjects with decreased UGT1A1 activity (study included as a category 3 additional pharmacovigilance study/activity in the RMP), in order to address post-authorisation measure MEA 006. A revised RMP version 1.0 has been provided as part of the application. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	26/02/2015	n/a		
PSUV/0006	Periodic Safety Update	11/09/2014	n/a		PRAC Recommendation - maintenance
IG/0469	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	07/08/2014	n/a		

WS/0567	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Submission of the final study report for Study PC-183-2030 to investigate the effect of elvitegravir on human gut flora to address a recommendation C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	24/07/2014	n/a		Results of study PC-183-2030 show that elvitegravir, at concentrations of up to 8 µg/mL, does not possess anti-bacterial activity against the range of organisms studied.
IG/0447	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	04/07/2014	n/a		
IG/0448	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	02/07/2014	n/a		
IG/0422	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	28/03/2014	n/a		
WS/0530	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of section 4.4 "Special warnings and precautions for use" of the SmPC for Atripla,	20/03/2014	11/02/2015	SmPC, Labelling and PL	During recent years conclusive evidence has been collected which shows that the risk for HIV patients, who are well treated, to sexually transmit HIV to their partner is exceedingly low. A position statement on the use of antiretroviral therapy to reduce HIV transmission was published by the British HIV Association (BHIVA) in January

	Emtriva, Eviplera, Stribild, Truvada, Viread and Vitekta to revise the wording regarding the risk of sexual transmission of HIV infection following CHMP request adopted in December 2013. The PL has been updated accordingly. Furthermore, the MAH took the opportunity of this worksharing to update the PL with the details of the local representatives for Croatia and to introduce the Croatian language annexes for Emtriva and to update the bottle label to include the EDQM short standard term for the pharmaceutical form for Stribild. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation				2013. As a consequence, the recommendations for post-exposure prophylaxis have also been changed in recently updated HIV treatment guidelines. For example, the 2013 BHIVA guideline does not generally recommend post-exposure prophylaxis (PEP) after exposure from a patient with well treated HIV. Based on these data, the wording on the risk of transmission for HIV products was revised to reflect the current scientific knowledge. While effective suppression with antiretroviral therapy has been proven to substantially reduce the risk of sexual transmission, a residual risk cannot be excluded. Precautions to prevent transmission should be taken in accordance with national guidelines.
WS/0484	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Worksharing procedure to update of section 4.5 of the SmPC of Stribild, Tybost and Vitekta based on a phase 1 study evaluating the drug interaction potential between telaprevir (TVR) and elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate single tablet regimen and between telaprevir and ritonavir-boosted atazanavir plus elvitegravir. . This study was conducted in fulfilment of MEA009 for Tybost. The PI is updated accordingly as relevant. Furthermore the MAH took the opportunity to revise section 6.1 of the SmPC list of excipients, to update the designation of the excipients.	20/02/2014	12/02/2015	SmPC and PL	Study GS-US-236-0135, is a Phase I study in healthy subjects that evaluated the drug-drug interaction potential of the HCV protease inhibitor telaprevir with the fixed dose combination tablet Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir DF) and with Vitekta 85mg (elvitegravir) and atazanavir boosted by ritonavir. The study results did not indicate clinically significant interactions between telaprevir and Stribild nor between telaprevir and elvitegravir (with atazanavir/ritonavir). Section 4.5 of the SmPCs (and corresponding sections of the PLs) were updated to state that no dose adjustments are required when Stribild or Tybost are administered with telaprevir, nor when Vitekta is administered with ritonavir-boosted atazanavir plus telaprevir. The most frequently reported adverse events reported in the study were in line with the safety profiles of the drugs administered and no new safety concerns were identified.

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
WS/0488/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. This was an application for a group of variations. To add an alternative site responsible for the manufacture of a starting material used in the synthesis of the elvitegravir active substance. To add an alternative site responsible for the manufacture of a starting material used in the synthesis of the elvitegravir active substance. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer	20/02/2014	n/a		