EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Onduarp

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
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/10/2013		PL	
PSU/0004	Periodic Safety Update	25/04/2013	13/02/2014	SmPC and PL	For further information please refer to: Onduarp-H-2118-Grounds-PSU-04-en.
WS/0362	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	25/04/2013		SmPC, Annex II, Labelling and PL	For Micardis, Micardis Plus, Kinzalmono, kinzalkomb, Pritor, Pritor Plus Update of sections 4.2, 4.3, 4.4 and 4.5 of the SmPC to

[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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	The requested variation worksharing procedure proposed amendments to the Summary of Product Characteristics, Annex II, Labelling and Package Leaflet. C.I.3.b - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under Article 45/46, or amendments to reflect a Core SPC - Change(s) with new additional data submitted by the MAH				implement recommendations regarding the use of telmisartan with aliskiren as requested by the CHMP in the PSUR following the outcome of Article 20 related to aliskiren. In addition, information related to interaction with digoxin is added in section 4.5 of the SmPC. The Package leaflet is updated accordingly. Furthermore, the WSA took the opportunity to sort out a number of inconsistencies in content between SmPCs and PILs for the different products as follows: For Micardis, Micardis Plus, Kinzalmono, kinzalkomb, Pritor, Pritor Plus - Inconsistency between SmPC section 4.5 and PIL regarding interaction with alcohol, barbiturates, narcotics or antidepressants - Inconsistency between SmPC section 4.2 and PIL regarding the storage recommendation. For Twynsta, Onduarp PIL section 4 will be brought in line with SmPC section 4.8 with regard to the side effect hyperglycaemia (amlodipine component) For Micardis Plus, Kinzalkomb, Pritor Plus In the PIL section 2, there is a different wording of telmisartan mono products compared to the telmisartan/HCTZ products for the explanation of cholestasis or biliary obstruction. The MAH proposes to align the wording in the PIL of the telmisartan/HCTZ products so that it is identical with telmisartan mono products. Besides, editorial changes are proposed for Twynsta, Onduarp, Micardis, MicardisPlus, Pritor, PritorPlus, Kinzalmono and Kinzalkomb regarding storage

					recommendations in Annex IIIA in bold characters to bring them in line with the printing style on the actual, marketed products. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet. Micardis and Micardis Plus: (Belgium, Bulgaria and Luxembourg, Estonia, Lithuania) Twynsta/Onduarp (Estonia, Belgium and Luxembourg) Furthermore, the WSA proposed this opportunity to bring the PI in line with the latest QRD template (Version 9).
WS/0320	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	15/11/2012	15/11/2012		
WS/0283	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 4.5 of the SmPC in order to include a statement on a drug-drug interaction between amlodipine and simvastatin when used concomitantly. Section 2 of the Package Leaflet is updated accordingly. In addition the MAH has taken the opportunity to make a correction on the 360 tablets multipack in section 6 of the PIL for Twynsta and Onduarp and in Annex A for Twynsta only. C.I.4 - Variations related to significant modifications of	20/09/2012	24/10/2012	SmPC and PL	This type II variation concerns an update of section 4.5 the SmPC to include a new drug-drug interaction between amlodipine and simvastatin. When used concomitantly with amlodipine, the maximum daily dose of simvastatin should not exceed 20 mg.

	the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data				
IG/0211	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	05/09/2012	n/a		
WS/0236	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update to section 4.4 of the SmPC to include a warning for diabetic patients when treated with insulin or oral antidiabetics and to include a warning on RAAS blockage in patients with uncontrolled blood pressure. Furthermore the MAH has corrected the visual description of the appearance of the product in section 3 of the SmPC and section 6 of the PL. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is being brought in line with the latest QRD template version 8. Finally the MAH took the opportunity to make some editorial changes in the English Annexes, to make some corrections in the DE, FR, IT, LV, NL and SK Annexes for Onduarp, in the DE, FR, IT, LV, NL and SK Annexes for Twynsta. C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	19/04/2012	25/05/2012	SmPC, Annex II, Labelling and PL	This type II variation concerns an update of section 4.4 the SmPC to include a warning for diabetic patients when treated with insulin or oral antidiabetics and to include a warning on RAAS blockage in patients with uncontrolled blood pressure, in line with the telmisartan SmPC.
WS/0255/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.	24/05/2012	24/05/2012		Changes to an existing pharmacovigilance system as described in the DDPS. The MAH update the Detailed Description of the Pharmacovigilance System (DDPS) for

	Update of the Description of Pharmacovigilance System (DDPS). C.I.9.z - Changes to an existing pharmacovigilance system as described in the DDPS - Other variation C.I.9.z - Changes to an existing pharmacovigilance system as described in the DDPS - Other variation C.I.9.f - Changes to an existing pharmacovigilance system as described in the DDPS - Deletion of topics covered by written procedure(s) describing pharmacovigilance activities C.I.9.d - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the safety database C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system				Aptivus, MicardisPlus, Mirapexin, Onduarp, Pradaxa, Sifrol, Trajenta, Twynsta and Viramune.
IG/0165	B.III.1.a.1 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	10/04/2012	n/a		
IB/0001/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	13/02/2012	n/a		

	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate				
IB/0002/G	This was an application for a group of variations. B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products B.II.b.3.a - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	30/01/2012	n/a		