Quadramet

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
IG/0557	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	21/05/2015	n/a		
IAIN/0019	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	04/05/2015		SmPC and PL	

[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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II/0018	To widen the specification limits for samarium content B.I.b.1.g - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Widening of the approved specs for starting mat./intermediates, which may have a significant effect on the quality of the AS and/or the FP	24/05/2012	14/06/2012	SmPC and PL	
IG/0015	C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DD	06/08/2010	n/a	Annex II	
II/0016	Update to SmPC section 4.8 and PL following a signal detection assessment. Update of Summary of Product Characteristics and Package Leaflet	26/06/2008	23/07/2008	SmPC and PL	Following the assessment of a signal detection, the CHMP requested that the product information for Quadramet should be amended to include post-marketing reports of thrombocytopenia in section 4.8. The PL has been amended accordingly. These changes were requested further to a review performed following the detection of a signal where post-marketing cases of thrombocytopenia including isolated reports of intracranial haemorrhage, and cases in which the outcome was fatal have been reported.
N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/04/2008	n/a	PL	
R/0014	Renewal of the marketing authorisation.	18/10/2007	12/12/2007	SmPC,	Based upon data that have become available since the

				Labelling and PL	granting of the marketing authorisation, the CHMP considers that the benefit-risk balance of Quadramet remains positive ad thus recommends the renewal of the Marketing Authorisation with unlimited validity.
N/0013	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/04/2007	n/a	PL	
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/09/2006	n/a	PL	
IA/0011	IA_11_a_Change in batch size of active substance or intermediate - up to 10-fold	23/06/2004	n/a		
N/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/05/2004	n/a	PL	
R/0009	Renewal of the marketing authorisation.	18/12/2002	17/03/2003	SmPC, Annex II, Labelling and PL	
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/06/2002	27/06/2002	PL	
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/03/2002	19/04/2002	PL	
N/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/10/2001	17/12/2001	PL	
N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/10/2001	n/a	PL	

N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/08/2000	09/10/2000	PL	
I/0003	15_Minor changes in manufacture of the medicinal product	23/12/1998	n/a		
I/0002	15_Minor changes in manufacture of the medicinal product	23/12/1998	n/a		
I/0001	12_Minor change of manufacturing process of the active substance	23/12/1998	n/a		