EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Focetria

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
IAIN/0035	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	29/07/2015	n/a		
PSUV/0033	Periodic Safety Update	23/10/2014	15/01/2015	SmPC and PL	Please refer to Focetria PSUV-33 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

[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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IG/0426	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	11/04/2014	n/a		
IAIN/0031	C.I.9.i - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH	05/10/2012	n/a		
II/0030	C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	15/03/2012	20/04/2012	SmPC, Annex II and PL	The MAH performed a cumulative review of all cases of convulsive disorders in temporal association with Focetria vaccination. A total of 59 cases of convulsion were reported, of which 22 occurred concomitantly with fever while 37 cases occurred without fever. The majority of febrile convulsions occurred in paediatric patients and some cases were observed in subjects with a history of epilepsy. These data guaranteed an update to update section 4.4 to adequately inform prescribers.
IA/0029/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the contact details of the QPPV 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.e - Changes to an existing pharmacovigilance	27/09/2011	n/a		

	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 C.I.9.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site undertaking pharmacovigilance activities 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				
IA/0027/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV 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.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 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.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site	06/05/2011	n/a	Annex II	

	undertaking pharmacovigilance activities 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				
SW/0024		24/06/2010	12/08/2010	SmPC and Annex II	
II/0019	Update of sections 4.2, 4.8 and 5.1 of the summary of product characteristics regarding administration of Focetria to children of 12 to 35 months of age based on results of study V111_3 in children. Furthermore, posology recommendation in children is updated in light of the availability of the overall data set of study V111_3. The Package Leaflet has been updated accordingly. C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	22/04/2010	12/08/2010	SmPC and PL	Please refer to the scientific discussion Focetria-H-C-710-II-19-AR.
IB/0021	To update the relevant section 3.2.S.2.1 with regards to a contact manufacturer B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	09/07/2010	n/a		
IA/0023/G	This was an application for a group of variations.	12/05/2010	n/a	Annex II	

	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 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.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site undertaking pharmacovigilance activities				
IA/0022	To change the name from Novartis Vaccines and Diagnostics GmbH & Co.KG to Novartis Vaccines and Diagnostics GmbH for a manufacturer responsible for production of adjuvant bulk. A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release)	06/05/2010	n/a		
II/0017	Update of the Detailed Description of the Pharmacovigilance System Update of DDPS (Pharmacovigilance)	18/03/2010	29/04/2010	Annex II	
II/0020	Update of section 4.2, 4.5, 4.8 and 5.1 of the SPC to include safety and immunogenicity information following assessment of the H1N1 data available with Focetria in children, adults and the elderly. Annex II	18/03/2010	27/04/2010	SmPC, Annex II and PL	

	is updated to reflect the current status of Specific Obligations. The package leaflet is updated accordingly. C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data				
II/0014	Changes in the sterilty test methods of the drug substance and drug product. Change(s) to the test method(s) and/or specifications for the active substance	18/02/2010	02/03/2010		
II/0018	To update section 4.2, 4.8 and 5.1 of the SPC regarding administration of Focetria to children of 3 to 8 years of age based on results of a study in children as requested by the CHMP. Section 4.8 is updated to include Adverse Drug Reactions reported in Post Marketing Surveillance for Focetria further to the assessment of sPSUR 1 and 2. Furthermore data on H1N1 has been moved to the beginning of section 5.1. Annex II and the Package Leaflet were updated accordingly. Update of Summary of Product Characteristics and Package Leaflet	17/12/2009	23/12/2009	SmPC, Annex II and PL	Please refer to the scientific discussion Focetria-H-710-II-18-AR.
II/0016	To change the Product Information to include the shelf life of a Multi Dose Vial after first dose withdrawal. Update of Summary of Product Characteristics, Labelling and Package Leaflet	17/12/2009	23/12/2009	SmPC, Labelling and PL	

II/0015	Update of Summary of Product Characteristics, Labelling and Package Leaflet	19/11/2009	27/11/2009	SmPC, Labelling and PL	
II/0013	Update of Summary of Product Characteristics and Package Leaflet	19/11/2009	27/11/2009	SmPC, Annex II and PL	
II/0011	Update of Summary of Product Characteristics, Labelling and Package Leaflet	22/10/2009	11/11/2009	SmPC, Labelling and PL	
II/0010	Update of Summary of Product Characteristics, Labelling and Package Leaflet	22/10/2009	11/11/2009	SmPC, Labelling and PL	
II/0009	Update of Summary of Product Characteristics	22/10/2009	11/11/2009	SmPC	
II/0008	To change of the reassortant derived from A/California/7/2009 (H1N1)v strain from X-179A to X-181 Change(s) to the manufacturing process for the active substance	22/10/2009	11/11/2009	SmPC and PL	
II/0007	Addition of a new manufacturing line for the manufacture of the adjuvant MF-59. Change(s) to the manufacturing process for the finished product	15/10/2009	20/10/2009		
II/0006	Changes in analytical methods used for control of critical steps of the adjuvant MF-59. Change(s) to the test method(s) and/or	15/10/2009	20/10/2009		

	specifications for the finished product				
PU/0005	To change the pandemic vaccine strain composition from A/Vietnam/1194/2004 (H5N1) to A/California/7/2009 (H1N1)v like strain (X-179A) Pandemic Update	24/09/2009	29/09/2009	SmPC, Labelling and PL	
IA/0004	IA_47_a_Deletion of a pharmaceutical form	28/08/2009	n/a	SmPC, Labelling and PL	
II/0001	Update of or change(s) to the pharmaceutical documentation Update of or change(s) to the pharmaceutical documentation	23/07/2009	12/08/2009		
IA/0003	IA_19_a_Change in specification of an excipient - tightening of specification limits	02/07/2009	n/a		
IA/0002	IA_12_a_Change in spec. of active subst./agent used in manuf. of active subst. - tightening of spec.	02/07/2009	n/a		