EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Unituxin

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
PSUSA/10420 /201608	Periodic Safety Update EU Single assessment - dinutuximab	23/03/2017	n/a		CHMP Recommendation – variation The CHMP agreed to update of section 4.4 of the SmPC to add the following warning on the occurrence of transverse myelitis: "Transverse myelitis has been observed in patients treated with Unituxin. A diagnosis of transverse myelitis in any patient presenting with weakness, paraesthesia, sensory loss, marked discomfort and/or incontinence should be considered. Furthermore, urinary retention and/or

[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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					constipation can be an initial presentation of myelitis or other neurologic disorders. Evaluation of transverse myelitis includes, but is not limited to, consultation with a neurologist, spinal MRI, and lumbar puncture. Unituxin therapy should be permanently discontinued in patients who develop transverse myelitis.". Transverse myelitis is also added as an adverse drug reaction with the frequency "uncommon" in section 4.8 of the SmPC. The Package Leaflet is updated accordingly.
IB/0011	B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	17/10/2016	n/a		
II/0008	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol	06/10/2016	n/a		
PSUSA/10420 /201602	Periodic Safety Update EU Single assessment - dinutuximab	02/09/2016	n/a		PRAC Recommendation - maintenance
IB/0010	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	15/08/2016	n/a		
N/0009	Update of the package leaflet to include the contact details of a local representative of the MAH and to include the contact details of the manufacturing site responsible for batch release that was previously approved but erroneously omitted in the package leaflet. In addition, the MAH amended the MAH's telephone and fax numbers, corrected a heading,	12/07/2016	20/03/2017	PL	

	reintroduced a standard QRD statement that was erroneously deleted in the package leaflet. They also took the opportunity to make editorial changes in the English package leaflet. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)				
II/0002/G	This was an application for a group of variations. B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an approved protocol B.II.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an approved protocol B.II.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an	28/04/2016	n/a		

	approved protocol				
IA/0006	A.7 - Administrative change - Deletion of manufacturing sites	17/02/2016	n/a		
IB/0004/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.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	17/02/2016	n/a		
IA/0005	B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier	03/02/2016	n/a		
IB/0003	B.II.e.3.b - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)	27/01/2016	n/a		
IB/0001	B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB	19/11/2015	n/a		