



## Imraldi

### Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
IA/0026	B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol	06/05/2019	n/a		
IB/0023	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the	17/04/2019		SmPC and Annex II	

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



	MAH				
IB/0022	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	15/03/2019		SmPC and PL	
II/0021	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	14/03/2019	n/a		
IA/0024/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.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	21/02/2019	n/a		
IB/0020	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	24/01/2019	12/02/2019	SmPC and PL	

IB/0018	B.I.d.1.b.3 - Stability of AS - Change in the storage conditions - Change in storage conditions of the AS	18/01/2019	n/a		
T/0015	Transfer of Marketing Authorisation	02/10/2018	29/10/2018	SmPC, Labelling and PL	
IB/0017/G	This was an application for a group of variations.  C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH  C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	11/10/2018	12/02/2019	SmPC and PL	
IB/0014/G	This was an application for a group of variations.  C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH  C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following	20/08/2018	28/09/2018	SmPC and PL	

	<p>assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH</p>				
IAIN/0013/G	<p>This was an application for a group of variations.</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p>	12/07/2018	28/09/2018	SmPC, Labelling and PL	
PSUSA/10589/201712	Periodic Safety Update EU Single assessment - adalimumab (biosimilars)	12/07/2018	n/a		PRAC Recommendation - maintenance
IAIN/0012/G	<p>This was an application for a group of variations.</p> <p>B.II.b.1.a - Replacement or addition of a</p>	06/06/2018	n/a		

	<p>manufacturing site for the FP - Secondary packaging site</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p>				
II/0005/G	<p>This was an application for a group of variations.</p> <p>B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product</p> <p>B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method</p> <p>B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method</p>	25/05/2018	28/09/2018	Annex II	<p>Annex II.A has been updated as follows:</p> <p>Name and address of the manufacturer(s) of the biological active substance(s)</p> <p>Biogen (Denmark) Manufacturing ApS Biogen Allé 1 3400 Hillerød Denmark</p>
IB/0010	<p>B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking</p>	24/05/2018	28/09/2018	SmPC, Labelling and PL	

II/0007/G	<p>This was an application for a group of variations.</p> <p>B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes</p> <p>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</p>	26/04/2018	n/a		
IB/0009/G	<p>This was an application for a group of variations.</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place</p>	23/04/2018	n/a		
II/0004	<p>Submission of an updated RMP version 2.1 in order to indicate changes in the distribution method for the Imraldi Patient Alert Card (PAC) from being included in the Annex IIIA of the Product Information to be provided to patients by healthcare professionals by including the PAC in the physician educational</p>	12/04/2018	28/09/2018	SmPC, Annex II, Labelling and PL	The product information has been updated to change the Patient Alert Card (PAC) distribution; PAC will be given by the HCP and not included in the commercial package.

	<p>material. The Annexes I, II, IIIA and IIIB of the PI are updated accordingly.</p> <p>C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required</p>				
II/0002/G	<p>This was an application for a group of variations.</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>B.II.b.1.d - Replacement or addition of a manufacturing site for the FP - Site which requires an initial or product specific inspection</p> <p>B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place</p> <p>B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing</p> <p>B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products</p> <p>B.II.e.5.a.1 - Change in pack size of the finished</p>	08/02/2018	28/09/2018	SmPC, Annex II, Labelling and PL	The Product information has been updated to introduce the new 40mg solution for injection in prefilled pen presentations.

	<p>product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p>				
IB/0006/G	<p>This was an application for a group of variations.</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH</p> <p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH</p>	23/01/2018	28/09/2018	SmPC and PL	
IA/0003	<p>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</p>	15/12/2017	n/a		



IA/0001	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)	12/09/2017	n/a		
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