Nevanac

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/0055	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	28/02/2024		SmPC, Annex II 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).

IB/0054/G	This was an application for a group of variations. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	11/11/2023		SmPC and PL	
PSUSA/2143/ 202205	Periodic Safety Update EU Single assessment - nepafenac	12/01/2023	n/a		PRAC Recommendation - maintenance
IB/0052/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.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products	14/02/2022	n/a		
IB/0051	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	18/10/2021	14/10/2022	SmPC, Annex II, Labelling and PL	
IA/0050	B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-	01/02/2021	n/a		

	significant specification parameter (e.g. deletion of an obsolete parameter)				
IA/0049/G	This was an application for a group of variations. 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 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 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 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 B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.III.2.b - Change to comply with Ph. Eur. or with a	07/01/2021	n/a		

	national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State				
IAIN/0048/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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 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	26/06/2020	n/a		
IB/0047	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	28/05/2020	n/a		
IB/0046/G	This was an application for a group of variations. 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	21/02/2020	n/a		

	B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.c.2.b - Change in the specification parameters and/or limits of the immediate packaging of the AS - Addition of a new specification parameter to the specification with its corresponding test method				
PSUSA/2143/ 201905	Periodic Safety Update EU Single assessment - nepafenac	16/01/2020	n/a		PRAC Recommendation - maintenance
IB/0045	B.II.a.3.z - Changes in the composition (excipients) of the finished product - Other variation	16/10/2019	n/a		
IB/0043	B.II.e.1.z - Change in immediate packaging of the finished product - Other variation	04/10/2019	n/a		

IB/0044	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	16/09/2019	n/a		
IA/0041/G	This was an application for a group of variations. B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	17/05/2019	n/a		
IB/0040/G	This was an application for a group of variations.	05/02/2019	n/a		

	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 B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.c.2.b - Change in the specification parameters and/or limits of the immediate packaging of the AS - Addition of a new specification parameter to the specification with its corresponding test method				
IA/0039/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name	29/11/2018	n/a		

	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 B.II.c.4.a - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient - Minor change				
IA/0038	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/08/2018	26/08/2019	SmPC, Annex II, Labelling and PL	
IB/0037	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)	08/08/2018	n/a		
T/0036	Transfer of Marketing Authorisation	20/03/2018	23/04/2018	SmPC, Labelling and PL	
T/0035	Transfer of Marketing Authorisation	04/04/2017	16/05/2017	SmPC, Labelling and PL	
PSUSA/2143/ 201605	Periodic Safety Update EU Single assessment - nepafenac	12/01/2017	n/a		PRAC Recommendation - maintenance
II/0033	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	10/11/2016	n/a		
II/0032	Extension of indication to include the indication 'reduction in the risk of postoperative macular	23/06/2016	29/07/2016	SmPC, Annex II, Labelling	Please refer to the scientific discussion 'Nevanac H-818-II-

	oedema associated with cataract surgery in diabetic patients' also for the 3 mg/ml strength based on data from the phase III studies C-12-067 and C-12-071. As a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC have been updated and the Package Leaflet has been updated accordingly. In addition, the MAH took the opportunity to implement editorial changes in SmPC and to update the annexes in line with the latest QRD template. An updated RMP version 8 was agreed during the procedure. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one			and PL	32-AR'.
PSUSA/2143/ 201505	Periodic Safety Update EU Single assessment - nepafenac	14/01/2016	n/a		PRAC Recommendation - maintenance
IB/0030/G	This was an application for a group of variations. B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation B.II.c.4.z - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient - Other variation	03/07/2015	n/a		
PSUV/0029	Periodic Safety Update	22/01/2015	31/03/2015	SmPC and PL	Please refer to Nevanac PSUV-0029 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation.

IB/0028/G	This was an application for a group of variations. B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products B.II.e.6.a - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that affects the product information	17/10/2014	31/03/2015	SmPC, Labelling and PL	
IG/0452	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	28/07/2014	n/a		
PSUV/0024	Periodic Safety Update	10/07/2014	n/a		PRAC Recommendation - maintenance
N/0026	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/06/2014	31/03/2015	PL	
II/0022	Update of sections 4.5 and 4.8 of the SmPC following	25/04/2014	31/03/2015	SmPC,	In this variation the company proposed to update the

	the review of clinical data supporting the safety profile of the product. The Package Leaflet is updated accordingly. Minor editorial changes have been introduced throughout the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data			Labelling and PL	product information of Nevanac to include newly identified safety information derived from analysis of available clinical data and post-marketing reports. As a result new side effects were included in the product information of Nevanac and the frequency of known side effects was updated.
PSUV/0023	Periodic Safety Update	09/01/2014	n/a		PRAC Recommendation - maintenance
N/0020	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/08/2013	03/06/2014	PL	
IG/0324	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	22/07/2013	n/a		
X/0016	Annex I_2.(c) Change or addition of a new strength/potency	21/02/2013	03/05/2013	SmPC, Annex II, Labelling and PL	Please refer to the Assessment Report: Nevanac-H-818-X-16-AR.
IG/0274	A.1 - Administrative change - Change in the name and/or address of the MAH	19/03/2013	03/06/2014	SmPC, Labelling and PL	
R/0015	Renewal of the marketing authorisation.	19/07/2012	24/09/2012	SmPC, Annex II, Labelling and PL	The CHMP reviewed data on quality, safety and efficacy of Nevanac, including all variations introduced since the marketing authorisation was granted, and based on these data considered that the risk-benefit balance of Nevanac in the prevention and treatment of postoperative pain and inflammation associated with cataract surgery and for the reduction in the risk of postoperative macular oedema

					associated with cataract surgery in diabetic patients remains favourable. The CHMP recommended the renewal of the Marketing Authorisation with unlimited validity. Due to the limited data available for long-term use of Nevanac, the CHMP re-confirmed its previous decision that periodic safety update reports should be submitted every 6 months.
IG/0149/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.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	06/03/2012	06/03/2012	Annex II	
II/0007/G	This was an application for a group of variations. Update of sections 4.1, 4.2, 4.8 and 5.1 of the SmPC in order to reflect on the new approved indication "reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients. Update of SmPC section 4.8 in order to include all available safety data and information on the new approved population, ie diabetic patients. Minor amendments to the SmPC were proposed by the MAH to reflect the SmPC guidelines of September, 2009.	17/11/2011	22/12/2011	SmPC and PL	Please refer to the scientific discussion H-000818-II-0007-G-AR

	The sections 1, 3 and 4 of the Package Leaflet were amended accordingly Furthermore, the CHMP reviewed the data submitted by the Marketing Authorisation Holder, taking into account the provisions of Article 14(11) of Regulation (EC) No 726/2004 and does not consider by consensus, that the new therapeutic indication brings significant clinical benefit in comparison with existing therapies, as set out in Annex IV. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data				
IG/0107/G	This was an application for a group of variations. 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 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.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	19/09/2011	n/a		

	DD				
WS/0075	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. To replace the current resin which is used for the closures for the drop-trainer packaging system, with two new resins. B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products	20/01/2011	20/01/2011		
IG/0039	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	17/01/2011	n/a	Annex II	
II/0006	To change the specification limit for colour of the finished products (eye drops suspension) from "Light Yellow to Dark Yellow" to "Light Yellow to Light Orange". B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	18/11/2010	17/01/2011	SmPC and PL	
N/0005	The Marketing Authorisation Holder (MAH) took the	04/11/2010	n/a	PL	

	opportunity to update details of local representatives in Annex IIIB as well as some corrections of the Norwegian package leaflet in order to reflect the original English version. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)				
IA/0004	IA_11_a_Change in batch size of active substance or intermediate - up to 10-fold	29/09/2009	n/a		
IA/0003	IA_11_a_Change in batch size of active substance or intermediate - up to 10-fold	29/09/2009	n/a		
N/0002	Update of the list of the local representatives in section 6 of the Package Leaflet and translation of INN into Bulgarian and Braille in the Bulgarian Labelling. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/01/2009	n/a	Labelling and PL	
II/0001	Change(s) to the manufacturing process for the active substance	25/09/2008	01/10/2008		