Akynzeo

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
N/0055	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/10/2024		PL	
IA/0054/G	This was an application for a group of variations. B.III.1.b.2 - Submission of a new/updated or	26/02/2024	n/a		

[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).

	deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure 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 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 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				
IB/0053	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	22/12/2023		SmPC	

IB/0052	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	12/12/2023	n/a		
IB/0051	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	12/12/2023	n/a		
N/0050	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/09/2023		PL	
N/0049	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/05/2023		PL	
N/0048	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/02/2023		PL	
IB/0046/G	This was an application for a group of variations. 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.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	02/12/2022	n/a		
N/0047	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/11/2022		PL	

IB/0045	B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	20/10/2022	n/a		
IB/0044	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	20/10/2022	n/a		
IA/0043/G	This was an application for a group of variations. B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	11/07/2022	n/a		
IA/0042/G	This was an application for a group of variations. 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 A.7 - Administrative change - Deletion of manufacturing sites	11/07/2022	n/a		
PSUSA/10393 /202110	Periodic Safety Update EU Single assessment - netupitant / palonosetron	05/05/2022	n/a		PRAC Recommendation - maintenance
N/0041	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/02/2022		PL	

IB/0039/G	This was an application for a group of variations. 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.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process 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 B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products	04/02/2022	n/a		

X/0031	Extension application to include a new pharmaceutical form (concentrate for solution for infusion) Annex I_2.(d) Change or addition of a new pharmaceutical form	16/09/2021	12/11/2021	SmPC, Labelling and PL	
II/0034	Submission of the results of the in vitro study assessing the ability of fosnetupitant to inhibit all UGTs of interest: UGT1A1, 1A3, 1A4, 1A6, 1A9, and 2B7 following a recommendation from the CHMP. Update of section 4.5 of the SmPC in order to include a warning on the concomitant use of fosnetupitant with oral substrates of UGT2B7/UGT2B15. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	20/05/2021	12/11/2021	SmPC	In vitro data show that fosnetupitant inhibits UGT2B7 / UGT2B15. Similar to concomitant use of netupitant with oral substrates of UGT2B7 (e.g. zidovudine, valproic acid, morphine) caution is recommended when fosnetupitant is combined with such medicines.
PSUSA/10393 /202010	Periodic Safety Update EU Single assessment - netupitant / palonosetron	06/05/2021	n/a		PRAC Recommendation - maintenance
IB/0038	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	09/04/2021	27/05/2021	SmPC	
IA/0037	A.7 - Administrative change - Deletion of manufacturing sites	12/02/2021	n/a		
IB/0035	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	08/01/2021	n/a		

IA/0033/G	This was an application for a group of variations. A.8 - Administrative change - Changes to date of the audit to verify GMP compliance of the manufacturer of AS 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.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.f.1.e - Stability of FP - Change to an approved stability protocol	08/12/2020	n/a		
IB/0032	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	18/11/2020	n/a		

IB/0030/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF 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	14/08/2020	n/a		
IB/0029	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	29/05/2020	27/05/2021	SmPC	
PSUSA/10393 /201910	Periodic Safety Update EU Single assessment - netupitant / palonosetron	17/04/2020	n/a		PRAC Recommendation - maintenance
X/0018	Annex I_2.(c) Change or addition of a new strength/potency Annex I_2.(d) Change or addition of a new pharmaceutical form Annex I_2.(e) Change or addition of a new route of administration	12/12/2019	16/03/2020	SmPC, Labelling and PL	Extension application concerning changes to the active substance: use of fosnetupitant, a pro-drug of netupitant in association with: a new strength: 235 mg / 0.25 mg a new pharmaceutical form: powder for concentrate for solution for infusion

					a new route of administration: intravenous use
IB/0027	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	03/03/2020	n/a		
IA/0028/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material) B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material)	10/02/2020	n/a		
R/0024	Renewal of the marketing authorisation.	14/11/2019	09/01/2020	SmPC, Annex II, Labelling	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of

				and PL	Akynzeo in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0025	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	04/12/2019	n/a		
N/0023	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/06/2019	09/01/2020	PL	
PSUSA/10393 /201810	Periodic Safety Update EU Single assessment - netupitant / palonosetron	16/05/2019	n/a		PRAC Recommendation - maintenance
N/0022	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/04/2019	09/01/2020	PL	
IA/0021/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.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	18/02/2019	n/a		
IB/0019	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	03/01/2019	n/a		
PSUSA/10393 /201804	Periodic Safety Update EU Single assessment - netupitant / palonosetron	31/10/2018	n/a		PRAC Recommendation - maintenance

N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/04/2018	06/09/2018	PL	
IA/0014/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material) B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material) B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material) B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material)	28/02/2018	n/a		

PSUSA/10393 /201704	Periodic Safety Update EU Single assessment - netupitant / palonosetron	26/10/2017	n/a		PRAC Recommendation - maintenance
IB/0013	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	21/09/2017	06/09/2018	SmPC, Labelling and PL	
PSUSA/10393 /201610	Periodic Safety Update EU Single assessment - netupitant / palonosetron	05/05/2017	n/a		PRAC Recommendation - maintenance
IA/0011/G	This was an application for a group of variations. B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material	20/04/2017	n/a		
IA/0010/G	This was an application for a group of variations. B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-	01/03/2017	n/a		

	significant specification parameter (e.g. deletion of an obsolete parameter) B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material)				
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/01/2017	08/05/2017	Labelling and PL	
PSUSA/10393 /201604	Periodic Safety Update EU Single assessment - netupitant / palonosetron	27/10/2016	n/a		PRAC Recommendation - maintenance

IB/0006	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	16/06/2016	08/05/2017	SmPC	
II/0005	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	16/06/2016	n/a		
PSUSA/10393 /201510	Periodic Safety Update EU Single assessment - netupitant / palonosetron	13/05/2016	n/a		PRAC Recommendation - maintenance
IA/0004/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer	29/02/2016	n/a		
IB/0002/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	10/12/2015	n/a		

	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation				
IB/0001/G	This was an application for a group of variations. B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products 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 B.II.c.1.g - Change in the specification parameters and/or limits of an excipient - Where there is no monograph in the European/National Ph. for the excipient, a change in specification from in-house to a non-official/third country Ph. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	09/12/2015	n/a		