EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pixuvri

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/0050	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/11/2021		PL	
IA/0049	A.7 - Administrative change - Deletion of manufacturing sites	09/01/2020	18/12/2020	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).

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PSUSA/9261/ 201905	Periodic Safety Update EU Single assessment - pixantrone	28/11/2019	n/a		PRAC Recommendation - maintenance
T/0048	Transfer of Marketing Authorisation	29/08/2019	08/10/2019	SmPC, Labelling and PL	
R/0046	Renewal of the marketing authorisation.	28/03/2019	06/06/2019	SmPC, Annex II and PL	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated. Furthermore, the CHMP considered that, as all Specific Obligations have been fulfilled, there are no remaining grounds for the marketing authorisations to remain conditional and therefore recommends the granting of the MA no longer subject to Specific Obligations for Pixuvri.
T/0045	Transfer of Marketing Authorisation	13/12/2018	18/02/2019	SmPC, Labelling and PL	
PSUSA/9261/ 201805	Periodic Safety Update EU Single assessment - pixantrone	29/11/2018	n/a		PRAC Recommendation - maintenance
PSUSA/9261/ 201711	Periodic Safety Update EU Single assessment - pixantrone	28/06/2018	23/08/2018		Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/9261/201711.
R/0042	Renewal of the marketing authorisation.	25/01/2018	23/03/2018		
PSUSA/9261/	Periodic Safety Update EU Single assessment -	14/12/2017	21/03/2018	SmPC and PL	Refer to Scientific conclusions and grounds recommending

201705	pixantrone				the variation to terms of the Marketing Authorisation(s)' for PSUSA/9261/201705.
II/0040	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	07/12/2017	n/a		
IA/0041	B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	30/10/2017	n/a		
PSUSA/9261/ 201611	Periodic Safety Update EU Single assessment - pixantrone	09/06/2017	n/a		PRAC Recommendation - maintenance
N/0038	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/05/2017	21/03/2018	PL	
R/0034	Renewal of the marketing authorisation.	26/01/2017	22/03/2017	SmPC, Labelling and PL	
IA/0037	B.I.d.1.b.1 - Stability of AS - Change in the storage conditions - Change to more restrictive storage conditions of the AS	20/03/2017	n/a		
IB/0035	B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	15/12/2016	n/a		
II/0032/G	This was an application for a group of variations.	15/12/2016	n/a		

	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 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.3.z - Change in source of an excipient or reagent with TSE risk - Other variation B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information 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.1.z - Change in immediate packaging of the finished product - Other variation				

PSUSA/9261/201605	Periodic Safety Update EU Single assessment - pixantrone	01/12/2016	n/a		PRAC Recommendation - maintenance
IAIN/0033/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.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	28/11/2016	22/03/2017	Annex II and PL	
IA/0031	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	14/09/2016	n/a		
IA/0029	B.I.d.1.b.1 - Stability of AS - Change in the storage conditions - Change to more restrictive storage conditions of the AS	24/08/2016	n/a		
IB/0030	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	22/08/2016	22/03/2017	Annex II	
PSUSA/9261/201511	Periodic Safety Update EU Single assessment - pixantrone	09/06/2016	n/a		PRAC Recommendation - maintenance
R/0025	Renewal of the marketing authorisation.	28/01/2016	22/03/2016	SmPC, Annex II and PL	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and

					having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Pixuvri, subject to the Specific Obligations and Conditions as laid down in Annex II to the Opinion.
IAIN/0026	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	11/12/2015	n/a		
PSUSA/9261/ 201505	Periodic Safety Update EU Single assessment - pixantrone	03/12/2015	n/a		PRAC Recommendation - maintenance
IA/0024/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.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	21/08/2015	n/a		
PSUSA/9261/ 201411	Periodic Safety Update EU Single assessment - pixantrone	11/06/2015	n/a		PRAC Recommendation - maintenance
IA/0022	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder	09/04/2015	n/a		

	or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient				
R/0020	Renewal of the marketing authorisation.	22/01/2015	23/03/2015	Annex II	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Pixuvri, subject to the Specific Obligations and Conditions as laid down in Annex II to the Opinion.
PSUV/0018	Periodic Safety Update	04/12/2014	n/a		PRAC Recommendation - maintenance
N/0019	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/10/2014	23/03/2015	PL	
PSUV/0015	Periodic Safety Update	26/06/2014	01/09/2014	SmPC and PL	Please refer to Pixuvri (EMEA/H/C/2055/PSUV/0015) EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IB/0017	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	10/07/2014	n/a		
IB/0016	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)	12/06/2014	01/09/2014	SmPC	

R/0014	Renewal of the marketing authorisation.	20/02/2014	10/04/2014		The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Pixuvri, subject to the Specific Obligations and Conditions as laid down in Annex II to the Opinion.
IAIN/0013	B.IV.1.b - Change of a measuring or administration device - Deletion of a device	16/12/2013	10/04/2014	SmPC and PL	
IA/0012	B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	04/10/2013	n/a		
IB/0009	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)	01/10/2013	10/04/2014	SmPC	
IB/0011	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	20/08/2013	n/a		
IB/0010	B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation	08/08/2013	n/a		
IB/0008	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	08/08/2013	n/a		

	data				
IB/0006	The MAH applied to update section 4.4 of the SmPC with regards to the photosensitivity statement following the EMA conclusion to the assessment of the Follow-up Measure MEA002 - In vivo phototoxicity study to further investigate the phototoxic potential of Pixuvri. C.I.3.a - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under A 45/46, or amendments to reflect a Core SPC - Changes with NO new additional data are submitted by the MAH	01/07/2013	10/04/2014	SmPC	
IAIN/0007/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	14/06/2013	10/04/2014	SmPC, Annex II, Labelling and PL	
R/0005	Renewal of the marketing authorisation.	17/01/2013	22/03/2013	Annex II and PL	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the renewal of the conditional MA for Pixuvri, subject to the Specific Obligations and Conditions as laid down in Annex II

					to the Opinion.
IB/0003	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)	10/07/2012	29/10/2012	SmPC	
IB/0004	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	04/07/2012	n/a		
IB/0002	B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation	04/07/2012	n/a		
IB/0001	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	04/07/2012	n/a		