Holoclar

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
IB/0023	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	28/03/2019	n/a		
PSUSA/10352 /201808	Periodic Safety Update EU Single assessment - ex vivo expanded autologous human corneal epithelial cells containing stem cells	14/03/2019	n/a		PRAC Recommendation - maintenance

[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).

N/0024	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/02/2019		PL	
R/0021	Renewal of the marketing authorisation.	15/11/2018	15/01/2019	SmPC	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 Holoclar, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
PSUSA/10352 /201802	Periodic Safety Update EU Single assessment - ex vivo expanded autologous human corneal epithelial cells containing stem cells	06/09/2018	n/a		PRAC Recommendation - maintenance
IB/0019	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	18/05/2018	n/a		
IB/0018/G	This was an application for a group of variations. B.I.z - Quality change - Active substance - Other variation B.I.z - Quality change - Active substance - Other variation	18/05/2018	n/a		
PSUSA/10352 /201708	Periodic Safety Update EU Single assessment - ex vivo expanded autologous human corneal epithelial cells containing stem cells	08/03/2018	n/a		PRAC Recommendation - maintenance

IB/0017	B.I.z - Quality change - Active substance - Other variation	04/01/2018	n/a		
R/0015	Renewal of the marketing authorisation.	12/10/2017	11/12/2017		The CAT, 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 Holoclar, subject to the Specific Obligations and Conditions as laid down in Annex II to the Opinion.
PSUSA/10352 /201702	Periodic Safety Update EU Single assessment - ex vivo expanded autologous human corneal epithelial cells containing stem cells	28/09/2017	n/a		PRAC Recommendation - maintenance
IA/0014/G	This was an application for a group of variations. B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.2.b - Change in test procedure for AS or starting material/reagent/intermediate - Deletion of a test procedure for the AS or a starting material/reagent/intermediate, if an alternative test	28/07/2017	n/a		

	procedure is already authorised 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.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				
II/0012/G	This was an application for a group of variations. B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	22/06/2017	11/12/2017	SmPC and PL	
PSUSA/10352 /201608	Periodic Safety Update EU Single assessment - ex vivo expanded autologous human corneal epithelial cells containing stem cells	09/03/2017	n/a		PRAC Recommendation - maintenance

IB/0011	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	07/02/2017	n/a		
R/0008	Renewal of the marketing authorisation.	13/10/2016	08/12/2016		The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligation 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 Holoclar, subject to the Specific Obligation and Conditions as laid down in Annex II to the Opinion.
N/0010	Update of the labelling to include the unique identifier 2D barcode as per QRD template v.10 and update of the package leaflet with the revised contact details of the local representative for France. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	03/11/2016	11/12/2017	Labelling and PL	
PSUSA/10352 /201602	Periodic Safety Update EU Single assessment - ex vivo expanded autologous human corneal epithelial cells containing stem cells	02/09/2016	n/a		PRAC Recommendation - maintenance
IA/0007/G	This was an application for a group of variations. 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	23/06/2016	n/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				
IB/0006	B.II.c.2.z - Change in test procedure for an excipient - Other variation	10/06/2016	n/a		
IA/0005/G	This was an application for a group of variations. 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.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	27/05/2016	n/a		
PSUSA/10352 /201508	Periodic Safety Update EU Single assessment - ex vivo expanded autologous human corneal epithelial cells containing stem cells	17/03/2016	n/a		PRAC Recommendation - maintenance
IB/0003	B.II.z - Quality change - Finished product - Other variation	18/12/2015	n/a		
R/0001	Renewal of the marketing authorisation.	22/10/2015	10/12/2015		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 Holoclar, subject to the Specific Obligations and Conditions as laid down in Annex II to the Opinion.