EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

MACI

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
PSUSA/10116 /201506	Periodic Safety Update EU Single assessment - MATRIX APPLIED CHARACTERISED AUTOLOGOUS CULTURED CHONDROCYTES	14/01/2016	n/a		PRAC Recommendation - maintenance
IAIN/0009	A.1 - Administrative change - Change in the name and/or address of the MAH	17/09/2015		SmPC, Labelling and PL	
PSUSA/10116	Periodic Safety Update EU Single assessment -	09/07/2015	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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

/201412	MATRIX APPLIED CHARACTERISED AUTOLOGOUS CULTURED CHONDROCYTES				
IAIN/0008	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	06/07/2015	n/a		
IAIN/0006	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	10/03/2015	n/a		
PSUV/0005	Periodic Safety Update	09/01/2015	n/a		PRAC Recommendation - maintenance
A20/0004	On 8 September 2014, the MAH notified the European Medicines Agency of the withdrawal by the Danish authorities of the manufacturing licence for the manufacturing site for the active substance, finished product and batch release of MACI (matrix-applied characterised autologous cultured chondrocytes). The European Commission therefore initiated a procedure under Article 20 of Regulation (EC) No 726/2004 on 10 September 2014, requesting the Agency to give its opinion on whether the marketing authorisation for MACI should be suspended or revoked in accordance with Article 118 of Directive 2001/83/EC.	25/09/2014	19/11/2014		Please refer to the CHMP assessment report: MACI EMEA/H/A20/1409/C/002522/0004
PSUV/0002	Periodic Safety Update	11/09/2014	n/a		PRAC Recommendation - maintenance

T/0003	Transfer of Marketing Authorisation	13/08/2014	26/08/2014	SmPC, Labelling and PL	
IG/0418	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	11/04/2014	n/a		