ChondroCelect

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/0012/G	This was an application for a group of variations. 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 A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder	14/10/2014		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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	or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient				
R/0009	Renewal of the marketing authorisation.	26/06/2014	22/08/2014	SmPC, Annex II, Labelling and PL	Based upon the data that have become available since the granting of the initial Marketing Authorisation, the CHMP considers that the benefit-risk balance of ChondroCelect remains positive, but considers that post-marketing experience with respect to patient number and duration of follow-up is still quite limited, and doesn't warrant granting a renewal with unlimited validity. Therefore one additional renewal application should be submitted in 5 years' time. Due to the strong influence of hormones on ossification, cartilage formation and repair and the limited experience in patients below 18 years ChondroCelect was contraindicated in patients with a femoral epiphyseal growth plate that is not fully closed.
IA/0008	B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test	12/11/2013	n/a		
IA/0007	A.7 - Administrative change - Deletion of manufacturing sites	11/11/2013	22/08/2014	Annex II and PL	
II/0006	to add a new manufacturing site for ChondroCelect drug product and to submit results from user testing of package leaflet. B.II.b.2.b.3 - Change to batch release arrangements and quality control testing of the FP - Including batch control/testing for a biol/immunol product and one of the test methods is a biol/immunol/immunochemical	20/09/2012	24/10/2012	Annex II and PL	

	method				
IB/0004	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	24/05/2012	24/10/2012	SmPC, Annex II, Labelling and PL	
IA/0005	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	07/05/2012	n/a		
IB/0002	B.III.1.b.2 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer	10/11/2011	n/a		
IA/0003/G	This was an application for a group of variations. A.6 - Administrative change - Change in ATC Code/ATC Vet Code 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	29/09/2011	n/a	SmPC and Annex II	
II/0001	Changes to the manufacturing process of the active substance. B.I.d.1.b.2 - Stability of AS - Change in the storage conditions - Change in storage conditions of biological/immunological ASs, when the stability studies have not been performed in accordance with a	17/02/2011	02/03/2011		

	currently approved stability protocol				