EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CERTIFECT

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
R/0011	Renewal of the marketing authorisation.	18/02/2016	18/04/2016	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for CERTIFECT.
IG/0592	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure	04/09/2015	n/a		The Agency accepted the variation to change the QPPV.
IB/0009	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	05/06/2015	n/a		The Agency accepted the variation to tighten the current shelf-life limits.
IB/0008	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)	26/03/2014	26/02/2015	SPC	The Agency accepted the variation to extend the shelf-life up to 3 years for the 2.14 ml, 4.28 ml and 6.42 ml pipette.
IAIN/0007	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	14/03/2014	26/02/2015	Annex II and PL	The Agency accepted the variation to change the address of the manufacturer of the finished product, which is also responsible for batch release.
II/0006/G	This was an application for a group of variations. C.I.4 - Variations related to significant modifications of	12/09/2013	20/11/2013	SPC and PL	The European Commission amended the decision granting the marketing authorisation to introduce additional safety information in the product literature and to implement a

[1] Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.
[2] A CD is issued for procedures that affect the terms of the marketing authorisation (e.g. SPC, Annex II, Labelling, PL). The CD is issued within 2 months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within 1 year for other procedures.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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	the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data 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				change requested by the authorities following assessment of a Periodic Safety Update Report.
IB/0004	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	27/03/2013	n/a		The Agency accepted the variation to extend the re-test period of an active substance.
IA/0005	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	22/03/2013	n/a		The Agency accepted the variation for a minor change in the test procedure for the active substance
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)	09/11/2012	20/11/2013	SPC	The Agency accepted the variation to increase the shelf life from 18 to 24 months.
IB/0002	B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	22/12/2011	n/a		The Agency accepted the variation to make minor changes in the manufacturing process
IA/0001	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	26/08/2011	26/08/2011		The Agency accepted the variation for a minor change to an approved test procedure.