Contacera

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued / amended on	Product Information affected[2]	Summary[3]
IA/0011	A.7 - Administrative change - Deletion of manufacturing sites	30/03/2020		SPC, Annex II, Labelling and PL	The Agency accepted the variation to remove a batch release site. The MAH took the opportunity to remove the local representatives from the package leaflet.
IG/0951	C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) in the safety database and/or major contractual arrangements for the fulfilment of PhV obligations, and/or change of the site undergoing PhV activities	05/07/2018	n/a		The Agency accepted the variation to update the current detailed description of the pharmacovigilance system (DDPS).
R/0009	Renewal of the marketing authorisation.	07/09/2017	15/11/2017	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for Contacera.
IG/0747	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	23/03/2017	15/11/2017	SPC, Labelling and PL	The Agency accepted the variation to update the list of local representatives in the product information.
IG/0538	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	01/04/2015	n/a		The Agency accepted the variation to change the QPPV.

[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] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).
[3] Since October 2019 summary information is no longer published for variations that do not impact upon the product information

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IB/0006	C.II.6.b - Changes to the labelling or the PL which are not connected with the SPC - Other changes	10/07/2014	20/07/2015	Labelling	The Agency accepted the variation relating to the text on the carton/label.
X/0002	Annex I_2.(e) Change or addition of a new route of administration Annex I_2.(c) Change or addition of a new strength/potency Annex I_2.(d) Change or addition of a new pharmaceutical form	12/12/2013	13/02/2014	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to include a new strength meloxicam 15 mg/ml and a new pharmaceutical form oral suspension for horses.
IB/0005	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	27/09/2013	16/01/2014	SPC, Labelling and PL	The Agency accepted the variation to add indication for the relief of post-operative pain following dehorning in calves.
IG/0328	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	05/09/2013	n/a		The Agency accepted the variation to update the contact details of the QPPV.
T/0003	Transfer of Marketing Authorisation	26/04/2013	13/06/2013	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Pfizer Ltd' to 'Zoetis Belgium SA'.
II/0001	B.II.a.3.b.2 - Changes in the composition (excipients) of the finished product - Other excipients - Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the product	11/04/2013	13/06/2013	SPC	The Agency accepted the variation to change the composition - removal of disodium edetate as excipient.