Improvac

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/0038	B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	26/01/2022	n/a		n/a
II/0036	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	09/12/2021	20/01/2022	SPC, Labelling and PL	To modify the indication by adding female pigs and subsequent changes to the product information. Additionally, MAH is proposing to correct translation mistakes in different languages.
IB/0037	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	15/12/2021	n/a		
IG/0976	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	26/10/2018	25/10/2019	PL	The Agency accepted the variation to delete the list of local representatives from the product information.
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	05/07/2018	n/a		n/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] 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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

	arrangements for the fulfilment of PhV obligations, and/or change of the site undergoing PhV activities				
IB/0033	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	16/03/2018	30/10/2018	SPC and PL	The Agency accepted the variation to update SPC section 4.5 and the corresponding section 12 of the package leaflet to add a new warning related to accidental self-injection.
IG/0851	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	15/11/2017	n/a		The Agency accepted the variation to change the name of the secondary packaging site.
IA/0031	B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)	13/10/2017	30/10/2018	SPC, Labelling and PL	The Agency accepted the variation to remove the 20ml (10 dose) presentation of the product Improvac, additionally accepting QRD updates in the product information and updates to the local representatives.
IB/0030/G	This was an application for a group of variations. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation 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	25/11/2016	n/a		The Agency accepted the group of variations to make changes to the specification limits of a starting material and for a change in a test method. In addition, the MAH took the opportunity to introduce an editorial change in Part 2 of the dossier.
IB/0029	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	02/09/2015	n/a		The Agency accepted a variation to replace a QC release test.
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.
IB/0027	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	27/03/2015	n/a		The Agency accepted the variation to extend the shelf-life of the active substance from 48 months to 60 months.
IA/0026	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	13/02/2015	n/a		The Agency accepted the variation to modify the specifications for one component of the starting material.
IA/0025	A.7 - Administrative change - Deletion of manufacturing sites	08/08/2014	n/a		The Agency accepted the variation to delete a manufacturing site responsible for quality control/ testing of Improvac.
R/0024	Renewal of the marketing authorisation.	13/02/2014	10/04/2014	SPC, Annex II, Labelling and PL	The European Commission accepted the renewal of the marketing authorisation.
IG/0359	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	25/10/2013	n/a		The Agency accepted the variation to add a manufacturing site for secondary packaging of the finished product.

II/0019	C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	12/09/2013	10/04/2014	SPC and PL	The European Medicines Agency accepted a type II variation to expand the description of needle length in the product information.
II/0018	B.II.a.3.b.3 - Changes in the composition (excipients) of the finished product - Other excipients - Change that relates to a biological/immunological product	12/09/2013	10/04/2014	SPC, Labelling and PL	The European Medicines Agency accepted a type II variation to change the composition from excipient thiomersal to chlorocresol.
IAIN/0021/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	05/09/2013	10/04/2014	SPC, Annex II, Labelling and PL	The Agency accepted a grouped type IA and type IAIN variation to change the names of the manufacturers of the active substance and to change the name of the manufacturer of the finished product and manufacturer responsible for batch release.
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/0020	Transfer of Marketing Authorisation	26/04/2013	22/05/2013	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to transfer the marketing authorisation from 'Pfizer Ltd' to 'Zoetis Belgium SA'.
IA/0017	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	07/09/2012	29/10/2012	SPC and PL	The European Medicines Agency accepted a type IA variation to change the ATCvet code from QI09AX to QG03XA91.
IB/0015	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Extension of storage period of a biological/immunological medicinal product in accordance with an approved stability protocol	16/05/2012	29/10/2012	SPC	The European Medicines Agency accepted a type IB variation to extend the shelf life of the finished product from 24 months to 36 months.
II/0016	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological medicinal product and is not related to a protocol	11/10/2012	n/a		The European Medicines Agency acdepted the variation on minor change to the manufacturing process for the N-Chloroacetyl-2-10-GnRF peptide used as a critical starting material for the preparation of Improvac conjugate.
II/0014	B.I.d.1.a.3 - Stability of AS - Change in the re-test period/storage period - Extension of storage period of a biological/immunological AS not in accordance with	16/05/2012	16/05/2012		The European Medicines Agency accepted a type II variation to extend the shelf life of the active substance

	an approved stability protocol				from 36 months to 48 months at +2 °C to +8 °C.
II/0013	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological medicinal product and is not related to a protocol	08/03/2012	08/03/2012		The European Medicines Agency accepted a type II variation to make adjustments to production fermentation steps in the manufacturing process.
II/0009	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	14/07/2011	05/09/2011	SPC, Labelling and PL	The European Commission approved a type II variation for the addition of a claim to the existing marketing authorisation to allow a third dose of the vaccine to be given 10 weeks or more after the second dose to entire male pigs intended for slaughter at heavy weights.
IG/0005/G	This was an application for a group of variations. C.I.9.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site undertaking pharmacovigilance activities	05/08/2011	05/08/2011		The Agency accepted the group of variations to change the location of the Qualified Person for Pharmacovigilance.
II/0011	B.I.d.1.a.3 - Stability of AS - Change in the re-test period/storage period - Extension of storage period of a biological/immunological AS not in accordance with an approved stability protocol	09/02/2011	16/02/2011		The European Commission approved a type II variation to extend the current shelf-life of the diphtheria toxoid (active substance) from 24 months to 36 months at +2 °C to +8 °C.
II/0007/G	This was an application for a group of variations. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one 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	07/12/2010	20/12/2010	SPC, Labelling and PL	The European Commission approved a type II grouped variation for the addition of a behaviour claim and the addition of anaphylactoid like reactions.
II/0008	B.I.d.1.a.3 - Stability of AS - Change in the re-test period/storage period - Extension of storage period of a biological/immunological AS not in accordance with an approved stability protocol	13/10/2010	03/11/2010		The European Commission approved a type II variation extending the shelf life of the conjugate from 12 to 24 months at +2 °C to +8 °C.
IA/0006/G	This was an application for a group of variations. B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	08/07/2010	14/10/2010	SPC, Labelling and PL	The European Medicines Agency accepted a group of three type IAIN variations to add three new presentations.

IB/0005	B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening (supported by real time data)	09/03/2010	14/10/2010	SPC, Labelling and PL	The European Medicines Agency accepted a type IB variation to prolong the shelf life of the finished product after first opening.
II/0004	II - Other quality changes	10/03/2010	24/03/2010		The European Commission approved a type II variation extending the re-test period for the peptide of active substance.
II/0003	II - Other quality changes	10/03/2010	24/03/2010		The European Commission approved a type II variation extending the shelf life for the toxoid.
II/0002	II - Other quality changes	13/01/2010	21/01/2010		The European Commission approved a type II variation for the removal of the Target Animal Batch Safety Test (TABST) from the control tests performed on the finished product in the interest of animal welfare.
IB/0010	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	06/01/2010	06/01/2010		The The European Medicines Agency accepted a type IB variation concerning finished product testing.
II/0001	II - Other quality changes	14/10/2009	19/11/2009	SPC, Labelling and PL	The European Commission approved a type II variation for the removal of the Potency Test in pigs from the control tests performed on the finished product in the interest of animal welfare.