Ingelvac CircoFLEX

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]
IG/1419	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)	18/08/2021	n/a		n/a
WS/1921	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	15/07/2021		SPC and PL	The Agency accepted the variation to add the associated use of Ingelvac CircoFLEX and Ingelvac PRRSFLEX EU.
WS/1920/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.e.5.a.2 - Change in pack size of the finished	18/03/2021		SPC, Labelling and PL	The Agency accepted the group of variations to introduce a new container closure system and to add new pack-sizes. Additionally, the MAH is introducing a QR code in the Labelling and Package Leaflet. Furthermore, the product information has been aligned with the latest QRD template.

[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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	product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside 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 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 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 C.II.6.b - Changes to the labelling or the PL which are not connected with the SPC - Other changes				
IG/1337	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	10/02/2021	n/a		n/a
IA/0034	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)	01/10/2020	n/a		Th Agency accepted the variation to change the name of the secondary packaging site.
IB/0033/G	This was an application for a group of variations. 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 B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	14/08/2020	n/a		n/a
IA/0032/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	28/08/2019	08/09/2020	Annex II	The Agency accepted the group of variations to change the name of the manufacturer of active substance and finished product.

	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.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)				
IG/1128/G	This was an application for a group of variations. 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 C.I.9.c - 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 PhV system	17/07/2019	n/a		n/a
II/0030/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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 substance which may have a significant impact on the medicinal product and is not related to a protocol B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	22/05/2019	n/a		The Agency accepted the group of variations to register a change in the manufacturing process of the active substance, and consequential changes to adapt the in-process potency testing for the active substance and to adapt the carbomer testing for the finished product.
IG/1031/G	This was an application for a group of variations. 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 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 C.I.9.c - 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 PhV system	14/12/2018	n/a		n/a
WS/1249/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.2.a - Change in test procedure for AS or starting	15/02/2018	n/a		The Agency accepted the group of variations to change the manufacturing process of the medicinal product concerned or its active substance.

	material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test				
IG/0855/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	24/11/2017	17/12/2018	Annex II and PL	The Agency accepted the group of variations to delete two manufacturing sites and to add a new secondary packaging site. In addition, the product information was aligned with the latest QRD template and a minor editorial change was made in the SPC.
IG/0831	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	01/09/2017	24/10/2017	PL	The Agency accepted the variation to delete the list of local representatives from the package leaflet.
IA/0025	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	12/10/2016	n/a		The Agency accepted the variation to delete a non-significant in-process test.
IG/0722	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	27/09/2016	24/10/2017	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.
IA/0023	B.II.e.3.a - Change in test procedure for the immediate packaging of the finished product - Minor changes to an approved test procedure	07/01/2016	n/a		The Agency accepted the variation to revise the primary packaging documentation.
IAIN/0022	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	20/10/2015	29/07/2016	Annex II and PL	The Agency accepted the variation to register an additional batch release site for the finished product.
II/0020	B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method	10/09/2015	n/a		The Agency accepted the variation to register an additional testing site for the final product.
II/0019	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	09/07/2015	29/07/2016	SPC, Labelling and PL	The Agency accepted the variation to update the statement on use during pregnancy and lactation in the product information. Additional minor changes (editorial and QRD alignment) have been included.
IAIN/0021	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	19/06/2015	n/a		The Agency accepted the variation to register an alternative site for secondary packaging of the finished product, located within the USA.
IB/0018/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished	29/08/2014	30/09/2014	SPC, Annex II, Labelling and PL	The Agency accepted the group of variations as outlined in the scope.

	product - Other changes to a test procedure (including replacement or addition) 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) B.II.d.2.z - Change in test procedure for the finished product - Other variation				
IA/0017	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	16/04/2014	n/a		The Agency accepted the variation to increase the inoculum volume used for the sterility testing.
IG/0380	C.I.9.d - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH	05/12/2013	n/a		The Agency accepted the variation to harmonise the Detailed Description of the Pharmacovigilance System (DDPS).
IAIN/0015	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	06/11/2013	30/09/2014	PL	The Agency accepted the variation to update the list of local representatives with the information on the Croatian local representative. Translations of the SPC in Croatian language are officially forwarded to the EMA/EC.
R/0013	Renewal of the marketing authorisation.	08/11/2012	14/01/2013	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for Ingelvac CircoFLEX.
IAIN/0014	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	19/10/2012	n/a		The Agency accepted the variation to add an alternative manufacturing site for secondary packaging of the finished product.
IB/0012	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	13/07/2012	n/a		The Agency accepted the variation to register an alternative method for sterility-testing of the in-process antigen of Ingelvac CircoFLEX.
WS/0243	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	14/06/2012	12/07/2012	SPC and PL	The European Commission amended the decision granting the marketing authorisation on a type II variation concerning amendment of SPCs and package leaflets of Ingelvac CircoFLEX (centrally authorised product) and Ingelvac MycoFLEX (non centrally authorised product) to reflect changed mixing instructions, allowing mixing of Ingelvac CircoFLEX directly in the Ingelvac MycoFLEX container.
IB/0010/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	09/03/2012	n/a		The Agency accepted the group of variations for a replacement of the positive and negative controls used for the finished product ELISA potency test and for the in-process ELISA of the antigen harvest test.
IB/0009	B.I.a.3.e - Change in batch size (including batch size ranges) of AS or intermediate - The scale for a biological/immunological AS is increased/decreased without process change (e.g. duplication of line)	17/02/2012	n/a		The Agency accepted the variation to scale-up the vaccine antigen production.

II/0008/G	This was an application for a group of variations. B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line) B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	08/12/2011	08/12/2011		The European Commission amended the decision granting the marketing authorisation by a grouping of type II and IB variations to add an alternative co-infection process for antigen preparation in order to reduce the total incubation time needed to grow the antigen; and to scale-up the batch size from 2,000 litres to 4,000 litres.
IAIN/0007	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	22/07/2011	22/07/2011		The Agency accepted the variation to add a secondary manufacturer.
II/0005	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	14/07/2011	14/07/2011		The European Commission amended the decision granting the marketing authorisation to replace an immunological reference preparation in an immunological test method.
IB/0006/G	This was an application for a group of variations. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	06/05/2011	06/05/2011	SPC, Labelling and PL	The Agency accepted the group of variations concerning the addition of 12 x 10 ml, 12 x 50 ml, 12 x 100 and 12 x 250 ml pack sizes.
IB/0003	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	07/07/2010	27/01/2011	SPC and PL	The Agency accepted the variation to update the product literature (statement on anaphylactic reactions).
IA/0004	B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	29/07/2010	29/07/2010		The Agency accepted the variation concerning a change in the primary packaging material.
II/0002	II - SPC update	19/05/2010	01/07/2010	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to indicate the compatibility of mixing Ingelvac CircoFLEX with Ingelvac MycoFLEX.
II/0001	II - Other quality changes	16/04/2009	29/04/2009		The European Commission amended the decision granting the marketing authorisation regarding a scale-up of PCV2 ORF-2 antigen production.