Mosquirix

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
II/0085/G	This was an application for a group of variations. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.4 - Change(s) in the SPC, Labelling or PL due to	10/04/2025		SmPC and PL	Interim results from study EPI-MAL-003 showed no evidence of an increased risk of meningitis following primary vaccination with Mosquirix: meningitis events were rare (i.e., 6 and 10 cases reported in vaccinated and unvaccinated children, respectively). Consequently, the warning and precaution related to meningitis has been removed from the

[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).

	new quality, preclinical, clinical or pharmacovigilance data				SmPC 4.4. In addition, no evidence of an increased risk of cerebral malaria or gender specific mortality rates were observed. The study also provided evidence of vaccine impact on any and severe malaria, all-cause and malaria-attributed hospitalisation, and hospitalised anaemia. The SmPC section 5.1 has been updated accordingly. Furthermore, the final study report of WHO's Malaria Vaccine Pilot Evaluation (MVPE) was provided which supports all the conclusions above. The RMP has also been updated to remove meningitis as an important potential risk. The benefit risk balance of Mosquirix remains positive. For more information, please refer to the Summary of Product Characteristics.
II/0086	Update of sections 4.2, 4.5, 4.8 and 5.1 of the SmPC in order to update posology, efficacy and safety information based on final results from study MALARIA-094 and literature. This is a Phase 2b, randomised, open-label, controlled, multi-centre study of the efficacy, safety and immunogenicity of RTS,S/AS01E evaluating schedules with or without fractional doses, early dose 4 and yearly doses, in children living in sub-Saharan Africa. Editorial amendments to section 4.1 are implemented. The Labelling and the Package Leaflet are updated accordingly. In addition, the SOH took the opportunity to update the list of local representatives	27/03/2025		SmPC, Labelling and PL	Results from study Malaria-094 show that significant vaccine efficacy against clinical malaria was maintained until end of the study (Month 50) with up to 3 annual revaccinations, irrespective of schedule. Vaccine efficacy of a standard fourth dose administered at Month 12 and at Month 18 after the third dose was evaluated for the standard 0, 1, 2-month primary dose schedule in two of the study arms. Vaccine efficacy was similar when the fourth dose was given at 12 months or 18 months after the third dose [51% (95% CI: 35; 63) and 43% (95% CI: 21; 59), respectively]. Vaccine efficacy at 12 months post-Dose 4 was shown to be similar to post-Dose 3 and was maintained post-Dose 5 and -Dose 6. The safety profile

	in the Package Leaflet, to bring the PI in line with the latest QRD template version 10.4, to update the PI in accordance with the latest EMA excipients guideline, and to implement editorial changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				remains unchanged and annual re-vaccination does not increase the frequency or severity of reported adverse events. Consequently, the SmPC sections 4.2, 4.8 and 5.1 have been updated accordingly. Furthermore, literature data from clinical studies Malaria-099/-106 showed that Mosquirix vaccination with seasonal malaria chemoprevention provided superior vaccine efficacy as compared to Mosquirix alone or seasonal malaria chemoprevention alone. Based on these results, SmPC sections 4.5 and 5.1 have been updated to allow vaccination with Mosquirix in combination with seasonal chemoprevention. For more information, please refer to the Summary of Product Characteristics.
IB/0084	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	03/10/2024	n/a		
PSUV/0083	Periodic Safety Update	03/10/2024	n/a		PRAC Recommendation - maintenance
IB/0082/G	This was an application for a group of variations. B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	06/03/2024	n/a		
IA/0081	B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply	21/02/2024	n/a		

	with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material				
WS/2585	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.c.4.c - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient excipient - The excipient is a biological/immunological substance	01/02/2024	n/a		
II/0077	Submission of the final report from study EPI-MALALARIA-002 VS AME (115055). This is a non-interventional study, designed to estimate the incidence of diseases specified as adverse events of special interest, of other adverse events leading to hospitalisation or death, and of meningitis in infants and young children in sub-Saharan Africa. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	11/01/2024	n/a		
IB/0080	B.I.c.1.z - Change in immediate packaging of the AS - Other variation	19/12/2023	n/a		
IG/1677	B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation	27/11/2023	n/a		
IB/0075	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting	02/10/2023	n/a		

	material/intermediate/reagent - Other variation				
PSUV/0071	Periodic Safety Update	28/09/2023	n/a		PRAC Recommendation - maintenance
IA/0076/G	This was an application for a group of variations. B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits	07/09/2023	n/a		
IB/0072	B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS	22/08/2023	n/a		
IB/0073/G	This was an application for a group of variations. B.II.f.z - Stability of FP - Other variation B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	25/07/2023	n/a		
II/0069	B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability	20/07/2023	n/a		

WS/2471/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.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an approved protocol B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS	13/07/2023	n/a		
IA/0074	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	07/07/2023		SmPC	
IB/0068	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	06/01/2023	n/a		
IB/0065/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of	04/01/2023	n/a		

	the finished or intermediate product - Minor change in the manufacturing process				
IG/1575/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	01/12/2022	n/a		
IB/0064/G	This was an application for a group of variations. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	25/11/2022	n/a		
WS/2325	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished	17/11/2022	n/a		

	product - Other variation				
PSUV/0062	Periodic Safety Update	29/09/2022	n/a		PRAC Recommendation - maintenance
II/0061/G	This was an application for a group of variations. B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS	14/07/2022	n/a		
II/0060	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	17/03/2022	n/a		
II/0059/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability	13/01/2022	n/a		
PSUV/0056	Periodic Safety Update	30/09/2021	n/a		PRAC Recommendation - maintenance
IB/0058	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	29/07/2021		SmPC and PL	

IB/0057	B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)	05/07/2021	n/a		
IG/1379	B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	30/03/2021	n/a		
WS/1961	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	25/03/2021	n/a		
WS/1987	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e.z - Change in container closure system of the Finished Product - Other variation	11/02/2021	n/a		
WS/1949/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. A.7 - Administrative change - Deletion of manufacturing sites	14/01/2021	n/a		

	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.c.z - Change in control of excipients in the Finished Product - Other variation B.II.c.z - Change in control of excipients in the Finished Product - Other variation B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including				

	replacement or addition)				
IA/0054	B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits	11/01/2021	n/a		
IB/0049	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	23/11/2020	n/a		
IA/0051	B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	06/11/2020	n/a		
PSUV/0045	Periodic Safety Update	01/10/2020	n/a		PRAC Recommendation - maintenance
IB/0048/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of	24/09/2020	n/a		

	a Member State - Excipient/AS starting material				
II/0047	B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS	24/09/2020	n/a		
IG/1244	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	12/06/2020	n/a		
II/0043	Update of section 4.5 of the SmPC in order to add immunogenicity data following the interim results from study Malaria-073 listed as a category 3 study in the RMP; this is a phase 3 randomized, open, controlled study to evaluate the immunogenicity and safety of Mosquirix when administered as a primary vaccination schedule at 6, 7.5 and 9 months-of-age, with or without co-administration of measles and rubella and yellow fever vaccines, to children living in sub-Saharan Africa. The RMP version 5.1 has also been submitted. In addition, the Scientific opinion Holder (SOH) took the opportunity to bring the PI in line with the latest QRD template version 10.1. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	16/01/2020		SmPC and Annex II	Data from study 073 showed that co-administration of Mosquirix, YF-vaccine and measles-rubella-vaccine did not interfere with the immune reaction to any of the antigens. All non-inferiority endpoints were met. No new safety issues were seen, and co-administration did not show differences to the use of Mosquirix alone. The product information is therefore updated to indicate that Mosquirix can be given concomitantly with rubella vaccine (based on data generated in clinical study 073), in addition to yellow fever and measles vaccines already mentioned in the approved PI.

IB/0044/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.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	07/01/2020	n/a		
PSUV/0042	Periodic Safety Update	03/10/2019	n/a		PRAC Recommendation - maintenance
WS/1556/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.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition) B.II.c.2.z - Change in test procedure for an excipient - Other variation	11/04/2019	n/a		
II/0036	Update of section 4.4 of the SmPC in order to indicate that protection against Plasmodium falciparum malaria wanes over time and vaccination may delay the acquisition of natural immunity. In addition, section 5.1 of the SmPC has been updated with long-term efficacy data. This update is based on final results from study MALARIA-076 listed as a category 3 study in the RMP. This was an open	11/04/2019		SmPC	The Phase III efficacy study MALARIA-55 was extended for 3 additional calendar years in 3 centres (follow-up study MALARIA-076). Vaccine efficacy from the first vaccine dose given in the efficacy study to the end of the follow-up (median duration of follow-up: 6.2 years in infants aged 6-12 weeks at first dose and 6.8 years in children aged 5-17 months at first dose) was evaluated. During the follow-up period, waning of vaccine efficacy was observed, but the

	extension to the phase III, multi-centre study MALARIA-055 PRI (110021) to evaluate long-term efficacy, safety and immunogenicity of the GSK Biologicals' candidate malaria vaccine in infants and children. The RMP version 4.3 has also been submitted. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				number of cases in either vaccination group (5-17 months of age and 6-12 weeks of age) did not exceed that of the control group. The data of MALARIA-076 did not raise any new significant information regarding the risk of rebound, which remains an important potential risk of Mosquirix.
IA/0041	B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol	04/03/2019	n/a		
II/0038	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	28/02/2019	n/a		
IB/0039	B.II.f.1.a.1 - Stability of FP - Reduction of the shelf life of the finished product - As packaged for sale	19/12/2018		SmPC	
WS/1450	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.z - Quality change - Finished product - Other variation	18/10/2018	n/a		
II/0035	Submission of the final report from study MALARIA-071. This is a phase IIA, open-label, controlled, single-centre, single-country study, to evaluate	04/10/2018	n/a		

	efficacy, safety, reactogenicity and immunogenicity of GSK Biologicals' candidate malaria vaccine in healthy malaria-naïve adults. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				
PSUV/0033	Periodic Safety Update	04/10/2018	n/a		PRAC Recommendation - maintenance
WS/1434	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.c.4.a - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient - Minor change	27/09/2018	n/a		
IB/0032	B.II.c.4.a - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient - Minor change	25/05/2018	n/a		
IB/0029	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	30/04/2018		SmPC and Labelling	
IG/0915	B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material	26/04/2018	n/a		
II/0028	B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial	12/04/2018	n/a		

	change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS				
IB/0030/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)	04/04/2018	n/a		
IB/0027	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	24/01/2018	n/a		
IB/0026	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	18/12/2017	n/a		
II/0025/G	This was an application for a group of variations. B.I.b.1.g - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Widening of the approved specs for starting mat./intermediates, which may have a significant effect on the quality of the AS and/or the FP B.I.b.2.b - Change in test procedure for AS or	14/12/2017	n/a		

	starting material/reagent/intermediate - Deletion of a test procedure for the AS or a starting material/reagent/intermediate, if an alternative test procedure is already authorised B.II.c.4.z - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient - Other variation				
PSUV/0022	Periodic Safety Update	28/09/2017	n/a		PRAC Recommendation - maintenance
II/0020	Update of the RMP (version 3.0) in order to add cerebral malaria as an important potential risk, add mortality by gender as missing information, add the WHO Pilot Implementation Programme as a category 3 study and make amend dates and protocols for a number of studies (Malaria-073, EPI-MAL-002, EPI-MAL-003, EPI-MAL-005, EPI-MAL-010 and the Pilot Implementation Programme). C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	28/09/2017	n/a		
IB/0024	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	18/08/2017	n/a		
IG/0811	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	19/06/2017	n/a		

IB/0021/G	This was an application for a group of variations. B.II.f.1.e - Stability of FP - Change to an approved stability protocol B.II.f.1.a.3 - Stability of FP - Reduction of the shelf life of the finished product - After dilution or reconstitution	04/05/2017		SmPC	
IB/0019/G	This was an application for a group of variations. B.I.b.z - Change in control of the AS - 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 B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	28/03/2017	n/a		
II/0018	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	16/02/2017	n/a		
II/0017	B.II.c.4.c - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient excipient - The excipient is a biological/immunological substance	19/01/2017	n/a		
II/0015	The SOH submitted the final study report of study Malaria-066, a non-interventional ancillary study to	19/01/2017	n/a		The study Malaria-066 was a non-interventional ancillary study to Malaria-055 to evaluate the genetic polymorphism

	Malaria-055 to evaluate the genetic polymorphism of the circumsporozoite (CS) protein of P. falciparum found in infants and children who developed clinical malaria in Malaria-055 study or with prevalent parasitaemia at cross-sectional survey. The SOH did not propose any changes to the product information. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				of the circumsporozoite (CS) protein of P. falciparum found in infants and children who developed clinical malaria in Malaria-055 study or with prevalent parasitaemia at cross-sectional survey. In the study Malaria-066, the repeat and the C-terminal regions of the CS protein from the P. falciparum parasites were sequenced in order to compare the genotypes present in breakthrough infections to the genotype of the vaccine strain. The relationship between CS protein sequences and the vaccine efficacy (VE) against first or only malaria episode or against prevalent infection was evaluated in the 2 age categories of children enrolled in the study Malaria-055 (6 to 12 weeks of age at first dose and 5-17 months of age at first dose). The analyses made show that there is a very diverse genotype pool responsible for the malarial infections seen in the efficacy study. It is also seen that the genotype present in the vaccine is underrepresented in nearly all study sites and it could be indicative (at least in the older age groups) of the low VE seen in the efficacy study. The study Malaria-066 had several restraints but gives, nevertheless, a good general estimate of circulating strains. From the results with only slightly differing VE considering match/ non-match serotype it can at least be hoped that strain replacement due to the introduction of the vaccine is not to be expected. It is awaited that the studies covering the introduction of the vaccine will show the real efficiency of the vaccine and thus showing whether the analyses made here are of predictive value for other vaccine/ vaccination attempts.
IB/0014	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a	06/12/2016	n/a		

	biological/immunological medicinal product				
PSUV/0011	Periodic Safety Update	27/10/2016	n/a		PRAC Recommendation - maintenance
IB/0013	B.II.b.z - Change in manufacture of the Finished Product - Other variation	30/09/2016	n/a		
IB/0012	B.II.c.z - Change in control of excipients in the Finished Product - Other variation	26/07/2016	n/a		
IB/0010	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	21/06/2016		SmPC	
II/0006	B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS	09/06/2016	n/a		
IG/0679	B.II.e.2.b - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specification with its corresponding test method	01/06/2016	n/a		
IB/0008/G	This was an application for a group of variations. B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method	17/05/2016	n/a		

	B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation				
II/0003	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	12/05/2016	n/a		
IA/0007	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	04/05/2016	n/a		
IB/0005	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	11/03/2016	n/a		
WS/0864	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	25/02/2016	n/a		
IB/0004	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	16/02/2016	n/a		
IB/0002	B.II.c.z - Change in control of excipients in the Finished Product - Other variation	03/02/2016	n/a		
