Prevenar 13

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
IAIN/0218	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	03/04/2024		Annex II and PL	
IB/0217	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP -	08/02/2024	n/a		

[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).

	Replacement/addition of a site where batch control/testing takes place				
IB/0216/G	This was an application for a group of variations. B.II.z - Quality change - Finished product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	04/01/2024	n/a		
II/0215/G	This was an application for a group of variations. B.II.b.3.b - Change in the manufacturing process of the finished or intermediate product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product 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 the finished or intermediate product - Minor change in the manufacturing process B.II.e.4.b - Change in shape or dimensions of the container or closure (immediate packaging) - The change in shape or dimensions concerns a fundamental part, which may have a significant impact on the delivery, use, safety or stability of the FP B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished	05/10/2023	n/a		

	product - Addition of a new test(s) and limits				
PSUSA/9263/202301	Periodic Safety Update EU Single assessment - pneumococcal polysaccharide conjugate vaccine (adsorbed) - 13 valent	31/08/2023	n/a		PRAC Recommendation - maintenance
IB/0214	B.I.z - Quality change - Active substance - Other variation	07/07/2023	n/a		
IB/0213/G	This was an application for a group of variations. B.II.e.z - Change in container closure system of the Finished Product - Other variation B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	07/07/2023	n/a		
IB/0212/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.e - Stability of FP - Change to an approved stability protocol	01/06/2023	n/a		

IB/0209/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.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)	29/03/2023	n/a		
IB/0210/G	This was an application for a group of variations. B.II.z - Quality change - Finished product - Other variation B.II.z - Quality change - Finished product - Other variation	28/03/2023	n/a		
IA/0208	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	27/09/2022	n/a		
II/0206/G	This was an application for a group of variations. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting	01/09/2022	n/a		

	material [-] used in the manufacture of a biological/immunological product B.I.b.1.a - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits for medicinal products subject to OCABR B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB A.7 - Administrative change - Deletion of manufacturing sites B.I.b.1.a - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits for medicinal products subject to OCABR B.I.z - Quality change - Active substance - Other variation B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product				
IB/0207	B.II.b.3.z - Change in the manufacturing process of	08/07/2022	n/a		

	the finished or intermediate product - Other variation				
IB/0205/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.z - Quality change - Active substance - Other variation B.I.z - Quality change - Active substance - Other variation B.I.b.z - Change in control of the AS - Other variation B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.z - Change in control of the AS - Other variation	03/05/2022	n/a		
IB/0204/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.	21/12/2021	n/a		

	duplication of line) 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)				
IA/0203/G	This was an application for a group of variations. 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 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	07/10/2021	n/a		
IB/0202/G	This was an application for a group of variations. B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	07/10/2021	n/a		

	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits				
N/0201	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/10/2021		PL	
IB/0200	B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB	14/04/2021	n/a		
IB/0198	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	14/04/2021	n/a		
IB/0199	B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	31/03/2021	n/a		
IB/0197	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	08/01/2021	n/a		
IA/0196/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - 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 A.7 - Administrative change - Deletion of manufacturing sites	30/11/2020	n/a		

IB/0195/G	This was an application for a group of variations. B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.3.a - Change in batch size (including batch size	27/11/2020	n/a		

	ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size				
N/0194	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	27/11/2020		PL	
PSUSA/9263/ 202001	Periodic Safety Update EU Single assessment - pneumococcal polysaccharide conjugate vaccine (adsorbed) - 13 valent	17/09/2020	25/11/2020	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/9263/202001.

IA/0193/G	This was an application for a group of variations. B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	17/11/2020	n/a		
IB/0192/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	11/11/2020	n/a		
IB/0191	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	24/09/2020	n/a		
II/0190	B.I.b.1.e - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a specification parameter which may have a significant effect on the overall quality of the AS and/or the FP	23/07/2020	n/a		
II/0186/G	This was an application for a group of variations.	18/06/2020	n/a		

	B.II.b.4.d - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes 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				
II/0185/G	This was an application for a group of variations. 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 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 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 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	14/05/2020	n/a		

IB/0189	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	13/05/2020	n/a		
IB/0187	B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB	06/05/2020	n/a		
IA/0184/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	28/02/2020	25/11/2020	Annex II and PL	
II/0180/G	This was an application for a group of variations. B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes 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	12/12/2019	n/a		

	biol/immunol method B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation 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				
II/0181	Update of section 5.1 of the SmPC in order to update efficacy information based on results from a public health analysis and publication of data from the CAPiTA (Community-Acquired Pneumonia Immunization Trial in Adults), a double-blind, randomized, placebo-controlled efficacy trial of 13-valent pneumococcal conjugate vaccine (PCV13). C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	14/11/2019	25/11/2020	SmPC	A post-hoc analysis of study CAPiTA was performed to estimate vaccine efficacy (VE), incidence rate reduction (IRR) and number needed to vaccinate (NNV) against clinical Community-Acquired Pneumonia (CAP); defined as CAP based on clinical findings regardless of radiologic infiltrate or etiologic confirmation. The post-hoc analysis study shows that the impact of this vaccine remains positive in helping to prevent clinical CAP. The magnitude of overall VE 95% CI of 8.1 (-0.6, 16.1) against clinical CAP was statistically significant. The NNV reflects that at least 277 persons need to be vaccinated to prevent one clinical CAP case.
IB/0182/G	This was an application for a group of variations. B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	05/09/2019	n/a		
IA/0183	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	16/08/2019	n/a		

IB/0178/G	This was an application for a group of variations. 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.7 - Administrative change - Deletion of manufacturing sites B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer	28/06/2019	n/a		
IAIN/0179	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	12/06/2019	19/11/2019	SmPC, Labelling and PL	
IA/0177/G	This was an application for a group of variations.	06/06/2019	n/a		

	B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier				
IAIN/0176	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	24/05/2019	19/11/2019	SmPC, Labelling and PL	
IB/0175/G	This was an application for a group of variations. B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits 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	14/02/2019	19/11/2019	SmPC	

IA/0174/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.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	12/12/2018	19/11/2019	Annex II	
IAIN/0173/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	12/12/2018	n/a		
T/0170	Transfer of Marketing Authorisation	11/07/2018	27/09/2018	SmPC, Labelling and PL	
II/0161	Submission of the final study report from study B1851041, a phase 4 post marketing study to determine 'National trends in Ambulatory Care Visits for Otitis Media in Children Under the Age of Five in the United States.' Consequently, the RMP version 12 has been updated.	06/09/2018	n/a		

	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				
IB/0171/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 the finished or intermediate product - Minor change in the manufacturing process B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure	14/08/2018	n/a		
N/0169	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/08/2018	19/11/2019	Labelling	
IB/0167	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	02/07/2018	n/a		
IB/0168	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	28/06/2018	n/a		
IB/0166/G	This was an application for a group of variations. B.II.h.z - Adventitious Agents Safety - Other variation B.III.1.z - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Other	15/05/2018	n/a		

	variation				
II/0163	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	22/03/2018	n/a		
IAIN/0165/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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	19/03/2018	27/09/2018	Annex II and PL	
IB/0164/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation 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	14/03/2018	n/a		
IB/0162/G	This was an application for a group of variations.	16/02/2018	n/a		

	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.z - Change in the manufacturing process of the finished or intermediate product - Other variation				
IB/0160	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	05/01/2018	27/09/2018	SmPC, Labelling and PL	
IB/0158	B.II.c.4.a - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient - Minor change	20/11/2017	n/a		
IB/0159	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	15/11/2017	n/a		
PSUSA/9263/ 201701	Periodic Safety Update EU Single assessment - pneumococcal polysaccharide conjugate vaccine (adsorbed) - 13 valent	01/09/2017	n/a		PRAC Recommendation - maintenance
II/0156	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	01/06/2017	n/a		
IB/0157	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	21/04/2017	n/a		
II/0149	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	23/03/2017	n/a		

II/0145	Update of the SmPC section 5.1 to add information related to antibiotic susceptibility. Editorial changes have also been proposed throughout the SmPC. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	23/02/2017	23/10/2017	SmPC	In a randomised double-blind study in which infants received either Prevenar 13 or Prevenar (7-valent) at 2, 4, 6 and 12 months of age in Israel, reductions of S. pneumoniae serotypes 19A, 19F, and 6A not susceptible to a number of antibiotics were documented. The reductions ranged between 34% and 62% depending on serotype and antibiotic.
IA/0153	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	20/02/2017	n/a		
IAIN/0154	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	15/02/2017	23/10/2017	Annex II and PL	
IA/0152	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	15/02/2017	23/10/2017	Annex II	
II/0147/G	This was an application for a group of variations. 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.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of	02/02/2017	n/a		

	specification limits 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.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				
IB/0151/G	This was an application for a group of variations. B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	09/01/2017	n/a		
IA/0150/G	This was an application for a group of variations.	05/01/2017	n/a		

	A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites				
IB/0148/G	This was an application for a group of variations. B.II.c.4.z - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient - Other variation B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products	13/12/2016	n/a		
II/0146	Update of the SmPC section 4.5 to include information on Prevenar 13 co-administration with the tetanus toxoid conjugated meningococcal polysaccharide serogroups A, C, W and Y vaccine based on the results of study MenACWY-TT-104. Minor editorial changes have been introduced throughout the PI. Additionally the MAH took the opportunity to align the PI with the latest QRD template version 10.0.	17/11/2016	23/10/2017	SmPC and Labelling	Prevenar 13 can also be given concomitantly between 12-23 months with the tetanus toxoid conjugated meningococcal polysaccharide serogroups A, C, W and Y vaccine to children who have been adequately primed with Prevenar 13 (as per local recommendations).

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
PSUSA/9263/ 201601	Periodic Safety Update EU Single assessment - pneumococcal polysaccharide conjugate vaccine (adsorbed) - 13 valent	02/09/2016	n/a		PRAC Recommendation - maintenance
IA/0144	A.7 - Administrative change - Deletion of manufacturing sites	19/08/2016	n/a		
IB/0143/G	This was an application for a group of variations. B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	10/08/2016	n/a		
IB/0140/G	This was an application for a group of variations. B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.1.f - Replacement or addition of a	25/07/2016	n/a		

	manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process				
IB/0142	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	19/07/2016	n/a		
IB/0141	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	15/07/2016	21/10/2016	SmPC, Labelling and PL	
II/0138	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	14/07/2016	n/a		
II/0136	Update of section 4.5 of the SmPC in order to add information regarding the concomitant use of 13vPnC with Quadrivalent Influenza Vaccine (QIV) based on data from a phase IV, randomized, placebo-controlled, double-blind, multicentre trial (study B1851138). The Package Leaflet has been updated accordingly. Furthermore, the MAH took the opportunity to correct a discrepancy between the PL	30/06/2016	21/10/2016	SmPC and PL	In this variation the MAH updated the PI with results from a study in adults aged 50-93 years, where it was demonstrated that Prevenar 13 may be given concomitantly with the seasonal quadrivalent inactivated influenza vaccine (QIV). The immune responses to all four QIV strains were noninferior when Prevenar 13 was given concomitantly with QIV compared to when QIV was given alone. The immune responses to Prevenar 13 were

	and SmPC sections 4.2 and 5.1 and to update the list of local representatives in the Package Leaflet. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				noninferior when Prevenar 13 was given concomitantly with QIV compared to when Prevenar 13 was given alone. As with concomitant administration with trivalent vaccines, immune responses to some pneumococcal serotypes were lower when both vaccines were given concomitantly.
IB/0137	B.II.c.4.z - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient - Other variation	18/05/2016	n/a		
IB/0139	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	17/05/2016	n/a		
II/0134	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	12/05/2016	n/a		
II/0130/G	This was an application for a group of variations. 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 B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.1.c - Change in the specification parameters	01/04/2016	21/10/2016	SmPC, Annex II, Labelling and PL	

	and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure 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.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				
IB/0133	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	22/03/2016	n/a		

IB/0132	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	10/02/2016	n/a		
IB/0131	B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products	15/12/2015	n/a		
IB/0129	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	11/11/2015	n/a		
II/0126	Update of section 5.1 of the SmPC in order to add information on effectiveness following the use of Prevenar 13 since granting of the EU Marketing Authorisation. In addition, the MAH took the opportunity to add a statement in section 4.7 of the SmPC regarding ability to drive and use machines, and to update Package Leaflet accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	22/10/2015	21/10/2016	SmPC and PL	Effectiveness studies with Prevenar 13 regarding prophylaxis from pneumococcal otitis media, pneumonia and invasive pneumococcal disease produced results generally in line with the known efficacy profile of the vaccine. No concerns regarding lack of efficacy were raised. For more detailed information, please refer to the Summary of Product Characteristics.
IB/0128	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	02/10/2015	n/a		
II/0124	C.I.13 - Other variations not specifically covered	24/09/2015	21/10/2016	SmPC	

	elsewhere in this Annex which involve the submission of studies to the competent authority				
PSUSA/9263/ 201501	Periodic Safety Update EU Single assessment - pneumococcal polysaccharide conjugate vaccine (adsorbed) - 13 valent	10/09/2015	n/a		PRAC Recommendation - maintenance
IB/0127	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	05/08/2015	n/a		
II/0123	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	23/07/2015	n/a		
N/0120	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/06/2015	21/10/2016	PL	
IB/0125/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	16/06/2015	n/a		
II/0118	Submission of three supplemental CSRs from the completed Community Acquired Pneumonia Immunization Trial in Adults (CAPiTA) (study 6096A1-3006 (B1851025)) in order to fulfil MEA 045.1. The variation proposed no changes to the Product Information.	21/05/2015	n/a		N/A

	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				
II/0117/G	This was an application for a group of variations. B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.c.3 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing for a biol/immunol product and any of the test methods is a biol/immunol/immunochemical method 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 B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	21/05/2015	21/10/2016	Annex II and PL	

	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products				
IA/0122	A.7 - Administrative change - Deletion of manufacturing sites	20/05/2015	n/a		
IB/0121	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	30/04/2015	n/a		
II/0116	Submission of the final report of the post-authorisation observational safety study 6096A1-4002 (B1851044) of 13-valent pneumococcal conjugate vaccine (13vPnC) administered in routine use to infants and toddlers. This observational study was conducted as a post-marketing commitment, MEA 012. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	23/04/2015	n/a		

II/0111	Extension of Indication to add "pneumonia" to the authorised indication for adults (≥18 years of age), based on data from the recently completed Community–Acquired Pneumonia Immunization Trial in Adults (CAPiTA). As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC were updated and the Package Leaflet was updated accordingly. The provision of the CAPiTA study addresses MEA 045. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	22/01/2015	26/02/2015	SmPC and PL	Please refer to Prevenar-13-H-C-1104-II-111
IB/0115	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	18/12/2014	n/a		
II/0114	B.II.b.4.d - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes	20/11/2014	n/a		
II/0106	Change in storage conditions of the single dose vial presentations to allow a onetime temperature excursions up to 40°C for 3 days. B.II.f.1.c - Stability of FP - Change in storage conditions for biological medicinal products, when the stability studies have not been performed in accordance with an approved stability protocol	20/11/2014	26/02/2015	SmPC, Labelling and PL	Change in storage conditions of the single dose vial presentations to allow a onetime temperature excursions up to 40°C for 3 days.

IB/0113	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	24/09/2014	n/a		
R/0104	Renewal of the marketing authorisation.	24/07/2014	18/09/2014	SmPC, Labelling and PL	
PSUV/0107	Periodic Safety Update	11/09/2014	n/a		PRAC Recommendation - maintenance
IB/0110	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	13/08/2014	n/a		
IA/0112	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	12/08/2014	n/a		
II/0108/G	This was an application for a group of variations. to add an alternate site responsible for the manufacturing of the active substance B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product 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)	24/07/2014	n/a		

	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS				
II/0102	Change in the test procedure of the finished product. 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	24/07/2014	n/a		
II/0105/G	This was an application for a group of variations. to add an alternate site responsible for the manufacturing of the active substance B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product 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) 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)	26/06/2014	n/a		

II/0101/G	This was an application for a group of variations. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product 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) 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)	26/06/2014	n/a		
IA/0109	B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer	24/06/2014	n/a		
II/0098	Update of sections 4.2, 4.4 and 5.1 of the SmPC in order to include the final results from the paediatric studies 6115A1-3002 (B1851021) conducted in HIV-infected individuals, 6115A1-3003 (B1851022) conducted in recipients of allogeneic hematopoietic stem cell transplant (HSCT) and 6096A1-3014 (B1851013) conducted in children and adolescents with sickle cell disease (SCD). The Package Leaflet is updated accordingly. With the submission of the final	22/05/2014	23/06/2014	SmPC and PL	In the study 6115A1-3002 (B1851021), HIV-infected children and adults with CD4 ≥ 200 cells/µL (mean 717.0 cells/µL), viral load < 50,000 copies/mL (mean 2090.0 copies/mL), free of active AIDS-related illness and not previously vaccinated with a pneumococcal vaccine received 3 doses of Prevenar 13. After the first dose, Prevenar 13 elicited antibody levels, measured by both IgG GMCs and OPA GMTs that were statistically significantly higher when compared to levels prior to vaccination. After

	study results for study 6115A1-3002, the MAH fulfils MEA 013. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				the second and third dose of Prevenar 13, immune responses were similar or higher than those after the first dose. In the study 6115A1-3003 (B1851022), recipients of allogeneic hematopoietic stem cell transplant Children and adults with an allogeneic haematopoietic stem cell transplant (HSCT) at ≥ 2 years of age received three doses of Prevenar 13 with an interval of at least 1 month between doses. Prevenar 13 elicited increased antibody levels after each dose. Immune responses after the fourth dose of Prevenar 13 were significantly increased for all serotypes compared with the third dose. In study 6096A1-3014 (B1851013), 2 doses of Prevenar 13 were given 6 months apart to 158 children and adolescents ≥ 6 to < 18 years of age with sickle cell disease (SCD) who were previously vaccinated with one or more doses of 23-valent pneumococcal polysaccharide vaccine at least 6 months prior to enrolment. One year after the second dose, antibody levels measured by both IgG GMCs and OPA GMTs were higher than levels prior to the first dose of Prevenar 13, except for the IgG GMCs for serotypes 3 and 5 that were numerically similar.
II/0103/G	This was an application for a group of variations. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.a.3.e - Change in batch size (including batch size ranges) of AS or intermediate - The scale for a	22/05/2014	n/a		

	biological/immunological AS is increased/decreased without process change (e.g. duplication of line) 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)				
II/0100	Update of section 4.5 of the SmPC in order to add information on the concomitant use of Prevenar 13 and prophylactic antipyretics. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	20/02/2014	23/06/2014	SmPC	Study B1851047 assessed the impact of prophylactic paracetamol or ibuprofen administration on the immunogenicity and safety of 13vPnC and Infanrix hexa in infants and toddlers. The findings from this study support the hypothesis that use of antipyretic agents as a prophylactic measure to prevent fever associated with vaccination may interfere with immune responses to vaccine antigens, especially when given at the time of vaccination. These effects vary depending on the prophylactic agent and the vaccine. Paracetamol appears to impact the response to pneumococcal antigens but not to any antigen included in Infanrix hexa, which was given concomitantly in this study, and ibuprofen appears to impact the response to pertussis FHA and tetanus antigens but not to any pneumococcal antigen. The majority of subjects in all prophylaxis groups achieved immune responses that are likely to be adequate to prevent disease. Furthermore, these effects are observed only following the infant series and not following the toddler dose, suggesting that despite this early reduction in immune response, adequate priming is achieved and the ability to mount a robust toddler response is preserved. The use of antipyretics on the day of vaccination seems to have the most effect on the immune

					response. The clinical significance of these findings is not known. The CHMP considered the proposed text in section 4.5 regarding the interaction adequate and that the changes introduced do not affect the positive risk/benefit balance of the product.
II/0099/G	This was an application for a group of variations. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product 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) B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	20/02/2014	n/a		
PSUV/0093	Periodic Safety Update	05/02/2014	n/a		PRAC Recommendation - maintenance
IA/0097/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.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder	20/12/2013	23/06/2014	Annex II	

	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) A.7 - Administrative change - Deletion of manufacturing sites				
IB/0095	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	12/12/2013	n/a		
IA/0096	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	04/12/2013	n/a		
PSUV/0090	Periodic Safety Update	19/09/2013	20/11/2013	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUV/0090.
IB/0094	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	07/11/2013	n/a		
IA/0091	A.7 - Administrative change - Deletion of manufacturing sites	18/10/2013	n/a		
IB/0089	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	25/09/2013	n/a		

II/0087	Update of section 4.8 of the SmPC to align the frequencies of adverse reactions with the Company core data sheet (CDS), upon the conduct of a safety review. The package leaflet is updated in accordance. C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	19/09/2013	20/11/2013	SmPC and PL	The MAH has submitted a type II to revise the frequency of adverse reactions that are currently labelled in 4.8 of the Summary of Product Characteristics (convulsions, rash, urticaria, vomiting, and diarrhoea). The difference resulted from inclusion of all adverse events in the estimations of frequency for the Reference Safety Information and only those adverse events reported as vaccine-related in the estimations of frequency were included in the SmPC. The CHMP considered appropriate to align the SmPC with the Company RSI to provide health care providers and patients with the most update and relevant safety information. Therefore the CHMP endorsed.
II/0076	Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC to add information from 3 clinical studies on the use of 13vPnC in populations with specific conditions associated with increased risk of pneumococcal disease. The PL was updated accordingly. C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	19/09/2013	20/11/2013	SmPC and PL	Three studies were submitted to provide relevant information on protection against pneumococcal infections after vaccination in pre-term infants as well as immunosuppressed subjects such as sickle cell disease patients and HIV infected subjects. The preterm infants generally had lower responses than the full term infants, but the responses were considered adequate to provide a significant benefit for these children. The immune responses in SCD patients were lower than what has been reported in studies of healthy subjects in the same age group, although no formal comparison across studies can be performed. However, there appears to be a clear benefit also in this group for vaccination with Prevenar 13. Likewise, the responses in HIV infected subjects were lower than reported from non-HIV infected adults, but still represent a benefit for this group of patients. There was no indication of hyporesponsiveness following repeated vaccinations, as similar immune responses were seen after

					each vaccination. In view of safety in these populations, children and adolescents with sickle cell disease have similar frequencies of adverse reactions, except that headaches, vomiting, diarrhoea, pyrexia, fatigue, arthralgia, and myalgia were very common. Adults with HIV infection previously vaccinated with the 23-valent pneumococcal polysaccharide vaccine, have similar frequencies of adverse reactions, except that vomiting was very common and nausea common. The CHMP considered the benefit of vaccinating the above risk groups was demonstrated, and the proposed update of the relevant sections of the Product Information to include information on these studies was endorsed.
IA/0088	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	14/08/2013	n/a		
IB/0085/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	22/07/2013	n/a		
II/0071	Extension of indication to include adults aged from 18 to 49 years for Prevenar 13. As a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8 and 5.1 of the Summary of Product Characteristics have been updated with data from study 6115A1-004. The Package Leaflet is updated in	30/05/2013	09/07/2013	SmPC and PL	Please refer to Assessment Report EMEA/H/C/1104/II/71.

	accordance. Furthermore, the Product Information is being brought in line with the latest QRD template version 9.0. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet. The requested variation proposed amendments to the Summary of Product Characteristics, Annex II and Package Leaflet. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IA/0086	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	08/07/2013	n/a		
II/0081	B.II.g.2 - Design Space - Introduction of a post approval change management protocol related to the finished product	27/06/2013	n/a		
II/0080/G	This was an application for a group of variations. Changes in the manufacturing process of the finished product. B.II.b.3.b - Change in the manufacturing process of the finished product - Substantial changes to a manufacturing process that may have a significant	30/05/2013	n/a		

	impact on the quality, safety and efficacy of the medicinal product B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation				
IB/0083/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.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	23/05/2013	n/a		
IA/0082/G	This was an application for a group of variations. B.III.1.b.3 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - Updated certificate from an already approved manufacturer B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new tests and limits	03/05/2013	n/a		
II/0077	Change in the manufacturing process of the active substance, additional processing rooms. B.I.a.2.b - Changes in the manufacturing process of the AS - Substantial change to the manufacturing process of the AS which may have a significant	25/04/2013	n/a		

	impact on the quality, safety or efficacy of the medicinal product				
IA/0079	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	05/04/2013	n/a		
IB/0078/G	This was an application for a group of variations. B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	03/04/2013	n/a		
II/0075/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging	21/03/2013	21/03/2013	SmPC, Labelling and PL	

	site B.II.e.1.b.2 - Change in immediate packaging of the finished product - Type of container - Sterile medicinal products and biological/immunological medicinal products 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				
IB/0074	B.I.b.1.a - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits for medicinal products subject to Official Batch Release	29/01/2013	n/a		
IG/0235/G	This was an application for a group of variations. C.I.z - Changes (Safety/Efficacy) of Human and	06/12/2012	n/a		C.I.z - To replace the Detailed Description of the Pharmacovigilance System (DDPS) with the Pharmacovigilance System Master File (PSMF).

	Veterinary Medicinal Products - Other variation C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the contact details of the QPPV				
II/0059	Update of section 5.1 of the Summary of Product Characteristics to add information on the reduction of nasopharyngeal carriage of vaccine serotypes as a result of vaccination with Prevenar 13. 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	18/10/2012	22/11/2012	SmPC	Data from two phase 3 trials, 6096A1-3006 and 6096A1-3010, together with post-marketing surveillance data from France (Cohen et al, ACTIV study) and the United States (Desai et al, Atlanta study) were submitted in support of this application. The overall results presented indicate that vaccination with Prevenar 13 leads to decreased nasopharyngeal carriage of the 6 additional vaccine serotypes compared to Prevenar. The studies compared carriage rates after vaccination with Prevenar 13 and Prevenar, and therefore carriage reductions could be demonstrated for the 6 additional serotypes. The reduction was mainly driven by a reduction in serotype 19A, and to some extent in serotype 6A/6C. The CHMP endorsed the inclusion of these data in section 5.1 of the SmPC.
II/0056	Update of section 4.4 to harmonise the wording of 13vPnC SmPC with the SmPCs of Infanrix hexa and Prevenar (7v) and reflect the increase rate of febrile reactions when the vaccines are administered concomitantly. This update is reflected in section 4.5 as well as in section 4.8 of the Prevenar 13 SmPC. In addition the MAH took the opportunity to align the Product Information with the QRD template version 8.0. The requested variation proposed amendments to the SmPC, Annex II, Labelling and Package Leaflet.	18/10/2012	22/11/2012	SmPC, Annex II, Labelling and PL	The Assessment of PSUR 4 concluded that the benefit/risk profile of Prevenar 13 remained positive, but that a potential safety concern regarding neurological events in patients receiving Prevenar 13 concomitantly with hexavalent vaccines required further investigation and discussion. Upon a cumulative review of neurological reactions in individuals who were reported to have received Prevenar 13 concomitantly with hexavalent vaccine, an update of the warning section of the SmPC was warranted. The proposed variation was to harmonise the Prevenar 13 SmPC with the Prevenar and Infanrix hexa SmPCs to reflect an increased incidence of fever with co-administration of

	C.I.3.b - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under Article 45/46, or amendments to reflect a Core SPC - Change(s) with new additional data submitted by the MAH				Prevenar 13 and Infanrix hexa.
II/0067	Additional manufacturing facility for the active substance B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	15/11/2012	n/a		
II/0055	Update of sections 4.1, 4.2, 4.5, 4.8 and 5.1 of the SmPC to include information related to the extension of the indication to include children from 6 to 17 years of age. The MAH took the opportunity to revise the local representative details for Cyprus that are listed in the Package Leaflet. The Package Leaflet was updated accordingly. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	15/11/2012	20/12/2012	SmPC and PL	Please refer to Assessment Report EMEA/H/C/1104/II/55.
IA/0072	B.III.1.b.3 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - Updated certificate from an already approved manufacturer	24/10/2012	n/a		

IB/0070	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	18/10/2012	n/a		
IB/0069	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	17/10/2012	22/11/2012	SmPC, Labelling and PL	
IAIN/0068	A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	21/09/2012	n/a		
II/0064	Change in the manufacturing process of the finished product B.II.b.3.b - Change in the manufacturing process of the finished product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product	20/09/2012	n/a		
II/0063	Alternative manufacturing site for an intermediate B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	20/09/2012	n/a		
IB/0066	B.I.a.4.b - Change to in-process tests or limits	30/08/2012	n/a		

	applied during the manufacture of the AS - Addition of a new in-process test and limits				
IAIN/0065/G	This was an application for a group of variations. C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DD C.I.9.h - 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 pharmacovigilance system	23/07/2012	n/a		
II/0058	Extension of shelf life on an intermediate 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	19/07/2012	19/07/2012		
IB/0062	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	18/07/2012	n/a		
T/0061	MA transfer from Wyeth Lederle Vaccines S.A. to Pfizer Ltd. Transfer of Marketing Authorisation	15/06/2012	03/07/2012	SmPC, Labelling and PL	

IB/0060	B.V.c.1.c - Change management protocol - Update of the quality dossier to implement changes, requested by the EMA/NCA, following assessment of a change management protocol - Implementation of a change for a biological/immunological medicinal product	14/06/2012	n/a		
IA/0057	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	16/05/2012	n/a		
IB/0054	B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation	03/05/2012	n/a		
II/0041	C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	16/02/2012	19/03/2012	SmPC, Annex II and PL	Immunogenicity data from three clinical studies; 6096A1-008, 6096A1-3021 and 6096A1-3012 were submitted to support the recommendation for catch-up vaccination in children aged over 12 months who are considered completely immunized with Prevenar a 7–valent pneumococcal vaccine (7vPnC). In these studies, subjects received 1 or 2 doses of Prevenar 13, a 13-valent pneumococcal vaccine (13vPnC) administered after 1, 2, 3, or 4 doses of 7vPnC in infants and young children ranging in age, across the 4 studies, from 2 months to less than 5 years. The additional benefit of a second catch-up dose of Prevenar 13 in children fully vaccinated with Prevenar was considered small and the adverse reactions of an additional dose are generally expected to be mild and transient. The recommendation to give a single catch-up dose of Prevenar 13 to children 12-23 months of age instead of 2 doses was

					introduced in section 4.2 of the SmPC.
IB/0052	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	21/02/2012	n/a		
II/0049	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	16/02/2012	16/02/2012		
IB/0051	B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	26/01/2012	n/a		
IB/0050	B.I.b.1.a - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits for medicinal products subject to Official Batch Release	26/01/2012	n/a		
II/0047	Alternative manufacturing process facility for the active substance. 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	15/12/2011	15/12/2011		
II/0045	A Post Approval Change Management Protocol to introduce a modified manufacturing process for the Finished Product at a manufacturing site.	17/11/2011	17/11/2011		

	B.II.g.2 - Design Space - Introduction of a post approval change management protocol related to the finished product				
II/0043/G	This was an application for a group of variations. To introduce an alternate manufacturing facility for the Pneumococcal Polysaccharide Serotype 4. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product 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	17/11/2011	17/11/2011		
II/0028	Extension of indication to include active immunisation for the prevention of invasive disease caused by Streptococcus pneumoniae in adults aged 50 years and older. To update sections 4.1, 4.2, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1, 5.2 and 5.3 of the SmPC and corresponding sections of the PL, to include information pertaining to the proposed new indication for use in adults aged 50 years and older based upon the results of the pivotal clinical trials. Update of Annex II.B to remove the RMP version number as per QRD templates. The MAH took the opportunity to update	22/09/2011	24/10/2011	SmPC, Annex II and PL	Please refer to Assessment Report EMEA/H/C/1104/II/28.

	section 6 of the Package Leaflet, by introducing changes to the local representatives. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IB/0046	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	19/10/2011	n/a		
II/0044	To introduce an additional manufacturing facility for Activated Saccharide and Monovalent Bulk Conjugate (MBC) Serotype 6B. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	22/09/2011	22/09/2011		
II/0038	Adjustment to the phophate content of the diafiltration buffer. 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	21/07/2011	21/07/2011		
II/0037	Registration of additional manufacturing site for production of pneumococcal polysaccharide Serotype	21/07/2011	21/07/2011		

	19F. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product				
IB/0042	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	15/07/2011	n/a		
II/0039	Registration of alternative manufacturing site for production of pneumococcal activated saccharide and MBC Serotype 18C. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	23/06/2011	23/06/2011		
II/0036	Registration of alternative manufacturing site for production of pneumococcal activated saccharide and MBC Serotype 19F. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a	23/06/2011	23/06/2011		

	biological/immunological product				
IB/0035	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	10/06/2011	n/a		
II/0033	Registration of alternative manufacturing site for production of pneumococcal polysaccharide Serotype 9V. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	19/05/2011	19/05/2011		
II/0032	Registration of alternative manufacturing site for production of pneumococcal polysaccharide Serotype 3 conjugate. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	19/05/2011	19/05/2011		
IA/0040/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 supplier of the	19/05/2011	n/a	Annex II	

	AS, starting material, reagent or intermediate used in the manufacture of the AS A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release)				
IA/0034	B.I.b.1.a - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits for medicinal products subject to Official Batch Release	18/04/2011	n/a		
WS/0117	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.8.b - Introduction of a new Pharmacovigilance system - which has been assessed by the relevant NCA/EMA for another product of the same MAH	14/04/2011	14/04/2011		
IB/0030	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	10/03/2011	n/a		
IB/0027	B.I.d.1.a.1 - Stability of AS - Change in the re-test period/storage period - Reduction	04/03/2011	n/a		
IB/0026/G	This was an application for a group of variations. B.I.b.1.a - Change in the specification parameters	04/03/2011	n/a		

	and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits for medicinal products subject to Official Batch Release B.I.d.1.a.1 - Stability of AS - Change in the re-test period/storage period - Reduction				
IA/0031	B.III.1.b.3 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - Updated certificate from an already approved manufacturer	23/02/2011	n/a		
IB/0029	B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	03/02/2011	n/a		
II/0024/G	This was an application for a group of variations. Addition of a manufacturing site and extension of the shelf life of the active substance. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation	20/01/2011	01/02/2011		
IB/0025	B.II.f.1.a.1 - Stability of FP - Reduction of the shelf life of the finished product - As packaged for sale	13/12/2010	n/a		

IA/0023	A.1 - Administrative change - Change in the name and/or address of the MAH	11/12/2010	n/a	SmPC, Annex II, Labelling and PL	
IB/0022/G	This was an application for a group of variations. B.I.b.1.a - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits for medicinal products subject to Official Batch Release B.I.d.1.a.1 - Stability of AS - Change in the re-test period/storage period - Reduction	30/11/2010	n/a		
II/0021	Addition of a new manufacturing site. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	18/11/2010	29/11/2010		
II/0020	Addition of a new manufacturing site. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	18/11/2010	29/11/2010		
II/0019	To update section 4.4 and 5.1 of the SmPC to include a statement on subcutaneous administration based	21/10/2010	26/11/2010	SmPC	The MAH submitted the final study report evaluating the Safety, Tolerability, and Immunogenicity of a 13-valent

	on data from clinical study 6096A1-3003-JA. The MAH takes also the opportunity to update the SmPC to comply with the latest QRD template and to update the details of the local representatives. C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data				Pneumococcal Conjugate Vaccine in Healthy Infants in Japan. It should be noted that in Japan, subcutaneous (SC) administration is the standard route for childhood vaccination, although adults are vaccinated by the intramuscular (IM) route. Although the study did not directly compare subcutaneous and intramuscular administration, the immune response and safety profile of Prevenar 13 given subcutaneously were generally similar to those observed in other clinical studies in which Prevenar 13 was given intramuscularly. In this study 185 healthy children received 4 doses of Prevenar 13 at 2, 4, 6 and 12-15 months of age. This information can be useful for prescribers when vaccinating children with thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injection. As a consequence the CHMP agreed to update section 4.4 and 5.1 of the Summary of Product Characteristics.
II/0017	Change in the manufacturing process of the finished product. B.II.b.3.b - Change in the manufacturing process of the finished product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product	23/09/2010	01/10/2010		
II/0014	B.I.a.2 Changes in the manufacturing process of the active substance c) The change refers to a biological / immunological substance or use of a different chemically derived	23/09/2010	01/10/2010		

	substance in the manufacture of a biological/immunological medicinal product and is not related to a protocol. 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				
II/0016	C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	22/07/2010	01/09/2010	SmPC and PL	Based on data obtained from a clinical trial evaluating the safety profile of Prevenar 13 in concomitant administration with other routine pediatric vaccines, the product information is updated to reflect that hypotonic-hyporesponsive episode has been identified as an adverse event for Prevenar 13 with a frequency of 'rare'. Overall, the safety results for Prevenar 13 show that the product is safe and well tolerated when given to infants according to the Brazil national schedule and with routine pediatric vaccinations. The Local Representatives details were also updated in the package leaflet.
II/0015/G	This was an application for a group of variations. Changes in the manufacturing process of the active substance. 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 B.I.a.2.c - Changes in the manufacturing process of	22/07/2010	16/08/2010		

	the AS - The change refers to a [-] substance in the manufacture of a biological/immunological medicinal product and is not related to a protocol				
IB/0018	To change the manufacturing process of the finished product B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	16/07/2010	n/a		
IB/0013	To extend the shelf life of the finished product to 3 years. 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	18/05/2010	n/a	SmPC and PL	
IB/0012	To tighten the release specifications for particle size of Aluminium Phosphate suspension. B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits	17/05/2010	n/a		
II/0004/G	This was an application for a group of variations. Addition of manufacturing site of intermediates and extension of shelf life of intermediate.	22/04/2010	04/05/2010		

	B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product				
IA/0011	C.I.9.h - 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 pharmacovigilance system	29/03/2010	n/a	Annex II	
IA/0010	C.I.9.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site undertaking pharmacovigilance activities	29/03/2010	n/a	Annex II	
IA/0009	C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DD	29/03/2010	n/a	Annex II	
IA/0008	C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV	29/03/2010	n/a	Annex II	
IA/0007	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the	29/03/2010	n/a	Annex II	

	QPPV				
IB/0006	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	25/03/2010	n/a		
II/0001	Change(s) to the manufacturing process for the finished product	18/03/2010	23/03/2010		
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/03/2010	n/a	PL	
IB/0003	B.I.a.z - Change in manufacture of the AS - Other variation	10/02/2010	n/a		