Wyeth Lederle Vaccines S.A.
Pleinlaan 17 Boulevard de la Plaine
1050 Brussel – Bruxelles
Belgium

Wyeth

Internal Reference: VP-058025

Date: 4 January 2012

Dr S Spinosa
Central Information Group (CIG)
F.A.O. H-PACS
European Medicines Agency (EMA)
Loading Dock
Ontario Way
Canary Wharf
London, E14 4 HB
United Kingdom

Subject: **Prevenar 13 : PSUR 04 – Response to RSI**
MA numbers: EU/1/09/590/001-006

1	**Applicant/MAH Name**	Wyeth Lederle Vaccines SA[1]				
2	**Customer Account Number**	EMA 48				
3	**Customer Reference / Purchase Order Number**	NOT APPLICABLE'				
4	**Product Name**	Prevenar 13				
5	**Procedure Number**	EMEA/H/C/1104/				
6	**INN / Active substance**	Pneumococcal polysaccharide conjugate vaccine 13-valent (adsorbed)				
7*	**Application Type**	Response to RSI	P	☐	Q	☐
8*	**Description of Submission**	Response to PSUR 04 RSI				
9*	**eCTD sequence**	0135	Related sequence	115		
10*	**Checksum**	See index-md5.txt				

[1] Wyeth is now a wholly owned subsidiary of Pfizer Inc. The merger of local Wyeth and Pfizer entities may be pending in various jurisdictions and integration is subject to completion of various local legal and regulatory obligations.

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11	**Contact Persons' details (include email address)**	**A) Regarding the content of the submission:** Helen Edwards Tel: +44 (0) 1737 331759 e-mail: Helen.Edwards@pfizer.com **B) Regarding technical questions:** Tom Smith Email: eSubmissions@pfizer.com Tel: +44 1304 644139 Leigh Sandwell Email: eSubmissions@pfizer.com Tel: +44 1304 643538 **C) Regarding financial queries:** Julie Kennelly Email: Julie.Kennelly@pfizer.com Tel: +44.1304.646405
12	**Medium Identifier**	VP-058025
13	**Virus Checking Information**	The electronic media has been verified as virus free, having been checked with McAfee VirusScan Enterprise 8.7.0i (virus definitions 04 Mar 2011 or later).

Dear Dr Spinosa,
Please find enclosed our response to the question below that came from the RSI received following Assessment of the fourth PSUR for Prevenar 13 which covered the period 10 January 2011 to 9 July 2011. The CHMP requested that this Response was submitted within 6 weeks (5 January 2012). In agreement with CHMP other questions raised in the RSI will be addressed in the next PSUR due February 2012.

Request for Supplementary Information

Area	Description	Due Date
Pharmacovigilance	Neurological events in subjects receiving Prevenar 13 concomitantly with hexavalent vaccines. Following an inquiry at the October Pharmacovigilance Working Party regarding a potential increase in the incidence of neurological reactions with coadminstered	5 January 2012

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	vaccines noted in a national vaccination program in Italy, the MAH is requested to provide a cumulative review of neurological reactions in those cases who were reported to have received Prevenar 13 concomitantly with hexavalent vaccine. This review is expected within 6 weeks.	

You will find enclosed with the submission dossier the documentation hereafter:

Module 1

1.0 Cover Letter

Responses

Module 5

5.4 Literature References

The contents of this submission are in line with the requirements detailed in the Notice to Applicants Volume 2B for an eCTD application and consistent with the guidance provided by the EMA. Electronic Copies of Copyrighted Material Are Made and Delivered to the Government Under License from the Copyright Clearance Center - No Further Reproduction is Permitted.

I herewith confirm that the above data does not require an update of the Product Information.

Should you have any questions relating to this submission please contact Mary Allin on +44 79197 172702 mary.allin@pfizer.com

Yours sincerely,

Mary Allin
Senior Director Worldwide Regulatory Strategy
Pfizer

Helen Edwards
Director Worldwide Regulatory Strategy
Pfizer

Encl(s)
<CD-ROM(s) / DVD(s)>

cc: Sabrina Spinosa (EMA PTL_
Rapporteur : Dr K. Dunder
Co-Rapporteur : Dr. P. Neels
CHMP members
SIAMED Database Administrators