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1. Background information on the procedure

1.1. Requested type II variation

Pursuant to Article 16 of Commission Regulation (EC) No 1234/2008, Sanofi Pasteur MSD SNC submitted to the European Medicines Agency on 9 December 2014 an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.

Pursuant to section 10 of the CHMP "Guideline on procedural aspects regarding a CHMP scientific opinion in the context of cooperation with the World Health Organisation (WHO) for the evaluation of medicinal products intended exclusively for markets outside the community" (EMEA/CHMP/5579/04), Sanofi Pasteur MSD SNC submitted to the EMA on 9 December 2014 an application for a variation[1] to the CHMP Scientific Opinion.

The following changes were proposed:

Variation requested		Type	Annexes affected
C.I.4	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	Type II	I and IIIB

Update of sections 4.5 and 5.1 of the SmPC in order to add the information on co-administration of the hexavalent vaccine with meningococcal serogroup C vaccine. The Package Leaflet is updated accordingly. The MAH/SOH took also the opportunity to make minor editorial changes throughout the PI.

The requested worksharing procedure proposed amendments to the Summary of Product Characteristics and Package Leaflet.

1.2. Rationale for the proposed change

In this application the MAH/SOH updated the SmPCs of Hexacima, Hexyon and Hexaxim based on the results of the HXM01C study assessing the immunogenicity and safety of the concomitant administration of the hexavalent vaccine when given with meningococcal serogroup C (MenC) vaccine at 2, 3 and 4 months of age in healthy infants during primary series immunisation.

This application also fulfils the below described REC:

Description	Due Date
The applicant will conduct a clinical study to assess the concomitant use of Hexyon with a monovalent conjugated meningococcal vaccine. The results of this study are expected by Q1/2015.	Q1 2015

As per Article 46 of Regulation (EC) No 1901/2006 this application fulfils the MAH obligation to submit MAH-sponsored studies involving the use of an authorised medicinal product in the paediatric population.

[1] Which corresponds, by analogy, to a Type II variation pursuant to Commission Regulation (EC) 1234/2008