22 July 2010
EMA/CHMP/477330/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (post authorisation)

M-M-RVAXPRO

measles, mumps and rubella vaccine (live)

On *22* July 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product M-M-RVAXPRO. The marketing authorisation holder for this medicinal product is Sanofi Pasteur MSD, SNC. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a change to the indication as follows:

"M-M-RVAXPRO can be administered to infants from 9 months of age under special circumstances.

For use in measles outbreaks, or for post-exposure vaccination, or, for use in previously unvaccinated individuals older than 9 months who are in contact with susceptible pregnant women, and persons likely to be susceptible to mumps and rubella"

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indication for *M-M-RVAXPRO* will be as follows[2]::

"M-M-RVAXPRO is indicated for simultaneous vaccination against measles, mumps, and rubella in individuals 12 months or older (see section 4.2).

M-M-RVAXPRO can be administered to infants from 9 months of age under special circumstances. (see sections 4.2, 4.4 and 5.1)

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

[2] The text in bold represents the new or the amended indication.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom

For use in measles outbreaks, or for post-exposure vaccination, or, for use in previously unvaccinated **individuals** older than **9** months who are in contact with susceptible pregnant women, and persons likely to be susceptible to mumps and rubella, see section 5.1."