15 March 2012
EMA/CHMP/168236/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Proquad

measles, mumps, rubella and varicella vaccine (live)

On 15 March 2012, 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 Proquad. 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 an indication as follows:
"ProQuad can be administered to individuals from 9 months of age under special circumstances (e.g., to conform with national vaccination schedules, outbreak situations, or travel to a region with high prevalence of measles; see sections 4.2, 4.4, and 5.1)."

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 Proquad will be as follows[2]:

"ProQuad is indicated for simultaneous vaccination against measles, mumps, rubella and varicella in individuals from 12 months of age.

ProQuad can be administered to individuals from 9 months of age under special circumstances (e.g., to conform with national vaccination schedules, outbreak situations, or travel to a region with high prevalence of measles; 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.

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