25 May 2012
EMA/CHMP/178705/2012 Rev. 1
EMEA/H/A-30/1283

Questions and answers on Priorix (measles, mumps and rubella vaccine (live))

Outcome of a procedure under Article 30 of Directive 2001/83/EC

On 15 March 2012, the European Medicines Agency completed a review of Priorix. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the prescribing information for Priorix in the European Union (EU).

What is Priorix?

Priorix is a vaccine used to protect against measles, mumps and rubella (German measles). It can be used in adults, adolescents and children from nine months of age.

Priorix contains small amounts of attenuated (weakened) forms of the viruses that cause measles, mumps and rubella. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. When a person is given Priorix, the immune system recognises the viruses as 'foreign' and makes antibodies against them. In the future, the immune system will be able to produce antibodies more quickly when it is exposed to these viruses.

Priorix is marketed in all EU Member States as well as in Norway and Iceland. The company that markets the medicine is GlaxoSmithKline (GSK) Biologicals.

Why was Priorix reviewed?

Priorix is authorised in the EU via national procedures. This has led to divergences across Member States in the way the medicine can be used, as seen in the differences in the summaries of product characteristics (SmPCs), labelling and package leaflets in the countries where the medicine is marketed.

Due to the divergent national positions, on 20 May 2011, GlaxoSmithKline Biologicals referred the matter to the CHMP in order to harmonise the marketing authorisations for Priorix in the EU.

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What are the conclusions of the CHMP?

The CHMP, in the light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs, labelling and package leaflets should be harmonised across the EU.

The areas harmonised include:

4.1 Therapeutic indications

There was some inconsistency between EU countries regarding the approved lower age limit for Priorix, which varied from nine months to 15 months of age. The CHMP recommended that this should be harmonised to nine months of age. However, since a single dose of Priorix produces a lower immune response in children under 12 months old, the CHMP decided to include a reference to the other sections containing specific information on the use of Priorix in children between nine and 12 months old.

4.2 Posology and method of administration

The CHMP recommended arranging this section according to the dosing recommendations for different age groups. For children between nine and 12 months old, the CHMP decided to include a recommendation to give a second dose preferably within three months of the first dose.

4.3 Contra-indications

There was some inconsistency between EU countries regarding the use of Priorix in patients infected with HIV. The CHMP decided to contraindicate the use of Priorix in people with symptomatic, advanced HIV, since these patients have a severely weakened immune system which puts them at risk of serious health problems following vaccination with attenuated measles virus. Priorix is also contraindicated in people with certain other conditions which severely weaken the immune system.

Other changes

The CHMP also harmonised other sections of the SmPC, including sections 4.4 (warnings and precautions for use), 4.5 (interaction with other medicinal products and other forms of interaction), 4.6 (fertility, pregnancy and lactation) and 5.1 (pharmacodynamic properties).

The amended information to doctors and patients is available here.

The European Commission issued a decision on 25 May 2012.