



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA starts review of Havrix and associated names (*hepatitis A virus (inactivated, adsorbed), suspension for injection*)

The European Medicines Agency (EMA) has started a review of Havrix and associated names, a vaccine used to protect adults and children against hepatitis A virus infection. The vaccine contains the inactivated (killed) hepatitis A virus and cannot cause the disease.

Havrix has been authorised in the EU via national procedures. This has led to inconsistency across Member States in the way the vaccine can be used, as seen in the differences in the prescribing information (summaries of product characteristics, labelling and package leaflets) in the countries where the vaccine is available.

EMA will consider the available data on Havrix and will amend the prescribing information to harmonise the way Havrix is used in the EU.

The amended information for doctors and patients will be available on the EMA website once the review has concluded.

More about the medicine

Havrix is a vaccine that contains inactivated (killed) hepatitis A virus; it can be used in children and adults to protect against hepatitis A infection. Havrix is authorised in all EU Member States with the exception of Croatia, plus Norway and Iceland.

More about the procedure

The review of Havrix and associated names has been initiated at the request of the marketing authorisation holder, GlaxoSmithKline Biologicals SA, under [Article 30 of Directive 2001/83/EC](#).

The review is being carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU and EEA Member States.

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