PUBLIC ASSESSMENT SUMMARY REPORT – Havrix™

What is Havrix™?

Havrix™ is a vaccine with the following composition:

	Havrix™ 1440 Adult	Havrix™ 720 Junior
	Per dose (1 ml)	Per dose (0.5 ml)
Hepatitis A virus antigen (HAV) HM175 strain (active)	1440 ELISA Units (EL.U.)	720 EL.U.
Aluminium (as AlOH) (adjuvant)	0.50 mg	0.25 mg
Excipients:		
Amino acids for injection	3.00 mg	1.50 mg
Disodium phosphate anhydrous	1.150 mg max.	0.575 mg max.
Monopotassium phosphate	0.20 mg max.	0.10 mg max.
Sodium chloride	9.00 mg max.	4.50 mg max.
Potassium chloride	0.230 mg max.	0.115 mg max.
Polysorbate 20	0.050 mg	0.025 mg
Water for injections	q.s. ad 1.0 ml	q.s. ad 0.5 ml

The vaccine is supplied in transparent glass vials of 3 mL capacity, 13 mm diameter

Real time and accelerated stability data reviewed support the use of a VVM type 14. The VVM is located on the flip off cap of the vial.

What is Havrix™ used for?

Havrix™ is indicated for active immunization against hepatitis A. Havrix™ 1440 Adult is for recipients 16 years and older. Havrix™ 720 Junior is for recipients aged 1 – 15 years

How is Havrix™ used?

The primary course of Havrix™ is administered in 1 dose. A booster dose is recommended in order to ensure long term protection. This booster dose should be given at any time between 6 months and 5 years, but preferably between 6 and 12 months after the primary dose.

The vaccine is administered intramuscularly, in the deltoid muscle of the upper arm in adults and children or in the anterolateral aspect of the thigh in young children.

Coadministration: Clinical trial data indicated that Havrix™ can be safely and effectively co-administered with other vaccines that may be recommended at the same time, such as DTPa and Hib vaccines in children; typhoid, yellow fever and HBV vaccines or other travellers' vaccines in adults.

What are the vaccine characteristics?

Havrix™ must be stored at 2-8°C. It must not be frozen. Under these recommended storage conditions, the vaccine is stable for 36 months after the date of manufacture.

The vaccine does not contain a preservative.

The secondary cartons proposed for supply through UN agencies contain 1, 10, 25 or 100 vials, with a cold chain volume per dose of 57.7, 11.5, 11.3 and 9.7 cc respectively. For all packaging presentations except the one vial cartons, this is less than the maximum recommended volume indicated in the Guidelines on the international packaging and shipping of vaccines for other monodose liquid vaccines.

Who is the regulatory authority responsible for its oversight vis a vis WHO?

Havrix™ 1440 Adult was licensed in Belgium on 28 November 1994, and Havrix™ 720 Junior was licensed in Belgium on 27 January 1997. The NRA of Record for this vaccine is Belgian Federal Agency for Medicines and Health Products.

How has Havrix™ been studied from the clinical point of view?

Data from 36 clinical studies support the strengths and indications of Havrix™ as presented in the prescribing information. These studies took place between 1989 and 2010 and were conducted in 28 countries in Europe, Asia, Latin America and North America. They have shown efficacy, effectiveness, immunogenicity and safety of the product in children, adolescents and adults. Their findings are considered applicable for the United Nations target population for this vaccine. There is evidence to support the co-administration of Havrix™ with other vaccines both in adults and children.

Other information about evaluation of Havrix™:

The vaccine was accepted for review under the streamlined procedure as described in the Prequalification Procedure. Evaluation was based on the NRA quality and clinical reviews provided. In addition, WHO specific requirements were evaluated. On the basis of review of the NRA's GMP inspection reports of the manufacturing sites, a site audit by WHO as part of the prequalification process was waived. On the basis of review of summary annual testing results by the NRA, independent testing in WHO contracted laboratories, as part of the prequalification evaluation, was waived.

The vaccine meets WHO requirements of WHO TRS 858, Annex 2.

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