



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Opinions on safety variations

Adopted at the CHMP meeting of 14-17 November 2011

Name of medicine	INN	Marketing authorisation holder	Scope
Emselex	darifenacin hydrobromide	Novartis Europharm Ltd.	CHMP Opinion recommending the introduction of a new warning in section 4.4 of the SmPC regarding oedema of the tongue or larynx, or difficulty breathing.
Onglyza	saxagliptin	Bristol-Myers Squibb / AstraZeneca EEIG	CHMP Opinion recommending to update section 4.4 of the SmPC in order to add a warning on pancreatitis as well as to update section 4.8 with regard to additional adverse reactions (nausea, pancreatitis, dermatitis, pruritus)
Ozurdex	dexamethasone	Allergan Pharmaceuticals Ireland	CHMP Opinion recommending to: <ul style="list-style-type: none">• update sections 4.4 and 4.8 of the SmPC in order to add a warning with regard to implant migration to reflect the changes proposed in PSUR 1 (27 July 2010 to 27 January 2011)

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

Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8669

E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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Name of medicine	INN	Marketing authorisation holder	Scope
Injectable Vaccines: - Centrally Authorised Products:		GlaxoSmithKline Biologicals S.A.	<ul style="list-style-type: none"> update section 4.2 of the SmPC in order to include advice on the use of povidone iodine drops 5% to disinfect the periocular skin, eyelid and ocular surface prior to the injection procedure
Pumarix	Pandemic Influenza Vaccine (H5n1) (Split Virion, Inactivated, Adjuvanted)		
Pandemrix	Pandemic Influenza Vaccine (H1n1) (Split Virion, Inactivated, Adjuvanted) A/California/7/2009 (H1n1)V Like Strain (X-179a)		
Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals	Pandemic Influenza Vaccine (H5n1) (Split Virion, Inactivated, Adjuvanted) A/Vietnam/1194/2004 Nibrg-14		In addition to the new warning on psychogenic syncope in section 4.4 of the SmPC, the CHMP adopted an opinion recommending to update sections 4.6 and 4.8 of the SmPC with data on experience gained with AS03-adjuvanted H1N1 vaccine

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Prepandrix	Prepandemic Influenza Vaccine (H5n1) (Split Virion, Inactivated, Adjuvanted)		In addition to the new warning on psychogenic syncope in section 4.4 of the SmPC, the CHMP adopted an opinion recommending to update sections 4.6 and 4.8 of the SmPC with data on experience gained with AS03-adjuvanted H1N1 vaccine
Twinrix adult	Hepatitis A (inactivated) and hepatitis B (rDNA) (HAB) vaccine (adsorbed)		
Twinrix paediatric	Hepatitis A (inactivated) and hepatitis B (rDNA) (HAB) vaccine (adsorbed)		
Ambirix	Hepatitis A (inactivated) and hepatitis B (rDNA) (HAB) vaccine (adsorbed)		
Fendrix	Hepatitis B (rDNA) vaccine (adjuvanted, adsorbed)		
- Non-Centrally Authorised Products:			
Infanrix-IPV/Infanrix Tetra/Infanrix Polio	Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed)		

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Boostrix	Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content)		
Hepatyrix	Hepatitis A (inactivated) and Typhoid Polysaccharide vaccine (adsorbed)		
Engerix B	Hepatitis B (rDNA) vaccine (adsorbed) (HBV)		
Engerix B Junior	Hepatitis B (rDNA) vaccine (adsorbed) (HBV)		
Typherix	Typhoid Polysaccharide vaccine		
Mencevax ACWY	Meningococcal polysaccharide groups A, C, Y and W ₁₃₅ vaccine		