



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 June 2014
EMA/125340/2014
Press Office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 23-26 June 2014

Name of medicine	INN	Scope
Adjupanrix, Prepandrix	prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)	CHMP opinion to update sections section 4.4 of the SmPCs to include a statement regarding the observed increased risk of narcolepsy following vaccination with Pandemrix, based on a review of epidemiologic or post-marketing surveillance.
Arzerra	ofatumumab	CHMP opinion to update sections 4.2, 4.4 and 4.8 of the SmPC with regards to infusion reactions further to a report of a fatal case. A Direct Healthcare Professional Communication has been agreed.

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Chondrocelect	characterised viable autologous cartilage cells expanded ex vivo expressing specific marker proteins	Renewal procedure resulting in an update of section 4.3 of the SmPC to contraindicate use in patients with not fully closed femoral epiphyseal growth plate (due to the strong influence of hormones on ossification, cartilage formation and repair and the limited experience in patients below 18 years).
Exjade	deferasirox	<p>PSUR assessment leading to the following changes to the SmPC:</p> <ul style="list-style-type: none"> strengthened wording on the renal safety profile of Exjade, with the addition of "renal tubular necrosis" and "nephrolithiasis" to section 4.8; addition of a warning on the risk of gastrointestinal perforation to section 4.4; addition of the risk of "metabolic acidosis" to section 4.4 and 4.8 with frequency "unknown"; update of section 4.4 to include information on the risk of severe skin reactions; addition of "optic neuritis" with frequency "rare" (following the report of 1 case) and "neutropenia" with frequency "not known" to section 4.8.
Eylea	aflibercept	PSUR assessment leading to an update of section 4.8 of the SmpC to include "blindness" and "visual acuity reduced".
Pandemrix	influenza vaccine (H1N1)v (split virion, inactivated, adjuvanted) A/California/7/2009 (H1N1)v like strain (x-179a)	<p>CHMP opinion to:</p> <ul style="list-style-type: none"> restrict the indication to reflect that Pandemrix should only be used if the recommended annual seasonal trivalent/ quadrivalent influenza vaccines are not available and if immunisation against (H1N1)v is considered necessary. update sections 4.4 and 4.8 of the SmPC to reflect the totality of the data on the risk of narcolepsy and to provide an updated benefit-risk assessment of Pandemrix, based on currently available data on H1N1 influenza disease burden, effectiveness and safety of Pandemrix, and epidemiology data on narcolepsy.
Procoralan/ Corlentor	ivabradine	PSUR assessment leading to an update of section 4.8 of the SmPC to add "abdominal pain" as a new adverse reaction with frequency "uncommon".
Victralis	boceprevir	<p>PSUR assessment leading to the following changes to the SmPC:</p> <ul style="list-style-type: none"> update of section 4.4 of the SmPC to add a warning about use in patients with advanced liver disease and recommendations on laboratory testing to be performed during therapy;

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		<ul style="list-style-type: none"> update of sections 4.4 and 4.5 of the SmPC to add a recommendation advising against the co-administration of boceprevir with doxazosin or tamsulosin.
Imvanex	modified vaccinia ankara virus	PSUR assessment leading to an update of section 4.8 of the SmPC to add the adverse reaction angioedema with a frequency of rare.
Pixuvri	pixantrone	PSUR assessment leading to an update of section 4.4 and 4.8 of the SmPC with respect to the occurrence of secondary malignancies (specifically acute myeloid leukaemia and myelodysplastic syndromes).
Fareston	toremifene	PSUR assessment leading to an update of section 4.4 of the SmPC to add a warning that anemia, leukopenia and thrombocytopenia have been reported with the use of fareston. Red blood cell, leukocyte or platelet counts should be monitored when using Fareston. In addition, events of thrombocytopenia, anaemia and leukopenia were added to section 4.8 of the SmPC ('Undesirable effects') with frequency 'unknown'. The Package leaflet is updated accordingly.
Komboglyze Onglyza	Saxagliptin/metformin hydrochloride, saxagliptin	The application proposes an update of section 4.4 of the SmPC in order to implement the recommendations of an Art 5(3) procedure on GLP-1-based therapies and pancreatic safety.