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Press Office

Opinions on safety variations

Adopted at the CHMP meeting of 17-20 October 2011

Name of medicine	INN	Marketing authorisation holder	Scope
Dynastat	parecoxib	Pfizer Ltd.	CHMP opinion recommending to introduce warnings to section 4.4 on the mode of administration and the risk of severe hypotension as well as the adverse event "circulatory collapse" to section 4.8 of the SmPC.
Pandemrix	influenza vaccine (H1N1)v (split virion, inactivated, adjuvanted)	GlaxoSmithKline Biologicals S.A.	This variation aimed to update SmPC section 4.8 to include Guillain-Barré syndrome (GBS). After considering further available safety information from epidemiological studies (including VAESCO data), the CHMP considered that the available data are not suggestive of a causal association between Pandemrix and GBS. Therefore the CHMP did not agree to include GBS into section 4.8 of the SmPC for Pandemrix.

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Pradaxa	dabigatran etexilate mesilate	Boehringer Ingelheim International GmbH	CHMP opinion amending SmPC section 4.2 with a recommendation to measure renal function before start of treatment and regularly during treatment.
Sutent	sunitinib	Pfizer Ltd.	<p>CHMP opinion recommending to add a warning on cases of tumour lysis syndrome (TLS) and cases of pulmonary haemorrhage in SmPC section 4.4 as well as to list these cases in SmPC section 4.8.</p> <p>Additionally, the CHMP recommended an update of SmPC section 4.4 regarding tumor haemorrhage, tumor necrosis and infections. In section 4.8 the adverse reaction "pancytopenia" was added as well as information on cardiac disorders and infections, in particular the adverse reaction "necrotising fasciitis".</p>
Thalidomide Celgene	thalidomide	Celgene Europe Limited	CHMP opinion recommending to add warnings on atrioventricular block, amenorrhoea and serious infections in SmPC sections 4.4 and 4.8. Furthermore, the adverse reactions of atrial fibrillation, pancreatitis and convulsions were also added in SmPC section 4.8. These changes were made further to the request of the CHMP during the assessment of the 5 th Periodic Safety Update Report.