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Press Office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 20-23 October 2014

Name of medicine	INN	Scope
Cimzia	Certolizumab pegol	PSUR assessment resulting in a CHMP opinion to update sections 4.4 and 4.8 of the SmPC to inform that despite previous or concomitant prophylactic treatment for tuberculosis, cases of active tuberculosis have occurred in patients treated with TNF antagonists including Cimzia and that some patients who have been successfully treated for active tuberculosis have redeveloped tuberculosis while being treated with Cimzia. The Package Leaflet is updated accordingly. Update of section 4.8 of the SmPC to add "zoster" to the term "herpes" (frequency 'common') and to clarify that tuberculosis infections may include miliary, disseminated and extrapulmonary disease.
Brintellix	Vortioxetine	CHMP opinion to update section 4.8 of the SmPC to add serotonin syndrome with a frequency of "unknown". The Package Leaflet is updated accordingly.
Stivarga	Regorafenib	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC to add hypersensitivity reaction as a new adverse drug reaction with a frequency "uncommon".



Name of medicine	INN	Scope
Savene	Dexrazoxane	<p>PSUR assessment resulting in a CHMP opinion to update section 4.4 of the SmPC to inform that anaphylactic reactions including angioedema, skin reactions, bronchospasm, respiratory distress, hypotension and loss of consciousness have been observed in patients treated with dexrazoxane and anthracyclines and that previous history of allergy to dexrazoxane should be carefully considered prior to administration.</p> <p>Update of Section 4.8 to add anaphylactic reactions and hypersensitivity with a frequency "not known". In addition section 6.6 is updated with further handling instructions including a statement that the preparation should not be handled by pregnant staff.</p>
Afinitor	Everolimus	<p>PSUR assessment resulting in a CHMP opinion to update of section 4.4 of the SmPC to add a warning regarding the fact that cases of pneumocystis jirovecii (carinii) pneumonia (PJP, PCP), some with fatal outcome, have been reported in patients who received everolimus. PJP/PCP may be associated with concomitant use of corticosteroids or other immunosuppressive agents. Prophylaxis for PJP/PCP should be considered when concomitant use of corticosteroids or other immunosuppressive agents are required. In addition, the existing section 4.8 of the SmPC on "Infections and infestations" is updated with information that cases of opportunistic infections may include the adverse reaction pneumocystis jirovecii (carinii) pneumonia (PJP, PCP).</p>
Fasturtec	Rasburicase	<p>PSUR assessment resulting in a CHMP opinion to an update of section 4.8 of the SmPC to add the adverse reaction 'convulsion' with a frequency 'common' and the adverse reaction 'muscle contraction involuntary' with a frequency 'unknown'.</p>
Votubia	Everolimus	<p>PSUR assessment resulting in a CHMP opinion to update section 4.4 of the SmPC to add a warning regarding the fact that cases of pneumocystis jirovecii (carinii) pneumonia (PJP, PCP), some with fatal outcome, have been reported in patients who received everolimus. PJP/PCP may be associated with concomitant use of corticosteroids or other immunosuppressive agents. Prophylaxis for PJP/PCP should be considered when concomitant use of corticosteroids or other immunosuppressive agents are required. In addition, the existing section 4.8 of the SmPC on "Infections and infestations" is updated with information that cases of pneumonia may include the adverse reaction pneumocystis jirovecii (carinii) pneumonia (PJP, PCP).</p>

Name of medicine	INN	Scope
Ultibro Breezhaler, Ulunar Breezhaler, Xoterna Breezhaler	Glycopyrronium bromide, indacaterol	PSUR assessment in a CHMP opinion to update sections 4.4 and 4.8 of the SmPC to add a warning on angioedema and to add the adverse reaction angioedema with a frequency 'uncommon'. In this regard the SmPC has been aligned with the SmPC of glycopyrronium bromide containing products.
Focetria	Pandemic influenza vaccine (H1N1v) (surface antigen, inactivated, adjuvanted)	PSUR assessment resulting in a CHMP opinion to an update of section 4.6 of the SmPC to revise the information on the use of Focetria and pregnancy. Post-marketing data do not suggest harmful effects, especially in the second or third trimester of pregnancy. Therefore, the relevant SmPC wording currently stating the limited availability of clinical data in pregnant women should be changed to reflect the newly available information.
Incivo	Telaprevir	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC to add pancreatitis as a new adverse drug reaction with a frequency 'uncommon'. In addition, section 4.5 of the SmPC has been updated in order to reflect an interaction with maraviroc based on pharmacokinetic data.
Stelara	Ustekinumab	CHMP opinion to update sections 4.4 and 4.8 of the SmPC with regards to serious skin conditions (exfoliative dermatitis and erythrodermic psoriasis) further to the request of the CHMP to implement the outcome of a PRAC signal recommendation. A Direct Healthcare Professional Communication has been agreed.