



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 16-19 December 2013

Name of medicine	INN	Scope
Constella	inaclotide	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the Summary of Products Characteristics (SmPC) to add rash with an “unknown” frequency.
Sifrol/Mirapexin	pramipexole	PSUR assessment resulting in a CHMP opinion to update sections 4.4 and 4.8 of the SmPC to include mania and delirium as side effects and to add a new warning about these side effects as well as the need for monitoring patients and dose adjustment.
Taxotere/Docetaxel Winthrop	docetaxel	CHMP opinion to update sections 4.4 and 4.5 of the SmPC to add a warning and update the safety information on interactions with CYP3A4 inhibitors further to the PRAC assessment of a signal.

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Name of medicine	INN	Scope
Prepandrix	prepandemic influenza vaccine (H5N1)	PSUR assessment resulting in a CHMP opinion to update sections 4.4 and 4.8 of the SmPC to include a warning and information on increased risk of side effects, particularly fever, in children below 6 years of age after the second dose.
Adjupanrix/Pumarix	pandemic influenza vaccine (H5N1)	
Victralis	boceprevir	PSUR assessment resulting in a CHMP opinion with: <ul style="list-style-type: none"> - update of section 4.4 and 4.8 of the SmPC to add the risk of pancytopenia. - update of section 4.8 of the SmPC to add the risk of agranulocytosis. - update of section 4.3 and 4.5 of the SmPC to include a contra-indication with alfuzosin and silodosin. - update of section 4.8 of the SmPC to add Steven Johnson syndrome. These issues have been reflected in the package leaflet accordingly.
Effentora/Instanyl/Pecfent	fentanyl	PSUR assessment resulting in a CHMP opinion to update sections 4.3, 4.4, 4.5, 4.6, 4.8 and 5.3 of the SmPC consisting, in particular, of adding a contraindication to patients without maintenance opioid therapy and to treatment of acute pain other than breakthrough pain, inserting a warning on bradyarrhythmias, including the risk of serotonin syndrome, adding adverse reactions (fall, flushing and hot flush, diarrhoea, fatigue, respiratory depression, malaise, peripheral oedema, convulsion, hallucination), and inserting preclinical safety data related to carcinogenicity studies and brain lesions in animals. The Package Leaflet is updated accordingly.
Revatio	sildenafil	CHMP opinion to update sections 4.2, 4.4, 4.5 and 5.1 of the SmPC based on the results of study A1481243 sildenafil in combination with bosentan to: <ul style="list-style-type: none"> - include a warning on the concomitant use of sildenafil with bosentan. - reflect the drug-drug interaction data on the concomitant use of sildenafil with bosentan. - describe the relevant efficacy results of study A1481243.
Pradaxa	dabigatran etexilate	CHMP opinion to update section 4.3 of the SmPC (to change a contraindication for a concomitant use with tacrolimus to a non-recommendation) and section 4.5 of the SmPC (to change a non-recommendation for concomitant use with posaconazole to a cautionary statement) for both registered indications following the Assessment Report for PSUR No 8.