



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 March 2014
EMA/CHMP/123245/2014
Press Office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 17-20 March 2014

Name of medicine	INN	Scope
Busilvex	Busulfan	PSUR assessment leading to a recommendation for an update of section 4.8 of the SmPC to list interstitial lung disease as an adverse reaction of unknown frequency.
Xalkori	Crizotinib	PSUR assessment leading to a recommendation for an update of sections 4.4 and 4.8 of the SmPC to reflect the risk of gastrointestinal perforation including reports of fatal cases. The package leaflet is updated accordingly.
Incivo	Telaprevir	CHMP opinion to update sections 4.2 and 4.4 of the SmPC with a description of decompensated liver disease, information on the laboratory parameter albumin and a warning regarding anemia in patients with advanced liver disease. The changes were made at the request of CHMP further to the assessment of the latest PSUR.

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

An agency of the European Union



Name of medicine	INN	Scope
Pegintron, Viraferonpeg	Peginterferon alfa-2b	PSUR assessment leading to a recommendation for an update of section 4.8 of the SmPC to include the adverse drug reaction tongue pigmentation. The package leaflet is updated accordingly.
Gilenya	fingolimod	CHMP opinion to update sections 4.4 and 4.8 of the SmPC to strengthen warnings on the need to assess patient's immunity to varicella and on the concomitant use of corticosteroids. In addition, safety information regarding posterior reversible encephalopathy syndrome (PRES) is being included as a warning with physicians advised to stop Gilenya treatment if PRES is suspected.
Invirase	saquinavir	CHMP opinion to update section 4.4 of the SmPC to amend recommendations for on-treatment ECG during initiation of treatment with saquinavir. Results from a study investigating the effects on the QTc interval, pharmacokinetics and antiviral activity are included in sections 5.1 and 5.2 of the SmPC.
Tasigna	nilotinib	CHMP opinion to update sections 4.4 and 4.8 of the SmPC regarding fluid retention and cardiovascular events.
Hepsera	adefovir dipivoxil	CHMP opinion to update of sections 4.4 and 4.8 of the SmPC to inform prescribers that long term treatment with Hepsera may increase the risk of renal impairment and to strengthen the monitoring of the renal function, as requested by the CHMP, following the evaluation of the last PSUR and to address a post-authorisation measure on this topic also requested following evaluation of the PSUR.