EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 22-25 June 2015

Name of medicine	INN	Scope
Cialis, Adcirca	tadalafil	PSUSA procedure resulting in an update of sections 4.3 and 4.5 of the SmPC to add concomitant use with riociguat as a contraindication due to increased risk of hypotension. The Package leaflet is updated accordingly.
Eliquis	apixaban	PSUR assessment resulting in update of section 4.8 of the SmPC to add “pruritus” as an adverse reaction (with a frequency “uncommon”). The package leaflet will be updated accordingly.
Entyvio	vedolizumab	CHMP opinion to update sections 4.2 and 4.4 of the SmPC to strengthen the warning concerning hypersensitivity reactions and to update section 4.8 of the SmPC to include the adverse event “pain in the extremity” with a frequency “common”. The Package Leaflet is updated accordingly.
Atripla	efavirenz/ emtricitabine/ tenofovir	CHMP opinion to update section 4.5 of the SmPC to add information that co administration of simeprevir with Atripla is not recommended.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5550
Send a question via our website www.ema.europa.eu/contact

Name of medicine	INN	Scope
Fareston	toremifene	Following a PSUSA assessment, update of sections 4.4 and 4.8 of the SmPC to add the adverse reaction “hepatitis” (with a frequency “unknown”) and to add a warning on liver injury. In addition, update of section 4.5 of the SmPC to revise the information on drug interactions with CYP3A inhibitors. The package leaflet will be updated accordingly.
Infanrix hexa	(diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV), poliomyelitis (inactivated) (IPV) and Haemophilus Influenza type-b (Hib) conjugate vaccine (adsorbed)	PSUR assessment resulting in update of section 4.8 of the SmPC to add the adverse reaction “upper respiratory tract infection” (with a frequency “uncommon”) and “bronchitis” (with a frequency “rare”), and “thrombocytopenia” (“rare”). The package leaflet will be updated accordingly. Furthermore, update of section 4.8 of the SmPC to amend the information on experience with hepatitis B vaccine with addition of the events “allergic reactions mimicking serum sickness, neuritis, hypotension, vasculitis, lichen planus, erythema multiforme, arthritis and muscular weakness”.
Invokana, Vokanamet	canagliflozin canagliflozin/ metformin	PSUSA assessment resulting in an update of section 4.8 of the SmPC to add the adverse reaction “angioedema” with a frequency “unknown” and to amend the wording in section 4.8 regarding urinary tract infections. Additional minor amendments to footnotes in 4.8 have been made to align the information with the above changes. The package leaflet is updated accordingly.
Olysio	simeprevir	PSUSA assessment resulting in an update of section 4.4 to add a warning on the risk of hepatic decompensation and hepatic failure. In addition sections 4.4, 4.5 and 4.8 have been updated to include warnings on the risk of bradycardia when simeprevir is used in combination with sofosbuvir and amidarone. The Package leaflet is updated accordingly. CHMP opinion to update sections 4.2 and 4.4 of the SmPC in order to remove the information that had previously limited the use of IFN-free therapy with Olysio (ie, the use of simeprevir+ sofosbuvir ± ribavirine) to patients who are intolerant to, or ineligible for IFN therapy, and are in urgent need of treatment.

Name of medicine	INN	Scope
Tracleer, Stayveer and nationally authorised medicines	bosentan, bosentan monohydrate	PSUSA assessment resulting in an update of section 4.8 of the SmPC to add the adverse reaction “nasal congestion” (with a frequency “common”) and to add additional wording regarding autoimmune hepatitis. The package leaflet will be updated accordingly.
Komboglyze	metformin/ saxagliptin	PSUSA assessment resulting in an update of section 4.8 of the SmPC to add the adverse reaction “constipation” with a frequency “unknown”. The Package leaflet is updated accordingly.
Xyrem	sodium oxybate	PSUSA assessment resulting in an update of section 4.8 of the SmPC to add the adverse reaction “angioedema” and “dry mouth” (with a frequency “not known”). The package leaflet will be updated accordingly.