



26 February 2015
EMA/27949/2015
Press Office

Opinions on safety variations/PSURs

Adopted at the CHMP meeting of 23-26 February 2015

Name of medicine	INN	Scope
Abilify and Abilify Maintena	aripiprazole	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC of Abilify to add 'hypersexuality' with a frequency uncommon. The Package leaflet for both Abilify and Abilify Maintena is updated accordingly.
Eklira Genuair/ Bretaris Genuair	acclidinium bromide	PSUR assessment resulting in a CHMP opinion to update: <ul style="list-style-type: none">• section 4.2 of the SmPC to include reference to a feeling a grainy texture in the mouth after inhalation;• section 4.7 of the SmPC to reflect that dizziness may affect the ability to drive and use machinery, and• section 4.8 of the SmPC to add 'dizziness' and 'stomatitis' with a frequency of 'uncommon' and 'nausea' with a frequency of 'common'
Imbruvica	ibrutinib	CHMP opinion to update section 4.4 of the SmPC in order to include a new warning regarding 'tumour lysis syndrome' (TLS).



Name of medicine	INN	Scope
Onglyza	saxagliptin	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC to add the adverse reaction constipation with a frequency 'not known'. The Package leaflet is updated accordingly
Tivicay	dolutegravir	PSUR assessment resulting in a CHMP opinion to update section 4.8 of the SmPC to add the term depression with a frequency 'common' and the term suicidal ideation or suicide attempt (particularly in patients with a pre-existing history of depression or psychiatric illness) with a frequency 'uncommon'. The Package leaflet is updated accordingly.
Tritanrix	diphtheria, tetanus, pertussis (whole cell) and hepatitis B (rDNA) vaccine (adsorbed)	PSUR assessment resulting in the update of Annex II of the product information to include a frequency of 5-yearly PSUR submissions in line with products authorised in the Union as defined in the updated list of Union reference dates (EURD list).
Xiapex	collagenase clostridium histolyticum	PSUR assessment resulting in a CHMP opinion to update of section 4.4 of the SmPC to add a warning on serious skin lacerations requiring skin graft and to modify the existing warning on tendon injury to add information on higher risk of tendon/ ligament damage for patients where Xiapex is injected in the proximal interphalangeal (PIP) joint of the fifth finger.