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Press Office

Opinions on annual re-assessments, renewals of marketing authorisations and accelerated assessment procedures

Adopted at the CHMP meeting of 17-20 March 2014

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Ceplene (histamine dihydrochloride) Meda AB	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Evoltra (clofarabine) Genzyme Europe BV	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Xagrid (anagrelide) Shire Pharmaceutical Contracts Ltd.	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Yondelis (trabectedin) Pharma Mar, S.A.	Positive Opinion	Marketing Authorisation remains under exceptional circumstances

Table 2. Opinion for renewals of conditional Marketing Authorisation

Name of medicinal product (INN) MAH	Outcome	Comments
Fampyra (fampridine) Biogen Idec Ltd.	Positive Opinion	Recommending renewal of conditional Marketing Authorisation

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Osseor (strontium ranelate) Les Laboratoires Servier	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Protelos (strontium ranelate) Les Laboratoires Servier	Positive Opinion	Unlimited validity
Afinitor (everolimus) Novartis Europharm Ltd	Positive Opinion	Recommending additional renewal
Cimzia (certolizumab pegol) UCB Pharma SA	Positive Opinion	Unlimited validity
Clopidogrel DURA (clopidogrel) Mylan dura GmbH	Positive Opinion	Unlimited validity
Clopidogrel Krka (clopidogrel) Krka d.d. Novo mesto	Positive Opinion	Unlimited validity
Clopidogrel Krka d.d. (clopidogrel) Krka d.d. Novo mesto	Positive Opinion	Unlimited validity
Clopidogrel Mylan (clopidogrel) MYLAN S.A.S.	Positive Opinion	Unlimited validity
Clopidogrel ratiopharm GmbH (clopidogrel) Archie Samuel s.r.o.	Positive Opinion	Unlimited validity
Clopidogrel TAD (clopidogrel) TAD Pharma GmbH	Positive Opinion	Unlimited validity
Clopidogrel Teva (clopidogrel) Teva Pharma B.V.	Positive Opinion	Unlimited validity
Clopidogrel Teva Pharma (clopidogrel) Teva Pharma B.V.	Positive Opinion	Unlimited validity
Isentress (raltegravir) Merck Sharp & Dohme Limited	Positive Opinion	Unlimited validity
Javlor (vinflunine ditartrate) Pierre Fabre Médicament	Positive Opinion	Unlimited validity
Pandemic Influenza Vaccine H5N1 Baxter (substance to be reviewed) pandemic influenza vaccine (h5n1) (whole virion, inactivated, prepared in cell culture)), Baxter AG	Positive Opinion	Unlimited validity
Topotecan Actavis (topotecan) Actavis Group hf	Positive Opinion	Unlimited validity
Vizarsin (sildenafil) Krka d.d. Novo mesto	Positive Opinion	Unlimited validity
Zylagren (clopidogrel) Krka d.d. Novo mesto	Positive Opinion	Unlimited validity
Zyllt (clopidogrel) Krka d.d. Novo mesto	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

Substance (Chemical/Biological)	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
No items			

