



26 June 2014
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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 23-26 June 2014

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
No product this month		

Table 2. Opinion for renewals of conditional Marketing Authorisation

Name of medicinal product (INN) MAH	Outcome	Comments
Adcetris (brentuximab vedotin) Takeda Pharma A/S	Positive Opinion	Recommending renewal of conditional Marketing Authorisation
XALKORI (crizotinib) Pfizer Limited	Positive Opinion	Recommending renewal of conditional Marketing Authorisation

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
ChondroCelect (characterised viable autologous cartilage cells expanded ex vivo expressing specific marker proteins) TiGenix NV	Positive Opinion	Recommending additional renewal
Biopoin (epoetin theta) TEVA GmbH	Positive Opinion	Unlimited validity
Elonva (corifollitropin alfa) Merck Sharp & Dohme Limited	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Enyglid (repaglinide) Krka d.d. Novo mesto	Positive Opinion	Unlimited validity
Eporatio (epoetin theta) ratiopharm GmbH	Positive Opinion	Unlimited validity
Irbesartan/ Hydrochlorothiazide Teva (irbesartan / hydrochlorothiazide) Teva Pharma B.V.	Positive Opinion	Unlimited validity
Nevirapine Teva (nevirapine) Teva Pharma B.V.	Positive Opinion	Unlimited validity
Olanzapine Glenmark (olanzapine) Glenmark Pharmaceuticals Europe Limited	Positive Opinion	Unlimited validity
Olanzapine Glenmark Europe (olanzapine) Glenmark Pharmaceuticals Europe Limited	Positive Opinion	Unlimited validity
Olazax (olanzapine) Glenmark Pharmaceuticals s.r.o.	Positive Opinion	Unlimited validity
Olazax Disperzi (olanzapine) Glenmark Pharmaceuticals s.r.o.	Positive Opinion	Unlimited validity
Repaglinide Krka (repaglinide) Krka d.d. Novo mesto	Positive Opinion	Unlimited validity
Scintimun (besilesomab) CIS BIO International	Positive Opinion	Unlimited validity
Temozolomide Teva (temozolomide) Teva Pharma B.V.	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Asfotase alfa	Long-term enzyme replacement therapy in patients with hypophosphatasia with either perinatale/infantile onset (0-6 months at onset of symptoms) or juvenile onset (6 months to 18 years at onset of symptoms)	x	