



22 July 2016
EMA/76612/2016
Press office

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

Adopted at the CHMP meeting of 18-21 July 2016

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Elaprase , (idursulfase), Shire Human Genetic Therapies AB	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
Adcetris , (brentuximab vedotin), Takeda Pharma A/S	Positive Opinion	Recommending renewal of conditional Marketing Authorisation
Blincyto , (blinatumomab), Amgen Europe B.V.	Positive Opinion	Recommending renewal of conditional Marketing Authorisation

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Adavance , (alendronic acid / colecalciferol), Merck Sharp & Dohme Limited	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Colobreathe , (colistimethate sodium), Forest Laboratories UK Limited	Positive Opinion	Unlimited validity
Eurartesim , (piperazine tetraphosphate / arteminol), Sigma-Tau Industrie Farmaceutiche Riunite S.p.A.	Positive Opinion	Unlimited validity
Efavirenz Teva , (efavirenz), Teva B.V.	Positive Opinion	Unlimited validity
Elaprase , (idursulfase), Shire Human Genetic Therapies AB	Positive Opinion	Unlimited validity
Levetiracetam Actavis , (levetiracetam), Actavis Group PTC ehf	Positive Opinion	Unlimited validity
Repaglinide Accord , (repaglinide), Accord Healthcare Ltd	Positive Opinion	Recommending additional renewal
Tandemact , (pioglitazone / glimepiride), Takeda Pharma A/S	Positive Opinion	Unlimited validity
Zelboraf , (vemurafenib), Roche Registration Limited	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Peramivir	Treatment of influenza		X
Cenegermis	Treatment of moderate or severe neurotrophic keratitis	X	