



20 November 2015
EMA/38688/2015
Press office

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

Adopted at the CHMP meeting of 16-19 November 2015

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Atriance , (nelarabine), Novartis Europharm Ltd	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Evoltra , (clofarabine), Genzyme Europe BV	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Lojuxta , (lomitapide), Aegerion Pharmaceuticals Limited	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Naglazyme , (galsulfase), BioMarin Europe Ltd	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
Bosulif , (bosutinib), Pfizer Limited	Positive Opinion	Recommending renewal of conditional Marketing Authorisation
Cometriq , (cabozantinib), TMC Pharma Services Ltd	Positive Opinion	Recommending renewal of conditional Marketing Authorisation
Sirturo , (bedaquiline), Janssen-Cilag International N.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
Eliquis , (apixaban), Bristol-Myers Squibb / Pfizer EEIG	Positive Opinion	Recommending additional renewal
Trobalt , (retigabine), Glaxo Group Ltd,	Positive Opinion	Recommending additional renewal
Evoltra , (clofarabine), Genzyme Europe BV	Positive Opinion	Unlimited validity
Methylthioninium chloride Proveblue , (methylthioninium chloride), Provepharm SAS	Positive Opinion	Unlimited validity
Pravafenix , (fenofibrate / pravastatin), Laboratoires SMB s.a.	Positive Opinion	Unlimited validity
Repro , (leflunomide), Teva B.V.	Positive Opinion	Unlimited validity
Rotarix , (human rotavirus, live attenuated), GlaxoSmithKline Biologicals S.A.	Positive Opinion	Unlimited validity
Yellox , (bromfenac), PharmaSwiss Ceska Republika s.r.o	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Lenvatinib	treatment for advanced and/or metastatic RCC following disease progression after failure of treatment with 1 prior VEGF-targeted therapy	X	