



20 November 2014
EMA/797634/2014 Corr*
Press Office

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

Adopted at the CHMP meeting of 17-20 November 2014

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Firdapse (amifampridine), BioMarin Europe Ltd	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Imvanex (modified vaccinia ankara virus) Bavarian Nordic A/S	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 Authorisation¹

Name of medicinal product (INN) MAH	Outcome	Comments
Cometriq (cabozantinib s-malate) 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

Corr*: Correction to remove reference to opinion (Bosulif) included by error in the table.



Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Leflunomide medac (leflunomide) Medac Gesellschaft für klinische Spezialpräparate mbH	Positive Opinion	Unlimited validity
Prolia (denosumab) Amgen Europe B.V.	Positive Opinion	Recommending additional renewal
Revolade (eltrombopag) GlaxoSmithKline Trading Services	Positive Opinion	Unlimited validity
Aclasta (zoledronic acid) Novartis Europharm Ltd	Positive Opinion	Unlimited validity
Raloxifene Teva (raloxifene) Teva Pharma B.V.	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Alirocumab	indicated, as adjunct therapy to diet, for long-term treatment of adult patients with primary hypercholesterolaemia (non-familial and heterozygous familial) or mixed dyslipidaemia to reduce low-density lipoprotein cholesterol (LDL-C). Combination therapy with a statin: indicated in combination with a statin (HMG-CoA reductase inhibitor), with or without other lipid modifying therapy (LMT), in patients not appropriately controlled with a statin alone. Monotherapy: indicated as monotherapy, or as add-on to other non-statin LMT, in patients who cannot tolerate statins)		X
Sacubitril/Valsartan	indicated for the treatment of heart failure (NYHA class II-IV) to reduce the rate of cardiovascular death and heart failure hospitalization	X	
Sebelipase Alfa	indicated for long-term enzyme replacement therapy (ERT) for patients with Lysosomal Acid Lipase Deficiency (LAL D)	X	