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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 20-23 June 2016

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

Table 2. Opinion for renewals of conditional Marketing Authorisation

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

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Dificlir , (fidaxomicin), Astellas Pharma Europe B.V.	Positive Opinion	Unlimited validity
Dasselta , (desloratadine), MAH: KRKA, d.d., Novo mesto	Positive Opinion	Unlimited validity
Desloratadine ratiopharm , (desloratadine), ratiopharm GmbH,	Positive Opinion	Unlimited validity
Desloratadine Teva , (desloratadine), Teva B.V.	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Levetiracetam Actavis Group , (levetiracetam), Actavis Group PTC ehf	Positive Opinion	Unlimited validity
Plenadren , (hydrocortisone), MAH: Shire Services BVBA	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Andexanet alfa	For adult patients treated with a direct or indirect factor Xa (FXa) inhibitor when reversal of anticoagulation is needed in situations such as: in life-threatening or uncontrolled bleeding; for emergency surgery/urgent procedures		X
Masitinib mesylate	Treatment of adults with Amyotrophic Lateral Sclerosis		X