



25 September 2015
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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 21-24 September 2015

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
Gilenya , (fingolimod), Novartis Europharm Ltd	Positive Opinion	Recommending additional renewal
Jevtana , (cabazitaxel), Sanofi-Aventis Groupe	Positive Opinion	Recommending additional renewal
Entacapone Teva , (entacapone), Teva B.V.	Positive Opinion	Unlimited validity
Halaven , (eribulin), Eisai Europe Ltd.	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Ifirmacombi , (irbesartan / hydrochlorothiazide), Krka d.d. Novo mesto	Positive Opinion	Unlimited validity
Lamivudine / Zidovudine Teva , (lamivudine / zidovudine), Teva B.V.	Positive Opinion	Unlimited validity
Macugen , (pegaptanib sodium), PharmaSwiss Ceska Republika s.r.o	Positive Opinion	Unlimited validity
Teysuno , (tegafur / gimeracil / oteracil), Nordic Group B.V.	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Daratumumab	treatment of patients with multiple myeloma, who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), or who are double-refractory to a PI and IMiD	X	
Chlorhexidine	prophylaxis of omphalitis (infection of the umbilical cord) in newborn infants	X	