



29 April 2016  
EMA/76598/2016  
Press office

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

Adopted at the CHMP meeting of 25-28 April 2016

**Table 1.** Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
<b>Defitelio</b> , (defibrotide), Gentium S.r.l.	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
<b>Champix</b> , (varenicline), Pfizer Limited	Positive Opinion	Unlimited validity
<b>Matever</b> , (levetiracetam), MAH: Pharmathen S.A.	Positive Opinion	Unlimited validity
<b>Telmisartan Teva Pharma</b> , (telmisartan), Teva B.V.,	Positive Opinion	Unlimited validity



**Table 4.** Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
177Lu-DOTA0-Tyr3-Octreotate	treatment of metastatic or unresectable, well differentiated, midgut (jejunum, ileum, appendix and ascending colon) neuroendocrine tumours, which overexpress somatostatin receptors	X	
Cerliponase alfa	Treatment of Neuronal Ceroid Lipofuscinosis Type 2 (CLN2)	X	
Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily A; Escherichia coli), Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily B; Escherichia coli)	Prevention of invasive meningococcal disease caused by Neisseria meningitidis (IMD) serogroup B in individuals 10 years and older		X