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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 April 2015

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

Name of medicinal product (INN) MAH	Outcome	Comments
<b>Defitelio</b> , (defibrotide) Gentium S.p.A.	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>VPRIV</b> , (velaglucerase alfa) Shire Pharmaceuticals Ireland Ltd.	Positive Opinion	Recommending additional renewal
<b>Aptivus</b> , (tipranavir) Boehringer Ingelheim International GmbH	Positive Opinion	Unlimited validity
<b>Clopidogrel HCS</b> , (clopidogrel) HCS bvba	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
<b>Ibandronic Acid Teva</b> , (ibandronic acid) Teva B.V.	Positive Opinion	Unlimited validity
<b>Leflunomide ratiopharm</b> , (leflunomide) ratiopharm GmbH	Positive Opinion	Unlimited validity
<b>Telmisartan Actavis</b> , (telmisartan) Actavis Group PTC ehf	Positive Opinion	Unlimited validity
<b>Xolair</b> , (omalizumab) Novartis Europharm Ltd	Positive Opinion	Unlimited validity

**Table 4.** Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Autologous CD34+ Cells Transduced with Retroviral Vector Containing the Adenosine Deaminase Gen	Severe combined immunodeficiency due to adenosine deaminase deficiency	X	