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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 22-25 June 2015

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

Name of medicinal product (INN) MAH	Outcome	Comments
<b>ATryn</b> , (antithrombin alfa) GTC Biotherapeutics UK Limited	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>Keppra</b> , (levetiracetam) UCB Pharma SA	Positive Opinion	Unlimited validity
<b>Twynsta</b> , (telmisartan / amlodipine) Boehringer Ingelheim International GmbH	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
<b>Xyrem</b> , (sodium oxybate) UCB Pharma Ltd.	Positive Opinion	Unlimited validity

**Table 4.** Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Elotuzumab	Treatment of multiple myeloma in combination with lenalidomide and dexamethasone in patients who have received one or more prior therapies	X	
Drisapersen Sodium	Treatment of Duchenne Muscular Dystrophy (exon 51 mutation specific)		X
Begelomab	Treatment of steroid resistant acute Graft-versus-Host Disease (GvHD) in adult patients who underwent allogeneic haematopoietic progenitor cell transplantation (HPCT) and received a standard immunosuppressive regimen		X
Elbasvir\Grazoprevir	Grazoprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor, in combination with elbasvir, a HCV NS5A inhibitor, is indicated for the treatment of chronic hepatitis C (CHC) Genotypes 1, 4, and 6 infection	X	