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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 May 2012

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

Name of medicinal product (INN) MAH	Outcome	Comments
<b>Increlex</b> (mecasermin), Ipsen Pharma	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
<b>Intelece</b> (etravirine), Janssen-Cilag International N.V.	Positive Opinion	Marketing Authorisation remains under conditional approval
<b>Votubia</b> (everolimus), Novartis Europharm Ltd.	Positive Opinion	Marketing Authorisation remains under conditional approval

**Table 3.** Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
<b>Increlex</b> (mecasermin), Ipsen Pharma	Positive Opinion	Recommending additional renewal
<b>Rasilez</b> (aliskiren), Novartis Europharm Ltd.	Positive Opinion	Recommending additional renewal
<b>Riprazo</b> (aliskiren), Novartis Europharm Ltd.	Positive Opinion	Recommending additional renewal



Name of medicinal product (INN) MAH	Outcome	Comments
<b>Sprimeo</b> (aliskiren), Novartis Europharm Ltd.	Positive Opinion	Recommending additional renewal
<b>Ambirix</b> (hepatitis A (inactivated) and hepatitis B(Rdna) (Hab) vaccine (adsorbed)), GlaxoSmithKline Biologicals S.A.	Positive Opinion	Unlimited validity
<b>BeneFIX</b> (nonacog alfa), Pfizer Ltd.	Positive Opinion	Unlimited validity
<b>Celsentri</b> (maraviroc), ViiV Healthcare UK Limited	Positive Opinion	Unlimited validity
<b>Cyanokit</b> (hydroxocobalamin), Merck Santé S.A.S.	Positive Opinion	Unlimited validity
<b>Eucreas</b> (vildagliptin/metformin), Novartis Europharm Ltd.	Positive Opinion	Unlimited validity
<b>Galvus</b> (vildagliptin), Novartis Europharm Ltd.	Positive Opinion	Unlimited validity
<b>InductOs</b> (dibotermin alfa), Medtronic BioPharna B.V.	Positive Opinion	Unlimited validity
<b>Silapo</b> (epoetin zeta), STADA Arzneimittel AG	Positive Opinion	Unlimited validity
<b>Yondelis</b> (trabectedin), Pharma Mar S.A.	Positive Opinion	Unlimited validity
<b>Zalasta</b> (olanzapine), Krka d.d. Novo mesto	Positive Opinion	Unlimited validity

**Table 4.** Accelerated Assessment Procedures

Substance (Chemical/Biological)	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
N/A			