



25 April 2014
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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 April 2014

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Increlex (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
Erivedge (vismodegib) Roche Registration Ltd	Positive Opinion	Recommending renewal of conditional Marketing Authorisation

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
ILARIS (canakinumab) Novartis Europharm Ltd	Positive Opinion	Recommending additional renewal
Angiox (bivalirudin) The Medicines Company UK Ltd	Positive Opinion	Unlimited validity
Copalia HCT (amlodipine / valsartan / hydrochlorothiazide) Novartis Europharm Ltd	Positive Opinion	Unlimited validity
Dafiro HCT (amlodipine / valsartan / hydrochlorothiazide) Novartis Europharm Ltd	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Exforge HCT (amlodipine / valsartan / hydrochlorothiazide) Novartis Europharm Ltd	Positive Opinion	Unlimited validity
Foclivia (influenza virus surface antigens (inactivated) of strain a/vietnam/1194/2004 (h5n1)) Novartis Vaccines and Diagnostics S.r.l.	Positive Opinion	Unlimited validity
Repaglinide Teva (repaglinide) Teva Pharma B.V.	Positive Opinion	Unlimited validity
Resolor (prucalopride succinate) Shire Pharmaceuticals Ireland Ltd.	Positive Opinion	Unlimited validity
Samsca (tolvaptan) Otsuka Pharmaceutical Europe Ltd	Positive Opinion	Unlimited validity
Simponi (golimumab) Janssen Biologics B.V.	Positive Opinion	Unlimited validity
Topotecan Teva (topotecan) Teva Pharma B.V.	Positive Opinion	Unlimited validity
Zeffix (lamivudine) Glaxo Group Ltd	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

Substance (Chemical/Biological)	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Chemical	Treatment of genotype 1 and 4 chronic hepatitis C	x	
Chemical	Treatment of genotype 1 chronic hepatitis C	x	
Chemical	Maintenance treatment of idiopathic pulmonary fibrosis	x	