

16 February 2012
EMA/CHMP/86232/2012
Press Office

Opinions on annual reassessments, 5-year renewals

Adopted at the CHMP meeting of 13-16 February 2012

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Ceprene (histamine dihydrochloride), Epicept GmbH	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Evoltra (clofarabine), Genzyme Europe B.V.	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Yondelis (trabectedin), Pharma Mar S.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
Tyverb (lapatinib), Glaxo Group 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
Advagraf (Tacrolimus), Astellas Pharma Europe B.V.	Positive Opinion	Unlimited validity
Altargo (retapamulin), Glaxo Group Ltd.	Positive Opinion	Unlimited validity

Name of medicinal product (INN) MAH	Outcome	Comments
Circadin (melatonin), RAD Neurim Pharmaceuticals EEC Ltd.	Positive Opinion	Unlimited validity
Revlimid (lenalidomide), Celgene Europe Ltd.	Positive Opinion	Recommending additional renewal
Sebivo (telbivudine), Novartis Europharm Ltd.	Positive Opinion	Recommending additional renewal The CHMP recommended to introduce in section 4.1 of the SmPC a restriction that initiation of Sebivo treatment should only be considered when the use of an alternative antiviral agent with a higher genetic barrier to resistance is not available or appropriate.
Tracleer (bosentan), Actelion Registration Ltd.	Positive Opinion	Unlimited validity

Table 4. Accelerated Assessment Procedures

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