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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 19-22 January 2015

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

Name of medicinal product (INN) MAH	Outcome	Comments
<b>Evoltra</b> (clofarabine) Genzyme Europe BV	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
<b>Orphacol</b> (cholic acid) LABORATOIRES CTRS - BOULOGNE BILLANCOURT	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
<b>Vedrop</b> (tocofersolan) Orphan Europe S.A.R.L.	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>Pixuvri</b> (pixantrone dimaleate) CTI Life Sciences Limited	Positive Opinion	Recommending renewal of conditional Marketing Authorisation
<b>Tyverb</b> (lapatinib) Glaxo Group 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
<b>Leflunomide medac</b> (leflunomide) medac Gesellschaft für klinische Spezialpräparate mbH	Positive Opinion	Unlimited validity
<b>Ozurdex</b> (dexamethasone) Allergan Pharmaceuticals Ireland	Positive Opinion	Unlimited validity
<b>Tolura</b> (telmisartan) Krka d.d. Novo mesto	Positive Opinion	Unlimited validity

**Table 4.** Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
No product this month			