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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 20-23 January 2014

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

Name of medicinal product (INN) MAH	Outcome	Comments
<b>Ceplene</b> (histamine dihydrochloride) Meda AB	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
<b>Replagal</b> (agalsidase alfa) Shire Human Genetic Therapies AB	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>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>Renvela</b> (sevelamer) Genzyme Europe BV	Positive Opinion	Recommending additional renewal
<b>Clopidogrel Acino</b> (clopidogrel) Acino AG	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
<b>Ziagen</b> (abacavir) ViiV Healthcare UK Limited	Positive Opinion	Unlimited validity
<b>ellaOne</b> (ulipristal acetate) Laboratoire HRA Pharma SA	Positive Opinion	Unlimited validity

**Table 4.** Accelerated assessment procedures

Substance (Chemical/Biological)	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
No items			