



24 July 2014  
EMA/125405/2014 Corr\*  
Press Office

## Opinions on annual re-assessments, renewals of marketing authorisations and accelerated assessment procedures

Adopted at the CHMP meeting of 21-24 July 2014

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

Name of medicinal product (INN) MAH	Outcome	Comments
<b>Elaprase</b> (idursulfase) Shire Human Genetic Therapies AB	Positive Opinion	Marketing Authorisation remains under exceptional circumstances

**Table 2.** Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
<b>Clopidogrel Apotex</b> (clopidogrel) Apotex Europe BV	Positive opinion	Unlimited validity
<b>Hirobriz Breezhaler</b> (indacaterol) Novartis Europharm Ltd	Positive opinion	Unlimited validity
<b>Lamivudine Teva</b> (lamivudine) Teva Pharma B.V.	Positive opinion	Unlimited validity
<b>Lamivudine Teva Pharma B.V.</b> (lamivudine) Teva Pharma B.V.	Positive opinion	Unlimited validity
<b>MULTAQ</b> (dronedarone) sanofi-aventis groupe	Positive Opinion	Recommending additional renewal
<b>Onbrez Breezhaler</b> (indacaterol) Novartis Europharm Ltd	Positive opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
<b>Oslif Breezhaler</b> (indacaterol) Novartis Europharm Ltd	Positive opinion	Unlimited validity
<b>Prevenar 13</b> (pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed)) Pfizer Limited	Positive opinion	Unlimited validity
<b>Prialt</b> (ziconotide) Eisai Ltd	Positive opinion	Unlimited validity
<b>Sildenafil Actavis</b> , (sildenafil) Actavis Group hf	Positive opinion	Unlimited validity
<b>Sildenafil ratiopharm</b> (sildenafil) ratiopharm GmbH	Positive opinion	Unlimited validity
<b>Sildenafil Teva</b> (sildenafil) Teva Pharma B.V.	Positive opinion	Unlimited validity
<b>Silodyx</b> (silodosin) Recordati Ireland Ltd.	Positive opinion	Unlimited validity
<b>Urorec</b> (silodosin) Recordati Ireland Ltd.	Positive opinion	Unlimited validity
<b>Vantavo</b> (alendronic acid / colecalciferol) Merck Sharp & Dohme Limited	Positive opinion	Unlimited validity
<b>Zutectra</b> (human hepatitis b immunoglobulin) Biotest Pharma GmbH	Positive opinion	Unlimited validity

**Table 3.** Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
evolocumab	hyperlipidaemia and mixed dyslipidaemia, homozygous familial hypercholesterolaemia		X
lenvatinib	treatment of radioiodine refractory differentiated thyroid cancer in adults	X	
nivolumab	treatment of advanced (unresectable or metastatic) melanoma <sup>1</sup>	X	

Corr\*<sup>1</sup> Correction of indication