



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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 27-30 May 2013

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Replagal (agalsidase alfa), Shire Human Genetic Therapies AB	Positive Opinion ¹	Marketing Authorisation remains under exceptional circumstances
Ventavis (iloprost), Bayer Pharma AG	Positive Opinion	No remaining grounds for the Marketing Authorisation to remain under exceptional circumstances

Table 2. Opinion for renewals of conditional Marketing Authorisation

Name of medicinal product (INN) MAH	Outcome	Comments
N/A		

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Icandra (metformin hydrochloride, vildagliptin), Novartis Europharm Ltd	Positive Opinion	Unlimited validity

¹ The opinion was adopted by written procedure after April 2013 CHMP meeting



Name of medicinal product (INN) MAH	Outcome	Comments
Ventavis (iloprost), Bayer Pharma AG	Positive Opinion	Unlimited validity
Biograstim (filgrastim), CT Arzneimittel GmbH	Positive Opinion	Unlimited validity
Ratiograstim (filgrastim), Ratiopharm GmbH	Positive Opinion	Unlimited validity
Tevagrastim (filgrastim), TEVA GmbH	Positive Opinion	Unlimited validity
Vimpat (lacosamide), UCB Pharma SA	Positive Opinion	Unlimited validity
Zomarist (metformin hydrochloride, vildagliptin), Novartis Europharm Ltd	Positive Opinion	Unlimited validity

Table 4. Accelerated Assessment Procedures

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