



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 16-19 September 2013

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
None this month		

Table 2. Opinion for renewals of conditional Marketing Authorisation

Name of medicinal product (INN) MAH	Outcome	Comments
None this month		

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Opgenra (eptoterminalfa), Olympus Biotech International Limited	Positive Opinion	Recommending additional renewal
Thymanax (Agomelatine), Servier Industries Ltd	Positive Opinion	Recommending additional renewal
Valdoxan (Agomelatine), Servier Industries Ltd	Positive Opinion	Recommending additional renewal
Rasilez HCT (aliskiren hydrochlorothiazide) Novartis Europharm Ltd	Positive Opinion	Recommending additional renewal
Vidaza Orphan , (azacitidine) Celgene Europe Limited	Positive Opinion	Unlimited validity
Efient (prasugrel) Eli Lilly Nederland	Positive Opinion	Unlimited validity
Firmagon (degarelix) Ferring	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Pharmaceuticals A/S		
Filgrastim Hexal (filgrastim) Hexal AG	Positive Opinion	Unlimited validity
Jalra (vidagliptin) Novartis Europharm Ltd	Positive Opinion	Unlimited validity
Kuvan Orphan , (saproterin) Merck Serono Europe Limited	Positive Opinion	Unlimited validity
ReFacto AF (moroctocog alfa) Pfizer Limited	Positive Opinion	Unlimited validity
Xiliarx (vildagliptin) Novartis	Positive Opinion	Unlimited validity
Zarzio (filgrastim) Sandoz GmbH	Positive Opinion	Unlimited validity

Table 4. Accelerated Assessment Procedures

Substance (Chemical/Biological)	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Biological	None this month	None this month	
Chemical	None this month	None this month	