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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 12-15 November 2012

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
ILARIS (Canakinumab), Novartis Europharm	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Elaprase (Idursulfase), Shire Human Genetic Therapies AB	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Xagrid (Anagrelide), Shire Pharmaceutical Contracts Limited	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
Vectibix (Panitumumab), Amgen Europe B.V.	Positive Opinion	Marketing Authorisation remains under conditional approval



Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Prepandrix (Prepandemic Influenza Vaccine (H5N1) (Split Virion, Inactivated, Adjuvanted)), GlaxoSmithKline Biologicals S.A.	Positive Opinion	Recommending additional renewal
Volibris (Ambrisentan), Glaxo Group Ltd.	Positive Opinion	Unlimited validity

Table 4. Accelerated Assessment Procedures

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