



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 December 2013

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
ILARIS (canakinumab), Novartis Europharm Ltd	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	Recommending renewal of conditional Marketing Authorisation

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Conbriza (bazedoxifene), Pfizer Limited	Positive Opinion	Unlimited validity
Modigraf (tacrolimus), Astellas Pharma Europe B.V.	Positive Opinion	Unlimited validity
Peyona (caffeine), Chiesi Farmaceutici S.p.A.	Positive Opinion	Unlimited validity
CONTROLOC Control (pantoprazole), Takeda GmbH	Positive Opinion	Unlimited validity
SOMAC Control (pantoprazole), Takeda GmbH	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Pantecta Control (pantoprazole), Takeda GmbH	Positive Opinion	Unlimited validity
Pantoloc Control (pantoprazole), Takeda GmbH	Positive Opinion	Unlimited validity
Fertavid (follitropin beta), Merck Sharp & Dohme Limited	Positive Opinion	Unlimited validity
Ixiaro (japanese encephalitis vaccine (inactivated, adsorbed)), Valneva Austria GmbH	Positive Opinion	Recommending additional renewal
Synflorix (pneumococcal polysaccharide conjugate vaccine (adsorbed)), GlaxoSmithKline Biologicals	Positive Opinion	Recommending additional renewal

Table 4. Accelerated assessment procedures

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