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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 14-17 December 2015

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
Xagrid (anagrelide), Shire Pharmaceutical Contracts 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
No product this month		

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Benlysta , (belimumab), Glaxo Group Ltd.	Positive Opinion	Unlimited validity
Bydureon , (exenatide), AstraZeneca AB	Positive Opinion	Unlimited validity
Hizentra , (human normal immunoglobulin), CSL Behring GmbH	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Nulojix , (belatacept), Bristol-Myers Squibb Pharma EEIG	Positive Opinion	Unlimited validity
Rivastigmine Actavis , (rivastigmine), Actavis Group PTC ehf	Positive Opinion	Unlimited validity
TOBI Podhaler , (tobramycin), Novartis Europharm Ltd.	Positive Opinion	Unlimited validity
Tygacil , (tigecycline), Pfizer Limited	Positive Opinion	Unlimited validity
Victrelis , (boceprevir), Merck Sharp & Dohme Limited	Positive Opinion	Unlimited validity
Zostavax , (shingles (herpes zoster) vaccine (live)), Sanofi Pasteur MSD SNC	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
No product this month			