

15 March 2012
EMA/CHMP/162993/2012
Press Office

Opinions on annual reassessments, 5-year renewals

Adopted at the CHMP meeting of 12-15 March 2012

Table 1. Opinions for annual re-assessment applications

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

Table 2. Opinion for renewals of conditional Marketing Authorisation

Name of medicinal product (INN) MAH	Outcome	Comments
Fampyra (Fampridine), Biogen Idec Ltd.	Positive Opinion	Marketing Authorisation remains under conditional approval
Votrient (Pazopanib), Glaxo Group Ltd.	Positive Opinion	Marketing Authorisation remains under conditional approval

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Optaflu (Influenza Vaccine (Surface Antigen, Inactivated, Prepared In Cell Cultures)), Novartis Vaccines and Diagnostics GmbH	Positive Opinion	Recommending additional renewal
Pergoveris (Follitropin Alfa / Lutropin Alfa), Merck Serono Europe Ltd.	Positive Opinion	Recommending additional renewal
Aerinaze (Desloratadine / Pseudoephedrine Sulphate), Merck Sharp & Dohme Ltd.	Positive Opinion	Unlimited validity

Name of medicinal product (INN) MAH	Outcome	Comments
Invega (Paliperidone), Janssen-Cilag International N.V.	Positive Opinion	Unlimited validity
Mircera (Methoxy Polyethylene Glycol-Epoetin Beta), Roche Registration Ltd.	Positive Opinion	Unlimited validity
Soliris (Eculizumab), Alexion Europe SAS	Positive Opinion	Unlimited validity
Tamiflu (Oseltamivir), Roche Registration Ltd.	Positive Opinion	Unlimited validity

Table 4. Accelerated Assessment Procedures

Substance (Chemical/Biological)	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Chemical	treatment of cystinosis		X
Chemical	treatment of gastrointestinal stromal tumour		X