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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 22-25 July 2013

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
ATryn (Antithrombin alfa), Biotherapeutics UK Limited	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Elaprase (Idursulfase), Shire Human Genetic Therapies AB	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Vyndaqel (Tafamidis), Pfizer 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
N/A		

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Intanza (Influenza vaccine (split virion, inactivated), Sanofi Pasteur MSD)	Positive Opinion	Unlimited validity
IDflu (Influenza vaccine (split	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
virion, inactivated), Sanofi Pasteur		
Prezista (Darunavir), Janssen-Cilag International N.V.	Positive Opinion	Unlimited validity
RoActemra (Tocilizumab), Roche Registration Ltd	Positive Opinion	Unlimited validity
Stelara (Ustekinumab), Janssen-Cilag International N.V.	Positive Opinion	Unlimited validity

Table 4. Accelerated Assessment Procedures

Substance (Chemical/Biological)	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Biological	Treatment of multicentric Castleman's disease	X	
Chemical	Treatment of autosomal dominant polycystic kidney disease		X