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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 18-21 June 2012

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Vedrop (Tocofersolan D-Alpha Tocopheryl Polyethylene Glycol Succinate), Orphan Europe S.A.R.L.	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
Flebogamma DIF (Human Normal Immunoglobulin (Ivigg)), Instituto Grifols S.A.	Positive Opinion	Recommending additional renewal
Ecalta (Anidulafungin), Pfizer Ltd	Positive Opinion	Recommending additional renewal
Gliolan (5-Aminolevulinic Acid Hydrochloride), medac Gesellschaft für klinische Spezialpräparate mbH	Positive Opinion	Unlimited validity



Table 4. Accelerated Assessment Procedures

Substance (Chemical/Biological)	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Chemical	prostate cancer		X
Biological	vaccination against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and invasive diseases caused by Haemophilus influenzae type b		X