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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 17-20 September 2012

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Atriance (Nelarabine), Glaxo Group Ltd.	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Naglazyme (Galsulfase), BioMarin Europe 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
Diacomit (Stiripentol), Biocodex,	Positive Opinion	Marketing Authorisation remains under conditional approval

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Mycophenolate mofetil Teva (Mycophenolate Mofetil), Teva Pharma B.V.	Positive Opinion	Unlimited validity
Myfenax (Mycophenolate Mofetil), Teva Pharma B.V.	Positive Opinion	Unlimited validity
Olanzapine Teva (Olanzapine), Teva Pharma B.V.	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Retacrit (Epoetin Zeta), Hospira UK Ltd.	Positive Opinion	Unlimited validity

Table 4. Accelerated Assessment Procedures

Substance (Chemical/Biological)	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Biological	Breast cancer		X