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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 April 2013

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	Positive Opinion	Marketing Authorisation remains under conditional approval
Intelece (Etravirine), Janssen-Cilag International N.V.	Positive Opinion	Marketing Authorisation remains under conditional approval
Votubia (Everolimus), Novartis Europharm 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
Bridion (Sugammadex), N.V. Organon	Positive Opinion	Unlimited validity

Table 4. Accelerated Assessment Procedures

Substance (Chemical/Biological)	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Biological	chronic lymphocytic leukaemia		X