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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 March 2013

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Xagrid (anagrelide), Shire Pharmaceutical Contracts Ltd.	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Yondelis (trabectedin), Pharma Mar, S.A.	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
Votrient (pazopanib), Glaxo Group Ltd.	Positive Opinion	Marketing Authorisation conditional approval lifted

¹ The document has been revised to correct information on opinion for renewal of conditional Marketing Authorisation for **Votrient (pazopanib)**, contained in Table 2.



Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Adcirca (tadalafil), Eli Lilly Nederland B.V.	Positive Opinion	Unlimited validity
Xarelto (rivaroxaban), Bayer Pharma AG	Positive Opinion	Recommending additional Renewal
Olanzapine Mylan (olanzapine), Generics (UK) Limited	Positive Opinion	Unlimited validity
Relistor (methylnaltrexone bromide), TMC Pharma Services Ltd	Positive Opinion	Unlimited validity

Table 4. Accelerated Assessment Procedures

Substance (Chemical/Biological)	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Chemical	Treatment of hepatitis C	X	