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Press Office

Opinions on annual reassessments, 5-year renewals

Adopted at the CHMP meeting of 12-15 December 2011

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Atryn (antithrombin alfa), GTC Biotherapeutics UK Limited	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Replagal (agalsidase alfa), Shire Human Genetic Therapies AB	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Velcade (bortezomib), Janssen-Cilag International N.V.	Positive Opinion	No remaining grounds for the Marketing Authorisation to remain under exceptional circumstances

Table 2. Opinion for renewals of conditional Marketing Authorisation

Name of medicinal product (INN) MAH	Outcome	Comments
Vectibix (panitumumab), Amgen Europe B.V.	Positive Opinion	Marketing Authorisation remains under conditional approval

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Docetaxel Winthrop (docetaxel), Aventis Pharma S.A.	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Vfend (voriconazole), Pfizer Ltd.	Positive Opinion	Unlimited validity

Table 4. Accelerated Assessment Procedures

Substance (Chemical/Biological)	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
N/A			