



23 October 2012
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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 15-18 October 2012

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
N/A		

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Pradaxa (dabigatran etexilate), Boehringer Ingelheim International GmbH	Positive Opinion	Recommending additional renewal
Thalidomide Celgene (thalidomide), Celgene Europe Ltd.	Positive Opinion	Recommending additional renewal
Mycamine (micafungin), Astellas Pharma Europe B.V.	Positive Opinion	Recommending additional renewal
Abraxane (paclitaxel), Celgene Europe Ltd.	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Adenuric (febuxostat), Menarini International Operations Luxembourg S.A.	Positive Opinion	Unlimited validity
Avamys (fluticasone furoate), Glaxo Group Ltd.	Positive Opinion	Unlimited validity
Clopidogrel Zentiva (clopidogrel), Sanofi-Aventis	Positive Opinion	Unlimited validity
Extavia (interferon beta-1b), Novartis Europharm Ltd.	Positive Opinion	Unlimited validity
Viramune (nevirapine), Boehringer Ingelheim International GmbH	Positive Opinion	Unlimited validity

Table 4. Accelerated Assessment Procedures

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