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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 24-27 June 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
Adcetris (BRENTUXIMAB VEDOTIN), Takeda Global Research and Development Centre (Europe)	Positive Opinion	Marketing Authorisation remains under conditional approval
XALKORI (CRIZOTINIB), Pfizer Limited	Positive Opinion	Marketing Authorisation remains under conditional approval

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Azarga (BRINZOLAMIDE, TIMOLOL), Alcon Laboratories (UK) Ltd	Positive Opinion	Unlimited validity
I firmasta (IRBESARTAN), Krka d.d. Novo mesto	Positive Opinion	Unlimited validity
Pramipexole Teva	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
(PRAMIPEXOLE), Teva Pharma B.V.		
Zypadhera (OLANZAPINE), Eli Lilly Nederland B.V.	Positive Opinion	Unlimited validity
Ceplene (HISTAMINE DIHYDROCHLORIDE), Meda AB	Positive Opinion	Recommending additional Renewal, Marketing Authorisation remains under exceptional circumstances

Table 4. Accelerated Assessment Procedures

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