



18 December 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 10-13 December 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
Arzerra (Ofatumumab), Glaxo Group Ltd.	Positive Opinion	Marketing Authorisation remains under conditional approval
Caprelsa (Vandetanib), AstraZeneca AB	Positive Opinion	Marketing Authorisation remains under conditional approval

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Effentora (Fentanyl), Cephalon Europe	Positive Opinion	Unlimited validity
Forsteo (Teriparatide), Eli Lilly Nederland B.V.	Positive Opinion	Unlimited validity



Table 4. Accelerated Assessment Procedures

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