



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

23 November 2011  
EMA/CHMP/877157/2011  
Press Office

## Opinions on annual reassessments, 5-year renewals

Adopted at the CHMP meeting of 14-17 November 2011

**Table 1.** Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
<b>ILARIS</b> (canakinumab), Novartis Europharm Ltd.	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
<b>Arzerra</b> (ofatumumab), Glaxo Group Ltd.	Positive Opinion	Marketing Authorisation remains under conditional approval
<b>Diacomit</b> (stiripentol), Biocodex	Positive Opinion	Marketing Authorisation remains under conditional approval

**Table 3.** Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
<b>Cystadane</b> (betaine anhydrous), Orphan Europe S.A.R.L.	Positive Opinion	Recommending additional renewal
<b>Dynastat</b> (parecoxib), Pfizer Ltd.	Positive Opinion	Unlimited validity
<b>Inovelon</b> (rufinamide), Eisai Ltd.	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
<b>Januvia</b> (sitagliptin), Merck Sharp & Dohme Ltd.	Positive Opinion	Unlimited validity
<b>Xelevia</b> (sitagliptin), Merck Sharp & Dohme Ltd.	Positive Opinion	Unlimited validity

**Table 4.** Accelerated Assessment Procedures

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