18 December 2014
EMA/129897/2014
Press Office

Opinions on annual re-assessments, renewals of marketing authorisations and accelerated assessment procedures

Adopted at the CHMP meeting of 15-18 December 2014

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Ilaris (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
Arzerra (ofatumumab) Glaxo Group Ltd	Positive Opinion	Recommending renewal of conditional Marketing Authorisation
Bosulif (bosutinib) Pfizer Limited	Positive Opinion	Recommending renewal of conditional Marketing Authorisation

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Lantus (insulin glargine) Sanofi-aventis Deutschland GmbH	Positive Opinion	Unlimited validity
Olanzapine Apotex (olanzapine) Apotex Europe BV	Positive Opinion	Unlimited validity
Optisulin (insulin glargine) Sanofi-aventis Deutschland GmbH	Positive Opinion	Unlimited validity

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Name of medicinal product (INN) MAH	Outcome	Comments
Ribavirin Mylan (ribavirin) Generics (UK) Limited	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	**Rejected**
carfilzomib	indicated for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies that included bortezomib (a proteasome inhibitor) and an immunomodulatory agent, or for whom such treatments are not appropriate	X	