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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 20-23 October 2014

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Atriance (nelarabine) Glaxo Group Ltd	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Evoltra (clofarabine) Genzyme Europe BV	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
Caprelsa (vandetanib) AstraZeneca AB	Positive Opinion	Recommending renewal of conditional Marketing Authorisation

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Menveo (meningococcal group a, c, w135 and y conjugate vaccine) Novartis Vaccines and Diagnostics S.r.l.	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Ristaben (sitagliptin) Merck Sharp & Dohme Limited	Positive Opinion	Unlimited validity
Ristfor (sitagliptin / metformin hydrochloride) Merck Sharp & Dohme Limited	Positive Opinion	Unlimited validity
Telmisartan Teva (telmisartan) Teva Pharma B.V.	Positive Opinion	Unlimited validity
Temozolomide Hospira (temozolomide) HOSPIRA UK LIMITED	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Lumacaftor\Ivacaftor	treatment of Cystic Fibrosis in patients aged 12 years and older who are homozygous for the <i>F508del</i> mutation in the CFTR gene	x	