



22 May 2014
EMA/124023/2014
Press Office

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

Adopted at the CHMP meeting of 19-22 May 2014

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Vyndaqel (tafamidis) Pfizer Limited	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Xagrid (anagrelide) Shire Pharmaceutical Contracts Ltd.	Positive Opinion	Unlimited validity Marketing Authorisation remains under exceptional circumstances

Table 2. Opinion for renewals of conditional Marketing Authorisation

Name of medicinal product (INN) MAH	Outcome	Comments
Votubia (everolimus) Novartis Europharm Ltd	Positive Opinion	Recommending renewal of conditional Marketing Authorisation

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Adjupanrix (pandemic influenza vaccine (h5n1) (split virion, inactivated, adjuvanted)) GlaxoSmithKline Biologicals	Positive Opinion	Recommending additional renewal



Name of medicinal product (INN) MAH	Outcome	Comments
Tasmar (tolcapone) Meda AB	Positive Opinion	Unlimited validity
Docetaxel TEVA (docetaxel) Teva Pharma B.V.	Positive Opinion	Unlimited validity
Irbesartan Teva (irbesartan) Teva Pharma B.V.	Positive Opinion	Unlimited validity
Onglyza (saxagliptin) Bristol-Myers Squibb/AstraZeneca EEIG	Positive Opinion	Unlimited validity
Rivastigmine 1A Pharma (rivastigmine) 1 A Pharma GmbH	Positive Opinion	Unlimited validity
Rivastigmine Hexal (rivastigmine) Hexal AG	Positive Opinion	Unlimited validity
Rivastigmine Sandoz (rivastigmine) Sandoz Pharmaceuticals GmbH	Positive Opinion	Unlimited validity
Temomedac (temozolomide) medac Gesellschaft fuer klinische Spezialpraeparate mbH	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Tasieteon	non-24-Hour Disorder (Non-24) in the totally blind		x