



25 September 2014
EMA/CHMP/129674/2014
Press Office

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

Adopted at the CHMP meeting of 22-25 September 2014

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Aldurazyme (Iaronidase) 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
No product this month		

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Avastin (bevacizumab) Roche Registration Ltd	Positive Opinion	Unlimited validity
DuoCover (clopidogrel / acetylsalicylic acid) Sanofi-Aventis Groupe	Positive Opinion	Unlimited validity
DuoPlavin (clopidogrel / acetylsalicylic acid) Sanofi Clir SNC	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Fendrix (hepatitis b (rdna) vaccine (adjuvanted, adsorbed)) GlaxoSmithKline Biologicals	Positive Opinion	Unlimited validity
Firdapse (amifampridine) BioMarin Europe Ltd	Positive Opinion	Recommending additional renewal
Kivexa (lamivudine / abacavir) ViiV Healthcare UK Limited	Positive Opinion	Unlimited validity
Leflunomide Winthrop (leflunomide) Sanofi-aventis Deutschland GmbH	Positive Opinion	Unlimited validity
Renagel (sevelamer) Genzyme Europe BV	Positive Opinion	Unlimited validity
Temozolomide Hexal (temozolomide) Hexal AG	Positive Opinion	Unlimited validity
Temozolomide Sandoz (temozolomide) Sandoz Pharmaceuticals GmbH	Positive Opinion	Unlimited validity
Tepadina (thiotepa) ADIENNE S.r.l. S.U.	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
No product this month			