



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 May 2015
EMA/28010/2015
Press office

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

Adopted at the CHMP meeting of 18-21 May 2015

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Replagal , (agalsidase alfa) Shire Human Genetic Therapies AB	Positive Opinion	Marketing Authorisation exceptional approval lifted

Table 2. Opinion for renewals of conditional Marketing Authorisation

Name of medicinal product (INN) MAH	Outcome	Comments
Translarna , (ataluren) PTC Therapeutics International Limited	Positive Opinion	Recommending renewal of conditional Marketing Authorisation
Votubia , (everolimus) Novartis Europharm Ltd	Positive Opinion	Recommending renewal of conditional Marketing Authorisation
Xalkori , (crizotinib) 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
Brinavess , (vernakalant) Cardiome UK Limited	Positive Opinion	Recommending additional renewal
Aflunov , (prepandemic influenza vaccine (h5n1) (surface antigen, inactivated, adjuvanted)) Novartis Vaccines and Diagnostics S.r.l.	Positive Opinion	Unlimited validity
Brilique , (ticagrelor) AstraZeneca AB	Positive Opinion	Unlimited validity
PecFent , (fentanyl) Archimedes Development Limited	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
AZD9291	treatment for patients with progressing advanced/metastatic EGFR T790M mutation-positive non-small cell lung cancer (NSCLC) who have received prior EGFR TKI therapy	X	
Migalastat Hydrochloride	indicated for long-term treatment of adult (18 to 74 years) and adolescent (16 to 18 years) patients with a confirmed diagnosis of Fabry disease (α -galactosidase-A deficiency) and who have an amenable genotype base as defined in: Amicus@look-upable.com	X	