



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 April 2014 Revision 1
EMA/54974/2014
Press Office

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

Adopted at the CHMP meeting of 17-20 February 2014

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Glybera (alipogene tiparvovec), uniQure biopharma B.V.	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
Pixuvri (pixantrone dimaleate) CTI Life Sciences 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
Instanyl (fentanyl) Takeda Pharma A/S	Positive Opinion	Recommending additional renewal
Victoza (liraglutide) Novo Nordisk A/S	Positive Opinion	Unlimited validity
Grepid (clopidogrel) Pharmathen S.A.	Positive Opinion	Unlimited validity
Iressa (gefitinib) AstraZeneca AB	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Mozobil (plerixafor) Genzyme Europe BV	Positive Opinion	Unlimited validity
Qutenza (capsaicin) Astellas Pharma Europe B.V.	Positive Opinion	Recommending additional renewal
Stocrin (efavirenz) Merck Sharp & Dohme Limited	Positive Opinion	Unlimited validity
Sustiva (efavirenz) Bristol-Myers Squibb Pharma EEIG	Positive Opinion	Unlimited validity
Vedrop (tocofersolan) Europe S.A.R.L.	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

Substance (Chemical/Biological)	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Chemical	Treatment of Cushing's syndrome	x	
Chemical	Treatment of chronic genotype 1 HCV infection in adults	x	