



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 January 2013
EMA/28121/2013
Press Office

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

Adopted at the CHMP meeting of 14-17 January 2013

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Aldurazyme (Laronidase), Genzyme Europe B.V.	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Firdapse (Amifampridine), BioMarin Europe Ltd.	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 Ltd.	Positive Opinion	Marketing Authorisation remains under conditional approval



Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Firazyr (Icatibant), Shire Orphan Therapies GmbH	Positive Opinion	Unlimited validity
Privigen (Human Normal Immunoglobulin (Ivig)), CSL Behring GmbH	Positive Opinion	Recommending additional renewal
Efficib (Sitagliptin / Metformin Hydrochloride), Merck Sharp & Dohme Ltd.	Positive Opinion	Unlimited validity
Janumet (Sitagliptin / Metformin Hydrochloride), Merck Sharp & Dohme Ltd.	Positive Opinion	Unlimited validity
Ranexa (Ranolazine), Menarini International Operations Luxembourg S.A.	Positive Opinion	Unlimited validity
Velmetia (Sitagliptin / Metformin Hydrochloride), Merck Sharp & Dohme Ltd.	Positive Opinion	Unlimited validity

Table 4. Accelerated Assessment Procedures

Substance (Chemical/Biological)	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Chemical	unresectable or metastatic melanoma	X	
Chemical	prostate cancer	X	