



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

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

Adopted at the CHMP meeting of 18-21 February 2013

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Increlex (Mecasermin), Ipsen Pharma	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Vedrop (Tocofersolan D-Alpha Tocopheryl Polyethylene Glycol Succinate), Orphan Europe S.A.R.L.	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
Tyverb (Lapatinib), Glaxo Group 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
Doribax (Doripenem), Janssen-Cilag International N V	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Opryme a (Pramipexole), Krka, d.d., Novo mesto	Positive Opinion	Unlimited validity

Table 4. Accelerated Assessment Procedures

Substance (Chemical/Biological)	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Chemical	Proliferating infantile hemangioma		X
Biological	Mucopolysaccharidosis type IVA (Morquio disease)	X	