



26 February 2015
EMA/27945/2015
Press Office

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

Adopted at the CHMP meeting of 23-26 February 2015

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Glybera (alipogene tiparovec), uniQure biopharma B.V.	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Increlex (mecasermin) Ipsen Pharma	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
Vyndaqel , (tafamidis) Pfizer Limited	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
Delytba (delamanid) Otsuka Novel Products GmbH	Positive Opinion	Recommending renewal of conditional Marketing Authorisation



Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Celvapan (pandemic influenza vaccine (h1n1) (whole virion, inactivated, prepared in cell culture)) Baxter AG	Positive Opinion	Unlimited validity
Daliresp (roflumilast) Takeda GmbH	Positive Opinion	Recommending additional renewal
Daxas (roflumilast) Takeda GmbH	Positive Opinion	Recommending additional renewal
Fosavance (alendronic acid / colecalciferol) Merck Sharp & Dohme Limited	Positive Opinion	Unlimited validity
Libertek (roflumilast) Takeda GmbH	Positive Opinion	Recommending additional renewal
Rapiscan (regadenoson) Rapiscan Pharma Solutions EU Ltd.	Positive Opinion	Unlimited validity
Sycrest (asenapine) N.V. Organon	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Idarucizumab	indicated in adults treated with dabigatran etexilate when rapid reversal of the anticoagulant effects of dabigatran is required: <ul style="list-style-type: none"> • life-threatening or uncontrolled bleeding • emergency surgery/procedures 	X	