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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 20-23 July 2015

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
Elaprase , (idursulfase), Shire Human Genetic Therapies AB	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
Adcetris , (brentuximab vedotin), Takeda Pharma A/S	Positive opinion	Recommending renewal of conditional Marketing Authorisation

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Ruconest , (conestat alfa), Pharming Group N.V	Positive Opinion	Unlimited validity
Esbriet , (pirfenidone), Roche Registration Limited	Positive Opinion	Unlimited validity
Iasibon , (ibandronic acid), Pharmathen S.A.	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Potactasol , (topotecan hydrochloride) Actavis GroupPTC ehf	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Eryaspase	treatment of Acute Lymphoblastic Leukaemia (with Philadelphia chromosome negative) in combination with a polychemotherapy		X
Paritaprevir / Ombitasvir / Ritonavir	treatment of chronic hepatitis C (CHC) in adults	X	
Ixazomib	indicated for the treatment of patients with multiple myeloma who have received at least one prior therapy	X	
Rociletinib	treatment of patients with mutant EGFR NSCLC who have received prior EGFR-directed therapy and have T790M-mediated resistant NSCLC	X	
Chenodeoxycholic acid	treatment of Cerebrotendinous xanthomatosis (CTX), an inborn error of primary bile acid synthesis due to sterol 27-hydroxylase (CYP27A1) deficiency	X	