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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 12-15 September 2016

Table 1. Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
No product this month		

Table 2. Opinion for renewals of conditional Marketing Authorisation

Name of medicinal product (INN) MAH	Outcome	Comments
No product this month		

Table 3. Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
Lucentis , (ranibizumab), Novartis Europharm Ltd	Positive Opinion	Unlimited validity
Desloratadine Actavis , (desloratadine), Actavis Group PTC ehf	Positive Opinion	Unlimited validity
Glidipion , (pioglitazone), Actavis Group PTC ehf	Positive Opinion	Unlimited validity
Pioglitazone Actavis , (pioglitazone), Actavis Group PTC ehf	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
Ameluz , (5-aminolevulinic acid), Biofrontera Bioscience GmbH	Positive Opinion	Unlimited validity
Signifor , (pasireotide), Novartis Europharm Ltd	Positive Opinion	Unlimited validity
Esmya , (ulipristal acetate), Gedeon Richter Plc	Positive Opinion	Unlimited validity
Levetiracetam SUN , (levetiracetam), Sun Pharmaceutical Industries Europe B.V.	Positive Opinion	Unlimited validity
Signifor , (pasireotide), Novartis Europharm Ltd	Positive Opinion	Unlimited validity
Sutent , (sunitinib), Pfizer Limited	Positive Opinion	Unlimited validity
Xaluprine , (mercaptapurine), NOVA LABORATORIES LIMITED	Positive Opinion	Unlimited validity
Edarbi , (azilsartan medoxomil), Takeda Pharma A/S	Positive Opinion	Unlimited validity
Cystadane , (betaine anhydrous), Orphan Europe S.A.R.L.	Positive Opinion	Unlimited validity

Table 4. Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Ribociclib	Treatment of breast cancer		X
Nusinersen	Treatment of Spinal Muscular Atrophy (SMA)	X	
Naloxone HCl Dihydrate	Emergency use for the complete or partial reversal of respiratory depression induced by natural or synthetic opioids		X