



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 22-25 February 2016

**Table 1.** Opinions for annual re-assessment applications

Name of medicinal product (INN) MAH	Outcome	Comments
<b>Increlex</b> , (mecasermin), Ipsen Pharma	Positive Opinion	Marketing Authorisation remains under exceptional circumstances
<b>Vyndaqel</b> , (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
No product this month		

**Table 3.** Opinion for 5-Year Renewal applications

Name of medicinal product (INN) MAH	Outcome	Comments
<b>Zoely</b> , (norgestrel / estradiol), Teva B.V.	Positive Opinion	Recommending additional renewal
<b>Competact</b> , (pioglitazone / metformin), Takeda Pharma A/S	Positive Opinion	Unlimited validity
<b>Entacapone Orion</b> , (entacapone), Orion Corporation	Positive Opinion	Unlimited validity



Name of medicinal product (INN) MAH	Outcome	Comments
<b>EXJADE</b> , (deferasirox), Novartis Europharm Ltd	Positive Opinion	Unlimited validity
<b>Ibandronic acid Sandoz</b> , (ibandronic acid), Sandoz GmbH	Positive Opinion	Unlimited validity
<b>Levetiracetam ratiopharm</b> , (levetiracetam), ratiopharm GmbH	Positive Opinion	Unlimited validity
<b>Temozolomide SUN</b> , (temozolomide), Sun Pharmaceutical Industries Europe B.V.	Positive Opinion	Unlimited validity
<b>Tysabri</b> , (natalizumab), Biogen Idec Ltd	Positive Opinion	Unlimited validity
<b>Yervoy</b> , (ipilimumab), Bristol- Myers Squibb Pharma EEIG	Positive Opinion	Unlimited validity

**Table 4.** Accelerated assessment procedures

INN	Intended indication(s)	Accelerated Assessment Request	
		Accepted	Rejected
Ancillary human blood derivative incorporated in a medical device: human fibrinogen and human thrombin	indicated for cancellous bone bleeding to promote haemostasis when control of bleeding by standard surgical methods of haemostasis (e.g. suture, ligature and cautery) is ineffective or impractical		X