



15 November 2018
EMA/CHMP/SAWP/800757/2018
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 12 – 15 November 2018

Pre-authorisation: scientific advice and protocol assistance EMA centralised procedures

	1995 - 2017	2018	Overall total
Scientific Advice	3550	289	3839
Follow-up to Scientific Advice	1052	89	1141
Protocol Assistance	830	93	923
Follow-up to Protocol Assistance	413	60	473
EMA/EUnetHTA parallel consultation advice	115	24	139
Qualification of novel methodologies	110	16	126
	6070	570	6641

Outcome of the November 2018 CHMP meeting in relation to scientific advice procedures

Final scientific advice procedures

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of chronic heart failure symptoms	x						x	
Chemical	Treatment of nonalcoholic steatohepatitis with fibrosis	x						x	
Advanced Therapy	Treatment of cerebral adrenoleukodystrophy				x	x			
Chemical	Treatment of myelodysplastic syndromes and acute	x				x			



Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
	myelogenous leukemia								
Biological	Treatment of ulcerative colitis			x				x	
Chemical	Treatment of autism spectrum disorder			x				x	
Biological	Treatment of non small cell lung cancer	x					x	x	
Chemical	Treatment of progressive familial intrahepatic cholestasis		x					x	
Biological	Treatment of non-small cell lung cancer	x						x	
Biological	Treatment of cervical cancer	x						x	
Biological	Treatment of non-small cell lung cancer	x						x	
Advanced Therapy	Treatment of sickle cell disease		x				x	x	
Biological	Treatment of paroxysmal nocturnal hemoglobinuria and atypical haemolytic uremic syndrome			x		x		x	
Advanced Therapy	Treatment of immunodeficiency after transplantation				x			x	
Chemical	Treatment of neurotrophic keratitis				x	x	x	x	
Biological	Treatment for Mild Cognitive Impairment due to Alzheimer's disease			x			x	x	
Chemical	Treatment of influenza A/B			x		x			
Chemical	Treatment of vulvovaginal candidiasis	x						x	
Chemical	Prevention of vulvovaginal candidiasis	x					x	x	
Biological	Treatment of multiple myeloma				x	x	x		
Chemical	Treatment of chronic hepatitis B infection			x				x	
Biological	Treatment of ventilator-associated pneumonia due to Staphylococcus aureus				x			x	
Chemical	Treatment of seizures	x					x	x	
Chemical	Treatment of long-chain fatty acid oxidation disorders		x					x	
Biological	Treatment of plaque psoriasis			x					
Chemical	Treatment of vitiligo	x					x		

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of Faecal incontinence		x				x	x	
Biological	Treatment of X-linked hypohidrotic ectodermal dysplasia (Christ-Siemens-Touraine Syndrome)		x			x	x	x	
Biological	Treatment of Staphylococcus aureus bloodstream infections	x						x	
Chemical	Treatment of Alzheimer's disease	x						x	
Biological	Treatment of melanoma	x				x	x	x	
Chemical	Treatment of thymidine kinase deficiency		x			x	x	x	
Chemical/Biological	Treatment of endometrial carcinoma	x						x	
Chemical/Biological	Treatment of Staphylococcus aureus bloodstream infections	x					x	x	
Chemical	Bowel cleansing prior to clinical procedures	x						x	
Chemical	Treatment of endophthalmitis	x				x	x	x	
Biological	Treatment of pancreatic exocrine insufficiency	x				x	x	x	
Biological	Treatment of plaque psoriasis	x				x	x	x	
Chemical	Treatment of Basal Cell Carcinoma		x				x	x	
Chemical	Treatment of chronic hepatitis C	x				x			
Chemical	Treatment of breast cancer	x						x	
Chemical	Treatment of melanoma	x						x	
Biological	Treatment of neovascular (wet) age-related macular degeneration; visual impairment due to diabetic macular oedema , choroidal neovascularisation and macular oedema secondary to retinal vein occlusion	x				x		x	
Biological	Treatment of focal segmental glomerulosclerosis	x					x	x	
Chemical	Treatment of C3 glomerulopathy	x					x	x	
Chemical	Treatment of IgA nephropathy	x						x	
Chemical	Treatment of type 2 diabetes mellitus	x				x		x	
Biological	Treatment of plaque psoriasis	x				x	x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of non-valvular atrial fibrillation, deep vein thrombosis and pulmonary embolism	x						x	
Biological	Treatment of Graves' disease	x				x	x	x	
Biological	Treatment of T-cell lymphoma	x						x	
Biological	Treatment of hepatic veno-occlusive disease	x				x	x	x	
Biological	Treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy	x							

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 33 Scientific Advice letters, 6 Protocol Assistance letters, 7 Follow-up Scientific Advice, 5 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 1 EMA/EUnetHTA parallel consultation advices, were adopted at the 12 – 15 November 2018 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 52 new Requests for which the procedure started at the SAWP meeting held on 29 – 31 October 2018. The new requests are divided as follows: 32 Initial Scientific Advice, 8 Follow-up Scientific Advice, 8 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 0 Qualification of novel methodologies and 2 EMA/EUnetHTA parallel consultation advice.