



26 April 2018
EMA/CHMP/SAWP/262775/2018
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 23 – 26 April 2018

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

	1995 - 2017	2018	Overall total
Scientific Advice	3550	90	3640
Follow-up to Scientific Advice	1052	32	1084
Protocol Assistance	830	36	866
Follow-up to Protocol Assistance	413	26	439
EMA/EU netHTA parallel consultation advice	115	6	121
Qualification of novel methodologies	110	10	120
	6070	199	6269

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

Final scientific advice procedures

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of neovascular age-related macular degeneration, diabetic macular oedema, visual impairment due to choroidal neovascularisation secondary to pathologic myopia, visual impairment due to macular oedema secondary to retinal vein occlusion	x				x	x	x	



Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Treatment of amyotrophic lateral sclerosis		x				x	x	
Chemical	Treatment of plaque psoriasis	x					x	x	
Chemical	Treatment of schizophrenia	x						x	
Biological	Prevention of vaso-occlusive crises in sickle cell disease		x					x	
Chemical	Treatment of epileptic encephalopathies	x					x	x	
Chemical	Rapid conversion of paroxysmal supraventricular tachycardia episodes to sinus rhythm	x				x	x	x	
Biological	Treatment of diabetes mellitus	x				x	x	x	
Chemical	Treatment of glomerular sickle cell nephropathy			x				x	
Chemical	Treatment of melanoma	x				x	x	x	
Chemical	Treatment of polycythemia vera			x			x		
Biological	Treatment of Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis			x				x	
Chemical	Treatment of hypotension			x				x	
Chemical	Treatment of schizophrenia	x				x	x	x	
Chemical	Treatment of type 2 diabetes mellitus			x				x	
Advanced therapy	Treatment of recurrent male urethral strictures			x				x	
Chemical	Treatment of complicated urinary tract infections			x				x	
Chemical	Therapy for opioid overdose	x						x	
Biological	Removal of eschar in deep burns		x					x	
Biological	Treatment of non-muscle invasive bladder cancer			x				x	
Chemical	Treatment of distal renal tubulopathy acidosis				x	x			
Biological	Treatment and prophylaxis of bleeding in haemophilia A	x					x	x	
Biological	Cardiovascular risk reduction within weight management	x						x	
Biological	Treatment of tuberous sclerosis		x			x	x	x	
Chemical	Treatment of complicated urinary tract infections			x				x	
Chemical	Treatment of cholangiocarcinoma	x						x	
Chemical	Treatment of paroxysmal movement disorders		x			x	x	x	
Chemical	Treatment of transfusion dependent-thalassemia	x				x	x	x	
Advanced therapy	Treatment of Wilson's disease				x	x	x	x	
Biological	Treatment of IgG4-related disease		x			x	x	x	

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of AL amyloidosis	x					x	x	
Advanced therapy	Treatment of relapsed or refractory multiple myeloma				x	x			
Advanced therapy	Treatment of aromatic L-amino acid decarboxylase deficiency		x				x	x	
Chemical	Treatment of acute sensorineural hearing loss				x			x	
Chemical	Treatment of chronic myelogenous leukaemia and acute lymphoblastic leukaemia	x						x	
Biological	Treatment of muscle invasive bladder cancer	x						x	
Advanced therapy	Treatment of Fabry disease	x					x	x	
Chemical/ Other innovative	Treatment of severe hypoglycaemia in diabetes			x		x	x	x	
Chemical	Treatment of vanishing white matter	x					x	x	
Biological	Treatment of ulcerative colitis	x					x	x	
Chemical	Treatment of human immunodeficiency virus infection	x				x			
Chemical	Treatment of Alzheimer's disease	x				x			
Biological	Prevention of infectious events and severe diarrhea	x				x		x	
Chemical	Treatment of Cushing's syndrome		x			x			
Biological	Prevention of RSV-associated lower respiratory tract disease	x					x	x	
Chemical	Prevention of acute kidney injury	x						x	
Chemical/ Other innovative	Measurement of Glomerular Filtration Rate	x				x	x	x	
Chemical	Treatment of pruritus	x				x	x		
Chemical	Treatment of immunoglobulin A nephropathy	x						x	
Biological	Treatment of severe asthma			x				x	
Chemical	Treatment of chronic lymphocytic leukaemia			x				x	
EUnetHTA parallel	Treatment of soft tissue sarcoma				x			x	

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
EUnetHTA parallel	Treatment of severe eosinophilic asthma	x				x	x	x	
Qualification opinion	Chronic obstructive pulmonary disease	x						x	
Qualification advice	Parkinson's disease	x						x	
Qualification opinion	Neuromuscular disorders	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 27 Scientific Advice letters, 8 Protocol Assistance letters, 11 Follow-up Scientific Advice, 5 Follow-up Protocol Assistance, 3 Qualifications of novel methodologies and 2 EMA/EUnetHTA parallel consultation advices, were adopted at the 23 – 26 April 2018 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 57 new Requests for which the procedure started at the SAWP meeting held on 9 – 12 April 2018. The new requests are divided as follows: 23 Initial Scientific Advice, 15 Follow-up Scientific Advice, 13 Initial Protocol Assistance, 4 Follow-up Protocol Assistance, 0 Qualification of novel methodologies and 2 EMA/EUnetHTA parallel consultation advices.