



22 March 2018
EMA/CHMP/SAWP/195437/2018
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 19 – 22 March 2018

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

	1995 - 2017	2018	Overall total
Scientific Advice	3550	63	3613
Follow-up to Scientific Advice	1052	21	1073
Protocol Assistance	830	28	858
Follow-up to Protocol Assistance	413	21	434
EMA/EU netHTA parallel consultation advice	115	4	119
Qualification of novel methodologies	110	6	116
	6070	143	6213

Outcome of the March 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				
Chemical	Treatment of eosinophilic esophagitis		x			x	x	x	x
Chemical/ Other innovative	Treatment of phosphomannomutase 2 congenital disorder of glycosylation.	x				x	x	x	
Chemical	Treatment of familial adenomatous polyposis.				x				



Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharma ceutical	Pre- clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Treatment of gastrointestinal stromal tumours.		x				x	x	x
Biological	Treatment of epithelial ovarian, fallopian tube or primary peritoneal cancer.	x						x	
Chemical/ Biological	Treatment of epithelial ovarian, fallopian tube or primary peritoneal cancer.	x						x	
Chemical/ Biological	Treatment of breast cancer.	x						x	
Biological	Treatment of gastric cancer.	x					x	x	
Advanced Therapy	Treatment of diffuse large B-cell lymphoma.		x			x		x	
Chemical	Treatment of ovarian cancer.		x					x	
Biological	Treatment of Neuromyelitis Optica Spectrum disorders.				x			x	
Chemical	Treatment of diffuse intrinsic pontine glioma.	x				x	x	x	
Chemical	Treatment of pulmonary arterial hypertension.		x			x	x	x	x
Chemical	Treatment of atopic dermatitis.	x						x	
Advanced Therapy	Treatment of pancreatic cancer.		x				x		
Biological	Prevention of intestinal acute graft-versus-host disease.	x						x	
Chemical	Treatment of non-small cell lung cancer.			x				x	
Biological	Prophylaxis to prevent bleeding episodes in haemophilia A or B.	x				x	x	x	
Biological	Prophylaxis of venous thromboembolism, treatment of deep vein thrombosis, treatment of acute ST-segment elevation myocardial infarction, treatment of unstable angina and myocardial infarction.	x				x		x	
Chemical	Replacement of iron.			x		x	x	x	
Chemical	Treatment of acute hepatic porphyria.				x		x	x	x
Chemical	Treatment of acute hepatic porphyria.		x			x			
Biological	Treatment of anaemia due to MDS				x			x	
Biological	Treatment of acute ischaemic stroke.	x					x	x	
Biological	Radiocephalic arteriovenous fistula increase for haemodialysis.		x				x	x	
Chemical	Treatment of pruritus associated with atopic dermatitis.	x				x	x	x	

Substance	Intended indication(s)	Type of request				Topic			Significant Benefit
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	
		SA	PA	SA	PA				
Chemical	Treatment of advanced neuroendocrine tumours of the midgut, treatment of TSH-secreting pituitary adenoma, treatment of acromegaly.	x				x		x	
Biological	Treatment of growth hormone deficiency.	x				x			
EUnetHTA parallel	Treatment of epithelioid sarcoma.	x					x	x	
EUnetHTA parallel	Treatment of multiple sclerosis.	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 21 Scientific Advice letters, 11 Protocol Assistance letters, 7 Follow-up Scientific Advice, 8 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 2 EMA/EUnetHTA parallel consultation advices, were adopted at the 19 – 22 March 2018 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 59 new Requests for which the procedure started at the SAWP meeting held on 5 – 8 March 2018. The new requests are divided as follows: 32 Initial Scientific Advice, 8 Follow-up Scientific Advice, 8 Initial Protocol Assistance, 7 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 3 EMA/EUnetHTA parallel consultation advices.