



28 June 2018
EMA/CHMP/SAWP/447681/2018
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 25 – 28 June 2018

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

	1995 - 2017	2018	Overall total
Scientific Advice	3550	152	3702
Follow-up to Scientific Advice	1052	57	1109
Protocol Assistance	830	61	891
Follow-up to Protocol Assistance	413	39	452
EMA/EUnetHTA parallel consultation advice	115	11	126
Qualification of novel methodologies	110	13	123
	6070	333	6403

Outcome of the June 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 progressive forms of multiple sclerosis	x						x	
Chemical	Treatment of systemic sclerosis				x				
Biological	Treatment of myelodysplastic syndromes		x				x	x	
Chemical	Prevention of severe oral mucositis		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 Crohn's disease			x				x	
Chemical	Treatment of calciphylaxis		x				x	x	
Biological	Treatment of cervical cancer	x						x	
Chemical/ Other innovative	Treatment of metastatic adenocarcinoma of the pancreas		x					x	
Chemical	Treatment of Autism Spectrum Disorder	x				x			
Chemical	Treatment of Fabry Disease				x		x		
Biological	Treatment of eosinophilic esophagitis	x						x	
Biological	Treatment of Alzheimer's disease	x				x			
Chemical	Treatment of necrotizing soft tissue infections		x			x			
Chemical	Treatment of pruritus	x					x	x	
Chemical	Treatment of colorectal cancer			x				x	
Chemical	Treatment of chronic GVHD		x					x	x
Biological	Prevention of chronic lung disease	x					x	x	
Biological	Reduction in recurrence of Clostridium difficile infection			x		x		x	
Biological/ Advanced therapy	Treatment of immunodeficiency following allogeneic transplantation				x	x			
Biological	Treatment of mucopolysaccharidosis type IIIB		x			x			
Advanced therapy – Parallel HTA	Treatment and prophylaxis of bleeding in haemophilia B			x				x	
Chemical	Treatment of liver fibrosis			x				x	
Chemical	Treatment of Fabry disease		x				x	x	x
Chemical	Treatment of Prader-Willi-Syndrome			x				x	
Advanced therapy	Treatment of haemophilia A				x	x			
Biological	Treatment of multiple myeloma		x			x	x	x	
Biological	Treatment of gastric or gastroesophageal junction adenocarcinoma	x						x	
Biological	Treatment of urothelial carcinoma	x						x	
Chemical	Treatment of schistosomiasis			x				x	
Chemical	Treatment of gastric cancer	x					x		
Chemical	Treatment of cystic fibrosis			x				x	
Chemical	Treatment of retinitis pigmentosa		x					x	
Chemical	Treatment of chronic schizophrenia	x					x	x	
Chemical	Treatment of post-traumatic stress disorder	x				x	x	x	
Chemical	Treatment of mitochondrial diseases	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/ Other innovative	Treatment of complicated urinary tract infections		x				x	x	
Chemical	Treatment of ocular GVHD					x	x	x	
Chemical	Treatment of actinic keratosis	x					x	x	
Advanced therapy	Treatment of GM1-gangliosidosis	x				x	x	x	
Chemical	Treatment and prevention of naevoid basal cell carcinoma syndrome		x			x	x	x	
Chemical	Treatment of congenital hyperinsulinism		x				x	x	x
Biological	Treatment of Ebola virus disease	x					x	x	
Chemical	Treatment of metastatic non-small cell lung cancer	x					x	x	
Chemical – Parallel HTA	Prophylaxis of migraine	x						x	
Chemical	Treatment of rectal cancer	x					x	x	
Biological	Prophylaxis of migraine	x				x		x	
Chemical	Treatment of cystic fibrosis	x						x	
Biological	Treatment of non-small cell lung cancer	x					x	x	
Biological	Treatment of chronic lymphocytic leukaemia, follicular lymphoma, diffuse large B cell non-Hodgkin's lymphoma, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis	x				x		x	
Biological	Prevention of influenza disease	x				x	x	x	
Advanced therapy	Treatment of dystrophic epidermolysis bullosa		x			x	x	x	
Biological	Treatment of head and neck squamous cell carcinoma	x					x	x	
Chemical	Treatment of breast cancer	x					x	x	
Chemical /Biological	Treatment of head and neck squamous cell carcinoma	x				x	x	x	
Chemical	Treatment of ulcerative colitis	x					x	x	
Biological	Treatment of melanoma	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 multiple myeloma		x					x	
Biological	Treatment of advanced solid tumours	x				x	x		
Biological	Treatment of emphysema				x			x	
Biological	Treatment of hairy cell leukaemia				x	x			
Biological	Treatment of immune idiopathic thrombocytopenic purpura		x					x	
Chemical	Treatment of chronic hand eczema	x						x	
Chemical	Treatment of septic shock	x				x	x		
Biological	Immunisation against poliomyelitis			x				x	
Chemical	Treatment of generalized hypoactive sexual desire disorder			x				x	
Advanced therapy	Treatment of oculopharyngeal muscular dystrophy	x						x	
Advanced therapy	Treatment of advanced retinitis pigmentosa	x				x			

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 34 Scientific Advice letters, 16 Protocol Assistance letters, 9 Follow-up Scientific Advice, 7 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 2 EMA/EUnetHTA parallel consultation advices, were adopted at the 25 – 28 June 2018 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 60 new Requests for which the procedure started at the SAWP meeting held on 11 – 14 June 2018. The new requests are divided as follows: 30 Initial Scientific Advice, 9 Follow-up Scientific Advice, 12 Initial Protocol Assistance, 6 Follow-up Protocol Assistance, 2 Qualification of novel methodologies and 1 EMA/EUnetHTA parallel consultation advice.