



20 September 2018
EMA/CHMP/SAWP/644162/2018
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 17 – 20 September 2018

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

	1995 - 2017	2018	Overall total
Scientific Advice	3550	216	3732
Follow-up to Scientific Advice	1052	73	1118
Protocol Assistance	830	82	898
Follow-up to Protocol Assistance	413	51	458
EMA/EUnetHTA parallel consultation advice	115	18	132
Qualification of novel methodologies	110	15	124
	6070	454	6461

Outcome of the September 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 glioblastoma				X			X	X
Chemical	Treatment of chronic lymphocytic leukaemia		X				X	X	
Chemical	Treatment of asthma	X					X	X	
Chemical	Perinatal asphyxia				X			X	
Biological	Treatment of idiopathic inflammatory myopathy	X						X	



Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of chronic Graft-versus-host disease		x				x	x	
Biological	Treatment of glioblastoma		x				x	x	x
Biological	Treatment of glioblastoma		x			x			
Chemical	Reduction of the duration, incidence and severity of severe oral mucositis	x				x	x	x	
Chemical	Treatment of epidermolysis bullosa				x			x	
Advanced Therapy	Treatment of complex perianal fistula	x						x	
Chemical	Treatment of chronic myelogenous leukaemia, acute lymphoblastic leukaemia			x				x	
Biological	Treatment of osteoporosis, treatment of bone loss, prevention of skeletal related events and treatment of giant cell tumour of bone	x				x	x	x	
Biological	Treatment of hepatocellular carcinoma	x						x	
Chemical	Management of obesity	x					x	x	
Biological	Treatment of type-2 diabetes mellitus			x				x	
Biological	Treatment of type-2 diabetes mellitus			x		x			
Chemical	Treatment of acute radiation syndrome	x					x	x	
Chemical	Emergency treatment of severe allergic reactions (anaphylaxis)	x						x	
Biological	Controlled ovarian hyperstimulation and follicle maturation during in vitro fertilization	x				x	x	x	
Biological	Treatment of multiple myeloma		x					x	
Chemical	Radiolabelling	x				x			
Chemical	Treatment of verruca vulgaris	x					x	x	
Chemical	Treatment of mantle cell lymphoma, multiple myeloma and myelodysplastic syndromes	x				x			
Biological	Treatment of type 2 diabetes	x						x	
Chemical	Treatment of urinary incontinence	x					x	x	
Chemical	Treatment of moderate to severely active rheumatoid arthritis	x					x	x	
Biological	Treatment and prophylaxis of bleeding in haemophilia B	x					x	x	
Chemical	Treatment of Alström syndrome		x				x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Reduction in incidence of febrile neutropenia	x				x			
Chemical	Treatment of epilepsy	x				x	x	x	
Chemical	Treatment of invasive candidiasis	x				x	x	x	
Chemical	Prophylaxis against invasive fungal infections	x					x	x	
Chemical	Treatment of Graft versus Host Disease				x		x	x	
Chemical	Treatment of penta-refractory multiple myeloma		x			x	x		
Biological	Treatment of growth hormone deficiency	x							
Biological	Treatment of children with short stature born small for gestational age	x						x	
Biological	Treatment of severe eosinophilic asthma	x					x	x	
Chemical	Treatment of neuroblastoma	x				x	x	x	
Biological	Treatment of breast cancer	x						x	
Advanced Therapy	Treatment of high grade glioma		x					x	x
Chemical	Treatment of hereditary transthyretin-mediated amyloidosis		x				x	x	x
Advanced Therapy	Treatment of haemophilia B		x				x	x	
Chemical	Treatment of amyotrophic lateral sclerosis				x		x		
Biological	Treatment of carcinoma of the cervix	x				x		x	
Biological	Treatment of non-squamous non-small cell lung cancer	x						x	
Chemical	Treatment of Alport syndrome		x			x	x	x	
Biological	Treatment of metastatic breast cancer, metastatic carcinoma of the colon or rectum, non-small cell lung cancer, renal cell cancer, epithelial ovarian, fallopian tube and primary peritoneal cancer, cervical cancer	x				x	x	x	
Chemical	Postpartum depression			x				x	
Chemical	Broad advice			x		x			
Biological	Prevention of lower respiratory tract diseases caused by RSV	x				x	x	x	
Advanced Therapy	Treatment of Fanconi anemia type A		x			x		x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Pre-transplant treatment for eligibility to kidney transplantation		x			x	x	x	x
Chemical	Treatment of amyotrophic lateral sclerosis		x					x	
Chemical	Treatment of mild to moderate idiopathic pulmonary fibrosis	x				x	x	x	
Chemical	Treatment of distal renal tubulopathy acidosis				x	x			
Biological	Prevention of rabies			x		x		x	
Biological	Treatment of diabetic macular oedema and neovascular (wet) age-related macular degeneration			x			x		
Biological	Treatment of Duchenne Muscular Dystrophy	x					x		
Chemical	Treatment of pruritus associated with prurigo nodularis	x				x			
Chemical	Treatment of infections due to Acinetobacter baumannii-calcoaceticus complex	x						x	
Chemical	Smoking cessation	x						x	
EunetHTA parallel	Treatment of focal-onset seizures in drug-resistant epilepsy.	x				x	x	x	
Qualification advice	Treatment of Crohn's disease	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 34 Scientific Advice letters, 14 Protocol Assistance letters, 7 Follow-up Scientific Advice, 6 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 1 EMA/EUnetHTA parallel consultation advices, were adopted at the 17 – 20 September 2018 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 63 new Requests for which the procedure started at the SAWP meeting held on 3 – 6 September 2018. The new requests are divided as follows: 42 Initial Scientific Advice, 8 Follow-up Scientific Advice, 8 Initial Protocol Assistance, 3 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 1 EMA/EUnetHTA parallel consultation advice.