



26 July 2018
EMA/CHMP/SAWP/517642/2018
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 23 – 26 July 2018

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

	1995 - 2017	2018	Overall total
Scientific Advice	3550	182	3732
Follow-up to Scientific Advice	1052	66	1118
Protocol Assistance	830	68	898
Follow-up to Protocol Assistance	413	45	458
EMA/EUnetHTA parallel consultation advice	115	17	132
Qualification of novel methodologies	110	14	124
	6070	391	6461

Outcome of the July 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	Improvement of glycaemic control and reduction of major CV adverse events in type 2 diabetes mellitus.	x				x	x	x	
Chemical	Treatment of distal ulcerative colitis.	x				x			
Biological	Treatment of diffuse large B-cell lymphoma.				x	x			
Biological	Treatment of diffuse large B-cell lymphoma.				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 pyridoxamine 5'-phosphate oxidase deficiency.		x			x	x	x	
Chemical	Treatment of type 1 and type 2 diabetes mellitus.	x				x			
Biological	Treatment of systemic lupus erythematosus.	x					x	x	
Chemical	Treatment of myelodysplastic syndromes.	x				x		x	
Chemical	Treatment of active psoriatic arthritis.	x						x	
Biological	Treatment of breast cancer, non-small cell lung cancer, renal cell carcinoma and ovarian cancer.	x				x	x	x	
Biological	Treatment of breast cancer, non-small cell lung cancer, renal cell carcinoma and ovarian cancer.			x		x			
Biological	Treatment of active psoriatic arthritis.			x				x	
Biological	Treatment of non-small cell lung cancer.	x						x	
Chemical	Treatment of bronchiolitis obliterans syndrome.		x					x	x
Chemical	Treatment of primary progressive multiple sclerosis.	x						x	
Chemical	Treatment of acute myeloid leukaemia.	x					x	x	
Biological	Treatment of small cell lung cancer.	x						x	
Chemical	Treatment of non-small cell lung cancer and locally advanced or metastatic tumours.			x		x			
Advanced therapy	Treatment of relapsing high-grade glioma.		x			x	x	x	
Chemical	Treatment of cholangiocarcinoma.	x				x			
Chemical	Treatment of acute graft-vs-host disease.				x			x	
Biological	Treatment of breast cancer.	x						x	
Biological	Treatment of hepatocellular carcinoma.	x						x	
Chemical	Treatment of castration-resistant prostate cancer.	x						x	
Biological	Cross-indication dosing regimen.	x						x	
Biological	Treatment of paroxysmal nocturnal haemoglobinuria.				x	x			
Chemical	Prophylaxis of organ rejection in allogeneic heart transplants.			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 breast cancer and gastric cancer.	x				x		x	
Biological	Treatment of adenocarcinoma of the pancreas.		x					x	
Chemical	Treatment of human African trypanosomiasis due to T. b. gambiense.			x				x	
Biological	Treatment of congenital thrombotic thrombocytopenic purpura.		x			x		x	
Biological	Prophylaxis of ischemic complications in unstable angina and non-Q-wave myocardial infarction, deep vein thrombosis and treatment of venous thromboembolism.	x				x	x		
Biological	Treatment of Shiga-Toxin producing Escherichia Coli haemolytic uremic syndrome.	x				x	x	x	
Biological	Adjunct to haemostasis.	x				x			
Biological	Prophylaxis of bleeding in haemophilia A.				x			x	
Advanced therapy	Treatment of haemophilia A.	x				x	x	x	
Biological	Treatment of diffuse cutaneous systemic sclerosis.	x					x	x	
Chemical	Treatment of bacterial infections.	x				x		x	
Biological	Active immunisation against disease caused by Vibrio cholerae serogroup O1.	x						x	
Chemical	Treatment of respiratory tract disease.			x		x		x	
Biological	Prevention of foetal and neonatal alloimmune thrombocytopenia.				x	x	x	x	
Advanced therapy	Treatment of localised, full-thickness cartilage defects of the knee joint .			x		x			
Chemical	Treatment of Friedreich's ataxia.	x				x	x	x	
Biological	Treatment of mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease dementia.	x				x			
Chemical	Treatment for prevention of relapse in schizophrenia.	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 Duchenne muscular dystrophy.		x					x	
Chemical	Treatment of hallucinations and delusions associated with dementia-related psychosis.	x						x	
Chemical	Treatment of Huntington's disease.	x					x	x	
Biological	Treatment of choroidal neovascularization.			x				x	
Chemical	Treatment of Stargardt disease.	x				x	x	x	
Chemical	Treatment of gastroenteropancreatic neuroendocrine tumours, carcinoid syndrome and acromegaly.			x				x	
Chemical	Treatment of MCT8 deficiency (Allan-Herndon-Dudley syndrome).		x				x	x	
EUnetHTA parallel	Treatment of Crohn's disease.	x				x		x	
EUnetHTA parallel	Treatment of metastatic castration-resistant prostate cancer with DNA damage repair deficiency.	x						x	
EUnetHTA parallel	Treatment of alopecia areata.	x					x	x	
EUnetHTA parallel	Treatment of alopecia areata.	x					x	x	
EUnetHTA parallel	Treatment of acute myeloid leukaemia.		x			x	x	x	
EUnetHTA parallel	Treatment of mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's dementia.	x						x	
Qualification advice	Treatment of mild cognitive impairment.	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 30 Scientific Advice letters, 7 Protocol Assistance letters, 9 Follow-up Scientific Advice, 6 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 6 EMA/EUnetHTA parallel consultation advices, were adopted at the 23 – 26 July 2018 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 62 new Requests for which the procedure started at the SAWP meeting held on 9 – 12 July 2018. The new requests are divided as follows: 32 Initial Scientific Advice, 9 Follow-up Scientific Advice, 8 Initial Protocol Assistance, 7 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 5 EMA/EUnetHTA parallel consultation advice.