



18 October 2018
EMA/CHMP/SAWP/742101/2018
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 15 – 18 October 2018

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

	1995 - 2017	2018	Overall total
Scientific Advice	3550	256	3806
Follow-up to Scientific Advice	1052	82	1134
Protocol Assistance	830	87	917
Follow-up to Protocol Assistance	413	55	468
EMA/EUnetHTA parallel consultation advice	115	23	138
Qualification of novel methodologies	110	16	126
	6070	518	6588

Outcome of the October 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				
Biological	Prevention of infection caused hepatitis B virus	x						x	
Biological	Treatment of dermatomyositis			x				x	
Chemical	Treatment of familial adenomatous polyposis				x			x	
Biological	Treatment of hyposecretive dry eye	x						x	



Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of diabetes mellitus			x		x			
Biological	Reduction of cardiovascular risk	x						x	
Biological	Adjuvant treatment of cutaneous squamous cell carcinoma	x						x	
Biological	Adjuvant treatment of melanoma	x						x	
Biological	Treatment of neuromyelitis optica and neuromyelitis optica spectrum disorders				x	x		x	
Chemical	Treatment of chronic hepatitis C virus infection			x				x	
Chemical	Treatment of diabetic kidney disease	x						x	
Advanced Therapy	Hematopoietic reconstitution in allogeneic hematopoietic stem cell transplantation				x	x	x		
Chemical	Treatment of non small cell lung cancer	x						x	
Chemical/Biological	Treatment of renal cell carcinoma			x				x	
Biological	Treatment of active axial spondyloarthritis			x				x	
Chemical	Prevention or reduction of frequency of bleeding episodes in haemophilia A or B				x			x	
Chemical	Treatment of invasive fungal infection due to olorofim-susceptible mould fungi	x					x	x	
Advanced Therapy	Treatment of haemophilia B	x						x	
Chemical	Treatment of vasomotor symptoms			x				x	
Biological	Treatment of neovascular (wet) age-related macular degeneration	x						x	
Chemical	Central Nervous System (CNS) MR imaging	x					x	x	
Chemical	Breast MR imaging	x						x	
Biological	Treatment of diabetes mellitus			x		x		x	
Chemical/Biological	Treatment of muscle invasive bladder cancer	x						x	
Advanced Therapy	Treatment of mucopolysaccharidosis type IIIA (Sanfilippo A syndrome)		x			x	x	x	
Biological	Treatment of hyperargininemia		x				x	x	
Biological	Prophylaxis of migraine	x					x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Advanced Therapy	Treatment of ornithine transcarbamylase deficiency		x			x	x	x	
Chemical	Treatment of acute vertigo	x						x	
Chemical	Treatment of hypertension	x				x	x	x	
Chemical	Treatment of cystic fibrosis		x			x	x	x	
Biological	Adjunct to chest tube insertion for drainage of complicated parapneumonic pleural effusions (CPE) and empyema	x						x	
Chemical/Biological	Treatment of ovarian cancer.	x						x	
Chemical	Treatment of Duchenne Muscular Dystrophy	x					x	x	
Biological	Detection of renal cell carcinoma	x						x	
Chemical	Treatment of acute myeloid leukaemia	x					x	x	
Chemical/Other innovative	Treatment of uncomplicated and complicated urinary tract infections	x					x	x	
Biological	Treatment of Hodgkin lymphoma	x					x	x	
Advanced Therapy	Treatment of ovarian, fallopian tube, and primary peritoneal carcinoma		x					x	x
Chemical	Treatment of prostate cancer	x				x	x	x	
Biological	Treatment of biliary tract cancer	x					x	x	
Chemical/Biological	Treatment of hepatocellular carcinoma	x						x	
Biological	Treatment of breast cancer	x				x		x	
Chemical	Treatment of chronic obstructive pulmonary disease	x					x	x	
Biological	Treatment of chronic kidney disease in type 2 diabetes mellitus	x						x	
Chemical	Treatment of type 2 diabetes mellitus	x				x	x	x	
Biological	Prevention of invasive disease and pneumonia caused by Streptococcus pneumonia	x				x	x	x	
Biological	Treatment of breast cancer and gastric cancer	x				x			
Biological	Prophylactic immunization against Lyme borreliosis	x				x	x	x	
Biological	Treatment of non alcoholic steatohepatitis	x					x	x	
Biological	Treatment of breast cancer and gastric cancer	x				x	x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of colorectal cancer	x						x	
Chemical	Prevention of atherothrombotic events	x				x			
Chemical	Treatment of colorectal cancer	x						x	
Chemical	Treatment of severe uncontrolled asthma and elevated eosinophil levels	x						x	
Chemical	Treatment of seizures	x						x	
Biological	Treatment of non-small cell lung cancer	x				x	x	x	
HTA parallel advice	Active immunisation for prevention of congenital CMV infection and disease	x						x	
HTA parallel advice	Detection and staging of prostate cancer	x						x	
HTA parallel advice	Prophylaxis of graft rejection	x				x	x	x	
HTA parallel advice	Chronic treatment of diabetic and idiopathic gastroparesis	x						x	
HTA parallel advice	Treatment of prostate cancer	x						x	
Qualification advice	Behavior assessment	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 40 Scientific Advice letters, 5 Protocol Assistance letters, 9 Follow-up Scientific Advice, 4 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 5 EMA/EUnetHTA parallel consultation advices, were adopted at the 15 – 28 October 2018 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 51 new Requests for which the procedure started at the SAWP meeting held on 1 – 4 October 2018. The new requests are divided as follows: 32 Initial Scientific Advice, 7 Follow-up Scientific Advice, 5 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 1 EMA/EUnetHTA parallel consultation advice.