



18 May 2017
EMA/CHMP/SAWP/321832/2017
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 15 – 18 May 2017

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

	1995 - 2016	2017	Overall total
Scientific Advice	3215	146	3361
Follow-up to Scientific Advice	938	50	988
Protocol Assistance	735	44	779
Follow-up to Protocol Assistance	355	15	370
HTA parallel advice	87	9	96
Qualification of novel methodologies	94	11	105
	5424	275	5699

Outcome of the May 2017 CHMP meeting in relation to scientific advice procedures

Final scientific advice procedures

Substance	Intended indication(s)	Type of request				Topic			Significant
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	
		SA	PA	SA	PA				
Chemical	Treatment of progressive familial intrahepatic cholestasis.		x				x	x	
Chemical	Treatment of eosinophilic oesophagitis.	x						x	
Chemical	Treatment of type 2 diabetes mellitus.			x		x			
Biological	Prevention of necrotizing enterocolitis.	x						x	
Biological	Treatment of neuroblastoma.		x			x		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 urothelial bladder cancer.	x					x	x	
Chemical	Treatment of liver fibrosis in non-alcoholic steatohepatitis.	x				x			
Biological	Treatment of hepatocellular carcinoma.	x						x	
Biological	Treatment of multiple myeloma.	x				x			
Advanced therapy	Treatment of synovial sarcoma.		x					x	x
Chemical	Treatment of myelodysplastic syndromes.				x			x	
Biological	Treatment of ulcerative colitis.	x					x	x	
Biological	Treatment of rheumatoid arthritis, chronic lymphocytic leukaemia, non-Hodgkin lymphoma.	x						x	
Chemical	Treatment of melanoma.			x				x	
Biological	Treatment of breast cancer and gastric cancer.			x		x	x	x	
Chemical	Treatment of Crohn's disease.	x						x	
Biological	Treatment of rheumatoid arthritis.	x					x	x	
Advanced therapy	Treatment of recombination-activating gene 1 deficient severe combined immunodeficiency.		x					x	
Advanced therapy	Treatment of sickle cell disease.	x				x	x	x	
Advanced therapy	Treatment of haemophilia A.		x			x	x	x	x
Biological	Prevention of acute graft-versus-host disease.		x				x	x	x
Advanced therapy	Treatment of haemophilia B.			x				x	
Advanced therapy	Treatment of haemophilia B.	x				x			
Biological	Treatment of diffuse large B-cell lymphoma.	x						x	
Chemical	Treatment of hypercholesterolaemia and reduction of cardiovascular mortality and morbidity in coronary disease.	x				x			
Chemical	Lowering of hypercholesterolemia.	x					x	x	
Chemical	Treatment of infection due to aerobic Gram-negative bacteria.			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 infection due to aerobic Gram-negative bacteria.	x				x			
Biological	Active immunization for prevention of influenza subtype viruses A and B.	x				x	x	x	
Chemical	Treatment of serious infections caused by Gram negative bacteria.	x				x			
Biological	Prevention of rabies.	x				x	x	x	
Biological	Prevention of RhD immunization and treatment of RhD negative individuals.			x				x	
Chemical	Treatment of chronic hepatitis C infection.	x				x			
Biological	Prevention of pneumococcal invasive disease and pneumococcal pneumonia caused by strains of <i>S.pneumoniae</i> .			x		x		x	
Chemical	Treatment of polycystic ovary syndrome.	x					x	x	
Chemical	Treatment of symptoms of uterine fibroids.			x		x			
Chemical	Treatment of antiphospholipid syndrome.		x					x	
Chemical	Treatment of Duchenne muscular dystrophy.	x					x	x	
Chemical	Treatment of Duchenne muscular dystrophy.	x					x	x	
Chemical	Treatment of autism spectrum disorder.	x						x	
Biological	Treatment of Alzheimer's disease.			x			x	x	
Advanced therapy	Treatment of Sanfilippo type A syndrome.		x			x	x	x	
Chemical	Treatment of major depressive disorder.	x				x	x	x	
Chemical	Treatment of Parkinson's disease.			x				x	
Chemical	Maintenance treatment of schizophrenia.			x				x	
Biological	Treatment of nasal polyposis.	x						x	
Chemical	Treatment of idiopathic pulmonary fibrosis.		x				x	x	
Chemical	Treatment of chronic obstructive pulmonary disease.			x		x		x	
Biological	Treatment of severe eosinophilic asthma.			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 cystic fibrosis.	x						x	
Chemical/ Other innovative	Treatment of vertigo in Meniere's disease.	x				x	x	x	
Chemical	Reduction of elevated intra-ocular pressure.	x				x			
Biological	Treatment of choroidal neovascularization.	x				x	x		
Biological	Treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy.			x				x	
Chemical	Treatment of acromegaly, gastro-entero-pancreatic endocrine tumours and TSH-secreting adenomas.	x						x	
Chemical	Treatment of neuroendocrine tumors.	x						x	
Chemical	Diagnosis of <i>Helicobacter pylori</i> infections .	x						x	
Other innovative	Treatment of primary immunoglobulin A nephropathy.		x			x	x	x	
Biological	Intraoperative imaging agent.	x				x	x	x	
Qualification advice.	Vascular injury detection.	x						x	
Qualification advice.	Treatment of multiple sclerosis, hip fracture, sarcopenia.	x						X	
HTA parallel	Prevention of cardiovascular death, myocardial infarction and stroke in acute coronary syndrome.	x				x	x	x	
HTA parallel	Reduction in incidence of bronchopulmonary dysplasia.	x					x	x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 34 Scientific Advice letters, 10 Protocol Assistance letters, 14 Follow-up Scientific Advice, 1 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 2 HTA Parallel advice, were adopted at the 15 – 18 May 2017 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 70 new Requests for which the procedure started at the SAWP meeting held on 2 – 5 May 2017. The new requests are divided as follows: 32 Initial Scientific Advice, 13 Follow-up Scientific Advice, 7 Initial Protocol Assistance, 11 Follow-up Protocol Assistance, 5 Qualifications of novel methodologies and 2 HTA Parallel advices.