



9 November 2017
EMA/CHMP/SAWP/743845/2017
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 6 – 9 November 2017

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

	1995 - 2016	2017	Overall total
Scientific Advice	3215	306	3521
Follow-up to Scientific Advice	938	100	1038
Protocol Assistance	735	84	819
Follow-up to Protocol Assistance	355	55	410
HTA parallel advice	87	25	112
Qualification of novel methodologies	94	19	113
	5424	589	6013

Outcome of the November 2017 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 Clostridium difficile infection.	x				x	x	x	
Chemical	Reduction of risk of cardiovascular death in chronic kidney disease.	x						x	
Biological	Treatment of Farber disease.				x		x		
Biological	Treatment of Farber disease.				x			x	
Biological	Weight management.	x					x	x	
Chemical	Treatment of enteral feeding intolerance.	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 distal renal tubulopathy acidosis.		x			x			
Advanced therapy	Treatment of glioblastoma.	x				x	x	x	
Biological	Treatment of hepatocellular carcinoma.	x						x	
Biological	Treatment of hepatocellular carcinoma.	x						x	
Chemical	Generic to Caelyx.	x						x	
Biological	Treatment of urothelial carcinoma.	x				x		x	
Chemical	Treatment of non-small cell lung cancer.	x						x	
Chemical	Treatment of NTRK fusion-positive tumours.			x				x	
Chemical	Treatment of ROS1 fusion-positive non-small cell lung cancer and NTRK fusion-positive tumours.	x				x			
Chemical	Treatment of urothelial carcinoma.	x					x	x	
Chemical	Treatment of chronic lymphocytic leukaemia.		x					x	x
Biological	Treatment of graft versus host disease.				x		x	x	
Chemical	Treatment of endometrial carcinoma.	x						x	
Advanced therapy	Treatment of chordoma.	x					x	x	
Chemical	Treatment of breast cancer.	x						x	
Biological	Biosimilar to Neulasta.	x				x	x	x	
Biological	Treatment of breast cancer.	x					x	x	
Biological	Treatment of non-small cell lung cancer.	x						x	
Biological	Treatment of ulcerative colitis.	x					x	x	
Biological	Biosimilar to MabThera.	x						x	
Biological	Treatment of small cell lung cancer.				x			x	x
Biological	Biosimilar to Herceptin.			x				x	
Biological	Treatment of gastric and breast cancer.			x		x			
Chemical	Treatment of breast carcinoma.	x				x			
Chemical	Treatment of giant cell arteritis.	x						x	
Biological	Treatment of lupus erythematosus.	x						x	
Chemical	Treatment of chronic lymphocytic leukaemia.				x		x		
Biological	Treatment and prophylaxis of hemorrhagic episodes in haemophilia B.				x	x	x	x	
Biological	Treatment of graft-versus-host disease.	x					x	x	

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Advanced therapy	Decrease in incidence of non-relapse morbidity and mortality associated with CBT in haematologic malignancies.	x					x	x	
Chemical	Treatment of immune thrombocytopenia.	x						x	
Advanced therapy	Treatment of transfusion dependent β -thalassaemia.				x	x			
Biological	Treatment of transfusion dependant β -thalassaemia and anaemia.	x				x			
Biological	Treatment of haemophilia B.	x					x	x	
Biological	Treatment of acquired thrombotic thrombocytopenic purpura.				x		x	x	
Advanced therapy	Treatment of chronic ischemic cardiomyopathy.	x					x	x	
Chemical	Prevention of ischemic complications in aneurysmal subarachnoid haemorrhage.				x			x	
Chemical	Treatment of allergic reactions.	x				x	x	x	
Chemical	Treatment of oedema due to large hemispheric infarction.	x					x	x	
Biological	Treatment of chronic spontaneous urticaria.				x	x	x		
Chemical	Treatment of adenovirus infection.						x	x	
Chemical	Treatment of smallpox.				x		x	x	
Biological	Prevention of hospitalisations and lower respiratory tract infections caused by respiratory syncytial virus.	x					x	x	
Chemical	Treatment of complicated urinary tract infections.	x				x	x	x	
Chemical	Treatment of hospital-acquired & ventilator-associated pneumonia.	x						x	
Chemical	Treatment of carbapenem-resistant Enterobacteriaceae infection.	x						x	
Biological	Prevention of disease caused by Vibrio cholerae serogroup O1.	x				x		x	
Chemical	Treatment of spinal muscular atrophy.	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	Prophylaxis of migraine.	x						x	
Chemical	Treatment of acute pain.	x						x	
Biological	Treatment of cervical dystonia.	x					x	x	
Chemical	Treatment of Alzheimer's dementia.			x		x		x	
Chemical	Treatment of excessive daytime sleepiness.	x				x	x	x	
Chemical	Treatment of post-cardiac arrest syndrome.		x					x	
Biological	Biosimilar to Pulmozyme.			x				x	
Biological	Biosimilar to Pulmozyme.	x				x			
Chemical	Treatment of chronic obstructive pulmonary disease.	x				x	x	x	
Chemical	Treatment of idiopathic pulmonary fibrosis.		x			x	x	x	x
Chemical	Treatment of F508del cystic fibrosis.		x				x	x	
Chemical	Treatment of cystic fibrosis.		x					x	
Chemical	Treatment of sudden sensorineural hearing loss.		x				x	x	
Biological	Treatment of growth disturbance due to insufficient secretion of growth hormone.			x				x	
Chemical	Physical-chemical identifiers for use in coding solid dosage form drugs as authentic as means to detect counterfeit products.	x				x	x	x	
HTA parallel advice	Treatment of non-small cell lung cancer.	x						x	
HTA parallel advice	Treatment of colorectal cancer.	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 44 Scientific Advice letters, 8 Protocol Assistance letters, 8 Follow-up Scientific Advice, 9 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 2 HTA Parallel advices, were adopted at the 6 – 9 November 2017 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 49 new Requests for which the procedure started at the SAWP meeting held on 23 – 26 October 2017. The new requests are divided as follows: 27 Initial Scientific Advice, 13 Follow-up Scientific Advice, 4 Initial Protocol Assistance, 4 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 1 HTA Parallel advice.