



25 January 2018
EMA/CHMP/SAWP/53915/2018
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 22 – 25 January 2018

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

	1995 - 2017	2018	Overall total
Scientific Advice	3550	16	3566
Follow-up to Scientific Advice	1052	8	1060
Protocol Assistance	830	9	839
Follow-up to Protocol Assistance	413	4	417
EMA/EUnetHTA parallel consultation advice	115	1	116
Qualification of novel methodologies	110	3	113
	6070	41	6111

Outcome of the January 2018 CHMP meeting in relation to scientific advice procedures

Final scientific advice procedures

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharma ceutical	Pre- clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of type 1 and type 2 diabetes.	x				x		x	
Biological	Treatment of diabetes mellitus.	x				x	x	x	
Biological	Treatment of acid sphingomyelinase deficiency.		x					x	
Chemical	Treatment of primary biliary cholangitis.		x				x	x	x
Chemical	Treatment of gastroparesis.	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				
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis.			x		x	x	x	
Chemical	Treatment of colorectal cancer.	x				x	x	x	
Biological	Treatment of breast cancer.	x						x	
Biological	Treatment of breast cancer, non-small cell lung cancer, renal cell carcinoma and ovarian cancer.			x				x	
Biological	Treatment of breast cancer, non-small cell lung cancer, renal cell carcinoma and ovarian cancer.	x				x			
Chemical	Treatment of gastric cancer.	x						x	
Chemical	Treatment of gastrointestinal stromal tumours.		x			x	x	x	x
Chemical	Treatment of diffuse large B-cell lymphoma.	x						x	
Biological	Treatment of chemotherapy-induced febrile neutropenia, acute myeloid leukaemia, severe chronic neutropenia.			x		x		x	
Biological	Treatment of Sézary syndrome.				x			x	x
Biological	Treatment of Sézary syndrome.		x			x			
Chemical	Treatment of acute myeloid leukemia.				x			x	x
Biological	Treatment of diffuse large B-cell lymphoma.		x					x	x
Chemical	Treatment of multiple myeloma.		x					x	x
Chemical	Treatment of multiple sclerosis.	x				x			
Other innovative	Prevention of arteriovenous access dysfunction.		x			x			
Chemical	Treatment of multiple myeloma.		x					x	x
Biological	Treatment and prevention of bleeding in haemophilia A or B.			x		x			
Chemical	Reduction of risk of stroke and systemic embolism in non-valvular atrial fibrillation, reduction in the risk of recurrence of deep venous thrombosis and pulmonary embolism, treatment of deep venous thrombosis and pulmonary embolism.	x				x	x	x	
Biological	Resolution of pre-eclamptic syndrome.	x					x		

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Coronary artery disease detection.			x				x	
Biological	Treatment of acute pneumonia caused by <i>Staphylococcus aureus</i> .		x			x	x	x	
Chemical	Treatment of hypoactive sexual desire disorder.			x			x	x	
Chemical	Prevention of pregnancy.			x			x	x	
Chemical	Treatment of primary focal segmental glomerulosclerosis.				x			x	x
Advanced therapy	Treatment of spinal muscular atrophy.				x	x	x		
Chemical	Improvement of walking in multiple sclerosis.	x						x	
Biological	Treatment of Parkinson's disease.	x				x	x	x	
Chemical	Treatment of seizures in epilepsy.	x						x	
Biological	Treatment of diffuse large B-cell lymphoma.	x				x	x		
Chemical	General anaesthesia.			x				x	
Chemical	Treatment of cystic fibrosis.	x					x	x	
Qualification advice	Treatment of cystic fibrosis.	x						x	
Qualification advice	Treatment of ulcerative colitis.	x						x	
Qualification advice	Treatment of Crohn's disease.	x						x	
EUnetHTA parallel	Treatment of breast cancer.	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 16 Scientific Advice letters, 9 Protocol Assistance letters, 8 Follow-up Scientific Advice, 4 Follow-up Protocol Assistance, 3 Qualifications of novel methodologies and 1 EMA/EUnetHTA parallel consultation advices, were adopted at the 22 – 25 January 2018 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 60 new Requests for which the procedure started at the SAWP meeting held on 8 – 11 Januarys 2018. The new requests are divided as follows: 31 Initial Scientific Advice, 10 Follow-up Scientific Advice, 6 Initial Protocol Assistance, 11 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 2 EMA/EUnetHTA parallel consultation advice.