



31 January 2019
EMA/CHMP/SAWP/49364/2019
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 28 – 31 January 2019

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

	1995 - 2018	2019	Overall total
Scientific Advice	3866	32	3898
Follow-up to Scientific Advice	1150	8	1158
Protocol Assistance	932	8	940
Follow-up to Protocol Assistance	477	3	480
EMA/EUnetHTA parallel consultation advice	139	3	142
Qualification of novel methodologies	126	0	126
	6689	54	6743

Outcome of the January 2019 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				
Chemical	Treatment of neuroendocrine tumours	x				x	x	x	
Chemical	Treatment of breast cancer and small cell lung cancer	x						x	
Chemical	Treatment of tumours	x				x	x	x	



Advanced Therapy	Treatment of haemophilia B		x			x			
Biological	Manufacturing and control testing site	x				x		x	
Advanced Therapy	Treatment of retinitis pigmentosa		x			x	x	x	
Chemical	Treatment of leukaemia	x				x			
Biological	Treatment of multiple myeloma				X		x	x	x
Biological	Treatment of chronic obstructive pulmonary disease			x				x	
Biological	Treatment of breast cancer, non-small cell lung cancer, cervical cancer, colon cancer, metastatic kidney cancer and ovarian cancer			x		x		x	
Biological	Treatment of hepatocellular carcinoma	x						x	
Chemical	Treatment of diabetic retinopathy	x						x	
Chemical/ Innovative product or therapy	Treatment of multiple sclerosis	x						x	
Biological	Treatment of non-small cell lung cancer			x				x	
Biological	Treatment of non-small cell lung cancer			x				x	
Biological	Treatment of men's infertility	x				x	x	x	
Chemical	Treatment of cystic fibrosis	x						x	
Chemical	Treatment of hepatitis B			x				x	
Advanced Therapy	Treatment of sickle cell disease	x				x	x	x	
Chemical	Treatment of human immunodeficiency virus type 1 infection	x						x	
Biological	Treatment of osteoporosis and bone loss, prevention of skeletal related events in bone metastases	x				x	x	x	
Biological	Treatment of mucopolysaccharidosis type II	x					x	x	
Advanced Therapy	Treatment of ornithine transcarbamylase deficiency	x					x	x	
Biological	Treatment of chronic obstructive pulmonary disease	x						x	
Biological	Treatment of biliary tract cancer	x						x	

Chemical	Treatment of onchocerciasis	x						x	
Chemical	Treatment of asthma and chronic obstructive pulmonary disease	x				x			
Biological	Treatment of diabetes type 1 and 2	x				x	x	x	
Biological	Treatment of hepatitis B	x						x	
Biological	Treatment of hepatitis B			x		x	x	x	
Biological	Treatment of multiple myeloma				x			x	
Chemical	Treatment of Hutchinson-Gilford progeria syndrome	x				x	x	x	
Biological	Treatment of non-small cell lung cancer	x						x	
Biological	Treatment of asthma	x				x		x	
Chemical	Treatment of acne	x					x		
Chemical	Treatment of chronic or complex wounds	x					x	x	
Biological	Treatment of renal cell carcinoma	x						x	
Chemical	Treatment of cystic fibrosis				x			x	
Advanced Therapy	Treatment of leukemia		x			x	x	x	
Biological	Treatment of rheumatoid arthritis	x				x	x	x	
Chemical	Treatment of cholangiocarcinoma		x			x		x	
Biological	Treatment of haemophilia A		x			x	x	x	
Biological	Treatment of haemophilia B	x						x	
Biological	Treatment of kidney injury			x				x	
Biological	Prevention of respiratory tract infection	x				x	x	x	
Biological	Treatment of rheumatoid arthritis, chronic lymphocytic leukaemia and non-Hodgkin lymphoma			x		x	x	x	
Biological	Treatment of B-cell hematologic malignancies	x					x		
Advanced Therapy	Treatment of leukaemia	x				x			
Chemical	Treatment of hyperglycinemia and urea cycle disorders		x			x	x	x	
Chemical	Treatment of B-cell lymphoma		x			x		x	x
Chemical	Treatment of seizures in mitochondrial disease	x						x	

Biological	Prevention and treatment of haemorrhage or surgical bleeding in von Willebrand disease	x						x	
Biological	Treatment of adenocarcinoma of the stomach and gastroesophageal junction		x			x			
Biological	Prevention of herpes zoster and post-herpetic neuralgia	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 32 Scientific Advice letters, 8 Protocol Assistance letters, 8 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 3 EMA/EUnetHTA parallel consultation advices, were adopted at the 28 – 31 January 2019 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 14 – 17 January 2019. The new requests are divided as follows: 25 Initial Scientific Advice, 14 Follow-up Scientific Advice, 12 Initial Protocol Assistance, 8 Follow-up Protocol Assistance, 3 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.