



17 October 2024
EMA/CHMP/SAWP/531144/2024
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 14-17 October 2024.

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

	1995-2023	2024	Overall total
Scientific Advice	6072	339	6411
Follow-up to Scientific Advice	1928	127	2055
Protocol Assistance	1343	68	1411
Follow-up to Protocol Assistance	719	39	758
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	228	18	246
	10455	592	11046

Outcome of the October 2024 CHMP meeting in relation to scientific advice procedures

Final scientific advice procedures

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Advanced Therapy	Treatment of Bietti Crystalline Dystrophy	x						x	
Advanced Therapy	Treatment of cancers	x				x	x	x	
Advanced Therapy	Treatment of autoimmune diseases	x				x	x	x	



Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Advanced Therapy	Treatment of acute myeloid leukaemia		x			x		x	x
Advanced Therapy	Treatment of type 1 diabetes (T1D) mellitus	x						x	
Advanced Therapy	Treatment of type 1 diabetes (T1D) mellitus	x				x		x	
Biological	Treatment of kidney disease	x						x	
Biological	Treatment of myeloma		x					x	
Biological	Treatment of cancer	x				x	x	x	
Biological	Treatment of Adult Lower Limb Spasticity	x				x	x	x	
Biological	Treatment of urothelial cancer	x						x	
Biological	Treatment of steatohepatitis	x					x		
Biological	Treatment of asthma	x						x	
Biological	Prevention of Neisseria meningitidis			x				x	
Biological	Treatment of alpha-1-antitrypsin deficiency (AATD)				x			x	
Biological	Treatment of ectodermal dysplasia				x			x	
Biological	Prevention of lower respiratory tract disease (LRTD)			x		x		x	
Biological	Prevention Human papillomavirus			x		x			
Biological	Treatment of gastric cancer			x				x	
Biological	Treatment of NSCLC	x						x	
Biological	Prevention of Neisseria meningitidis			x		x		x	
Biological	Treatment of ovarian cancer		x					x	
Biological	Treatment of idiopathic pulmonary fibrosis	x					x	x	
Biological	Treatment of cancer	x				x		x	
Biological	Treatment of rheumatoid arthritis	x					x	x	
Biological	Treatment of cancer			x				x	
Biological	Treatment of carcinoma	x						x	
Biological	Prevention of graft function in patients undergoing kidney transplant	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Biological	Treatment of lecithin-cholesterol acyltransferase deficiency				x	x			
Biological	Treatment of Alzheimer's disease	x					x	x	
Biological	Prevention of respiratory tract illness			x				x	
Biological	Treatment of purpura			x				x	
Biological	Treatment of small cell lung cancer		x					x	
Biological	Treatment of Sjögren syndrome	x						x	
Biological	Treatment of cancer	x						x	
Biological	Prevention of influenza	x					x	x	
Biological	Prevention of SARS-CoV-2			x				x	
Chemical	Treatment of chronic lymphocytic leukemia	x					x		
Chemical	Treatment of kidney transplantation	x					x	x	
Chemical	Treatment of refractory hypotension	x						x	
Chemical	Treatment of asthma			x		x		x	
Chemical	Treatment of Dravet syndrome	x					x	x	
Chemical	Treatment of Parkinson's disease	x						x	
Chemical	Treatment of HIV-1	x						x	
Chemical	Treatment of vasomotor symptoms	x						x	
Chemical	Treatment of Lupus			x				x	
Chemical	Treatment of bladder cancer	x				x		x	
Chemical	Treatment of menopause			x				x	
Chemical	Prevention of unplanned pregnancies	x				x		x	
Chemical	Treatment of amyotrophic lateral sclerosis		x				x		
Chemical	Treatment of breast cancer	x						x	
Chemical	Treatment of Angelman syndrome		x			x	x	x	x
Chemical	Treatment of hyperphenylalaninemia		x				x	x	x

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Chemical	Treatment of immunodeficiency	x					x	x	
Chemical	Treatment of osteoarthritis	x				x		x	
Chemical	Prevention of thromboembolic	x				x			
Chemical	Treatment of primary biliary cholangitis	x					x	x	
Chemical	Treatment of Spinal Muscular Atrophy	x				x	x	x	
Chemical	Treatment of NSCLC	x					x	x	
Chemical	Prevention of cardiovascular disease	x						x	
Chemical	Treatment of lymphoma			x				x	
Chemical	Treatment of obstructive sleep apnea	x						x	
Chemical	Treatment of carcinoma	x						x	
Chemical	Treatment of achondroplasia	x						x	
Chemical	Treatment of type 2 diabetes mellitus	x						x	
Chemical	Prevention of cardiovascular disease	x					x	x	
Chemical	Treatment of COVID-19	x				x	x	x	
Chemical	Treatment of polio virus			x		x		x	
Chemical	Treatment of influenza A or B			x				x	
Qualification	Medical tool								
Qualification	Medical tool								
Qualification	Medical tool								

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 72 Scientific Advice letters – 44 Initial Scientific Advice, 15 Follow-up Scientific Advice, 7 Protocol Assistance letters, 2 Follow-up Protocol Assistance, 3 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 14-17 October 2024.

New requests for scientific advice procedures

The Committee accepted 81 new Requests for which the procedure started at the SAWP meeting held on 30 September - 3 October 2024. The new requests are divided as follows: 55 Initial Scientific Advice, 17 Follow-up Scientific Advice, 7 Protocol Assistance letters, 2 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.