



21 March 2024
EMA/CHMP/SAWP/123600/2024
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 18-21 March 2024

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

	1995-2023	2024	Overall total
Scientific Advice	6072	98	6170
Follow-up to Scientific Advice	1928	39	1967
Protocol Assistance	1343	20	1363
Follow-up to Protocol Assistance	719	14	728
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	228	8	236
	10455	180	10629

Outcome of the March 2024 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				
ATMP	Treatment of muscle disorder		x			x		x	
ATMP	Treatment of retinitis pigmentosa		x			x			
ATMP	Treatment of bone marrow failure	x				x	x	x	



Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
	syndromes								
ATMP	Treatment of liver failure			x		x			
ATMP	Treatment of liver failure			x			x	x	
ATMP	Treatment of chronic venous ulcer	x					x	x	
ATMP	Treatment of spinal cord injury		x			x			
ATMP	Treatment of Retinitis Pigmentosa			x		x	x	x	
ATMP	Treatment of lymphoblastic leukaemia			x		x			
Biological	Treatment of Metastatic non-small cell lung cancer (mNSCLC)	x					x	x	
Biological	Treatment of age-related macular degeneration (AMD)	x				x	x	x	
Biological	Treatment of Endometrial carcinoma	x						x	
Biological	Treatment of osteoporosis			x		x		x	
Biological	Treatment of Haemophilia	x				x		x	
Biological	Treatment of blood disease	x					x	x	
Biological	Treatment of Relapsed/refractory multiple myeloma	x					x		
Biological	Treatment of SLE	x						x	
Biological	Treatment of Osteoarthritis	x				x	x	x	
Biological	Treatment of Neuroblastoma	x					x	x	
Biological	Treatment of Palmoplantar pustulosis	x				x		x	
Biological	Treatment of Ulcerative Colitis	x					x	x	
Biological	Treatment of melanoma	x				x		x	
Biological	Treatment of Primary progressive multiple sclerosis (PPMS)			x				x	
Biological	Treatment of Same as reference product Xolair			x		x		x	
Biological	Treatment of macular degeneration (AMD)	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Prevention of respiratory syncytial virus (RSV)			x				x	
Biological	Treatment of Acute myeloid leukaemia (AML)	x						x	
Biological	Treatment of Pyoderma gangrenosum	x						x	
Biological	Treatment of acute ischaemic stroke (AIS)	x				x			
Biological	Treatment of Breast cancer	x						x	
Biological	Diagnosis of renal cell carcinoma			x				x	
Chemical	Treatment of Amyotropic Lateral Sclerosis	x					x		
Chemical	Prevention of migraine	x						x	
Chemical	Treatment of Asthma			x				x	
Chemical	Treatment of breast cancer	x						x	
Chemical	Treatment of amyotrophic lateral sclerosis		x			x	x	x	
Chemical	Treatment of chronic kidney disease	x					x	x	
Chemical	Treatment of Cutaneous Lupus Erythematosus (CLE)			x				x	
Chemical	Treatment of allergic reactions			x			x	x	
Chemical	Treatment of seizures	x						x	
Chemical	Diagnosis of vascular disease	x						x	
Chemical	Treatment of amyotrophic lateral sclerosis				x			x	
Chemical	Treatment of Niemann-Pick disease				x			x	x
Chemical	Treatment of hypochondroplasia	x					x	x	
Chemical	Treatment of facioscapulohumeral muscular dystrophy		x			x	x	x	
Chemical	Treatment of liver disease				x	x		x	
Chemical	Treatment of immune disease				x		x		
Chemical	Treatment of plaque psoriasis	x				x	x	x	
Chemical	Treatment of Alzheimer's disease	x					x		

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of metabolic disorder				x			x	
Chemical	Treatment of COVID-19			x				x	
Chemical	Treatment of Spinal Muscular Atrophy			x		x		x	
Chemical	Treatment of depressive disorder			x		x			
Chemical	Treatment of hypertriglyceridemia	x					x	x	
Chemical	Treatment of multiple sclerosis			x				x	
Chemical	Treatment of Progressive Pulmonary Fibrosis	x						x	
Qualification	Medical Tool								
Qualification	Medical Tool								

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 58 Scientific Advice letters – 30 Initial Scientific Advice, 16 Follow-up Scientific Advice, 5 Protocol Assistance letters, 5 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 18-21 March 2024.

New requests for scientific advice procedures

The Committee accepted 67 new Requests for which the procedure started at the SAWP meeting held on 4-7 Mar 2024. The new requests are divided as follows: 43 Initial Scientific Advice, 16 Follow-up Scientific Advice, 3 Protocol Assistance letters, 5 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.