



14 December 2023
EMA/CHMP/SAWP/554627/2023
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 11-14 December 2023

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

	1995-2022	2023	Overall total
Scientific Advice	5684	388	6072
Follow-up to Scientific Advice	1783	145	1928
Protocol Assistance	1268	75	1343
Follow-up to Protocol Assistance	680	39	719
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	210	18	228
	9790	665	10455

Outcome of the December 2023 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 wet age-related macular degeneration	X				X	X	X	
Chemical	Treatment of chronic kidney disease	X					X	X	



Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of Prodromal (DLB-MCI)	X						X	
Chemical	Treatment of gastrointestinal tumours		X				X	X	X
Biological	Treatment of progressive fibrodysplasia	X				X	X	X	
ATMP	Treatment of Pompe's disease		X			X			
Chemical	Treatment of depressive disorder			X				X	
Chemical	Treatment of erythropoietic protoporphyria				X	X		X	
ATMP	Treatment of HPV-16 and/or HPV-18	X					X	X	
ATMP	Treatment of glioma		X				X	X	
Chemical	Treatment of thrombocytopenia		X					X	
Biological	Prevention of Prophylaxis of Migraine	X				X		X	
Chemical	Treatment of soft tissue sarcoma		X					X	
Biological	Prevention of Middle East Respiratory Syndrome	X				X	X	X	
Chemical	Treatment of acne vulgaris	X					X		
Biological	Treatment of Adenocarcinoma NSCLC	X						X	
Biological	Treatment of NSCLC	X						X	
Chemical	Treatment of Solid tumours	X				X			
Chemical	Treatment of hypercholesterolaemia	X				X			
Biological	Treatment of B-cell lymphoma				X			X	
Chemical	Treatment of Treatment of major depressive disorder	X						X	
Chemical	Treatment of sickle cell		X					X	
Biological	Prevention of disease caused by influenza subtype A and type B viruses	X						X	
Biological	Treatment of Plaque psoriasis	X				X			
ATMP	Treatment of Heart failure	X				X	X		
Biological	Treatment of Still's disease	X					X	X	
Biological	Prevention of HPV diseases			X		X		X	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Prevention of influenza	X				X	X	X	
Chemical	Prevention of Post-Operative Complications in Cardiothoracic Surgery	X				X	X	X	
Chemical	Treatment of acromegalic	X				X			
Chemical	Treatment of non-small cell lung cancer	X						X	
Chemical	Treatment of non-small cell lung cancer	X						X	
Chemical	Treatment of weight disease			X				X	
Biological	Treatment of patients with monogenic IL-18 driven autoinflammatory diseases	X						X	
Chemical	Treatment of amyotrophic lateral sclerosis				X			X	
Chemical	Treatment of Parkinson's disease			X				X	
Chemical	Treatment of pulmonary arterial hypertension	X					X		
Chemical	Treatment of Dry eye	X				X	X	X	
Biological	Treatment of Advanced melanoma			X		X			
Chemical	Treatment of invasive aspergillosis		X				X	X	
Chemical	Treatment of HPV16 and neck squamous cell carcinoma	X				X	X	X	
Chemical	Treatment of COVID-19			X				X	
Chemical	Treatment of tenosynovial giant cell tumour (TGCT)	X					X	X	
Biological	Treatment of Hip or knee Prosthetic Joint Infection (PJI)			X		X	X	X	
Chemical	Treatment of amyotrophic lateral sclerosis		X					X	
Chemical	Treatment of Multidrug-resistant tuberculosis	X					X	X	
Chemical	Treatment of osteoarthritis			X		X			
Biological	Prevention of respiratory tract illness			X				X	
ATMP	Treatment of Neovascular Age-Related Macular Degeneration	X				X	X	X	
Chemical	Treatment of immune thrombocytopenia		X			X			X
Biological	Treatment of Crohn's disease			X				X	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of Prurigo Nodularis	X						X	
Biological	Treatment of Polycythaemia vera	X				X		X	
Biological	Treatment of chronic plaque psoriasis	X				X		X	
Biological	Prevention of Covid-19.			X				X	
Chemical	Treatment of diabetes and deafness				X			X	
Chemical	Treatment of Vernal Keratoconjunctivitis	X				X	X		
Biological	Treatment of spinal muscular atrophy		X			X			
Chemical	Treatment of urinary tract infections	X					X	X	
Chemical	Diagnosis of subjective memory complaints and dementia	X						X	
Chemical	Treatment of Preclinical Alzheimer's disease	X						X	
Biological	Treatment of cancer	X						X	
Biological	Treatment of biliary tract cancer	X						X	
Biological	Treatment of Crohn's disease			X		X		X	
Biological	Prevention of pneumonia and acute otitis	X				X			
Chemical	Treatment of sickle cell disease				X			X	
ATMP	Treatment of type 1 diabetes (T1D)	X				X			
Biological	Prevention of SARS-CoV-2	X				X	X	X	
Chemical	Treatment of lupus erythematosus	X						X	
Qualification	Treatment of Alzheimer's disease								
Qualification	Treatment of kidney disease								
Qualification	Medical devices innovation								

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 72 Scientific Advice letters - 42 Initial Scientific Advice, 12 Follow-up Scientific Advice, 10 Protocol Assistance letters, 5 Follow-up Protocol Assistance, 3 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 11-14 December 2023 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 71 new Requests for which the procedure started at the SAWP meeting held on 27-30 November 2023. The new requests are divided as follows: 46 Initial Scientific Advice, 16 Follow-up Scientific Advice, 5 Initial Protocol Assistance, 3 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.