



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2025
EMA/CHMP/SAWP/114446/2025
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 24-27 March 2025.

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

	1995-2024	2025	Overall total
Scientific Advice	6457	142	6599
Follow-up to Scientific Advice	2071	14	2085
Protocol Assistance	1417	36	1453
Follow-up to Protocol Assistance	760	6	766
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	246	3	249
	11116	201	11317

Outcome of the March 2025 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 graft-versus-host disease		x					x	x
Advanced Therapy	Treatment of hearing loss		x			x		x	
Advanced Therapy	Treatment of Gaucher disease		x			x		x	



Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Biological	Treatment of allergic	x						x	
Biological	Treatment of cancer	x						x	
Biological	Treatment of cancer	x						x	
Biological	Treatment of carcinoma	x						x	
Biological	Treatment of dementia		x			x			
Biological	Treatment of tumors	x					x	x	
Biological	Treatment of Pulmonary Fibrosis	x					x	x	
Biological	Prevention of SPF eggs are used for vaccine production	x				x			
Biological	Treatment of adenocarcinoma	x						x	
Biological	Treatment of systemic lupus erythematosus	x				x	x		
Biological	Prevention of lyme disease	x						x	
Biological	Treatment of ovarian cancer	x					x		
Biological	Treatment of blood disease	x				x		x	
Biological	Treatment of amyloidosis		x					x	
Biological	Treatment of Osteogenesis Imperfecta	x					x	x	
Biological	Treatment of Non-alcoholic steatohepatitis	x						x	
Biological	Treatment of myositis		x			x			
Biological	Treatment of demyelinating polyneuropathy		x			x			
Biological	Treatment of leukemia	x					x	x	
Biological	Prevention of mpox virus	x					x	x	
Biological	Prevention of dengue disease	x						x	
Biological	Treatment of rheumatoid arthritis	x				x		x	
Biological	Treatment of multiple myeloma	x				x		x	
Biological	Treatment of multiple sclerosis	x						x	
Biological	Treatment of haemophilia	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Biological	Treatment of age-related macular degeneration	x				x	x		
Biological	Treatment of ulcerative colitis	x						x	
Biological	Treatment of plaque psoriasis	x				x		x	
Biological	Treatment of ITP	x						x	
Biological	Treatment of diabetes	x				x		x	
Chemical	Diagnosis of lymphoma		x					x	x
Chemical	Treatment of narcolepsy		x			x			
Chemical	Treatment of Parkinson's Disease	x						x	
Chemical	Treatment of multiple myeloma	x						x	
Chemical	Treatment of obesity and overweight	x					x	x	
Chemical	Treatment of sickle cell disease		x			x	x	x	x
Chemical	Treatment of Glioblastoma	x						x	
Chemical	Prevention of HIV-1 infection	x						x	
Chemical	Treatment of hypercholesterolemia	x				x			
Chemical	Treatment of acute kidney injury	x					x	x	
Chemical	Treatment of Hepatic Fibrosis	x						x	
Chemical	Treatment of encephalopathy		x					x	
Chemical	Treatment of glomerulonephritis	x				x	x	x	
Chemical	Treatment of excess subcutaneous fat	x						x	
Chemical	Treatment of Pulmonary hypertension	x				x	x	x	
Chemical	Treatment of HIV-1	x					x	x	
Chemical	Prevention of Axial myopia	x				x			
Chemical	Treatment of kidney cancer	x						x	
Chemical	Treatment of seizures	x						x	
Chemical	Treatment of acute ischemic stroke	x					x		

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Chemical	Treatment of Dry Eye	x					x	x	
Chemical	Treatment of tumor		x			x	x		
Chemical	Treatment of carcinoma		x			x			
Chemical	Treatment of seizures	x						x	
Chemical	Treatment of sclerosis	x					x	x	
Chemical	Treatment of active lupus nephritis	x					x	x	
Chemical	Prevention of migraine	x						x	
Chemical	Treatment of dehydrogenase deficiency		x			x	x	x	
Chemical	Prevention of cardiovascular disease	x						x	
Qualification	Medical Tool							x	
Qualification	Medical Tool							x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 64 Scientific Advice letters – 48 Initial Scientific Advice, 0 Follow-up Scientific Advice, 14 Protocol Assistance letters, 0 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 24-27 March 2025.

New requests for scientific advice procedures

The Committee accepted 72 new Requests for which the procedure started at the SAWP meeting held on 10 - 13 March 2025. The new requests are divided as follows: 60 Initial Scientific Advice, 1 Follow-up Scientific Advice, 10 Protocol Assistance letters, 1 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.