



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 May 2025
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Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 19-22 May 2025.

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

	1995-2024	2025	Overall total
Scientific Advice	6457	248	6705
Follow-up to Scientific Advice	2071	14	2085
Protocol Assistance	1417	59	1476
Follow-up to Protocol Assistance	760	6	766
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	246	6	252
	11116	333	11388

Outcome of the May 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 Pompe's disease		x					x	x
Advanced Therapy	Treatment of hearing loss		x				x	x	
Advanced Therapy	Treatment of Asherman's syndrome		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 muscular dystrophy		x			x	x	x	
Biological	Treatment of arthritis	x				x	x	x	
Biological	Prevention of organ damage	x						x	
Biological	Treatment of carcinoma	x						x	
Biological	Treatment of cancer	x						x	
Biological	Treatment of stroke	x					x	x	
Biological	Treatment of leukaemia		x					x	
Biological	Treatment of tumour	x				x	x	x	
Biological	Prevention of COVID-19	x				x			
Biological	Treatment of lupus erythematosus	x					x	x	
Biological	Treatment of celiac disease	x					x		
Biological	Treatment of atopic dermatitis	x				x			
Biological	Treatment of ulcerative colitis	x				x	x	x	
Biological	Treatment of anaemia	x				x		x	
Biological	Treatment of myeloma	x						x	
Biological	Treatment of anemia	x				x	x	x	
Biological	Treatment of NDMM	x						x	
Biological	Treatment of fertility	x				x	x	x	
Biological	Treatment of sclerosis	x						x	
Biological	Treatment of asthma	x				x	x	x	
Biological	Treatment of myotonic disorders		x					x	
Biological	Treatment of myeloma	x					x	x	
Biological	Treatment of regional pain syndrome		x			x	x	x	
Biological	Treatment of tumours	x						x	
Biological	Treatment of colorectal cancer	x						x	
Biological	Treatment of chronic weight management	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 pancreatic cancer		x			x	x	x	x
Biological	Prevention of mpox	x					x	x	
Biological	Prevention of lower respiratory tract disease	x				x	x	x	
Biological	Treatment of tumour	x						x	
Biological	Treatment of cancer	x					x	x	
Biological	Treatment of Alzheimer's disease	x						x	
Biological	Treatment of tumours	x					x	x	
Biological	Treatment of NSCLC	x						x	
Biological	Treatment of neoplasms	x				x			
Chemical	Treatment of Primary Aldosteronism	x						x	
Chemical	Treatment of Age-related macular degeneration	x				x	x	x	
Chemical	Treatment of tenosynovial giant-cell tumour, local and diffuse type		x			x		x	x
Chemical	Treatment of leukemia	x						x	
Chemical	Treatment of AML	x				x			
Chemical	Treatment of pancreatitis		x				x	x	
Chemical	Prevention of premature ovulation	x				x			
Chemical	Treatment of Paediatric and metabolic associated steatohepatitis (MASH)	x						x	
Chemical	Treatment of Lichen sclerosis	x						x	
Chemical	Treatment of sclerosis		x					x	
Chemical	Treatment of astrocytoma		x			x	x	x	
Chemical	Treatment of Non-Hodgkin Lymphoma	x						x	
Chemical	Treatment of sickle cell disease		x			x	x	x	
Chemical	Treatment of sickle cell disease		x			x			
Chemical	Prevention of human immunodeficiency virus (HIV-1) infection	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Chemical	Treatment of pulmonary sarcoidosis	x						x	
Chemical	Treatment of Immunoglobulin G4 related disease	x						x	
Chemical	Treatment of vitiligo	x						x	
Chemical	Treatment of hypertension		x					x	
Chemical	Treatment of polyposis	x				x		x	
Chemical	Treatment of Wilson's disease	x					x	x	
Qualification	Medical tool								
Qualification	Medical tool								

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 61 Scientific Advice letters – 44 Initial Scientific Advice, 15 Protocol Assistance letters, 2 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 19-22 May 2025.

New requests for scientific advice procedures

The Committee accepted 78 new Requests for which the procedure started at the SAWP meeting held on 5 - 8 May 2025. The new requests are divided into the following: 61 Initial Scientific Advice, 16 Protocol Assistance letters, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.