



27 February 2025
EMA/CHMP/SAWP/95093/2025
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 24-27 February 2025.

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

	1995-2024	2025	Overall total
Scientific Advice	6457	94	6505
Follow-up to Scientific Advice	2071	14	2082
Protocol Assistance	1417	22	1425
Follow-up to Protocol Assistance	760	6	766
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	246	1	246
	11116	137	11189

Outcome of the February 2025 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				
Advanced Therapy	Treatment of Age-Related Macular Degeneration	x						x	
Advanced Therapy	Treatment of Fabry disease		x					x	



Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Advanced Therapy	Treatment of corneal oedema	x				x	x	x	
Advanced Therapy	Treatment of LCA		x				x		
Advanced Therapy	Treatment of Hemophilia B	x				x	x	x	
Advanced Therapy	Treatment of lymphoma	x				x	x	x	
Advanced Therapy	Treatment of Crigler-Najjar syndrome		x			x		x	
Advanced Therapy	Treatment of retinitis pigmentosa			x		x			
Biological	Treatment of cancer	x				x			
Biological	Treatment of osteoporosis	x				x		x	
Biological	Prevention of pneumoniae	x						x	
Biological	Treatment of polyneuropathy	x					x	x	
Biological	Prevention of prophylaxis of BKV symptomatic infection in kidney transplant	x				x	x	x	
Biological	Treatment of osteosarcoma	x						x	
Biological	Treatment of NSCLC	x				x	x	x	
Biological	Treatment of arthritis	x				x	x	x	
Biological	Treatment of blood disease	x					x	x	
Biological	Treatment of cancer	x						x	
Biological	Treatment of Graves' disease	x						x	
Biological	Treatment of oedema	x					x	x	
Biological	Treatment of NSCLC	x						x	
Biological	Treatment of palmoplantar pustulosis	x						x	
Biological	Treatment of facioscapulohumeral muscular dystrophy		x				x	x	
Biological	Treatment of lupus	x					x		
Biological	Treatment of cancer		x					x	
Biological	Prevention of Lower respiratory tract disease (LRTD)	x				x	x	x	
Biological	Treatment of cancer	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Prevention of migraine	x					x	x	
Biological	Treatment of cancer	x						x	
Biological	Treatment of carcinoma	x				x	x	x	
Biological	Treatment of lipodystrophy		x					x	x
Biological	Treatment of wet age-related macular degeneration	x				x	x	x	
Biological	Treatment of thrombocytopenia		x					x	
Biological	Treatment of colitis	x				x	x	x	
Biological	Treatment of neurofibromatosis 1	x						x	
Biological	Prevention of respiratory syndrome	x				x			
Biological	Prevention of streptococcal disease			x				x	
Biological	Treatment of cancer	x				x	x	x	
Biological	Treatment of Relapsing multiple sclerosis	x				x		x	
Biological	Treatment of same indications as the reference product Eylea			x		x		x	
Chemical	Treatment of fragile X syndrome		x			x			
Chemical	Treatment of treatment of fibrosis	x				x			
Chemical	Treatment of tuberculosis		x				x	x	x
Chemical	Treatment of type 1 diabetes	x					x	x	
Chemical	Treatment of weight management	x					x	x	
Chemical	Treatment of leukaemia	x				x	x	x	
Chemical	Treatment of non-segmental	x				x			
Chemical	Treatment of autism	x					x		
Chemical	Treatment of Chronic obesity	x					x		
Chemical	Treatment of Diffuse Midline Glioma		x			x	x	x	
Chemical	Treatment of erythropoietic protoporphyria		x					x	x
Chemical	Treatment of tumours		x					x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of septic shock	x					x		
Chemical	Treatment of Angelman syndrome		x				x	x	
Chemical	Treatment of Chemotherapy-induced thrombocytopenia (CIT)	x					x	x	
Chemical	Treatment of Spinal Muscular Atrophy	x				x	x	x	
Chemical	Treatment of amyotrophic lateral sclerosis		x				x	x	
Chemical	Prevention of cardiovascular disease	x						x	
Chemical	Treatment of Progressive Keratoconus	x				x	x	x	
Chemical	Treatment of liver disease	x					x	x	
Chemical	Treatment of leukaemia	x				x	x	x	
Chemical	Treatment of cancer	x				x			
Chemical	Treatment of Crohn's disease	x					x	x	
Qualification	Medical Tool						x	x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 64 Scientific Advice letters – 46 Initial Scientific Advice, 3 Follow-up Scientific Advice, 14 Protocol Assistance letters, 0 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 24-27 February 2025.

New requests for scientific advice procedures

The Committee accepted 64 new Requests for which the procedure started at the SAWP meeting held on 10 - 13 February 2025. The new requests are divided as follows: 48 Initial Scientific Advice, 1 Follow-up Scientific Advice, 15 Protocol Assistance letters, 0 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.