



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 April 2025
EMA/CHMP/SAWP/162581/2025
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 22-25 Apr 2025.

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

	1995-2024	2025	Overall total
Scientific Advice	6457	204	6661
Follow-up to Scientific Advice	2071	14	2085
Protocol Assistance	1417	44	1461
Follow-up to Protocol Assistance	760	6	766
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	246	4	250
	11116	272	11317

Outcome of the April 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 Diabetic Retinopathy	x						x	
Advanced Therapy	Treatment of edema	x					x	x	
Advanced Therapy	Treatment of beta-thalassaemia intermedia		x			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 leukaemia	x						x	
Advanced Therapy	Treatment of carcinoma	x					x	x	
Advanced Therapy	Treatment of myeloma	x				x			
Biological	Prevention of sickle cell disease	x					x	x	
Biological	Treatment of myasthenia gravis	x					x		
Biological	Treatment of hepatitis D		x			x			
Biological	Treatment of muscular dystrophy		x					x	
Biological	Treatment of haemophilia	x					x	x	
Biological	Prevention of diphtheria	x				x			
Biological	Treatment of edema	x				x			
Biological	Prevention of kidney rejection in adult patients receiving kidney transplant.	x						x	
Biological	Treatment of cancer	x				x		x	
Biological	Treatment of cancer	x						x	
Biological	Prevention of cancer	x						x	
Biological	Prevention of Influenza	x				x	x	x	
Biological	Prevention of cardiovascular events	x						x	
Biological	Treatment of obesity	x				x	x	x	
Biological	Treatment of cancer	x				x	x		
Biological	Prevention of lower respiratory tract disease	x						x	
Biological	Treatment of cancer		x					x	x
Biological	Treatment of acute ischaemic stroke (AIS)	x						x	
Biological	Treatment of eye disease	x				x			
Biological	Treatment of cancer	x					x	x	
Chemical	Treatment of Acute Myeloid Leukemia	x						x	
Chemical	Treatment of porphyria		x				x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Chemical	Treatment of vitiligo	x					x	x	
Chemical	Treatment of patients with HR-positive	x					x		
Chemical	Treatment of idiopathic pulmonary fibrosis		x					x	
Chemical	Treatment of epilepsy	x				x			
Chemical	Treatment of cancer	x				x			
Chemical	Treatment of infections	x				x			
Chemical	Treatment of hyperuricemia in association with gout	x						x	
Chemical	Treatment of hypercholesterolaemia	x						x	
Chemical	Treatment of cancer	x						x	
Chemical	Diagnosis of adenocarcinoma	x						x	
Chemical	Diagnosis of cancers	x					x	x	
Chemical	Treatment of growth hormone deficiency		x					x	
Chemical	Treatment of Crohn's disease	x					x	x	
Chemical	Treatment of hypercholesterolaemia	x					x	x	
Chemical	Treatment of chemotherapy-induced nausea	x					x		
Chemical	Treatment of cancer	x						x	
Chemical	Prevention of HIV-1 infection	x					x	x	
Chemical	Prevention of cardiovascular event.	x					x	x	
Chemical	Treatment of gastroparesis	x						x	
Chemical	Treatment of polyneuropathy	x					x	x	
Chemical	Treatment of Spinal Muscular Atrophy	x				x		x	
Chemical	Treatment of Non-small Cell Lung Cancer	x					x		
Chemical	Treatment of non-active secondary progressive multiple sclerosis	x						x	
Chemical	Treatment of cancer	x					x	x	
Chemical	Treatment of HR-positive	x					x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Chemical	Treatment of multiple sclerosis	x						x	
Chemical	Treatment of asthma	x						x	
Chemical	Treatment of cancer	x				x	x	x	
Chemical	Treatment of diabetes	x					x		
Chemical	Treatment of primary biliary cholangitis		x					x	
Chemical	Treatment of adult patients with R/R CLL	x						x	
Chemical	Treatment of hematologic malignancies	x						x	
Chemical	Treatment of cancer	x					x	x	
Chemical	Treatment of tumour	x					x	x	
Chemical	Treatment of neurodevelopmental disorder	x				x	x	x	
Biological	Treatment of cancer	x				x	x	x	
Biological	Treatment of blood disease	x				x		x	
Biological	Prevention of osteoporosis	x				x	x	x	
Biological	Treatment of cancer	x				x			
Biological	Treatment of lung cancer	x						x	
Biological	Treatment of psoriasis	x				x	x	x	
Biological	Treatment of growth hormone deficiency (GHD)	x				x	x	x	
Qualification	Simcyp Simulator								

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 71 Scientific Advice letters – 62 Initial Scientific Advice, 0 Follow-up Scientific Advice, 8 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 March 2025.

New requests for scientific advice procedures

The Committee accepted 63 new Requests for which the procedure started at the SAWP meeting held on 7 - 10 April 2025. The new requests are divided as follows: 45 Initial Scientific Advice, 0 Follow-up Scientific Advice, 14 Protocol Assistance letters, 1 Follow-up Protocol Assistance, 3 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.