



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 June 2025
EMA/CHMP/SAWP/162581/2025
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 16-19 June 2025.

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

	1995-2024	2025	Overall total
Scientific Advice	6457	261	6718
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	4	250
	11116	344	11460

Outcome of the June 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 leukaemia		x			x		x	
Advanced Therapy	Treatment of Duchenne muscular dystrophy		x			x	x	x	
Advanced Therapy	Prevention of cancer	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 tumours	x					x	x	
Advanced Therapy	Treatment of relapsed/refractory (r/r) LBCL	x						x	
Advanced Therapy	Treatment of lymphoma	x						x	
Advanced Therapy	Treatment of carcinoma	x				x			
Biological	Treatment of multiple myeloma		x			x			
Biological	Treatment of lupus erythematosus	x					x	x	
Biological	Treatment of muscular dystrophy		x					x	
Biological	Treatment of Duchenne muscular dystrophy		x					x	
Biological	Treatment of myasthenia gravis		x				x	x	
Biological	Treatment of nephropathy	x						x	
Biological	Treatment of dermatitis	x					x	x	
Biological	Treatment of cancer	x				x	x	x	
Biological	Prevention of CDI	x					x	x	
Biological	Treatment of hyperplasia	x					x	x	
Biological	Treatment of haemophilia	x						x	
Biological	Treatment of immune thrombocytopenia		x				x	x	
Biological	Prevention of pneumococcal	x				x	x	x	
Biological	Treatment of lymphoma		x				x	x	x
Biological	Treatment of cancer	x					x	x	
Biological	Treatment of cancer	x					x	x	
Biological	Treatment of chronic kidney disease	x						x	
Biological	Prevention of COVID-19	x				x			
Biological	Prevention of tuberculosis	x				x			
Biological	Treatment of IgG4-related disease		x			x	x	x	
Biological	Treatment of Obesity	x				x			

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Biological	Treatment of Early Alzheimer's Disease	x					x	x	
Biological	Treatment of Parkinson's disease	x						x	
Biological	Prevention of Alzheimer's disease	x						x	
Biological	Treatment of cancer	x						x	
Biological	Treatment of Inflammatory Bowel Disease	x					x		
Biological	Treatment of pulmonary alveolar proteinosis		x					x	
Biological	Treatment of multiple myeloma		x					x	
Biological	Treatment of Alzheimer's disease	x						x	
Biological	Treatment of myositis		x				x	x	
Biological	Treatment of cancer		x					x	
Biological	Treatment of cancer	x					x	x	
Biological	Treatment of psoriasis	x				x		x	
Biological	Treatment of cancer	x						x	
Biological	Treatment of tumour	x						x	
Biological	Treatment of tumour	x				x		x	
Biological	Treatment of psoriasis	x				x		x	
Biological	Treatment of GHD	x				x	x	x	
Biological	Treatment of ulcerative colitis	x				x		x	
Chemical	Treatment of tumour	x						x	
Chemical	Treatment of cancer	x						x	
Chemical	Treatment of eye infection	x				x		x	
Chemical	Treatment of cancer	x					x	x	
Chemical	Treatment of focal segmental glomerular sclerosis	x				x	x	x	
Chemical	Treatment of leukemia	x				x		x	
Chemical	Treatment of telangiectasia		x					x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Chemical	Treatment of heart failure	x				x	x	x	
Chemical	Treatment of achondroplasia	x					x	x	
Chemical	Treatment of candidiasis	x					x	x	
Chemical	Treatment of HIV-1 infection	x						x	
Chemical	Treatment of dyslipidaemia	x					x		
Chemical	Treatment of ulcerative colitis	x					x	x	
Chemical	Treatment of cancer	x						x	
Chemical	Treatment of Alzheimer's disease	x					x		
Chemical	Treatment of Parkinson's disease	x						x	
Chemical	Treatment of myelofibrosis	x					x	x	
Chemical	Treatment of leukaemia		x					x	x
Chemical	Treatment of migraine	x						x	
Chemical	Treatment of muscular atrophy	x					x	x	
Chemical	Treatment of pulmonary hypertension	x						x	
Chemical	Treatment of Hepatitis B	x						x	
Chemical	Treatment of kidney disease	x						x	
Chemical	Prevention of fibrodysplasia ossificans	x				x	x	x	
Chemical	Treatment of NSCLC	x						x	
Chemical	Treatment of NSCLC	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 72 Scientific Advice letters – 57 Initial Scientific Advice, 15 Protocol Assistance letters, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 16-19 June 2025.

New requests for scientific advice procedures

The Committee accepted 60 new Requests for which the procedure started at the SAWP meeting held on 2 - 5 June 2025. The new requests are divided into as follows: 53 Initial Scientific Advice, 6 Protocol Assistance letters, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.