



18 September 2025
EMA/289375/2025
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 15- 18 September 2025.

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

	1995-2024	2025	Overall total
Scientific Advice	6457	357	6814
Follow-up to Scientific Advice	2071	14	2085
Protocol Assistance	1417	74	1491
Follow-up to Protocol Assistance	760	6	766
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	246	12	258
	11116	463	11579

Outcome of the September 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			
Advanced Therapy	Treatment of arrhythmogenic cardiomyopathy			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 cancer	x				x		x	
Advanced Therapy	Treatment of myeloid leukaemia	x						x	x
Advanced Therapy	Treatment of head and neck squamous cell carcinoma (HNSCC)	x					x		
Advanced Therapy	Treatment of Danon disease	x				x			
Biological	Treatment of Duchenne muscular dystrophy			x				x	
Biological	Treatment of lecithin-cholesterol acyltransferase deficiency			x				x	
Biological	Treatment of acute radiation syndrome			x				x	
Biological	Treatment of Sjogren's syndrome	x				x	x	x	
Biological	Treatment of Alzheimer's Disease	x					x		
Biological	Treatment of solid tumours	x						x	
Biological	Treatment of extensive-stage small cell lung cancer (ES-SCLC)	x				x		x	
Biological	Treatment of Lymph histiocytosis	x				x	x	x	
Biological	Treatment of meningococcal disease	x					x	x	
Biological	Treatment of prostate cancer	x				x			
Biological	Treatment of MDD	x				x			
Biological	Treatment of measles, mumps, rubella and varicella.	x				x	x	x	
Biological	Treatment of severe asthma	x						x	
Biological	Treatment of colorectal cancer	x						x	
Biological	Treatment of heart failure	x				x	x	x	
Biological	Treatment of obesity	x				x			
Biological	Treatment of clostridioides difficile infection	x						x	
Biological	Treatment of autoimmune hepatitis (AIH)	x						x	x
Biological	Treatment of lower respiratory tract disease	x					x		
Biological	Treatment of tumours	x				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 alcohol use disorder	x						x	
Biological	Treatment of AMD	x				x	x	x	
Biological	Treatment of asthma	x				x	x	x	
Biological	Treatment of Plaque psoriasis	x					x	x	
Biological	Treatment of osteoporosis	x				x			
Biological	Treatment of cancer	x						x	
Biological	Treatment of cancer	x				x	x	x	
Biological	Treatment of psoriasis	x						x	
Biological	Treatment of myeloma	x							
Biological	Treatment of atopic dermatitis.	x					x		
Biological	Modification in the packaging	x							
Biological	Treatment of High risk relapsed/refractory neuroblastoma in paediatric patients	x							
Chemical	Treatment of achondroplasia			x		x		x	
Chemical	Treatment of acute myeloid leukaemia			x		x	x	x	
Chemical	Treatment of AML			x		x	x	x	
Chemical	Treatment of lymphoma			x		x	x	x	
Chemical	Treatment of Stargardt disease			x			x	x	
Chemical	Treatment of newly diagnosed localised uveal melanoma (neoadjuvant, as monotherapy)	x						x	
Chemical	Treatment of fibrosis	x				x	x	x	
Chemical	Treatment of cardiovascular events	x				x		x	
Chemical	Treatment of bronchiectasis	x				x		x	
Chemical	Treatment of gout flares	x						x	
Chemical	Treatment of bronchoconstriction	x					x		
Chemical	Treatment of schizophrenia	x				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 weight management	x				x		x	
Chemical	Treatment of stroke	x				x	x	x	
Chemical	Treatment of breast cancer	x					x	x	
Chemical	Treatment of molluscum contagiosum	x					x	x	
Chemical	Treatment of breast cancer	x						x	
Chemical	Treatment of lupus erythematosus	x						x	
Chemical	Treatment of diabetes mellitus	x						x	
Chemical	Treatment of acute hyperammonaemia	x				x	x	x	
Qualification	Medical Tool					x	x	x	
Qualification	Medical Tool						x	x	
Qualification	Medical Tool						x	x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 61 Scientific Advice letters – 48 Initial Scientific Advice, 10 Protocol Assistance letters, 3 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 15 - 18 Sept 2025.

New requests for scientific advice procedures

The Committee accepted 99 new Requests for which the procedure started at the SAWP meeting held on 1 - 4 September 2025. The new requests are divided into as follows: 78 Initial Scientific Advice, 17 Protocol Assistance letters, 4 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.