



16 October 2025
EMA/341128/2025
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 13- 16 October 2025.

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

	1995-2024	2025	Overall total
Scientific Advice	6457	427	6884
Follow-up to Scientific Advice	2071	14	2085
Protocol Assistance	1417	90	1507
Follow-up to Protocol Assistance	760	6	766
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	246	11	257
	11116	548	11664

Outcome of the October 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 CD19-expressing hematologic B-cell malignancies	x						x	
Advanced Therapy	Treatment of Rett syndrome	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 lymphoma	x						x	
Advanced Therapy	Treatment of hearing loss	x					x	x	
Advanced Therapy	Treatment of lupus erythematosus, inflammatory myopathy, systemic sclerosis	x				x	x	x	
Advanced Therapy	Treatment of Asherman's syndrome			x				x	
Advanced Therapy	Treatment of retinitis pigmentosa			x		x	x	x	
Advanced Therapy	Treatment of diabetes	x				x	x	x	
Advanced Therapy	Treatment of Neovascular Age-Related Macular Degeneration	x				x			
Advanced Therapy	Treatment of melanoma	x				x		x	
Biological	Treatment of amyotrophic lateral sclerosis			x		x	x	x	x
Biological	Treatment of Graft-versus-Host Disease			x				x	x
Biological	Treatment of Bordetella pertussis	x					x	x	
Biological	Treatment of pneumoniae	x						x	
Biological	Prevention of COVID-19	x				x			
Biological	Treatment of arthritis	x						x	
Biological	Treatment of arthritis	x					x	x	
Biological	Treatment of blinatumomab			x				x	
Biological	Treatment of weight management	x						x	
Biological	Treatment of arthritis	x				x		x	
Biological	Treatment of rheumatoid arthritis	x				x		x	
Biological	Treatment of glabellar Lines	x					x	x	
Biological	Treatment of Same indications as for the reference product Trulicity	x				x		x	
Biological	Treatment of same indications as for the reference product Dupixent	x				x		x	
Biological	Treatment of treatment of anaemia	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Biological	Treatment of motor neuropathy			x		x		x	
Biological	Treatment of septic shock	x					x	x	
Biological	Treatment of diabetes	x						x	
Biological	Treatment of plaque psoriasis	x				x		x	
Biological	Treatment of heart disease	x					x	x	
Biological	Treatment of kidney disease	x						x	
Biological	Treatment of myeloid leukaemia	x					x	x	
Biological	Treatment of atopic dermatitis	x					x	x	
Biological	Treatment of multiple myeloma	x						x	
Biological	Treatment of neuropathic pain associated with distal sensory polyneuropathy	x					x		
Biological	Treatment of weight management	x						x	
Biological	Treatment of primary sclerosing cholangitis			x		x	x	x	
Biological	Treatment of Non-Hodgkin Lymphoma	x						x	
Biological	Treatment of cancer	x						x	
Biological	Treatment of Non-small cell lung cancer (NSCLC)	x				x	x	x	
Biological	Treatment of Non-small cell lung carcinoma (NSCLC)	x				x		x	
Biological	Treatment of cancer	x				x		x	
Biological	Treatment of obesity	x						x	
Biological	Treatment of cancer	x						x	
Biological	Treatment of cancer	x						x	
Biological	Treatment of systemic lupus erythematosus	x					x		
Biological	Treatment of thrombocytopenia	x				x	x	x	
Biological	Treatment of myasthenia gravis			x				x	
Biological	Treatment of adenocarcinoma	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Biological	Treatment of tumour			x		x	x	x	
Biological	Treatment of tumours	x						x	
Biological	Treatment of tumours	x						x	
Biological	Treatment of cancer	x				x		x	
Biological	Treatment of cancer	x				x			
Biological	Treatment of fibrodysplasia ossificans progressive			x		x			
Biological	Treatment of hereditary angioedema			x		x			
Biological	Treatment of lower respiratory tract disease (LRTD)	x				x			
Biological	Treatment of cancer	x				x			
Biological	Treatment of acute ischaemic stroke	x				x			
Chemical	Treatment of tuberculosis	x						x	
Chemical	Treatment of mycobacterium tuberculosis	x					x	x	
Chemical	Treatment of tuberculosis	x					x	x	
Chemical	Treatment of serious infections	x				x	x	x	
Chemical	Treatment of epilepsy	x					x	x	
Chemical	Treatment of active ulcerative colitis	x						x	
Chemical	Treatment of acute myeloid leukaemia			x				x	
Chemical	Treatment of stroke	x					x	x	
Chemical	Treatment of geographic atrophy	x						x	
Chemical	Treatment of idiopathic pulmonary fibrosis	x					x	x	
Chemical	Treatment of bronchiectasis	x				x		x	
Chemical	Treatment of weight management	x				x		x	
Chemical	Treatment of multiple system atrophy			x			x	x	
Chemical	Treatment of allergic rhinitis	x				x	x	x	
Chemical	Treatment of Angelman syndrome			x				x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Chemical	Treatment of obesity	x				x		x	
Chemical	Treatment of mixed urinary incontinence	x					x		
Chemical	Treatment of carcinoma	x					x	x	
Chemical	Treatment of mild dementia	x						x	
Chemical	Treatment of VEXAS syndrome	x						x	
Chemical	Treatment of progressive supranuclear palsy	x				x	x	x	
Chemical	Treatment of hemochromatosis	x					x	x	
Chemical	Treatment of sclerosis	x					x	x	
Chemical	Treatment of immune-privileged sites			x		x			
Chemical	Treatment of lupus erythematosus	x				x			
Chemical	Treatment of primary sclerosing cholangitis			x		x			
Chemical	Treatment of non-small cell lung cancer (NSCLC)	x						x	
Qualification	Medical Tool								

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 87 Scientific Advice letters – 70 Initial Scientific Advice, 16 Protocol Assistance letters, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 13 - 16 October 2025.

New requests for scientific advice procedures

The Committee accepted 94 new Requests for which the procedure started at the SAWP meeting held on 29 September - 2 October 2025. The new requests are divided into as follows: 79 Initial Scientific Advice, 15 Protocol Assistance letters, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.