



26 February 2026
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Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 23-26 February 2026.

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

	1995-2025	2026	Overall total
Scientific Advice	7006	141	7147
Follow-up to Scientific Advice	2085	0	2085
Protocol Assistance	1528	36	1564
Follow-up to Protocol Assistance	766	0	766
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	264	6	270
	11814	184	11997

Outcome of the February 2026 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 mucopolysaccharidosis		x					x	x
Advanced Therapy	Treatment of inherited retinal dystrophies		x					x	
Advanced Therapy	Treatment of graft-versus-host disease		x			x	x		
Advanced Therapy	Treatment of acute myocardial infarction	x				x	x	x	

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Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Advanced Therapy	Treatment of multiple myeloma	x						x	
Advanced Therapy	Treatment of mesial temporal lobe epilepsy	x					x	x	
Advanced Therapy	Treatment of myasthenia Gravis	x						x	
Advanced Therapy	Treatment of melanoma	x				x			
Advanced Therapy	Treatment of lung cancer	x				x	x	x	
Advanced Therapy	Treatment of female infertility	x				x	x	x	
Advanced Therapy	Treatment of diabetic foot ulcer	x				x	x	x	
Advanced Therapy	Treatment of lupus erythematosus	x					x	x	
Advanced Therapy	Treatment of arterial disease	x				x	x	x	
Advanced Therapy	Treatment of melanoma	x						x	
Advanced Therapy	Treatment of breast cancer	x				x	x	x	
Advanced Therapy	Treatment of Duchenne Muscular Dystrophy	x				x	x	x	
Biological	Treatment of congenital myasthenic syndromes		x			x	x	x	
Biological	Treatment of myotonic dystrophy		x					x	
Biological	Treatment of allogeneic haematopoietic stem cell transplantation		x			x		x	
Biological	Treatment of Fabry disease		x			x	x		
Biological	Treatment of atrophy		x					x	
Biological	Treatment of myeloma		x			x	x		
Biological	Treatment of multiple myeloma		x					x	
Biological	Treatment of cancers		x			x		x	
Biological	Treatment of cancer		x					x	
Biological	Treatment of phosphodiesterase 1 deficiency		x			x		x	
Biological	Treatment of polyneuropathy		x					x	
Biological	Treatment of in solid organ transplantation		x				x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Prevention of RSV lower respiratory tract disease	x						x	
Biological	Treatment of Alzheimer's disease	x						x	
Biological	Prevention of influenza	x				x	x		
Biological	Prevention of COVID-19	x				x	x	x	
Biological	Prevention of Dengue Disease	x						x	
Biological	Treatment of Alzheimer's Disease	x					x	x	
Biological	Treatment of cancer	x				x		x	
Biological	Treatment of anaemia	x						x	
Biological	Treatment of ulcerative Colitis	x						x	
Biological	Treatment of Crohn's disease	x				x		x	
Biological	Treatment of lung cancer	x				x	x	x	
Biological	Treatment of carcinoma	x						x	
Biological	Treatment of weight management	x						x	
Biological	Treatment of carcinoma	x						x	
Biological	Treatment of liver fibrosis	x				x	x	x	
Biological	Treatment of Crohn's disease	x					x	x	
Biological	Treatment of tetanus infection	x				x	x	x	
Biological	Treatment of carcinoma	x						x	
Biological	Treatment of rhinosinusitis	x				x			
Biological	Prevention of skeletal-related events	x				x		x	
Biological	Treatment of dermatitis	x				x		x	
Biological	Treatment of dermatitis	x				x		x	
Biological	Treatment of asthma	x				x		x	
Biological	Treatment of growth issue	x				x	x	x	
Biological	Treatment of infertility	x				x			

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of Relapsed B-cell non-Hodgkin's lymphoma	x						x	
Chemical	Treatment of multiple myeloma	x				x	x	x	
Chemical	Treatment of tuberculosis		x					x	
Chemical	Treatment of Prader-Willi syndrome		x			x	x	x	
Chemical	Treatment of hypoparathyroidism		x					x	x
Chemical	Treatment of tumours		x				x	x	
Chemical	Treatment of hyperphenylalaninemia		x			x	x		
Chemical	Treatment of hepatitis E		x			x	x	x	
Chemical	Treatment of hypertension		x			x		x	
Chemical	Treatment of pulmonary hypertension		x				x	x	
Chemical	Treatment of Huntington's disease		x				x	x	
Chemical	Treatment of sickle cell disease		x			x			
Chemical	Treatment of carcinoma	x						x	
Chemical	Treatment of infections	x					x	x	
Chemical	Treatment of Fitzpatrick skin	x					x	x	
Chemical	Treatment of breast cancer	x				x		x	
Chemical	Treatment of cancers	x						x	
Chemical	Treatment of breast cancer	x					x	x	
Chemical	Treatment of melanoma	x				x	x	x	
Chemical	Treatment of fibrosis	x				x	x	x	
Chemical	Treatment of cardiovascular disease	x					x		
Chemical	Treatment of kidney disease	x						x	
Chemical	Treatment of diabetes mellitus	x					x	x	
Chemical	Treatment of weight management	x						x	
Chemical	Treatment of vasomotor symptoms	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of vasomotor symptoms	x				x	x	x	
Chemical	Treatment of hypercholesterolaemia	x				x		x	
Chemical	Treatment of acute ischemic stroke	x						x	
Chemical	Treatment of eosinophilic granulomatosis	x					x	x	
Chemical	Treatment of acute ischemic stroke	x					x	x	
Chemical	Treatment of prostate cancer	x					x		
Chemical	Treatment of Alzheimer's disease	x					x	x	
Chemical	Treatment of hypoparathyroidism	x				x			
Chemical	Treatment of generalized Myasthenia Gravis	x				x			
Chemical	Prevention of HIV-1	x				x			
Chemical	Treatment of hyperuricemia	x				x			
Qualification	Medical Tool								
Qualification	Medical Tool								
Qualification	Medical Tool								
Qualification	Medical Tool								
Qualification	Medical Tool								
Qualification	Medical Tool						x	x	
Qualification	Medical Tool								

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 96 Scientific Advice letters – 65 Initial Scientific Advice, 25 Protocol Assistance letters, 6 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 23-26 February 2026.

New requests for scientific advice procedures

The Committee accepted 80 new Requests for which the procedure started at the SAWP meeting held on 9 - 12 February 2026. The new requests are divided into as follows: 67 Initial Scientific Advice, 13 Protocol Assistance letters, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.