



21 May 2026
EMA/132508/2026
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 18-21 May 2026.

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

	1995-2025	2026	Overall total
Scientific Advice	7006	349	7355
Follow-up to Scientific Advice	2085	0	2085
Protocol Assistance	1528	69	1597
Follow-up to Protocol Assistance	766	0	766
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	264	7	271
	11814	426	12239

Outcome of the May 2026 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 heart failure	x					x	x	
Advanced Therapy	Treatment of Dravet syndrome		x			x	x	x	
Advanced Therapy	Treatment of multiple myeloma		x					x	
Advanced Therapy	Treatment of multiple myeloma	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 neuroblastoma	x				x			
Biological	Treatment of ulcerative colitis	x						x	
Biological	Treatment of macular degeneration	x				x			
Biological	Treatment of cancer	x						x	
Biological	Treatment of lung cancer	x						x	
Biological	Treatment of alcohol-related liver disease	x						x	
Biological	Prevention of herpes	x						x	
Biological	Treatment of immunodeficiency	x				x	x	x	
Biological	Treatment of immune thrombocytopenia							x	
Biological	Treatment of multiple myeloma	x						x	
Biological	Treatment of diabetes	x						x	
Biological	Treatment of haemophilia B	x						x	
Biological	Treatment of diabetic macular oedema	x				x	x	x	
Biological	Treatment of macular degeneration	x						x	
Biological	Treatment of multiple myeloma		x					x	
Biological	Treatment of multiple myeloma		x					x	
Biological	Treatment of autoimmune disease	x				x		x	
Biological	Treatment of tumours	x						x	
Biological	Treatment of weight management	x				x		x	
Biological	Treatment of Glanzmann thrombasthenia	x					x	x	
Biological	Treatment of tumour	x						x	
Biological	Treatment of type 1 diabetes	x						x	
Biological	Treatment of atopic dermatitis	x				x	x	x	
Biological	Treatment of asthma	x						x	
Biological	Treatment of cancer	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Biological	Treatment of cancer	x				x			
Biological	Treatment of haemoglobinuria	x					x	x	
Biological	Treatment of Type 2 diabetes mellitus	x						x	
Biological	Treatment of nephropathy		x			x		x	
Biological	Treatment of gastric cancer		x			x			
Biological	Prevention of infection	x				x	x		
Biological	Prevention of pulmonary tuberculosis	x				x			
Biological	Prevention of pandemic influenza A	x						x	
Biological	Treatment of tumour	x				x	x	x	
Biological	Treatment of tumour	x						x	
Biological	Treatment of cancer	x				x		x	
Biological	Treatment of cancer	x						x	
Biological	Treatment of osteoporosis	x				x			
Biological	Treatment of cancer	x				x	x	x	
Biological	Treatment of asthma	x				x		x	
Biological	Treatment of cancer	x						x	
Biological	Treatment of carcinoma	x				x		x	
Biological	Treatment of cancer	x				x		x	
Biological	Prevention of Covid-19 disease	x				x		x	
Biological	Treatment of Prader-Willi syndrome		x						
Chemical	Treatment of asthma	x				x		x	
Chemical	Treatment of Chronic weight management	x					x	x	
Chemical	Treatment of rheumatoid arthritis	x					x		
Chemical	Treatment of weight management	x					x	x	
Chemical	Treatment of allergy	x					x	x	
Chemical	Treatment of Chronic Kidney Disease	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 psoriasis vulgaris	x						x	
Chemical	Treatment of lymphocytic leukemia	x				x		x	
Chemical	Treatment of depressive disorder	x					x	x	
Chemical	Treatment of heart failure	x				x	x		
Chemical	Treatment of dysmenorrhea	x				x	x	x	
Chemical	Treatment of adults with overweight or obesity with and without type 2 diabetes mellitus as adjunct to diet and exercise	x						x	
Chemical	Treatment of Macular Degeneration	x				x	x	x	
Chemical	Treatment of melanoma		x					x	
Chemical	Prevention of cardiovascular events	x				x	x	x	
Chemical	Treatment of Alzheimer's disease	x				x	x	x	
Chemical	Diagnosis of small bladder tumours	x				x			
Chemical	Treatment of cancer	x				x			
Chemical	Treatment of adenocarcinoma	x				x			
Chemical	Treatment of endometriosis and uterine fibroids	x						x	
Chemical	Treatment of neuroblastoma	x						x	
Chemical	Treatment of neurodevelopmental symptoms	x				x	x	x	
Chemical	Treatment of hypercholesterolaemia	x				x	x	x	
Chemical	Treatment of myelofibrosis		x					x	x
Chemical	Treatment of lymphocytic leukaemia	x					x	x	
Chemical	Treatment of primary biliary cholangitis		x					x	
Chemical	Treatment of obesity	x					x	x	
Chemical	Treatment of Kennedy's disease		x			x	x	x	
Chemical	Treatment of carcinoma	x				x	x		
Chemical	Treatment of acute myocardial infarction	x				x			

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Chemical	Treatment of aerobic Gram-negative organisms	x						x	
Chemical	Treatment of COVID-19	x					x	x	
Chemical	Treatment of Influenza infection	x					x	x	
Chemical	Treatment of Relapsed B-cell non-Hodgkin's lymphoma	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 83 Scientific Advice letters – 72 Initial Scientific Advice, 11 Protocol Assistance letters, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 18-21 May 2026.

New requests for scientific advice procedures

The Committee accepted 76 new Requests for which the procedure started at the SAWP meeting held on 4 - 7 May 2026. The new requests are divided into as follows: 65 Initial Scientific Advice, 11 Protocol Assistance letters, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.