



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 June 2026
EMA/163533/2026
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 22-25 June 2026.

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

	1995-2025	2026	Overall total
Scientific Advice	7006	409	7415
Follow-up to Scientific Advice	2085	0	2085
Protocol Assistance	1528	79	1607
Follow-up to Protocol Assistance	766	0	766
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	264	8	272
	11814	497	12310

Outcome of the June 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 AML	x				x		x	
Advanced Therapy	Treatment of inflammatory myopathies	x				x	x	x	
Advanced Therapy	Treatment of Pompe's disease		x					x	x
Advanced Therapy	Treatment of multiple myeloma	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 mantle cell Lymphoma	x						x	
Advanced Therapy	Treatment of geographic atrophy	x				x	x	x	
Advanced Therapy	Treatment of sickle cell disease	x				x			
Biological	Treatment of beta-thalassaemia intermedia		x			x		x	
Biological	Treatment of soft tissue sarcoma		x					x	x
Biological	Medical Tool								
Biological	Prevention of streptococcus pneumoniae	x						x	
Biological	Prevention of SARS-CoV-2 infection	x						x	
Biological	Prevention of clostridioides difficile infection	x				x		x	
Biological	Prevention of pneumoniae							x	
Biological	Treatment of ES-SCLC		x					x	
Biological	Treatment of amyotrophic lateral sclerosis		x				x	x	
Biological	Prevention of LRTD	x					x	x	
Biological	Treatment of age-related macular degeneration	x				x	x	x	
Biological	Treatment of steatohepatitis	x						x	
Biological	Treatment of RRMM	x				x		x	
Biological	Treatment of pulmonary disease	x						x	
Biological	Treatment of asthma	x				x	x	x	
Biological	Treatment of chronic rhinosinusitis	x						x	
Biological	Treatment of B-cell	x						x	
Biological	Treatment of breast cancer	x						x	
Biological	Treatment of sarcopenic obesity	x						x	
Biological	Treatment of Non-segmental Vitiligo	x				x		x	
Biological	Treatment of IgA Nephropathy	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 uveal melanoma		x			x			
Biological	Treatment of diabetic macular edema	x				x			
Biological	Treatment of PNH	x				x			
Biological	Treatment of diabetes	x				x			
Chemical	Treatment of cancer	x						x	
Chemical	Treatment of colitis	x						x	
Chemical	Treatment of COVID-19	x						x	
Chemical	Treatment of psoriatic arthritis	x					x		
Chemical	Treatment of rheumatoid arthritis	x					x		
Chemical	Treatment of angiopathies		x			x	x	x	
Chemical	Diagnosis of ovarian cancer		x					x	
Chemical	Treatment of hyperlipidaemia	x					x	x	
Chemical	Treatment of hypertension	x						x	
Chemical	Treatment of PSMA-positive	x					x	x	
Chemical	Treatment of urinary incontinence	x						x	
Chemical	Treatment of oligomenorrhea	x						x	
Chemical	Treatment of seizures	x						x	
Chemical	Treatment of obesity	x						x	
Chemical	Treatment of Alzheimer's Disease	x						x	
Chemical	Treatment of polycythaemia	x						x	
Chemical	Treatment of pulmonary disease	x					x	x	
Chemical	Treatment of Weight Management	x						x	
Chemical	Treatment of carcinoma	x					x	x	
Chemical	Treatment of polycythemia vera		x				x	x	
Chemical	Treatment of hypertrophic cardiomyopathy	x					x	x	
Chemical	Treatment of dementia	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Chemical	Treatment of HIV-1 infection	x					x	x	
Chemical	Treatment of menopause	x				x	x	x	
Chemical	Treatment of primary hyperoxaluria		x			x		x	
Chemical	Treatment of tumours	x					x	x	
Chemical	Treatment of breast cancer	x					x	x	
Chemical	Treatment of obesity/weight management	x				x		x	
Chemical	Treatment of dry eye disease	x					x		
Chemical	Treatment of Irritability Associated with Autism Spectrum Disorder	x						x	
Chemical	Treatment of cancer	x				x			
Chemical	Treatment of age-related macular degeneration	x				x			
Medical Tool	Medical Tool	x						x	
Biological	Treatment of asthma	x				x	x	x	
Biological	Treatment of multiple myeloma	x						x	
Biological	Treatment of dermatitis	x				x		x	
Biological	Treatment of cancer	x				x		x	
Biological	Treatment of cancer	x				x		x	
Biological	Treatment of cancer	x				x		x	
Biological	Treatment of breast cancer	x						x	
Biological	Treatment of psoriasis	x				x		x	
Biological	Treatment of diabetes	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 75 Scientific Advice letters – 64 Initial Scientific Advice, 10 Protocol Assistance letters, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 22-25 June 2026.

New requests for scientific advice procedures

The Committee accepted 106 new Requests for which the procedure started at the SAWP meeting held on 8 – 11 June 2026. The new requests are divided into as follows: 85 Initial Scientific Advice, 20 Protocol Assistance letters, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.