



29 January 2026  
EMA/39865/2026  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 26-29 January 2026.

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

	1995-2025	2026	Overall total
Scientific Advice	7006	76	7082
Follow-up to Scientific Advice	2085	0	2085
Protocol Assistance	1528	11	1539
Follow-up to Protocol Assistance	766	0	766
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	264	0	264
	<b>11814</b>	<b>88</b>	<b>11901</b>

### ***Outcome of the January 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 tumour	x			x				
Advanced Therapy	Treatment of Retinitis Pigmentosa	x						x	



Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Precinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Advanced Therapy	Treatment of Asherman's syndrome		x			x			
Advanced Therapy	Treatment of lupus		x			x			
Advanced Therapy	Treatment of melanoma		x			x		x	
Advanced Therapy	Treatment of Parkinson's disease		x			x	x		
Advanced Therapy	Treatment of Myasthenia Gravis		x			x			
Advanced Therapy	Treatment of multiple myeloma		x			x			
Advanced Therapy	Treatment of melanoma		x						x
Advanced Therapy	Treatment of epilepsy		x			x	x		
Advanced Therapy	Treatment of inherited retinal dystrophies	x				x		x	
Advanced Therapy	Treatment of cancer		x			x			
Advanced Therapy	Treatment of acute myocardial infarction	x				x	x	x	
Advanced Therapy	Treatment of Duchenne muscular dystrophy	x				x	x		
Advanced Therapy	Treatment of mucopolysaccharidosis		x			x			x
Biological	Prevention of LRTD		x			x		x	
Biological	Treatment of cirrhosis		x			x			
Biological	Treatment of pulmonary sarcoidosis	x				x			
Biological	Prevention of immunodeficiency	x				x			
Biological	Treatment of oesophagitis	x						x	
Biological	Treatment of in tumours	x				x			

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Prevention of lower respiratory tract disease	x				x		x	
Biological	Prevention of COVID-19	x						x	
Biological	Treatment of nephropathy	x				x			
Biological	Treatment of polyneuropathy	x				x			
Biological	Treatment of Alzheimer's disease	x					x		
Biological	Treatment of atherosclerotic	x						x	
Biological	Treatment of rheumatologic disease	x				x	x		
Biological	Prevention of Rh(D) alloimmunization	x				x	x	x	
Biological	Treatment of cancer	x				x			
Biological	Treatment of leukaemia	x				x			
Biological	Treatment of neoplasm		x			x			x
Biological	Treatment of Alzheimer's disease	x				x			
Biological	Treatment of immunomodulation	x					x	x	
Biological	Treatment of congenital myasthenic syndromes		x			x	x	x	
Biological	Treatment of myotonic dystrophy		x			x			
Biological	Treatment of Parkinson's disease	x						x	
Biological	Treatment of hernia		x				x	x	
Biological	Treatment of cancer	x				x			
Biological	Treatment of leukaemia	x				x	x		
Biological	Prevention of pneumoniae	x				x	x		
Biological	Treatment of cancer	x				x		x	
Biological	Treatment of tumour	x				x			
Biological	Treatment of cancer	x				x	x	x	
Biological	Treatment of dermatitis	x				x	x	x	
Biological	Treatment of dermatitis	x				x		x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of sclerosis	x				x	x	x	
Biological	Treatment of sclerosis	x				x		x	
Biological	Treatment of cancer	x				x	x	x	
Biological	Treatment of neutropenia	x				x	x	x	
Biological	Treatment of cancer	x				x	x	x	
Chemical	Treatment of erectile dysfunction	x				x	x	x	
Chemical	Treatment of sickle cell disease	x						x	
Chemical	Treatment of keratosis	x				x			
Chemical	Treatment of osteoarthritis	x				x			
Chemical	Treatment of cataract	x				x		x	
Chemical	Treatment of heart failure	x				x	x	x	
Chemical	Treatment of tumours		x					x	
Chemical	Treatment of mitochondrial disease	x				x	x		
Chemical	Treatment of fibrosis	x				x			
Chemical	Treatment of idiopathic pulmonary fibrosis		x					x	
Chemical	Treatment of prostate cancer	x				x		x	
Chemical	Treatment of adenomatous polyposis	x				x			
Chemical	Diagnosis of peritoneal surface malignancy (PSM)	x				x	x	x	
Chemical	Treatment of adenocarcinoma	x				x	x		
Chemical	Treatment of obesity	x				x	x		
Chemical	Treatment of hepatitis B infection	x				x			
Chemical	Treatment of carcinoma	x				x			
Chemical	Treatment of gastroesophageal reflux	x						x	
Chemical	Treatment of breast cancer	x				x	x		
Chemical	Treatment of cancer	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Precinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of IR-NMIBC	x				x	x		
Chemical	Treatment of Leigh syndrome		x			x			
Chemical	Diagnosis of lesions of the body	x				x	x	x	
Chemical	Treatment of cancer	x				x			
Chemical	Prevention of mucositis	x				x	x		
Chemical	Treatment of NSCLC	x				x			
Chemical	Treatment of non-segmental vitiligo	x						x	
Chemical	Prevention of asthma	x				x		x	
Chemical	Diagnosis of carcinoma	x				x		x	
Chemical	Treatment of inadequate endometrial thickness	x				x	x		
Chemical	Treatment of psoriasis	x						x	
Chemical	Treatment of homocystinuria and/or methylmalonic		x			x			
Chemical	Prevention of pregnancy	x				x	x	x	
Chemical	Treatment of pain after spinal fusion surgery	x				x			
Chemical	Treatment of sarcoma		x			x			x
Chemical	Treatment of steatohepatitis	x				x			x

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 87 Scientific Advice letters – 76 Initial Scientific Advice, 11 Protocol Assistance letters, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 26-29 January 2026.

## New requests for scientific advice procedures

The Committee accepted 83 new Requests for which the procedure started at the SAWP meeting held on 12 - 15 January 2026. The new requests are divided into as follows: 60 Initial Scientific Advice, 22 Protocol Assistance letters, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.