



11 December 2025
EMA/16761/2026
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 8-11 December 2025.

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

	1995-2024	2025	Overall total
Scientific Advice	6457	549	7006
Follow-up to Scientific Advice	2071	14	2085
Protocol Assistance	1417	111	1528
Follow-up to Protocol Assistance	760	6	766
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	246	18	264
	11116	698	11814

Outcome of the December 2025 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
Advanced Therapy	Treatment of NDMM	x						x	
Advanced Therapy	Treatment of retinitis Pigmentosa	x				x			
Advanced Therapy	Treatment of lupus erythematosus	x						x	



Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Advanced Therapy	Treatment of metastatic melanoma	x				x		x	
Advanced Therapy	Treatment of Parkinson's disease	x					x	x	
Advanced Therapy	Treatment of inherited retinal dystrophies	x				x		x	
Advanced Therapy	Treatment of NDMM	x						x	
Advanced Therapy	Treatment of Duchenne muscular dystrophy	x					x	x	
Biological	Treatment of liver cirrhosis	x						x	
Biological	Treatment of pulmonary sarcoidosis	x						x	
Biological	Treatment of eosinophilic oesophagitis	x				x			
Biological	Treatment of tumours	x						x	
Biological	Prevention of lower respiratory tract disease	x				x		x	
Biological	Treatment of adult patients with primary membranous nephropathy (PMN)	x						x	
Biological	Treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP)	x						x	
Biological	Treatment of Alzheimer's Disease	x					x		
Biological	Treatment of hypercholesterolaemia and mixed dyslipidaemia	x				x			
Biological	Treatment of rheumatologic diseases	x					x	x	
Biological	Treatment of thrombotic thrombocytopenic purpura		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	Prevention of HPV infection	x				x			
Biological	Treatment of secondary immunodeficiencies	x				x	x		
Biological	Treatment of Parkinson's disease	x					x		

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of hernia		x			x	x		
Biological	Treatment of cancer	x						x	
Biological	Treatment of leukaemia	x					x	x	
Biological	Prevention of Lower Respiratory Tract Disease	x				x		x	
Biological	Treatment of cancer	x				x		x	
Biological	Treatment of dermatitis	x				x	x	x	
Biological	Treatment of multiple myeloma	x				x	x	x	
Biological	Treatment of dermatitis	x				x		x	
Biological	Treatment of multiple sclerosis	x				x	x	x	
Biological	Treatment of breast cancer	x				x	x	x	
Biological	Treatment of multiple sclerosis	x				x	x	x	
Biological	Treatment of psoriasis	x				x		x	
Biological	Treatment of cancer	x				x	x	x	
Biological	Treatment of melanoma	x				x	x	x	
Chemical	Treatment of erectile dysfunction	x				x	x	x	
Chemical	Treatment of Actinic keratosis	x						x	
Chemical	Treatment of glioma			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 gastrointestinal stromal tumours		x			x			
Chemical	Treatment of mitochondrial Diseases	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	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of Familial Adenomatous Polyposis (FAP)	x						x	
Chemical	Diagnosis of Positron emission tomography (PET)	x				x	x	x	
Chemical	Treatment of adenocarcinoma	x					x	x	
Chemical	Treatment of weight management	x					x	x	
Chemical	Treatment of hepatitis B infection	x						x	
Chemical	Treatment of gastroesophageal reflux disease	x				x			
Chemical	Treatment of breast cancer	x					x	x	
Chemical	Treatment of lung Cancer	x				x			
Chemical	Treatment of IR-NMIBC	x				x	x		
Chemical	Treatment of Leigh syndrome		x					x	
Chemical	Diagnosis of lesions of the brain, spine, and surrounding tissues, and the body	x				x	x	x	
Chemical	Treatment of cancer	x						x	
Chemical	Treatment of NSCLC	x						x	
Chemical	Treatment of Polycystic Ovary Syndrome	x						x	
Chemical	Treatment of vitiligo	x				x			
Chemical	Prevention of bronchoconstriction	x				x		x	
Chemical	Diagnosis of carcinoma	x				x		x	
Chemical	Treatment of pregnancy complications.	x					x	x	
Chemical	Treatment of plaque psoriasis	x				x			
Chemical	Treatment of homocystinuria		x					x	
Chemical	Treatment of systemic sclerosis		x			x	x	x	
Chemical	Prevention of pregnancy	x				x	x	x	
Chemical	Treatment of Erythropoietic Protoporphyrina (EPP) and X-linked Protoporphyrina (XLP)	x					x	x	
Chemical	Treatment of acute pain after spinal fusion surgery	x						x	

Substance	Intended indications	Type of request				Topic		
		New		Follow-up		Quality	Preclinical	Clinical
		SA	PA	SA	PA			
Chemical	Treatment of metabolic dysfunction-associated steatohepatitis	x					x	
Qualification	Medical Tool							
Qualification	Medical Tool							
Qualification	Medical Tool							

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 79 Scientific Advice letters – 67 Initial Scientific Advice, 9 Protocol Assistance letters, 3 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 8-11 December 2025.

New requests for scientific advice procedures

The Committee accepted 83 new Requests for which the procedure started at the SAWP meeting held on 24 - 27 November 2025. The new requests are divided into as follows: 74 Initial Scientific Advice, 9 Protocol Assistance letters, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.