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Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 23-26 March 2026.

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

	1995-2025	2026	Overall total
Scientific Advice	7006	210	7216
Follow-up to Scientific Advice	2085	0	2085
Protocol Assistance	1528	49	1577
Follow-up to Protocol Assistance	766	0	766
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	264	7	271
	<b>11814</b>	<b>267</b>	<b>12080</b>

### **Outcome of the March 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 Macular dystrophies	x						x	
Advanced Therapy	Treatment of melanoma	x				x			
Advanced Therapy	Treatment of Duchenne Muscular Dystrophy	x				x	x	x	
Biological	Treatment of adenocarcinoma	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				
Biological	Prevention of venous thromboembolism	x						x	
Biological	Treatment of dermatomyositis	x						x	
Biological	Treatment of neovascular age-related macular degeneration	x				x	x	x	
Biological	Treatment of anaemia	x						x	
Biological	Treatment of Cancer	x						x	
Biological	Treatment of thyroid eye disease	x					x	x	
Biological	Treatment of graft-versus-host disease	x				x	x	x	
Biological	Treatment of multiple system atrophy		x					x	
Biological	Treatment of Ulcerative Colitis	x						x	
Biological	Treatment of Crohn's Disease	x				x		x	
Biological	Prevention of influenza	x						x	
Biological	Treatment of immunodeficiency	x					x		
Biological	Treatment of small cell lung cancer		x			x			
Biological	Treatment of vaginosis	x				x	x	x	
Biological	Treatment of lymphoma		x					x	x
Biological	Treatment of asthma	x					x	x	
Biological	Treatment of weight management	x					x	x	
Biological	Treatment of mucopolysaccharidosis II		x					x	x
Biological	Treatment of moderate to severe plaque psoriasis	x				x	x	x	
Biological	Treatment of metastatic	x						x	
Biological	Treatment of cancer		x					x	
Biological	Treatment of atopic dermatitis	x					x	x	
Biological	Treatment of cancer	x						x	
Biological	Treatment of cancer	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of in solid organ transplantation		x				x	x	
Biological	Treatment of adenocarcinoma	x					x	x	
Biological	Treatment of asthma	x						x	
Biological	Treatment of Alzheimer's disease	x						x	
Biological	Prevention of Clostridioides difficile infection	x						x	
Biological	Prevention of COVID-19	x						x	
Biological	Treatment of Obesity	x						x	
Biological	Treatment of atopic dermatitis	x						x	
Biological	Treatment of atopic dermatitis	x				x		x	
Biological	Treatment of atopic dermatitis	x				x			
Biological	Treatment of the same as reference product Taltz	x						x	
Biological	Treatment of melanoma	x						x	
Biological	Treatment of melanoma	x				x		x	
Biological	Treatment of multiple sclerosis	x						x	
Biological	Treatment of multiple sclerosis	x				x	x	x	
Biological	Treatment of non-small cell lung cancer	x				x		x	
Biological	Treatment of non-small cell lung cancer	x						x	
Biological	Treatment of non-small cell lung cancer	x				x	x	x	
Biological	Treatment of tumour	x				x		x	
Biological	Treatment of immune thrombocytopenia	x				x	x	x	
Biological	Treatment of diabetes mellitus	x						x	
Biological	Treatment of breast cancer	x				x		x	
Biological	Treatment of cancer	x				x	x	x	
Chemical	Treatment of pancreatic cancer		x			x			
Chemical	Treatment of myopia	x				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 vitiligo lesions	x					x	x	
Chemical	Prevention of ischaemic stroke	x						x	
Chemical	Treatment of prostate cancer	x					x	x	
Chemical	Treatment of cirrhosis	x						x	
Chemical	Treatment of lymphoplasmacytic lymphoma		x					x	
Chemical	Treatment of hypoparathyroidism	x					x	x	
Chemical	Treatment of Parkinson's disease	x				x			
Chemical	Prevention of cardiovascular disease	x					x	x	
Chemical	Treatment of kidney disease	x						x	
Chemical	Treatment of hepatitis	x						x	
Chemical	Treatment of diabetes mellitus	x				x	x		
Chemical	Treatment of Covid-19	x					x	x	
Chemical	Treatment of myopathies	x					x	x	
Chemical	Treatment of transthyretin amyloidosis	x				x		x	
Chemical	Treatment of dystrophic myotonia		x				x	x	
Chemical	Treatment of neurodevelopmental disorder	x				x	x	x	
Chemical	Treatment of seizures	x					x	x	
Chemical	Treatment of diabetes mellitus	x					x	x	
Chemical	Treatment of polycythaemia vera	x					x	x	
Chemical	Treatment of cancer	x						x	
Chemical	Treatment of Leber's congenital amaurosis		x			x		x	
Chemical	Treatment of Duchenne muscular dystrophy		x					x	
Chemical	Treatment of arthritis	x						x	
Chemical	Treatment of pulmonary fibrosis	x						x	
Chemical	Treatment of soft tissue sarcoma		x					x	x
Chemical	Treatment of transthyretin amyloidosis		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 Dravet Syndrome	x				x	x	x	
Chemical	Treatment of ischemic stroke	x						x	
Medical Tool	Medical Tool								
Medical Tool	Medical Tool								

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 83 Scientific Advice letters – 69 Initial Scientific Advice, 13 Protocol Assistance letters, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 23-26 March 2026.

### **New requests for scientific advice procedures**

The Committee accepted 76 new Requests for which the procedure started at the SAWP meeting held on 9 - 12 March 2026. The new requests are divided into as follows: 69 Initial Scientific Advice, 7 Protocol Assistance letters, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.