



24 July 2025  
EMA/CHMP/SAWP/251225/2025  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 21- 24 July 2025

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

	1995-2024	2025	Overall total
Scientific Advice	6457	309	6766
Follow-up to Scientific Advice	2071	14	2085
Protocol Assistance	1417	64	1481
Follow-up to Protocol Assistance	760	6	766
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	246	9	255
	<b>11116</b>	<b>402</b>	<b>11518</b>

### ***Outcome of the July 2025 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 leukaemia		x			x		x	
Advanced Therapy	Treatment of Duchenne muscular dystrophy		x			x	x	x	
Advanced Therapy	Prevention of cancer	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 OTOF		x			X	X	X	
Advanced Therapy	Treatment of retinal dystrophies		x			X	X	X	
Advanced Therapy	Treatment of age-Related Macular Degeneration	x						X	
Advanced Therapy	Treatment of myeloma	x					X	X	
Advanced Therapy	Treatment of lymphoma	x					X	X	
Biological	Treatment of cancer	x				X		X	
Biological	Treatment of diabetes	x				X	X	X	
Biological	Treatment of cancer	x						X	
Biological	Treatment of multiple sclerosis	x				X	X	X	
Biological	Treatment of cancer	x				X		X	
Biological	Treatment of cancer	x				X		X	
Biological	Treatment of breast cancer	x				X		X	
Biological	Treatment of immune thrombocytopenic purpura	x				X		X	
Biological	Treatment of cancer	x				X			
Biological	Treatment of Crohn's disease	x				X		X	
Biological	Treatment of Crohn's disease	x				X		X	
Biological	Treatment of cancer	x					X	X	
Biological	Treatment of ulcerative colitis	x				X		X	
Biological	Treatment of primary IgA nephropathy		x					X	
Biological	Treatment of atrophy	x					X	X	
Biological	Treatment of monoclonal antibody toxin	x					X		
Biological	Prevention of infection	x						X	
Biological	Prevention of cystic fibrosis		x			X	X	X	X
Biological	Treatment of tumour	x				X			
Biological	Treatment of carcinoma	x				X	X	X	
Biological	Treatment of ulcerative colitis	x					X	X	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Biological	Treatment of Crohn's disease	x						X	
Biological	Treatment of liver fibrosis	x				X	X	X	
Biological	Treatment of acute radiation syndrome		x				X		
Biological	Prevention of venous thromboembolism	x						X	
Biological	Treatment of infertility in male	x				X	X	X	
Biological	Treatment of cancer	x						X	
Biological	Treatment of cancer	x					X	X	
Biological	Treatment of endometrial carcinoma	x						X	
Biological	Prevention of kidney disease	x						X	
Biological	Treatment of LBCL	x						X	
Chemical	Treatment of idiopathic pulmonary fibrosis	x				X		X	
Chemical	Treatment of atrophy	x						X	
Chemical	Treatment of with asthma	x				X		X	
Chemical	Treatment of lichen planus	x				X	X	X	
Chemical	Treatment of kidney disease	x				X		X	
Chemical	Treatment of kidney disease	x				X			
Chemical	Treatment of alpha-thalassaemia and beta-thalassaemia	x						X	
Chemical	Treatment of cancer	x					X	X	
Chemical	Treatment of Stargardt Disease	x				X	X	X	
Chemical	Treatment of Denovo Genomic Marker 4 (DGM4™)	x					X	X	
Chemical	Treatment of weight loss	x					X		
Chemical	Treatment of prostate malignant neoplasms	x				X		X	
Chemical	Treatment of breast cancer	x						X	
Chemical	Treatment of plaque psoriasis	x				X			
Chemical	Treatment of hypercholesterolaemia	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 bipolar disorder	x						X	
Chemical	Treatment of diabetes	x				X		X	
Qualification	Medical Tool								
Qualification	Medical Tool								
Qualification	Medical Tool								
Qualification	Medical Tool								
Qualification	Medical Tool								

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 59 Scientific Advice letters – 48 Initial Scientific Advice, 5 Protocol Assistance letters, 5 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 21 - 24 Jul 2025.

## New requests for scientific advice procedures

The Committee accepted 55 new Requests for which the procedure started at the SAWP meeting held on 7 - 10 Jul 2025. The new requests are divided into as follows: 44 Initial Scientific Advice, 11 Protocol Assistance letters, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.