



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 January 2025
EMA/CHMP/SAWP/64358/2025
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 27-30 January 2025.

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

	1995-2024	2025	Overall total
Scientific Advice	6457	48	6505
Follow-up to Scientific Advice	2071	11	2082
Protocol Assistance	1417	8	1425
Follow-up to Protocol Assistance	760	6	766
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	246	0	246
	11116	73	11189

Outcome of the January 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 DCM	x					x	x	
Advanced Therapy	Treatment of haemophilia A				x	x	x	x	
Advanced Therapy	Treatment of liver disease		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 hearing loss		x			x			
Advanced Therapy	Treatment of papillomatosis				x		x	x	
Advanced Therapy	Treatment of squamous cell carcinoma	x				x			
Advanced Therapy	Treatment of muscular dystrophy	x				x			
Advanced Therapy	Treatment of diabetic retinopathy	x					x	x	
Advanced Therapy	Treatment of squamous cell carcinoma			x		x			
Advanced Therapy	Treatment of pancreatic cancer		x				x	x	x
Biological	Treatment of mucopolysaccharidosis	x					x	x	
Biological	Treatment of eye disease	x						x	
Biological	Treatment of pulmonary disease	x				x	x	x	
Biological	Treatment of AMD			x		x		x	
Biological	Treatment of primary hypercholesterolemia	x				x			
Biological	Treatment of dermatitis			x		x		x	
Biological	Treatment of macular neovascularization			x				x	
Biological	Treatment of urticaria	x						x	
Biological	Treatment of Multiple myeloma	x						x	
Biological	Treatment of myasthenia gravis		x			x			
Biological	Treatment of fertility	x				x	x	x	
Biological	Treatment of Duchenne muscular dystrophy	x						x	
Biological	Prevention of GBS disease			x		x	x		
Biological	Treatment of cancer	x						x	
Biological	Prevention of cancer	x						x	
Biological	Treatment of leukoencephalopathy		x					x	
Biological	Treatment of prostate cancer	x					x	x	
Biological	Treatment of sepsis	x				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 systemic sclerosis	x						x	
Biological	Treatment of cancer			x				x	
Biological	Treatment of cancer	x				x		x	
Biological	Treatment of carcinoma		x					x	
Biological	Prevention of cardiovascular event	x						x	
Biological	Treatment of cancer	x				x			
Biological	Treatment of neoplasm	x				x			
Biological	Treatment of Non-small Cell Lung Cancer	x						x	
Biological	Treatment of solid tumour	x					x	x	
Biological	Treatment of psoriasis			x		x		x	
Biological	Treatment NSCLC	x						x	
Biological	Treatment of Carcinoma	x						x	
Biological	Treatment of acute ischaemic stroke	x				x			
Biological	Treatment of Amyotrophic lateral sclerosis	x				x	x	x	
Biological	Prevention of influenza	x				x	x	x	
Biological	Prevention of Ebola Virus Disease	x				x	x	x	
Chemical	Treatment of HIV-1 infection	x				x		x	
Chemical	Treatment of Prader-Willi syndrome				x			x	
Chemical	Treatment of neurodevelopmental disorder	x				x	x	x	
Chemical	Treatment of non-cystic fibrosis bronchiectasis	x				x	x	x	
Chemical	Treatment of prostate cancer			x				x	
Chemical	Treatment of steatohepatitis	x						x	
Chemical	Treatment of Heart failure	x					x	x	
Chemical	Treatment of generalized tonic-clonic seizures			x				x	
Chemical	Treatment of HIV-1	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 AML			x				x	
Chemical	Treatment of diabetes	x					x	x	
Chemical	Treatment of weight management	x						x	
Chemical	Treatment of Alzheimer	x						x	
Chemical	Treatment of Parkinson	x						x	
Chemical	Treatment of fibrodysplasia ossificans				x		x	x	
Chemical	Treatment of follicular lymphoma		x				x	x	
Chemical	Treatment of disorders in Children	x				x	x	x	
Chemical	Treatment of nephrotic syndrome				x		x	x	x
Chemical	Treatment of Parkinson	x					x	x	
Chemical	Treatment of Alzheimer	x						x	
Chemical	Treatment of transthyretin amyloidosis	x					x	x	
Chemical	Prevention of postpartum haemorrhage	x					x	x	
Chemical	Treatment of amyotrophic lateral sclerosis				x			x	
Chemical	Treatment of multiple sclerosis	x						x	
Chemical	Treatment of vitiligo			x				x	
Chemical	Treatment of diabetes mellitus	x					x		
Chemical	Treatment of pulmonary hypertension	x						x	
Chemical	Treatment of lymphoma	x				x			
Chemical	Treatment of myeloid leukaemia		x					x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 73 Scientific Advice letters – 48 Initial Scientific Advice, 11 Follow-up Scientific Advice, 8 Protocol Assistance letters, 6 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 27-30 January 2025.

New requests for scientific advice procedures

The Committee accepted 64 new Requests for which the procedure started at the SAWP meeting held on 13 - 16 January 2025. The new requests are divided as follows: 51 Initial Scientific Advice, 0 Follow-up Scientific Advice, 12 Protocol Assistance letters, 0 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.