

25 April 2024 EMA/CHMP/SAWP/179086/2024 Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 22-25 April 2024

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

	1995-2023	2024	Overall total
Scientific Advice	6072	141	6213
Follow-up to Scientific Advice	1928	55	1983
Protocol Assistance	1343	24	1367
Follow-up to Protocol Assistance	719	19	738
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	228	12	240
	10455	252	10706

Outcome of the April 2024 CHMP meeting in relation to scientific advice procedures

Final scientific advice procedures

Substance	Intended indications	Type of request					Торіс				
		New		Follow- up							
		SA	РА	SA	ΡΑ	Quality	Preclinical	Clinical	Significant benefit		
Advanced Therapy	Treatment of Wilson disease		х			х					
Advanced Therapy	Treatment of Multiple Myeloma			х				x			
Biological	Treatment of urticaria	x					х	x			

Official addressDomenico Scarlattilaan 61083 HS AmsterdamThe NetherlandsAddress for visits and deliveriesRefer to www.ema.europa.eu/how-to-find-usSend us a questionGo to www.ema.europa.eu/contactTelephone +31 (0)88 781 6000



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Substance	Intended indications	Type of request				Торіс				
		New		Follow up						
		SA	ΡΑ	SA	ΡΑ	Quality	Preclinical	Clinical	Significant benefit	
Biological	Treatment of rheumatoid arthritis			x		x		х		
Biological	Treatment of rheumatoid arthritis			х		х		х		
Biological	Treatment of colitis	x				x		х		
Biological	Treatment of rheumatoid arthritis	x				x				
Biological	Treatment of breast cancer	x				x	x	x		
Biological	Treatment of cancer			х				х		
Biological	Treatment of leptin deficiency	x						х		
Biological	Treatment of asthma	x					x	х		
Biological	Treatment of osteoporosis	x				x	x	х		
Biological	Treatment of herpes			x			x	x		
Biological	Prevention of Encephalitis	x				x	х	х		
Biological	Prevention of herpes			х				х		
Biological	Treatment of eczema	x				x	х	х		
Biological	Prevention of Lower Respiratory Tract Disease	x				х	x	x		
Biological	Treatment of non-small cell lung cancer	x					х	х		
Biological	Treatment of ischaemic stroke	x						х		
Biological	Treatment of obesity	x					х			
Biological	Treatment of genetic disorder	x						х		
Biological	Treatment of NSCLC	x						х		
Biological	Treatment of carcinoma				x			х		
Biological	Treatment of cancer			x				x		
Biological	Treatment of Amyotrophic Lateral Sclerosis	x					x	x		
Biological	Treatment of tumors	x					x			
Biological	Treatment of gravis		x			x		x		
Biological	Treatment of breast cancer			x		x		x		

Substance	Intended indications	Type of request				Торіс				
		New		Follow- up						
		SA	ΡΑ	SA	ΡΑ	Quality	Preclinical	Clinical	Significant benefit	
Biological	Prevention of pneumonia			х		x	x	х		
Biological	Treatment of Non-alcoholic steatohepatitis			x				х		
Biological	Treatment of non-alcoholic steatohepatitis			х				х		
Biological	Prevention of COVID-19	х				х	x	х		
Chemical	Treatment of Glaucoma			x		х		х		
Chemical	Treatment of leukaemia	x				х				
Chemical	Treatment of diabetes mellitus	x				х	x	x		
Chemical	Treatment of Generalized Myasthenia Gravis			x				х		
Chemical	Treatment of ISL/LEN	x					x	х		
Chemical	Treatment of Lymphocytic Leukaemia			x				х		
Chemical	Treatment of hypertension				х			х		
Chemical	Treatment of blood disease	x						х		
Chemical	Treatment of primary biliary cholangitis	x				x				
Chemical	Treatment of epilepsy	x					x	х		
Chemical	Treatment of Alzheimer's Disease	x					х			
Chemical	Treatment of bronchiectasis	x						х		
Chemical	Treatment of respiratory virus	x					x	х		
Chemical	Treatment of coeliac disease	x					x			
Chemical	Treatment of Chronic spontaneous urticaria	x						х		
Chemical	Treatment of lymphoblastic Leukaemia	x						х		
Chemical	Treatment of prurigo nodularis	x						x		
Chemical	Treatment of arthritis	x						x		
Chemical	Treatment of hypertension	x						х		
Chemical	Treatment of alpha-1 antitrypsin				x	x				
Chemical	Treatment of mCRPC	x					x	х		
Chemical	Treatment of Stargardt's disease				x			x		

Substance	Intended indications	Ту	pe of	requ	est	Торіс					
		New		Foll up	ow-						
		SA	РА	SA	РА	Quality	Preclinical	Clinical	Significant benefit		
Chemical	Treatment of amyotrophic lateral sclerosis				х			х			
Chemical	Treatment of Leigh syndrome		x				x	x			
Chemical	Treatment of prostate cancer	x				х		x			
Chemical	Treatment of anaphylaxis	x					x	х			
Chemical	Treatment of bronchospasm			х				х			
Chemical	Treatment of bladder cancer	х				х					
Chemical	Treatment of TiO2	x					x				
Chemical	Diagnosis of solid tumours	x				x	x	x			
Chemical	Treatment of infertility	x						x			
Chemical	Treatment of Alcohol-related liver disease	x						x			
Chemical	Treatment of neurofibromatosis		x			x	x	x	x		
Chemical	Treatment of metastatic NSCLC	x						x			
Chemical	Treatment of non-segmental vitiligo	x				x					
	Treatment of non-cystic fibrosis bronchiectasis			х		x					
Qualification	Medical tool							х			
Qualification	Simulation Tool										
Qualification	Medical tool										
Qualification	Medical tool										

SA: Scientific Advice PA: Protocol Assistance

The above-mentioned 72 Scientific Advice letters – 43 Initial Scientific Advice, 16 Follow-up Scientific Advice, 4 Protocol Assistance letters, 5 Follow-up Protocol Assistance, 4 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 22-25 April 2024.

New requests for scientific advice procedures

The Committee accepted 64 new Requests for which the procedure started at the SAWP meeting held on 8-11 Apr 2024. The new requests are divided as follows: 31 Initial Scientific Advice, 17 Follow-up Scientific Advice, 11 Protocol Assistance letters, 3 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.