



09 November 2023
EMA/CHMP/SAWP/498229/2023
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 06-09 November 2023

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

	1995-2022	2023	Overall total
Scientific Advice	5684	346	6030
Follow-up to Scientific Advice	1783	133	1916
Protocol Assistance	1268	65	1333
Follow-up to Protocol Assistance	680	34	714
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	210	15	225
	9790	593	10383

Outcome of the November 2023 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				
Chemical	Treatment of idiopathic pulmonary fibrosis					X			
Biological	Treatment of Alzheimer's disease	X						X	
Chemical	Treatment of amyotrophic lateral sclerosis		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				
Chemical	Treatment of hereditary cystatin C amyloid angiopathy	X					X	X	
Biological	Treatment of Alzheimer's disease	X				X	X	X	
Biological	Treatment of B-cell acute lymphoblastic leukaemia	X						X	
Chemical	Treatment of acute ischemic stroke	X				X		X	
Chemical	Treatment of progressive supranuclear palsy			X		X		X	
Biological	Treatment of Pompe disease	X				X	X		
Chemical	Treatment of Niemann-Pick type C		X					X	
Chemical	Treatment of GM1 and GM2 gangliosidosis		X					X	
Chemical	Treatment of chronic kidney disease	X					X	X	
Biological	Treatment of interstitial lung disease	X						X	
Biological	Treatment of breast cancer, non-small cell lung cancer, renal cell carcinoma and ovarian cancer		X			X		X	
Chemical	Treatment of pulmonary fibrosis		X			X			
Chemical	Treatment of non-small cell lung cancer	X				X			
Chemical	Treatment of genetic mutation	X					X	X	
Chemical	Treatment of non-cystic fibrosis bronchiectasis		X					X	
Biological	Treatment of non-small cell lung cancer	X						X	
Chemical	Treatment of breast cancer	X				X			
Chemical	Treatment of schizophrenia		X					X	
Biological	Treatment of non-small cell lung cancer	X						X	
Chemical	Treatment of generalized myasthenia gravis		X					X	
Chemical	Treatment of rhabdomyosarcoma	X						X	
Chemical	Treatment of acute otitis media	X						X	
Chemical	Treatment of amyotrophic lateral sclerosis	X					X	X	
Biological	Treatment of head and neck squamous cell carcinoma	X						X	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of breast cancer	X				X	X	X	
Biological	Treatment of multiple myeloma			X				X	
Biological	Treatment of follicular lymphoma				X			X	
Biological	Prevention of migraine		X			X		X	
Chemical	Treatment of bladder cancer	X					X	X	
Chemical	Treatment of hypercholesterolaemia or mixed hyperlipidaemia	X						X	
Chemical	Diagnosis of pathology by magnetic resonance imaging		X					X	
Chemical	Treatment of bladder cancer	X						X	
Biological	Treatment of acute ischemic stroke		X			X			
Biological	Prevention of COVID-19 disease	X					X	X	
Advanced Therapy	Treatment of heart failure	X				X	X		
Biological	Treatment of diabetes	X				X	X	X	
Chemical	Treatment of primary biliary cholangitis				X			X	
Chemical	Weight management	X				X	X	X	
Biological	Treatment of non-small cell lung cancer	X						X	
Chemical	Treatment of ovarian cancer			X				X	X
Chemical	Prevention of cardiovascular disease	X						X	
Biological	Treatment of acute myeloid leukaemia	X						X	
Biological	Treatment of eosinophilic asthma, chronic rhinosinusitis, eosinophilic granulomatosis with polyangiitis and hypereosinophilic syndrome	X						X	
Chemical	Treatment of pulmonary arterial hypertension	X						X	
Biological	Prevention of smallpox, monkeypox and disease caused by vaccinia virus	X				X	X	X	
Biological	Prevention of influenza	X				X		X	
Advanced Therapy	Treatment of cutaneous squamous cell carcinoma	X						X	
Biological	Treatment of rheumatoid arthritis	X						X	
Chemical	Treatment of COVID-19	X				X		X	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Diagnosis of abdominal surgery		X			X	X	X	
Chemical	Treatment of 5q spinal muscular atrophy			X		X	X	X	
Chemical	Treatment of respiratory syncytial virus	X					X	X	
Biological	Treatment of multiple sclerosis	X						X	
Chemical	Treatment of Seizures	X						X	
Biological	Treatment of non-alcoholic steatohepatitis	X					X	X	
Biological	Treatment of non-small cell lung cancer	X						X	
Biological	Prevention of COVID-19	X				X	X	X	
Chemical	Treatment of distal symmetrical polyneuropathy	X				X	X	X	
Biological	Prevention of acute otitis media, pneumonia and invasive pneumococcal disease		X			X	X	X	
Chemical	Treatment of non-segmental vitiligo	X				X			
Chemical	Prevention of iatrogenic ureteral injury		X			X			
Biological	Treatment of primary immunoglobulin A nephropathy	X						X	
Advanced Therapy	Treatment of X-linked myotubular myopathy				X	X			
Chemical	Treatment of infections due to Acinetobacter baumannii		X				X	X	
Biological	Treatment of primary immune thrombocytopenia		X			X		X	
Biological	Treatment of non-alcoholic steatohepatitis	X				X		X	
Chemical	Treatment of pulmonary arterial hypertension			X		X			
Chemical	Treatment of amyotrophic lateral sclerosis				X			X	
Advanced Therapy	Treatment of type 1 diabetes	X					X	X	
Biological	Treatment of small cell lung cancer	X						X	
Biological	Treatment of small cell lung cancer	X						X	
Biological	Treatment of small cell lung cancer	X						X	
Biological	Treatment of breast cancer	X						X	
Chemical	Treatment of Pulmonary hypertension	X					X		
Chemical	Treatment of advanced cancer	X				X			

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of sclerosing cholangitis	X					X	X	
Biological	Treatment of ulcerative colitis	X						X	
Biological	Treatment of ulcerative colitis, Crohn's disease and pouchitis	X				X			
Biological	Treatment of biliary tract cancer			X			X	X	
Chemical	Treatment of migraine		X					X	
Biological	Treatment of perennial allergic rhinitis	X						X	
Qualification	Artificial intelligence in clinical trials							X	
Qualification	Treatment of tuberculosis							X	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 86 Scientific Advice letters - 56 Initial Scientific Advice, 18 Follow-up Scientific Advice, 6 Protocol Assistance letters, 4 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices were adopted at the 06-09 November 2023 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 68 new Requests for which the procedure started at the SAWP meeting held on 09-12 October 2023. The new requests are divided as follows: 39 Initial Scientific Advice, 12 Follow-up Scientific Advice, 10 Initial Protocol Assistance, 6 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.