



10 November 2022
EMA/CHMP/SAWP/872304/2022
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 7 – 10 November 2022

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

	1995-2020	2022	Overall total
Scientific Advice	5226	422	5648
Follow-up to Scientific Advice	1623	146	1769
Protocol Assistance	1173	80	1253
Follow-up to Protocol Assistance	634	43	677
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	180	26	206
	9001	717	9718

Outcome of the November 2022 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 hypovolemic shock	X				X	X	X	
Biological	Treatment of eosinophilic oesophagitis			X				X	
Biological	Treatment of Hodgkin lymphoma			X				X	



Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of lung cancer			X		X			
Chemical	Treatment of colorectal cancer	X						X	
Biological	Prevention of influenza disease	X				X	X	X	
Biological	Treatment of eosinophilic esophagitis			X		X			
Chemical	Treatment of urinary infections			X				X	
Chemical	Treatment of prostate cancer			X				X	
Chemical	Treatment of multiple myeloma	X						X	
Biological	Treatment of plaque psoriasis	X						X	
Biological	Treatment of haemophilia B	X				X			
Chemical	Treatment of cholangiocarcinoma	X					X	X	
Biological	Prevention of haemophilia A	X				X			
Biological	Treatment of breast cancer			X				X	
Chemical	Diagnosis of cancer			X				X	
Biological	Treatment of multiple sclerosis			X				X	
Biological	Treatment of multiple sclerosis	X						X	
Chemical	Treatment of dry eye disease	X				X	X	X	
Biological	Treatment of atopic dermatitis	X				X	X	X	
Biological	Treatment of asthma	X					X	X	
Biological	Treatment of endometriosis	X					X	X	
Chemical	Treatment of hepatitis B	X				X		X	
Chemical	Treatment of cystic fibrosis		X				X	X	
Biological	Treatment of small cell lung cancer	X						X	
Chemical	Treatment of colorectal cancer	X						X	
Biological	Treatment of bullous pemphigoid			X				X	
Chemical	Treatment of leukemia	X				X		X	
Chemical	Treatment of atopic dermatitis	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 endometrial cancer	X						X	
Chemical	Treatment of hepatitis B	X				X			
Chemical	Treatment of myelofibrosis		X			X		X	
Advanced Therapy	Treatment of soft tissue sarcoma		X			X			
Chemical	Treatment of depression	X				X			
Chemical	Treatment of leukemia			X				X	
Chemical	Treatment of myotonic dystrophy type 1	X				X	X	X	
Biological	Treatment of hyperinsulinism		X			X	X	X	
Chemical	Treatment of osteoarthritis	X				X			
Biological	Treatment of non-alcoholic steatohepatitis	X				X		X	
Chemical	Treatment of lupus erythematosus	X					X	X	
Advanced Therapy	Treatment of retinitis pigmentosa				X			X	
Chemical	Treatment of bronchospasm	X				X	X	X	
Biological	Treatment of solid tumors	X						X	
Chemical	Treatment of primary IgA nephropathy		X				X	X	X
Chemical	Treatment of tuberculosis	X						X	
Chemical	Treatment of Lowe syndrome	X						X	
Chemical	Treatment of multiple sclerosis	X				X		X	
Biological	Treatment of diabetes	X				X		X	
Chemical	Treatment of methylmalonic acidemia			X				X	
Advanced Therapy	Treatment of propionic acidemia		X					X	
Chemical	Treatment of non-small cell lung cancer	X				X		X	
Advanced Therapy	Treatment of Parkinson's disease	X				X	X		
Biological	Treatment of rheumatoid arthritis	X					X		
Chemical	Treatment of obesity	X					X	X	
Chemical	Treatment of kidney disease		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 primary ciliary dyskinesia				X		X	X	
Biological	Treatment of eosinophilic esophagitis	X				X	X	X	
Chemical	Treatment of pulmonary disease			X		X	X	X	
Biological	Treatment of lacyltransferase deficiency				X	X		X	
Chemical	Treatment of hypertension	X				X			
Biological	Treatment of ischemic stroke	X					X	X	
Chemical	Treatment of propionic acidemia			X				X	
Biological	Treatment of cervical dystonia	X						X	
Chemical	Treatment of myelofibrosis		X				X	X	
Biological	Treatment of solid tumors	X				X	X	X	
Advanced Therapy	Treatment of methylmalonic acidaemia		X				X	X	
Biological	Treatment of osteoarthritis	X				X	X	X	
Biological	Treatment of cancer			X				X	
Chemical	Treatment of endometriosis	X				X	X	X	
Qualification	Acceptability score of oral medicines			X				X	
Qualification	Platform for quantification of white-matter alterations	X						X	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 71 Scientific Advice letters - 42 Initial Scientific Advice, 15 Follow-up Scientific Advice, 9 Protocol Assistance letters, 3 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices were adopted at the 7-10 November 2022 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 71 new Requests for which the procedure started at the SAWP meeting held on 24-27 October 2022. The new requests are divided as follows: 37 Initial Scientific Advice, 14 Follow-up Scientific Advice, 17 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.