



26 April 2023
EMA/CHMP/SAWP/188869/2023
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 24-26 April 2023

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

	1995-2022	2023	Overall total
Scientific Advice	5684	142	5826
Follow-up to Scientific Advice	1783	50	1833
Protocol Assistance	1268	24	1292
Follow-up to Protocol Assistance	680	12	692
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	210	4	214
	9790	232	10022

Outcome of the April 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						
Qualification	Methodology of covariates in clinical trials	x							
Advanced Therapy	Treatment of Crohn's disease		x			x			
Chemical	Treatment of Angelman's syndrome	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 melanoma	x					x	x	
Chemical	Treatment of myocardial infarction			x		x			
Biological	Treatment of plaque psoriasis	x				x			
Biological	Treatment of sinusoidal obstruction syndrome	x				x	x	x	
Chemical	Treatment of myeloid leukemia	x				x	x	x	
Advanced Therapy	Treatment of Parkinson's disease	x				x	x	x	
Chemical	Treatment of gastroparesis	x						x	
Advanced Therapy	Treatment of hearing loss				x	x	x	x	
Chemical	Treatment of non-small cell lung cancer	x						x	
Chemical	Treatment of Alport's syndrome	x						x	
Advanced Therapy	Treatment of Duchenne's muscular dystrophy			x			x	x	
Advanced Therapy	Treatment of urothelial carcinoma	x						x	
Chemical	Treatment of sclerosis	x				x	x	x	
Chemical	Treatment of non-cystic fibrosis bronchiectasis			x				x	
Chemical	Treatment of cirrhosis			x				x	
Biological	Treatment of melanoma				x			x	
Biological	Treatment of malignant pleural mesothelioma	x					x	x	
Chemical	Treatment of lung allograft dysfunction	x						x	
Biological	Treatment of prurigo nodularis			x				x	
Chemical	Treatment of heart failure			x				x	
Biological	Treatment of aid in smoking quit	x						x	
Biological	Treatment of acute kidney injury			x				x	
Biological	Treatment of rheumatoid arthritis	x						x	
Biological	Prevention of pneumococcal disease			x			x	x	
Biological	Treatment of non-small cell lung cancer	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of pneumonia				x			x	
Chemical	Treatment of bipolar depression	x				x	x	x	
Chemical	Treatment of hypertrophic cardiomyopathy			x				x	
Biological	Treatment of non-small cell lung cancer	x						x	
Biological	Treatment of lymphoblastic leukaemia			x		x			
Biological	Treatment of type 2 diabetes mellitus	x				x		x	
Chemical	Treatment of sclerosis				x			x	
Biological	Treatment of homocystinuria		x				x	x	x
Chemical	Treatment of creatine deficiency syndromes		x			x	x	x	x
Chemical	Treatment of Parkinson's disease			x				x	
Advanced Therapy	Treatment of melanoma	x					x	x	
Biological	Prevention of respiratory syncytial virus			x				x	
Advanced Therapy	Treatment of retinitis pigmentosa		x			x			
Biological	Prevention of respiratory syncytial virus	x				x			
Biological	Treatment of rheumatoid arthritis	x				x		x	
Biological	Treatment of hypercholesterolaemia	x					x	x	
Chemical	Treatment of peritoneal carcinomatosis	x						x	
Biological	Treatment of lung cancer			x				x	
Biological	Treatment of myasthenia gravis			x				x	
Biological	Prevention of meningococcal disease			x				x	
Chemical	Treatment of prostate cancer			x		x			

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 49 Scientific Advice letters - 24 Initial Scientific Advice, 16 Follow-up Scientific Advice, 4 Protocol Assistance letters, 4 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices were adopted at the 24-26 April 2023 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 56 new Requests for which the procedure started at the SAWP meeting held on 11-14 April 2023. The new requests are divided as follows: 30 Initial Scientific Advice, 12 Follow-up Scientific Advice, 5 Initial Protocol Assistance, 4 Follow-up Protocol Assistance, 5 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.