



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 May 2023
EMA/CHMP/SAWP/234267/2023
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 22-25 May 2023

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

	1995-2022	2023	Overall total
Scientific Advice	5684	170	5854
Follow-up to Scientific Advice	1783	62	1845
Protocol Assistance	1268	31	1299
Follow-up to Protocol Assistance	680	15	695
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	210	5	215
	9790	283	10073

Outcome of the May 2023 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 infections following hematopoietic stem cell transplantation			X		X		X	
Advanced Therapy	Treatment of multiple myeloma		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 emphysema				x			x	
Qualification	Methodology of covariates in clinical trials	x							
Chemical	Treatment fragile X syndrome	x					x	x	
Biological	Prevention of group B streptococcal invasive disease			x				x	
Biological	Treatment of follicular lymphoma		x					x	
Chemical	Treatment of schizophrenia			x		x	x	x	
Chemical	Treatment of hypercholesterolaemia	x						x	
Biological	Treatment of diabetes mellitus type I	x					x	x	
Chemical	Treatment of overactive bladder			x				x	
Chemical	Treatment of hyperuricemia	x						x	
Biological	Treatment of breast cancer			x		x		x	
Chemical	Treatment of myasthenia gravis	x						x	
Biological	Treatment of non-alcoholic steatohepatitis	x						x	
Chemical	Treatment of hemophagocytic lymphohistiocytosis	x				x	x	x	
Chemical	Treatment of migraine	x						x	
Chemical	Treatment of neuronal ceroid lipofuscinosis		x			x	x	x	
Biological	Treatment of Sjogren syndrome	x					x	x	
Biological	Treatment of idiopathic and progressive pulmonary fibrosis	x					x	x	
Biological	Treatment of biliary tract cancer	x					x	x	
Biological	Treatment of cervical cancer	x						x	
Biological	Treatment of cancers			x			x		
Biological	Treatment of cancers			x				x	
Chemical	Treatment of schizophrenia	x						x	
Chemical	Treatment of obesity	x					x	x	
Chemical	Treatment of Alzheimer's disease	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Biological	Treatment of advanced cell carcinoma	x					x	x	
Biological	Treatment of allogeneic hematopoietic stem cell transplantation			x				x	
Biological	Treatment of diabetes mellitus type I			x				x	
Biological	Treatment of non-alcoholic steatohepatitis	x						x	
Chemical	Treatment of sclerosis			x				x	
Chemical	Treatment of Becker muscular dystrophy	x						x	
Chemical	Treatment of psoriasis	x					x	x	
Biological	Treatment of non-small cell lung cancer	x					x	x	
Biological	Treatment of Crohn's disease	x				x			
Biological	Treatment of cancers	x				x			
Biological	Treatment of myeloma		x					x	
Biological	Treatment of myeloma	x						x	
Advanced Therapy	Treatment of deep dermal burns		x					x	
Biological	Treatment of obstructive pulmonary disease	x				x		x	
Biological	Treatment of Parkinson's disease	x					x	x	
Biological	Treatment of lung cancer			x				x	
Chemical	Treatment of skin cancer	x				x			
Chemical	Treatment of asthma			x				x	
Chemical	Treatment of Fabry disease				x			x	x
Advanced Therapy	Treatment of graft-versus-host disease				x	x	x		
Chemical	Treatment of acromegaly	x				x		x	
Chemical	Treatment of diabetes and deafness		x					x	
Chemical	Treatment of epithelioid haemangioendothelioma	x					x	x	
Chemical	Treatment of PIK3CA-related overgrowth spectrum		x				x	x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 51 Scientific Advice letters - 28 Initial Scientific Advice, 12 Follow-up Scientific Advice, 7 Protocol Assistance letters, 3 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices were adopted at the 22-25 May 2023 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 51 new Requests for which the procedure started at the SAWP meeting held on 08-12 May 2023. The new requests are divided as follows: 26 Initial Scientific Advice, 15 Follow-up Scientific Advice, 4 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.