



23 February 2023
EMA/CHMP/SAWP/84536/2023
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 20 – 23 February 2023

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

	1995-2022	2023	Overall total
Scientific Advice	5684	81	5765
Follow-up to Scientific Advice	1783	25	1808
Protocol Assistance	1268	15	1283
Follow-up to Protocol Assistance	680	3	683
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	210	2	212
	9790	126	9916

Outcome of the February 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	Diagnosis of abdominal surgery	x				x	x	x	
Qualification	Machine learning procedure	x							
Chemical	Treatment of type 2 diabetes	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 squamous cell carcinoma	x				x			
Biological	Treatment of allergic reactions	x						x	
Chemical	Treatment of Huntington's disease		x				x	x	
Biological	Treatment of bleeding episodes	x					x	x	
Biological	Treatment of small cell lung cancer	x					x		
Biological	Prevention of Neisseria meningitidis			x		x			
Chemical	Treatment of alpha-1 antitrypsin deficiency	x					x	x	
Chemical	Treatment of acute respiratory distress syndrome	x						x	
Chemical	Treatment of regional pain syndrome		x			x	x	x	
Chemical	Treatment of eczema	x					x	x	
Biological	Treatment of anaemia	x						x	
Chemical	Treatment of oral mucositis	x					x		
Chemical	Prevention of iatrogenic ureteral injury	x				x			
Biological	Treatment of type 2 diabetes			x				x	
Chemical	Treatment of Duchenne muscular dystrophy	x				x	x	x	
Chemical	Prevention of arteriovenous access dysfunction				x			x	
Chemical	Treatment of prostate cancer	x						x	
Chemical	Treatment of lupus nephritis	x				x		x	
Chemical	Treatment of erythropoietic protoporphyria	x				x	x	x	
Biological	Treatment of lung cancer	x				x	x	x	
Chemical	Treatment of fragile x syndrome	x						x	
Chemical	Treatment of hyperuricemia	x				x	x	x	
Chemical	Treatment of glioblastoma	x						x	
Chemical	Treatment of myelogenous leukaemia	x				x			
Biological	Treatment of bladder 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 prostate cancer	x				x			
Biological	Treatment of diphtheria	x					x		
Chemical	Treatment of African trypanosomiasis			x				x	
Chemical	Prevention of dermatitis	x					x	x	
Chemical	Treatment of cholangitis		x			x	x	x	
Chemical	Treatment of neuropathic pain	x					x	x	
Biological	Treatment of graft versus host disease		x			x	x	x	x
Chemical	Treatment of cholangitis	x					x	x	
Biological	Treatment of Pompe disease	x				x	x	x	
Chemical	Treatment of oligodendroglioma	x				x			
Biological	Treatment of lupus erythematosus			x				x	
Biological	Treatment of solid tumours	x						x	
Chemical	Treatment of gangliosidosis		x			x		x	
Advance Therapy	Treatment of Fabry disease		x			x	x	x	
Biological	Prevention of preterm birth	x				x	x	x	
Chemical	Treatment of Sjögren's syndrome	x						x	
Biological	Treatment of melanoma	x						x	
Biological	Treatment of diabetes mellitus			x				x	
Biological	Treatment of rheumatoid arthritis	x				x		x	
Advance Therapy	Treatment of haemophilia B		x			x	x		
Biological	Treatment of diabetes	x				x	x	x	
Chemical	Treatment of menopausal			x				x	
Chemical	Treatment of lymphocytic leukemia	x						x	
Chemical	Prevention of acute coronary syndrome			x				x	
Biological	Treatment of myelodysplastic syndromes				x			x	
Biological	Treatment of asthma	x				x			

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of birth control			x				x	
Chemical	Treatment of hyperphenylalaninemia				x	x			
Advance Therapy	Treatment of osteoarthritis			x			x	x	
Chemical	Treatment of Fabry disease		x				x	x	
Biological	Treatment of propionic acidaemia		x				x	x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 59 Scientific Advice letters - 37 Initial Scientific Advice, 9 Follow-up Scientific Advice, 9 Protocol Assistance letters, 3 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices were adopted at the 20-23 February 2023 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 55 new Requests for which the procedure started at the SAWP meeting held on 06-09 February 2023. The new requests are divided as follows: 33 Initial Scientific Advice, 10 Follow-up Scientific Advice, 5 Initial Protocol Assistance, 6 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.