



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 June 2023
EMA/CHMP/SAWP/287222/2023
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 19-22 June 2023

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

	1995-2022	2023	Overall total
Scientific Advice	5684	193	5877
Follow-up to Scientific Advice	1783	74	1857
Protocol Assistance	1268	35	1303
Follow-up to Protocol Assistance	680	20	700
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	210	8	218
	9790	330	10120

Outcome of the June 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
Qualification	Gene therapy registry	x							
Qualification	Machine learning algorithms for scoring endoscopy	x							



Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Qualification	Big data platform	x							
Chemical	Treatment of sickle cell disease		x				x	x	x
Chemical	Treatment of demodex blepharitis	x				x		x	
Biological	Treatment of multiple sclerosis			x				x	
Chemical	Treatment of psoriasis	x					x	x	
Biological	Treatment of rheumatoid arthritis	x						x	
Biological	Prevention of respiratory disease	x				x		x	
Advanced Therapy	Treatment of testicular or extragonadal germ cell tumour	x					x	x	
Chemical	Treatment of breast cancer	x						x	
Biological	Prevention of thrombocytopenia	x						x	
Biological	Treatment of head and neck squamous cell carcinoma	x				x		x	
Chemical	Treatment of cholangiocarcinoma	x				x	x	x	
Biological	Treatment of telangiectasia				x			x	
Biological	Treatment of enzymatic removal			x		x		x	
Biological	Treatment of diabetic retinopathy	x						x	
Chemical	Treatment of vitiligo	x						x	
Biological	Treatment of non-small cell lung carcinoma	x				x	x	x	
Biological	Treatment of hepatocellular carcinoma	x					x	x	
Biological	Treatment of hepatocellular carcinoma	x					x	x	
Chemical	Treatment of hypoparathyroidism		x			x	x	x	x
Chemical	Treatment of hypertension	x					x	x	
Chemical	Treatment of polyneuropathy	x						x	
Advanced Therapy	Treatment of fecal Incontinence			x				x	
Biological	Treatment of non-small cell lung cancer	x						x	
Chemical	Treatment of Friedreich's ataxia				x			x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Biological	Treatment of multiple myeloma	x					x		
Chemical	Treatment of the depressive disorder			x				x	
Advanced Therapy	Treatment of Duchenne muscular dystrophy		x			x		x	x
Biological	Treatment of osteoporosis			x		x		x	
Chemical	Treatment of adenocarcinoma	x				x	x		
Biological	Treatment of sclerosis	x				x	x	x	
Biological	Prevention of haemolytic disease				x			x	
Biological	Treatment of squamous cell carcinoma			x				x	
Biological	Treatment of neoplasm	x				x			
Biological	Treatment of anaemia		x					x	
Biological	Diagnosis of breast cancer	x				x	x		
Advanced Therapy	Treatment of acidaemia				x		x		
Chemical	Treatment of osteoarthritis			x				x	
Chemical	Treatment of Niemann-Pick disease type C			x		x			
Chemical	Treatment of anaemia			x				x	
Biological	Treatment of multiple myeloma			x		x			
Biological	Prevention of tetanus and diphtheria infection	x				x	x	x	
Biological	Prevention of papillomavirus diseases			x				x	
Biological	Treatment of acute ischemic stroke							x	
Advanced Therapy	Treatment of diffuse large B-cell lymphoma				x			x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 47 Scientific Advice letters - 23 Initial Scientific Advice, 12 Follow-up Scientific Advice, 4 Protocol Assistance letters, 5 Follow-up Protocol Assistance, 3 Qualifications of novel methodologies and 0 EMA/EUnethTA parallel consultation advices were adopted at the 19-22 June 2023 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 57 new Requests for which the procedure started at the SAWP meeting held on 05-08 June 2023. The new requests are divided as follows: 36 Initial Scientific Advice, 11 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.