



22 April 2021
EMA/CHMP/SAWP/232152/2021
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 19 – 22 April 2021

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

	1995-2020	2021	Overall total
Scientific Advice	4766	188	4954
Follow-up to Scientific Advice	1413	116	1529
Protocol Assistance	1076	33	1109
Follow-up to Protocol Assistance	576	19	595
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	161	7	168
	8157	363	8520

Outcome of the April 2021 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				
Biological	Treatment of COVID-19 disease	x				x	x	x	
Biological	Treatment of mesothelioma	x						x	
Chemical (Generic)	Prevention of atherothrombotic	x						x	

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
	events								
Advanced Therapy	Treatment of type 1 diabetes	x					x	x	
Biological	Prevention of respiratory papillomatosis	x						x	
Chemical	Treatment of bladder cancer	x				x			
Chemical	Treatment of Parkinson's disease	x						x	
Biological	Treatment of type 1 diabetes	x					x	x	
Biological	Treatment of asthma	x						x	
Biological	Treatment of hepatitis B	x					x	x	
Biological	Prophylaxis of malaria	x						x	
Biological	Treatment of diffuse large B cell lymphoma	x					x	x	
Chemical	Treatment of papillary renal cell carcinoma	x						x	
Advanced Therapy	Treatment of lymphocytic leukemia	x						x	
Biological	Treatment of Crohn's disease	x				x		x	
Biological	Treatment of rotator cuff tendinopathy	x						x	
Chemical	Treatment of multiple sclerosis	x						x	
Biological	Treatment of atopic	x						x	
Biological	Treatment of colon/rectum carcinoma	x				x			
Biological	Treatment of NSCLC	x						x	
Biological	Treatment of breast cancer	x						x	
Biological	Treatment of neurotrophic keratitis	x					x	x	
Chemical	Treatment of biliary cholangitis	x						x	
Biological	Treatment of rheumatoid arthritis	x				x	x	x	
Chemical	Treatment of hyperkalemia	x						x	
Chemical	Treatment of breast cancer	x						x	
Biological	Treatment of melanoma	x				x		x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Prevention of pneumococcal disease	x				x	x	x	
Biological	Treatment of cervix carcinoma	x						x	
Chemical	Treatment of hand eczema	x						x	
Biological	Treatment of masseter muscle prominence	x					x	x	
Advanced Therapy	Treatment of type I diabetes	x				x		x	
Chemical	Treatment of dry eye disease	x					x	x	
Chemical	Treatment of obesity	x				x	x	x	
Chemical	Treatment of neonatal encephalopathy	x				x	x	x	
Biological	Treatment of COVID19 disease	x				x	x	x	
Chemical	Treatment of COVID19 disease	x				x			
Chemical	Treatment of COVID19 disease	x				x			
Biological	Treatment of COVID19 disease			x		x	x	x	
Biological	Treatment of pulmonary disease			x				x	
Chemical	Treatment of Alzheimer's syndrome			x				x	
Chemical	Treatment of atopic dermatitis			x				x	
Chemical	Diagnosis of prostate cancer			x				x	
Biological	Treatment of type 1 diabetes			x		x	x	x	
Biological	Treatment of osteoporosis and tumours of the bone			x		x			
Biological	Immunization against yellow fever			x				x	
Biological	Treatment of clostridioides difficile infection			x				x	
Chemical	Treatment of cardiac death, ischemic stroke and arrhythmia			x				x	
Biological	Treatment of macular degeneration			x				x	
Biological	Treatment of diabetes mellitus			x		x		x	
Chemical	Treatment of ovarian, fallopian tube or primary peritoneal 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 myelodysplastic syndromes		x			x			
Advanced Therapy	Treatment of epidermolysis bullosa		x			x	x		
Advanced Therapy	Treatment of spinal muscular atrophy		x				x	x	
Chemical	Treatment of Gaucher disease		x					x	x
Chemical	Treatment of Angelman syndrome		x					x	
Advanced Therapy	Treatment of large B cell lymphoma				x		x		
Chemical	Treatment of Prader-Willi syndrome				x	x			x
Chemical	Diagnosis of amyloid light-chain amyloidosis				x		x	x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 60 Scientific Advice letters - 39 Initial Scientific Advice, 13 Follow-up Scientific Advice, 5 Protocol Assistance letters, 3 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 19-22 April 2021 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 06-09 April 2021. The new requests are divided as follows: 40 Initial Scientific Advice, 9 Follow-up Scientific Advice, 4 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.