



10 December 2020
EMA/CHMP/SAWP/667391/2020
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 07 – 10 December 2020

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

	1995 - 2019	2020	Overall total
Scientific Advice	4258	508	4766
Follow-up to Scientific Advice	1277	136	1413
Protocol Assistance	1003	73	1076
Follow-up to Protocol Assistance	525	51	576
EMA/EUnetHTA parallel consultation advice	159	6	165
Qualification of novel methodologies	142	19	161
	7364	793	8157

Outcome of the December 2020 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	Prevention of type I diabetes	x						x	
Chemical	Treatment of Wilson disease				x		x	x	
Biological	Treatment of prostate cancer	x					x	x	
Biological	Treatment of ovarian cancer	x					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				
Advanced Therapy	Treatment of multiple myeloma		x					x	
Advanced Therapy	Treatment of glioblastoma				x			x	x
Chemical	Treatment of supraventricular arrhythmia	x				x	x	x	
Chemical	Treatment of cardiomyopathy	x					x	x	
Chemical	Treatment of obsessive compulsive disorder	x					x	x	
Advanced Therapy	Treatment of ornithine transcarbamylase deficiency		x				x	x	x
Advanced Therapy	Treatment of glycogen storage disease type Ia		x				x	x	
Chemical	Treatment of short bowel syndrome			x				x	
Chemical	Treatment of cutaneous systemic sclerosis		x					x	
Advanced Therapy	Treatment of urea cycle disorders	x						x	
Chemical	Treatment of non-alcoholic steatohepatitis	x					x	x	
Chemical	Treatment of cholestatic pruritus			x		x	x	x	
Biological	Prevention of clinical type I diabetes	x				x			
Chemical	Treatment of postbariatric hypoglycemia		x			x	x		
Biological	Treatment of systemic sclerosis	x					x		
Biological	Treatment of chronic graft versus host disease	x				x	x	x	
Biological	Treatment of systemic lupus erythematosus	x				x			
Chemical	Treatment of lymphoplasmacytic lymphoma	x					x	x	
Biological	Treatment of cutaneous T-cell lymphoma		x			x	x	x	x
Biological	Treatment of lupus nephritis	x					x	x	
Chemical	Treatment of head and neck squamous cell carcinoma	x					x		
Biological	Treatment of multiple oncology indications	x						x	
Advanced Therapy	Treatment of multiple myeloma	x				x	x	x	
Biological	Treatment of cancer cells	x						x	
Biological	Treatment of breast cancer	x				x		x	
Biological	Treatment of myasthenia gravis	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of peripheral SpA	x						x	
Biological	Treatment of breast cancer	x						x	
Chemical	Treatment of chronic lymphocytic leukemia, small lymphocytic lymphoma, or acute myeloid leukemia	x						x	
Advanced Therapy	Treatment of large B cell lymphoma		x					x	
Advanced Therapy	Treatment of haemophilia A		x			x			
Biological	Prophylaxis of bleeding				x			x	
Biological	Prophylaxis of bleeding				x			x	
Chemical	Prophylaxis of angioedema	x					x	x	
Biological	Prophylaxis and treatment of bleeding			x			x	x	
Chemical	Treatment of thalassaemia		x					x	x
Chemical	Treatment of allergic reaction	x				x	x	x	
Biological	Reduction of major cardiovascular events	x						x	
Biological	Prevention of cardiovascular thrombosis	x						x	
Biological	Treatment of diabetic ulcers			x		x			
Chemical	Treatment of HIV-1 infection			x				x	
Chemical	Treatment of COVID-19	x					x	x	
Biological	Prevention of lower respiratory tract infection			x				x	
Chemical	Treatment of rheumatoid arthritis	x				x	x	x	
Biological	Treatment of osteogenesis imperfecta types I, III, IV		x					x	
Biological	Treatment of Parkinson's disease	x					x		
Chemical	Treatment of schizophrenia and bipolar disorder	x						x	
Chemical	Treatment of hyperinsulinism	x					x	x	
Chemical	Treatment of schizophrenia	x						x	
Chemical	Reduction in intracranial pressure				x			x	
Chemical	Treatment of multiple sclerosis			x				x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Advanced Therapy	Treatment of Sanfilippo A syndrome				x	x			
Biological	Treatment of MOG	x						x	
Chemical	Treatment of multiple sclerosis	x				x			
Chemical	Treatment of seizures	x					x	x	
Chemical	Treatment of seizures	x						x	
Chemical	Treatment of COVID-19	x				x	x	x	
Biological	Treatment of asthma and chronic idiopathic urticaria.			x				x	
Biological	Treatment of asthma and chronic idiopathic urticaria.			x				x	
Advanced Therapy	Treatment of RGPR				x			x	
Biological	Treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy	x				x	x	x	
Chemical	Treatment of glaucoma	x						x	
Chemical	Treatment of diabetic macular edema	x						x	
Biological	Treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy			x		x			
Biological	Treatment of neovascular macular degeneration	x						x	
Chemical	Treatment of Fuchs endothelial corneal dystrophy	x						x	
Chemical	Treatment of vasomotor symptoms	x					x	x	
Chemical	Treatment of fungal infection				x			x	
Advanced Therapy	Treatment of glycogen storage disease type Ia		x			x			
Chemical	Treatment of myasthenia gravis	x				x			
Biological	Prevention of SARS-CoV-2 infection			x		x			
Biological	Treatment of COVID-19	x				x	x	x	
Biological	Treatment of COVID-19	x						x	
Biological	Treatment of COVID-19	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Prevention of SARS-CoV-2 infection			x			x		
Biological	Treatment of COVID-19	x				x			
Biological	Prevention of SARS-CoV-2 infection	x					x		
Biological	Prevention of SARS-CoV-2 infection	x				x	x		
Biological	Prevention of SARS-CoV-2 infection	x				x			
Biological	Prevention of SARS-CoV-2 infection	x						x	
Biological	Treatment of COVID-19	x				x	x	x	
Biological	Prevention of SARS-CoV-2 infection	x						x	
Biological	Treatment of COVID-19	x						x	
Qualification Advice	Digital mobility assessment	x						x	
Qualification Opinion	Treatment of Type 1 Diabetes	x						x	
Qualification Advice	Detection of Drug-induced Kidney Injury	x						x	
EMA/EUnetHTA	Treatment of haemophilia A	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 91 Scientific Advice letters - 58 Initial Scientific Advice, 10 Follow-up Scientific Advice, 12 Protocol Assistance letters, 7 Follow-up Protocol Assistance, 3 Qualifications of novel methodologies and 1 EMA/EUnetHTA parallel consultation advices - were adopted at the 07-10 December 2020 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 79 new Requests for which the procedure started at the SAWP meeting held on 23-26 November 2020. The new requests are divided as follows: 49 Initial Scientific Advice, 12 Follow-up Scientific Advice, 11 Initial Protocol Assistance, 7 Follow-up Protocol Assistance, 0 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.