



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2021
EMA/CHMP/SAWP/355768/2021
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 21 – 24 June 2021

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

	1995-2020	2021	Overall total
Scientific Advice	4766	274	5040
Follow-up to Scientific Advice	1413	145	1558
Protocol Assistance	1076	52	1128
Follow-up to Protocol Assistance	576	27	603
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	161	10	171
	8157	508	8665

Outcome of the June 2021 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
Biological	Treatment of Parkinson's disease	x				x	x	x	
Chemical	Treatment of trypanosomiasis	x				x	x	x	
Advanced Therapy	Treatment of soft tissue sarcoma			x		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					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Biological	Treatment of macular degeneration	x				x	x	x	
Chemical	Prevention of stroke	x				x	x	x	
Chemical	Prevention of stroke	x				x	x	x	
Chemical	Prevention of stroke	x				x	x	x	
Chemical	Treatment of glioblastoma	x				x	x	x	
Biological	Treatment of amyloid light-chain amyloidosis			x		x	x	x	
Advanced Therapy	Treatment of epidermolysis bullosa	x				x	x	x	
Chemical	Treatment of overweight	x				x	x	x	
Biological	Treatment of head and neck carcinoma		x			x	x	x	
Chemical	Treatment of hypertrophic cardiomyopathy	x				x	x	x	
Biological	Prevention of COVID-19	x				x	x	x	
Chemical	Treatment of insufficiently controlled T2DM	x				x	x	x	
Chemical	Treatment of overweight	x				x	x	x	
Biological	Treatment of chronic rhinosinusitis	x				x	x	x	
Chemical	Treatment of diabetic macular edema		x			x	x	x	
Chemical	Treatment of agitation associated with dementia	x				x	x	x	
Chemical	Treatment of Friedreich's ataxia	x				x	x	x	
Biological	Treatment of non-small cell lung cancer	x				x	x	x	
Chemical	Prevention of stroke	x				x	x	x	
Chemical	Treatment of thrombocytopenia	x				x	x	x	
Biological	Treatment of haemophagocytic lymphohistiocytosis			x		x	x	x	
Chemical	Treatment of cutaneous lupus erythematosus	x				x	x	x	
Chemical	Treatment of systemic lupus erythematosus	x				x	x	x	
Biological	Treatment of colorectal cancer	x				x	x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Chemical	Treatment of iron deficiency		x			x	x	x	
Advanced Therapy	Treatment of OTC deficiency	x				x	x	x	
Chemical	Treatment of breast cancer	x				x	x	x	
Biological	Prevention of Neisseria meningitidis	x				x	x	x	
Chemical	Treatment of peripheral artery disease	x				x	x	x	
Advanced Therapy	Treatment of multiple myeloma				x	x	x	x	
Biological	Treatment of blastic plasmacytoid dendritic cell neoplasm			x		x	x	x	
Biological	Treatment of metastatic pancreatic cancer			x		x	x	x	
Biological	Treatment of cancer	x				x	x	x	
Chemical	Treatment of severe hypertriglyceridemia	x				x	x	x	
Chemical	Treatment of hypertension	x				x	x	x	
Advanced Therapy	Treatment of soft tissue sarcoma			x		x	x	x	
Chemical	Treatment of pancreatic adenocarcinoma	x				x	x	x	
Chemical	Treatment of pulmonary arterial hypertension			x		x	x	x	
Chemical	Treatment of pancreatic cancer		x			x	x	x	x
Biological	Prevention of Neisseria meningitis	x				x	x	x	
Chemical	Prevention of thromboembolic events	x				x	x	x	
Biological	Prevention of haemolytic disease			x		x	x	x	
Advanced Therapy	Treatment of Parkinson's disease		x			x	x	x	
Biological	Treatment of systemic lupus erythematosus	x				x	x	x	
Chemical	Treatment of non-small cell lung cancer	x				x	x	x	
Chemical	Treatment of myeloid leukaemia				x	x	x	x	x
Chemical	Treatment of myelodysplastic syndromes				x	x	x	x	x
Chemical	Treatment of COVID-19	x				x	x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Biological	Prevention of pneumonia	x				x	x	x	
Chemical	Diagnostic of prostate cancer		x			x	x	x	
Advanced Therapy	Treatment of chronic limb-threatening ischemia	x				x	x	x	
Chemical	Treatment of invasive candidiasis				x	x	x	x	
Chemical	Treatment of non-segmental vitiligo		x			x	x	x	
Biological	Treatment of rheumatoid arthritis	x				x	x	x	
Biological	autoimmune encephalitis	x				x	x	x	
Biological	Treatment of myelin oligodendrocyte glycoprotein	x				x	x	x	
Biological	Prevention of COVID-19		x			x	x	x	
Chemical	Treatment of primary biliary cholangitis				x	x	x	x	
Chemical	Treatment of multiple myeloma		x			x	x	x	
Biological	Treatment of type 2 diabetes mellitus		x			x	x	x	
Chemical	Treatment of hyperphenylalaninemia		x			x	x	x	
Chemical	Treatment of obesity			x		x	x	x	
Chemical	Treatment of myocardial infarction		x			x	x	x	
Biological	Treatment of multiple myeloma			x		x	x	x	
Chemical	Treatment of skin infections	x				x	x	x	
Biological	Treatment of non-cirrhotic non-alcoholic steatohepatitis		x			x	x	x	
Biological	Treatment of rheumatoid arthritis		x			x	x	x	
Biological	Treatment of Sanfilippo syndrome	x				x	x	x	
Chemical	Treatment of achondroplasia			x		x	x	x	
Biological	Treatment of non-small cell lung cancer	x				x	x	x	
Advanced Therapy	Treatment of Hodgkin lymphoma	x				x	x	x	
Biological	Treatment of lung cancer		x			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 psoriasis		x			x	x	x	
Biological	Treatment of psoriasis		x			x	x	x	
Chemical	Treatment of multiple sclerosis	x				x	x	x	
Chemical	Treatment of COVID-19	x				x	x	x	
Biological	Treatment of COVID-19	x				x	x	x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 80 Scientific Advice letters - 47 Initial Scientific Advice, 17 Follow-up Scientific Advice, 11 Protocol Assistance letters, 5 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 21-24 June 2021 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 105 new Requests for which the procedure started at the SAWP meeting held on 07-10 June 2021. The new requests are divided as follows: 61 Initial Scientific Advice, 18 Follow-up Scientific Advice, 14 Initial Protocol Assistance, 9 Follow-up Protocol Assistance, 3 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.