



25 March 2021
EMA/CHMP/SAWP/179045/2021
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 22 – 25 March 2021

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

	1995-2020	2021	Overall total
Scientific Advice	4766	149	4915
Follow-up to Scientific Advice	1413	103	1516
Protocol Assistance	1076	28	1104
Follow-up to Protocol Assistance	576	16	592
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	161	7	168
	8157	303	8460

Outcome of the March 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				
Chemical	Treatment of solid tumors	x						x	
Advanced Therapy	Treatment of osteoarthritis	x				x	x	x	
Biological	Treatment of myasthenia gravis	x					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 mycoses	x						x	
Biological	Treatment of lupus nephritis	x						x	
Chemical	Treatment of epilepsy	x				x	x	x	
Chemical	Prevention of thromboembolic events	x				x			
Biological	Treatment of lupus erythematosus	x						x	
Chemical	Treatment of breast cancer	x						x	
Chemical	Treatment of myeloid leukaemia	x				x			
Chemical	Treatment of skin infections	x						x	
Biological	Treatment of diabetes mellitus	x					x	x	
Biological	Treatment of large B-cell lymphoma	x						x	
Chemical	Treatment of anaemia	x				x	x	x	
Chemical	Treatment of epilepsy	x				x	x	x	
Chemical	Treatment of bladder cancer	x					x	x	
Biological	Treatment of polyposis	x						x	
Biological	Treatment of achondroplasia	x					x	x	
Chemical	Treatment of pulmonary arterial hypertension	x					x	x	
Biological	Prevention of COVID-19 disease	x				x	x	x	
Chemical	Treatment of mitochondrial disease	x						x	
Chemical	Treatment of pain	x				x	x	x	
Chemical	Treatment of diabetes mellitus	x						x	
Chemical	Treatment of attention-deficit hyperactivity disorder	x						x	
Chemical	Treatment of liposarcoma	x					x	x	
Chemical	Treatment of non–small-cell lung cancer	x						x	
Biological	Treatment of large B-cell lymphoma	x					x	x	
Biological	Treatment of diffuse large B-cell lymphoma	x					x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of hepatocellular carcinoma	x						x	
Biological	Treatment of follicular lymphoma	x						x	
Chemical	Treatment of hyperammonaemia and hepatic encephalopathy	x				x		x	
Biological	Treatment of multiple myeloma	x					x	x	
Chemical	Treatment of multiple sclerosis	x					x	x	
Chemical	Treatment of macular degeneration	x						x	
Chemical	Treatment of hepatitis B	x					x		
Biological	Treatment of Netherton syndrome	x					x	x	
Biological	Treatment of weight management	x					x	x	
Biological	Treatment of immunodeficiencies	x				x	x	x	
Chemical	Treatment of prostate cancer	x						x	
Chemical	Treatment of acute myeloid leukaemia	x					x		
Biological	Prevention of COVID-19 disease	x				x			
Chemical	Treatment of follicular lymphoma	x						x	
Biological	Prevention of major cardiovascular events	x				x	x	x	
Biological	Prevention of COVID-19 disease	x				x	x	x	
Biological	Prevention of lower respiratory tract disease			x		x	x	x	
Chemical	Treatment of schizophrenia			x				x	
Chemical	Treatment of pain			x			x		
Biological	Treatment of psoriatic arthritis			x				x	
Biological	Treatment of ulcerative colitis			x				x	
Biological	Treatment of Crohn's disease			x				x	
Biological	Treatment of Crohn's disease			x				x	
Biological	Treatment of Crohn's disease			x				x	
Chemical	Treatment of urothelial carcinoma			x				x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of diabetes mellitus			x		x			
Chemical	Treatment of diabetes mellitus			x				x	
Chemical	Treatment of non–small cell lung cancer			x		x			
Chemical	Treatment of schizophrenia			x		x			
Biological	Treatment of thrombotic microangiopathy			x				x	
Chemical	Treatment of T-cell lymphoma			x				x	
Biological	Treatment of rheumatoid arthritis			x		x			
Biological	Treatment of giant cell arteritis			x		x		x	
Chemical	Broad advice on new formulation			x				x	
Biological	Prevention of COVID-19 disease			x				x	
Chemical	Treatment of pancreatic cancer		x				x	x	x
Chemical	Treatment of myeloid leukaemia		x				x	x	
Biological	Treatment of leukaemia		x					x	
Chemical	Treatment of growth hormone deficiency		x				x	x	x
Chemical	Treatment of amyotrophic lateral sclerosis		x				x	x	
Biological	Treatment of myelodysplastic syndromes		x					x	
Chemical	Prevention of bronchopulmonary dysplasia		x			x		x	
Biological	Treatment of pulmonary arterial hypertension		x			x			
Chemical	Treatment of tenosynovial giant cell tumour		x				x	x	
Chemical	Treatment of sickle cell disease				x			x	
Biological	Treatment of graft versus host disease				x			x	
Qualification opinion	Biomarkers for type 1 diabetes			x					
Qualification advice	Niemann-Pick disease Registry	x							

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 76 Scientific Advice letters - 44 Initial Scientific Advice, 19 Follow-up Scientific Advice, 9 Protocol Assistance letters, 2 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 22-25 March 2021 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 60 new Requests for which the procedure started at the SAWP meeting held on 08-11 March 2021. The new requests are divided as follows: 34 Initial Scientific Advice, 13 Follow-up Scientific Advice, 7 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.