



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 January 2021
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Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 25 – 29 January 2021

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

	1995-2020	2021	Overall total
Scientific Advice	4766	45	4811
Follow-up to Scientific Advice	1413	13	1426
Protocol Assistance	1076	10	1086
Follow-up to Protocol Assistance	576	6	582
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	161	1	162
	8157	75	8232

Outcome of the January 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	Prevention of COVID-19	X				X	X	X	
Biological	Treatment of myeloid leukaemia		X				X	X	
Advanced Therapy	Treatment of ischaemic brain injury	X				X	X	X	

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Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Chemical	Treatment of fibrodysplasia ossificans progressiva				x		x	x	
Chemical	Prevention of HIV-1			x				x	
Biological	Treatment of Crohn's Disease			x				x	
Chemical	Treatment of cholangiocarcinoma		x			x		x	
Chemical	Treatment of cholangiocarcinoma				x			x	
Chemical	Treatment of subarachnoid haemorrhage		x			x	x	x	
Chemical	Reduction of intraocular pressure	x					x	x	
Chemical	Treatment of HIV-1	x						x	
Chemical	Treatment of methylmalonic acidemia	x					x	x	
Biological	Treatment of plaque psoriasis	x				x	x	x	
Biological	Treatment of eosinophilic oesophagitis	x						x	
Chemical	Treatment of neuropathic pain	x				x	x	x	
Biological	Treatment of eosinophilic gastritis	x				x	x	x	
Chemical	Diagnosis of supranuclear palsy		x				x	x	
Chemical	Treatment of peripheral neuropathy	x				x	x	x	
Biological	Treatment of platysma prominence	x					x	x	
Chemical	Treatment of pain	x				x			
Chemical	Treatment of Duchenne muscular dystrophy				x			x	
Advanced Therapy	Treatment of combined immunodeficiency		x					x	x
Chemical	Treatment of hypotension			x				x	
Advanced Therapy	Treatment of fecal incontinence			x				x	
Chemical	Treatment of anal fissure	x				x			
Biological	Treatment of cervical cancer	x						x	
Chemical	Treatment of psoriatic arthritis			x				x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Biological	Treatment of acid sphingomyelinase deficiency			x		x			
Chemical	Treatment of amyloidosis-polyneuropathy				x		x	x	x
Biological	Treatment of Dupuytren contracture	x						x	
Chemical	Treatment of solid tumours	x				x			
Chemical	Treatment of cardioplegia	x				x	x		
Biological	Treatment of non-small cell lung cancer			x				x	
Chemical	Treatment of alcohol use disorder	x				x	x	x	
Chemical	Treatment of follicular lymphoma		x				x	x	
Chemical	Treatment of asthma	x						x	
Biological	Treatment of Alzheimer's disease	x						x	
Biological	Treatment of neuroblastoma		x					x	
Chemical	Treatment of amyotrophic lateral sclerosis				x	x	x	x	
Chemical	Treatment of atopic dermatitis	x						x	
Chemical	Diagnosis of cancer	x				x	x	x	
Chemical	Treatment of dry eye disease	x						x	
Chemical	Treatment of Stargardt's disease				x			x	
Chemical	Treatment of hypertension	x					x	x	
Biological	Prevention of respiratory syncytial virus			x				x	
Biological	Treatment of non-muscle invasive bladder cancer	x						x	
Chemical	General anaesthesia	x				x	x	x	
Chemical	Treatment of lymphocytic leukaemia	x				x		x	
Chemical	Treatment of kidney disease	x						x	
Chemical	Treatment of Huntington's disease	x					x	x	
Chemical	Treatment of urticaria	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 NSCLC	x						x	
Chemical	Treatment of thalassaemia	x						x	
Biological	Treatment of macular degeneration	x					x	x	
Chemical	Treatment of myelofibrosis	x						x	
Chemical	Treatment of multiple myeloma		x					x	x
Chemical	Treatment of propionic acidemia	x					x	x	
Chemical	Treatment of sickle cell disease			x			x		
Biological	Prevention of tuberculosis			x				x	
Biological	Treatment of asthma			x			x	x	
Qualification Advice	Treatment of multiple myeloma	x						x	
Biological	Treatment of COVID-19	x						x	
Biological	Prevention of COVID-19			x		x	x		
Biological	Prevention of COVID-19	x						x	
Biological	Treatment of COVID-19			x		x		x	
Biological	Treatment of COVID-19	x				x	x	x	
Biological	Treatment of COVID-19	x				x		x	
Biological	Prevention of COVID-19	x				x		x	
Biological	Prevention of COVID-19	x				x			
Chemical	Treatment of hyperphenylalaninemia	x				x	x	x	
Biological	Broad advice on a study design	x					x	x	
Biological	Broad advice on platform study design	x					x		
Chemical	Treatment of multiple myeloma			x			x		
Chemical	Prophylaxis of HIV-1	x					x		
Chemical	Treatment of amyotrophic lateral sclerosis			x			x		

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 75 Scientific Advice letters - 45 Initial Scientific Advice, 13 Follow-up Scientific Advice, 10 Protocol Assistance letters, 6 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 25-29 January 2021 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 81 new Requests for which the procedure started at the SAWP meeting held on 11-14 January 2021. The new requests are divided as follows: 45 Initial Scientific Advice, 18 Follow-up Scientific Advice, 11 Initial Protocol Assistance, 3 Follow-up Protocol Assistance, 4 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.