



11 November 2021
EMA/CHMP/SAWP/586853/2021
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 08 – 11 November 2021

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

	1995-2020	2021	Overall total
Scientific Advice	4766	460	5226
Follow-up to Scientific Advice	1413	210	1623
Protocol Assistance	1076	97	1173
Follow-up to Protocol Assistance	576	58	634
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	161	19	180
	8157	844	9001

Outcome of the November 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 COVID-19 disease			x		x	x	x	
Chemical	Treatment of prostate cancer	x					x	x	
Advanced Therapy	Treatment of retinitis pigmentosa				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	Prevention of helminths infections			x				x	
Advanced Therapy	Treatment of organ failure	x				x	x		
Advanced Therapy	Treatment of COVID-19 disease	x						x	
Chemical	Treatment of breast cancer	x						x	
Chemical	Treatment of mycoses	x				x	x	x	
Chemical	Treatment of anaemia	x						x	
Chemical	Treatment for reduction of LDL-C	x					x	x	
Chemical	Treatment of chronic obstructive pulmonary disease			x				x	
Chemical	Treatment of non-alcoholic steatohepatitis	x						x	
Biological	Treatment of diabetic macular ischaemia	x						x	
Chemical	Treatment of schizophrenia	x						x	
Chemical	Treatment of chronic obstructive pulmonary disease	x				x	x	x	
Biological	Treatment of weight management			x				x	
Chemical	Treatment of fragile x syndrome	x					x	x	
Chemical	Treatment of prostate cancer	x						x	
Chemical	Treatment of melanoma	x					x	x	
Biological	Treatment of multiple myeloma		x				x	x	x
Chemical	Treatment of primary sclerosing cholangitis		x					x	
Chemical	Treatment of diabetic foot infection	x					x	x	
Chemical	Treatment of congenital adrenal hyperplasia		x				x	x	
Advanced Therapy	Treatment of beta-thalassaemia		x					x	
Chemical	Prevention of HIV-1			x			x	x	
Biological	Treatment of osteoporosis			x		x			
Biological	Treatment of severe eosinophilic asthma			x		x			
Chemical	Treatment of pain			x				x	
Biological	Treatment of non-small-cell lung 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 non-small-cell lung cancer	x						x	
Qualification	Registry for Huntington's disease	x							
Chemical	Treatment of breast cancer			x		x			
Chemical	Treatment of multiple sclerosis	x				x			
Chemical	Treatment of cholangiocarcinoma		x					x	
Biological	Treatment of Alzheimer's disease			x				x	
Biological	Treatment of Alzheimer's disease			x		x			
Advanced Therapy	Treatment of haemophilia A				x	x	x	x	
Qualification	Glo-BNHL platform trial	x							
Biological	Treatment of Crohn's disease	x					x	x	
Chemical	Treatment of fever	x					x	x	
Biological	Treatment of diabetes mellitus			x		x		x	
Qualification	Treatment of macular degeneration			x				x	
Chemical	Treatment of Friedreich's ataxia		x				x	x	
Biological	Treatment of soft tissue sarcoma				x	x			
Qualification	Non-alcoholic steato-hepatitis clinical trials	x							
Chemical	Treatment of pancreatic cancer			x				x	
Chemical	Treatment of WHIM syndrome		x			x	x		
Chemical	Treatment of depression	x				x	x	x	
Chemical	Treatment of motor seizures	x						x	
Biological	Treatment of thermal burns				x			x	
Biological	Treatment of haemolytic anaemia			x				x	
Biological	Treatment of hypercholesterolaemia	x					x		
Biological	Treatment of idiopathic nephrotic syndrome	x					x	x	
Biological	Treatment of urticaria	x				x		x	
Biological	Treatment and prophylaxis of bleeding			x		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 abeta related cognitive decline	x				x	x		
Biological	Prevention of respiratory syncytial virus infection	x				x		x	
Chemical	Treatment of agromegaly	x				x			
Biological	Treatment of non-small-cell lung cancer	x				x			
Biological	Treatment of solid tumors	x				x			
Chemical	Treatment of myeloid neoplasms				x			x	
Biological	Treatment of breast cancer	x				x		x	
Biological	Treatment of dermatomyositis			x				x	
Chemical	Treatment of retinitis pigmentosa		x					x	
Chemical	Treatment of ovarian cancer	x						x	
Chemical	Treatment of invasive candidiasis				x	x	x		
Biological	Treatment of rheumatoid arthritis			x		x			
Biological	Treatment of ulcerative colitis			x			x	x	
Chemical	Treatment of non-segmental vitiligo			x		x			
Biological	Treatment of urothelial carcinoma	x						x	
Biological	Treatment of triple-negative breast cancer	x						x	
Biological	Prevention of COVID-19 disease			x		x			
Biological	Treatment of psoriasis	x				x		x	
Biological	Treatment of idiopathic pulmonary fibrosis		x			x	x	x	
Biological	Treatment of osteogenesis imperfecta				x			x	
Qualification	Sjögren's tool for assessing response	x							
Advanced Therapy	Treatment of Duchenne muscular dystrophy	x				x	x	x	
Chemical	Treatment of hyperoxaluria		x				x	x	x
Biological	Treatment of solid tumors	x					x		
Biological	Treatment of multiple myeloma				x			x	x
Chemical	Treatment of cystic fibrosis		x			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 non-small-cell lung cancer	x						x	
Chemical	Treatment of dehydrogenase deficiency				x			x	
Chemical	Treatment of hemorrhagic telangiectasia	x						x	
Biological	Treatment of neovascular macular degeneration			x				x	
Chemical	Treatment of gangliosidosis				x			x	
Chemical	Treatment of Gaucher disease				x			x	
Chemical	Treatment of multiple system atrophy		x			x			
Biological	Treatment of cancers	x					x	x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 89 Scientific Advice letters - 40 Initial Scientific Advice, 21 Follow-up Scientific Advice, 12 Protocol Assistance letters, 11 Follow-up Protocol Assistance, 5 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 08-11 November 2021 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 73 new Requests for which the procedure started at the SAWP meeting held on 25-28 October 2021. The new requests are divided as follows: 43 Initial Scientific Advice, 15 Follow-up Scientific Advice, 12 Initial Protocol Assistance, 3 Follow-up Protocol Assistance, 0 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.