



15 October 2020
EMA/CHMP/SAWP/483496/2020
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 12 – 15 October 2020

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

	1995 - 2019	2020	Overall total
Scientific Advice	4258	402	4660
Follow-up to Scientific Advice	1277	115	1392
Protocol Assistance	1003	52	1055
Follow-up to Protocol Assistance	525	41	566
EMA/EU netHTA parallel consultation advice	159	5	164
Qualification of novel methodologies	142	14	156
	7364	629	7993

Outcome of the October 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				
Chemical	Treatment of neurofibromatosis				x	x		x	
Chemical	Reduction of atrial fibrillation and bradycardia	x						x	
Chemical	Treatment of glioblastoma	x					x	x	
Advanced Therapy	Treatment of osteoarthritis	x				x	x	x	



Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Broad advice on kidney transplantation	x						x	
Biological	Treatment of non-small cell lung cancer	x						x	
Chemical	Treatment of congenital adrenal hyperplasia		x					x	
Chemical	Treatment of asthma	x				x	x	x	
Chemical	Treatment of microvillus inclusion disease	x				x	x	x	
Advanced Therapy	Treatment of ornithine transcarbamylase deficiency	x				x			
Biological	Treatment of HER2 expressing cancers	x					x		
Chemical	Diagnosis of AL amyloidosis		x			x	x	x	
Biological	Prevention of lower respiratory tract disease			x				x	
Chemical	Treatment of gastroenteropancreatic tumor		x			x		x	
Biological	Treatment of follicular lymphoma			x			x	x	
Biological	Treatment of brain amyloid			x			x	x	
Chemical	Treatment of schizophrenia	x				x	x	x	
Chemical	Treatment of large hemispheric infarction	x				x	x	x	
Chemical	Treatment of pain	x				x	x	x	
Chemical	Treatment of epilepsy			x				x	
Chemical	Treatment of Parkinson's disease	x				x	x	x	
Chemical	Treatment of Parkinson's disease	x				x	x	x	
Chemical	Treatment of seizures	x					x	x	
Chemical	Treatment of seizures	x				x	x	x	
Chemical	Treatment of mitochondrial mutation			x				x	
Chemical	Treatment of asthma			x				x	
Biological	Treatment of asthma and chronic idiopathic urticaria	x				x		x	
Advanced Therapy	Treatment of retinitis pigmentosa			x		x			
Biological	Treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema and diabetic			x				x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
	retinopathy								
Biological	Treatment of breast cancer, non-small cell lung cancer, renal cell carcinoma and ovarian cancer.	x				x	x	x	
Chemical	Treatment of hearing loss			x			x		
Chemical	Treatment of Prader-Willi Syndrome	x					x	x	
Biological	Broad advice on evidence generation	x						x	
Chemical	Treatment of psoriasis	x				x	x	x	
Biological	Broad advice on technical change	x				x			
Chemical	Treatment of candidiasis			x			x		
Chemical	Treatment of candidiasis			x		x			
Biological	Prophylaxis against bacterial strains	x						x	
Biological	Treatment of dengue disease			x				x	
Chemical	Treatment of glomerulosclerosis		x			x			
Chemical	Treatment of prostatic hyperplasia	x						x	
Biological	Treatment of osteoporosis or increase of bone mass in osteoporosis at high risk of fracture	x				x	x	x	
Chemical	Treatment of pulmonary arterial hypertension			x			x		
Chemical	Treatment of chronic venous disorder	x				x			
Chemical	Treatment of acute ischaemic stroke			x			x	x	
Biological	Treatment of emphysema	x						x	
Advanced Therapy	Treatment of haemophilia B				x	x		x	
Chemical	Treatment of acute ischaemic stroke	x				x			
Chemical	Treatment of breast cancer	x						x	
Chemical	Treatment of immune thrombocytopenia		x				x	x	
Biological	Treatment of urothelial cancer	x						x	
Biological	Treatment of Crohn's disease			x		x			

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of neuroblastoma	x				x	x	x	
Chemical	Treatment of non-small cell lung cancer	x				x	x	x	
Biological	Treatment of immune-mediated disorders	x				x			
Biological	Treatment of non-small cell lung cancer			x			x	x	
Biological	Treatment of rheumatoid arthritis	x				x		x	
Biological	Treatment of breast cancer and gastric cancer			x		x			
Advanced Therapy	Treatment of large B cell lymphoma	x				x			
Biological	Treatment of large B cell and follicular lymphoma	x				x			
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile idiopathic arthritis, plaque psoriasis, ankylosing spondylitis			x		x			
Biological	Treatment of myeloid leukaemia	x				x	x	x	
Biological	treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis	x				x	x	x	
Advanced Therapy	Treatment of cutaneous melanoma	x				x	x	x	
Chemical	Treatment of renal cell carcinoma	x				x			
Biological	Treatment of neuroblastoma		x			x	x	x	x
Advanced Therapy	Treatment of multiple myeloma				x	x		x	
Advanced Therapy	Treatment of multiple myeloma		x					x	
Chemical	Treatment of breast cancer	x					x	x	
Chemical	Treatment of systemic mastocytosis				x			x	x
Biological	Treatment of bladder cancer	x						x	
Chemical	Treatment of eosinophilic esophagitis				x	x		x	
Biological	Treatment of diabetes mellitus			x		x	x	x	
Biological	Treatment of non-alcoholic steatohepatitis	x					x	x	
Biological	Treatment of neuroblastoma	x				x	x	x	
Chemical	Treatment of obesity	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of hypoactive sexual desire disorder			x				x	
Chemical	Treatment of COVID-19 disease	x						x	
Chemical	Treatment of COVID-19 disease	x				x	x	x	
Biological	Treatment and prevention of COVID-19 disease	x				x	x	x	
Biological	Prevention of COVID-19 disease	x				x	x	x	
Biological	Prevention of COVID-19 disease	x						x	
Biological	Prevention of COVID-19 disease	x				x	x	x	
Biological	Prevention of COVID-19 disease	x				x	x		
Biological	Prevention of COVID-19 disease	x						x	
Chemical	Treatment of COVID-19 disease	x				x	x	x	
Qualification Advice	Detection of CNS	x							

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 54 Scientific Advice letters, 18 Follow-up Scientific Advice, 10 Protocol Assistance letters, 4 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices, were adopted at the 12-15 October 2020 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 74 new Requests for which the procedure started at the SAWP meeting held on 28 Sept -1 Oct 2020. The new requests are divided as follows: 46 Initial Scientific Advice, 11 Follow-up Scientific Advice, 9 Initial Protocol Assistance, 6 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 1 EMA/EUnetHTA parallel consultation advices.