



25 February 2021
EMA/CHMP/SAWP/123436/2021
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 22 – 25 February 2021

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

	1995-2020	2021	Overall total
Scientific Advice	4766	105	4871
Follow-up to Scientific Advice	1413	84	1497
Protocol Assistance	1076	19	1095
Follow-up to Protocol Assistance	576	14	590
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	161	5	166
	8157	227	8384

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				
Advanced Therapy	Treatment of ischemia	x				x	x		
Chemical	Treatment of hyperglycaemia	x					x	x	
Chemical	Treatment of asthma	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				
Biological	Treatment of dermatomyositis	x						x	
Biological	Treatment of type 2 diabetes	x					x	x	
Biological	Treatment of non small cell lung cancer	x					x	x	
Biological	Treatment of rheumatoid arthritis	x				x	x	x	
Biological	Treatment of autoinflammatory syndromes	x						x	
Biological	Treatment of macular degeneration	x				x	x	x	
Biological	Treatment of adenocarcinoma	x					x	x	
Biological	Treatment of atopic dermatitis	x				x	x	x	
Biological	Treatment of follicular lymphoma	x					x	x	
Chemical	Treatment of bladder cancer	x					x		
Chemical	Prevention of HIV-1 infection	x				x	x		
Biological	Treatment of stroke	x				x			
Biological	Treatment of follicular lymphoma	x				x			
Chemical	Treatment of macular degeneration	x					x		
Biological	Triggering of final follicular maturation in controlled ovarian stimulation	x						x	
Biological	Treatment of myasthenia gravis	x					x	x	
Advanced Therapy	Treatment of Wiskott-Aldrich syndrome	x				x	x	x	
Biological	Treatment of atopic dermatitis	x				x			
Chemical	Treatment of sleep disorder	x						x	
Biological	Treatment of melanoma	x						x	
Biological	Treatment of melanoma	x						x	
Biological	Establishment of allogeneic renal tolerance	x					x	x	
Biological	Prevention of malaria	x						x	
Biological	Treatment of multiple myeloma	x					x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Prevention of myocardial infarction	x					x	x	
Advanced Therapy	Treatment of follicular lymphoma	x						x	
Biological	Treatment of Crohn's disease	x						x	
Chemical	Treatment of solid tumours	x				x	x		
Biological	Treatment of large B cell lymphoma	x					x	x	
Biological	Treatment of macular degeneration	x						x	
Chemical	Treatment of mitochondrial myopathies	x					x	x	
Biological	Treatment of EGFRm non small cell lung cancer	x						x	
Biological	Prevention of Covid-19 disease			x				x	
Biological	Prevention of Covid-19 disease	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 dengue disease			x		x			
Chemical	Treatment of urinary infections			x				x	
Biological	Treatment of diabetes mellitus			x				x	
Chemical	Treatment of breast cancer			x				x	
Biological	Treatment of osteoporosis			x				x	
Biological	Treatment of steatohepatitis			x			x	x	
Biological	Treatment of rheumatoid arthritis			x				x	
Chemical	Treatment of macular degeneration			x				x	
Biological	Treatment of macular degeneration			x		x	x	x	
Biological	Prevention of yellow fever			x				x	
Biological	Treatment of macular edema			x				x	
Chemical	Treatment of vascular disorders			x				x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of Merkel cell carcinoma			x				x	
Biological	Treatment of graft-versus-host disease		x						
Biological	Treatment of multiple myeloma		x			x		x	
Biological	Treatment of thrombocytopenia		x			x	x	x	
Chemical	Treatment of polycythaemia vera		x					x	
Chemical	Treatment of neurofibromatosis		x					x	
Chemical	Treatment of multiple system atrophy		x					x	
Advanced Therapy	Treatment of sickle cell disease		x					x	
Advanced Therapy	Treatment of retinal dystrophies		x					x	x
Advanced Therapy	Treatment of epidermolysis bullosa		x			x	x	x	
Chemical	Treatment of microvillus inclusion disease				x		x		
Chemical	Treatment of idiopathic pulmonary fibrosis				x		x		
Advanced Therapy	Treatment of large B-cell lymphoma				x			x	
Biological	Treatment of pulmonary arterial hypertension				x			x	
Chemical	Treatment of hepatitis delta				x			x	
Chemical	Treatment of Fabry disease				x		x	x	x
Advanced Therapy	Treatment of multiple myeloma				x	x	x	x	x
Chemical	Treatment of C3 glomerulopathy				x			x	
Qualification Advice	Detection of CNS Injury	x						x	
Qualification Advice	Detection of hypoglycaemia in diabetes	x						x	
Qualification Advice	Detection of drug-induced pancreas injury	x						x	
Qualification Advice	Treatment of type 1 diabetes	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 74 Scientific Advice letters - 37 Initial Scientific Advice, 16 Follow-up Scientific Advice, 9 Protocol Assistance letters, 8 Follow-up Protocol Assistance, 4 Qualifications of novel

methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 22-25 February 2021 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 71 new Requests for which the procedure started at the SAWP meeting held on 08-11 February 2021. The new requests are divided as follows: 46 Initial Scientific Advice, 13 Follow-up Scientific Advice, 9 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.