

22 April 2022 EMA/CHMP/SAWP/181972/2022 Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 19– 22 April 2022

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

	1995-2020	2022	Overall total
Scientific Advice	5226	165	5391
Follow-up to Scientific Advice	1623	48	1671
Protocol Assistance	1173	28	1201
Follow-up to Protocol Assistance	634	19	653
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	180	4	184
	9001	264	9265

Outcome of the April 2022 CHMP meeting in relation to scientific advice procedures

Final scientific advice procedures

Substance	Intended indications	Type of request					Торіс				
		New		Follow- up							
		SA	РА	SA	РА	Quality	Preclinical	Clinical	Significant benefit		
Biological	Treatment of melanoma							x			
Chemical	Prevention of arteriovenous access dysfunction				x			x			

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	Intended indications		requ	est	Торіс				
		New		Follow- up					
		SA	ΡΑ	SA	ΡΑ	Quality	Preclinical	Clinical	Significant benefit
Biological	Treatment of multiple myeloma		х					х	х
Biological	Treatment of osteogenesis imperfecta						х	х	
Chemical	Treatment of periodic paralysis		х				х	х	
Chemical	Treatment of ATTR amyloidosis				х			х	
Chemical	Treatment of non-small-cell lung cancer						х	х	
Biological	Treatment of genetic disorders					x			
Chemical	Treatment of Angelman syndrome					x	х	х	
Biological	Treatment of melanoma							x	
Chemical	Treatment of esophagitis						х	х	
Chemical	Treatment of peripheral neuropathic pain							x	
Biological	Treatment of type 1 diabetes mellitus					x	х	х	
Biological	Treatment of neoplasm					x			
BIOIOGICAL	Treatment of chronic inflammatory demyelinating polyneuropathy						x	x	
Chemical	Treatment of brain injury				x			х	
Chemical	Treatment of non-small cell lung cancer					x			
Chemical	Treatment of ovarian cancer					x			
Biological	Treatment of multiple myeloma		x					х	
Chemical	Treatment of elevated LDL-Cholesterol			x				х	
Biological	Treatment of osteoporosis					x	х	х	
Chemical	Treatment of multiple sclerosis							х	
Biological	Treatment of rheumatoid arthritis			x		x		х	
Biological	Treatment of non-small cell lung cancer					х		x	
Biological	Prevention of respiratory tract infections			х				х	
Chemical	Prevention of bronchopulmonary dysplasia					x			
Biological	Treatment of achondroplasia				x	х		х	

Substance	Intended indications	Ту	be of	requ	est	Торіс				
		New		Foll up	ow-					
		SA	ΡΑ	SA	ΡΑ	Quality	Preclinical	Clinical	Significant benefit	
Biological	Prevention of respiratory tract infections			х				х		
Chemical	Treatment of seizures							х		
Chemical	Treatment of acinetobacter infections			x			х	х		
Chemical	Treatment of menopause			x			х			
Chemical	Treatment of idiopathic pulmonary fibrosis							х		
Chemical	Treatment of hypercholesterolaemia						х			
Biological	Treatment of hypotransferrinemia				x			х		
Chemical	Treatment of cholangiocarcinoma					x	х	x		
Chemical	Treatment of schizophrenia					x		х		
Chemical	Treatment of hypertension							х		
Chemical	Treatment of non-alcoholic steatohepatitis						х	x		
Biological	Treatment of rheumatoid arthritis					x	х	х		
Biological	Treatment of osteoporosis			x		x		х		
Biological	Treatment of mantle cell lymphoma							х		
Chemical	Treatment of hypoparathyroidism		х				х	х		
Chemical	Treatment of subarachnoid haemorrhage				x		х			
Biological	Treatment of neovascular macular degeneration			x		x		x		
Chemical	Treatment of urticaria						х	х		
Chemical	Treatment of schizophrenia			x				х		
Chemical	Treatment of acute pain					x		х		
Biological	Treatment of metachromatic leukodystrophy		x					x		
Biological	Prevention of middle east respiratory syndrome						x	x		
Biological	Prevention of influenza					х	х	х		
Chemical	Treatment of multiple sclerosis					х		х		
Chemical	Treatment of non-small cell lung cancer							х		

Substance	Intended indications	Type of request				Торіс				
		New		Foll up	ow-					
		SA	РА	SA	PA	Quality	Preclinical	Clinical	Significant benefit	
Biological	Treatment of mucopolysaccharidosis type I		x					x	x	
Biological	Treatment of multiple sclerosis					x				
Chemical	Treatment of non-alcoholic steatohepatitis						х	х		
Biological	Prevention of clostridioides difficile infection						x	х		
Chemical	Treatment of pulmonary arterial hypertension					x		x		
Qualification	Monitoring of chronic heart failure									
Biological	Prevention of influenza A					x	х	х		
Chemical	Detection of coronary artery disease			х			x	х		
Chemical	Treatment of hepatitis B			х			х			
Biological	Treatment of hypercholesterolaemia					х	х	х		
Chemical	Treatment of hyperinsulinism		х			х	х	х		
Advanced Therapy	Treatment of diamond blackfan anaemia					х	x	х		
Biological	Prevention of respiratory syncytial virus					x	x	х		

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 65 Scientific Advice letters - 40 Initial Scientific Advice, 11 Follow-up Scientific Advice, 7 Protocol Assistance letters, 6 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 19-22 April 2022 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 83 new Requests for which the procedure started at the SAWP meeting held on 04-07 April 2022. The new requests are divided as follows: 44 Initial Scientific Advice, 23 Follow-up Scientific Advice, 6 Initial Protocol Assistance, 8 Follow-up Protocol Assistance, 2 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.