



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				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
SA	PA	SA	PA						
Biological	Treatment of melanoma							X	
Chemical	Prevention of arteriovenous access dysfunction				X			X	



Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of multiple myeloma		x					x	x
Biological	Treatment of osteogenesis imperfecta						x	x	
Chemical	Treatment of periodic paralysis		x				x	x	
Chemical	Treatment of ATTR amyloidosis				x			x	
Chemical	Treatment of non-small-cell lung cancer						x	x	
Biological	Treatment of genetic disorders					x			
Chemical	Treatment of Angelman syndrome					x	x	x	
Biological	Treatment of melanoma							x	
Chemical	Treatment of esophagitis						x	x	
Chemical	Treatment of peripheral neuropathic pain							x	
Biological	Treatment of type 1 diabetes mellitus					x	x	x	
Biological	Treatment of neoplasm					x			
Biological	Treatment of chronic inflammatory demyelinating polyneuropathy						x	x	
Chemical	Treatment of brain injury				x			x	
Chemical	Treatment of non-small cell lung cancer					x			
Chemical	Treatment of ovarian cancer					x			
Biological	Treatment of multiple myeloma		x					x	
Chemical	Treatment of elevated LDL-Cholesterol			x				x	
Biological	Treatment of osteoporosis					x	x	x	
Chemical	Treatment of multiple sclerosis							x	
Biological	Treatment of rheumatoid arthritis			x		x		x	
Biological	Treatment of non-small cell lung cancer					x		x	
Biological	Prevention of respiratory tract infections			x				x	
Chemical	Prevention of bronchopulmonary dysplasia					x			
Biological	Treatment of achondroplasia				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 mucopolysaccharidosis type I		x					x	x
Biological	Treatment of multiple sclerosis					x			
Chemical	Treatment of non-alcoholic steatohepatitis						x	x	
Biological	Prevention of clostridioides difficile infection						x	x	
Chemical	Treatment of pulmonary arterial hypertension					x		x	
Qualification	Monitoring of chronic heart failure								
Biological	Prevention of influenza A					x	x	x	
Chemical	Detection of coronary artery disease			x			x	x	
Chemical	Treatment of hepatitis B			x			x		
Biological	Treatment of hypercholesterolaemia					x	x	x	
Chemical	Treatment of hyperinsulinism		x			x	x	x	
Advanced Therapy	Treatment of diamond blackfan anaemia					x	x	x	
Biological	Prevention of respiratory syncytial virus					x	x	x	

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.