



24 March 2022  
EMA/CHMP/SAWP/181972/2022  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 21– 24 March 2022

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

	1995-2020	2022	Overall total
Scientific Advice	5226	125	5351
Follow-up to Scientific Advice	1623	37	1660
Protocol Assistance	1173	21	1194
Follow-up to Protocol Assistance	634	13	647
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	180	3	183
	<b>9001</b>	<b>199</b>	<b>9200</b>

### **Outcome of the March 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				
Chemical	Treatment of amyotrophic lateral sclerosis		x				x	x	
Chemical	Treatment of pulmonary arterial hypertension	x				x	x	x	



Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of gastroenteropancreatic neuroendocrine tumours	x						x	
Chemical	Treatment of diabetic macular oedema	x				x	x	x	
Biological	Treatment of myelodysplastic syndromes		x					x	
Chemical	Treatment of gastrointestinal stromal tumours	x					x	x	
Biological	Treatment of osteoarthritis	x						x	
Chemical	Treatment of primary biliary cholangitis				x	x	x	x	
Chemical	Treatment of acute myeloid leukaemia		x					x	x
Biological	Treatment of non-squamous non-small cell lung carcinoma	x						x	
Chemical	Treatment of psoriasis			x			x		
Biological	Treatment of lupus nephritis	x				x	x	x	
Advanced Therapy	Treatment of ATTR amyloidosis				x	x			
Chemical	Treatment of squamous cell carcinoma of the head and neck	x				x		x	
Biological	Treatment of ulcerative colitis			x				x	
Chemical	Treatment of squamous cell carcinoma of the head and neck	x				x	x		
Chemical	Treatment of systemic sclerosis	x					x	x	
Chemical	Treatment of idiopathic pulmonary fibrosis	x					x	x	
Chemical	Treatment of menopause			x				x	
Biological	Prevention of herpes zoster			x				x	
Advanced Therapy	Treatment of sickle cell disease				x	x			
Chemical	Treatment of hepatic encephalopathy	x				x		x	
Biological	Treatment of diabetes mellitus	x				x	x	x	
Chemical	Treatment of eosinophilic asthma	x					x	x	
Biological	Treatment of Alzheimer's disease			x				x	
Biological	Treatment of asthma	x				x			
Chemical	Treatment of Friedreich's ataxia				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 melanoma	x						x	
Advanced Therapy	Treatment of Crigler-Najjar syndrome				x			x	
Biological	Prevention of atherosclerotic cardiovascular disease	x					x	x	
Biological	Treatment of diabetes mellitus			x		x	x	x	
Biological	Treatment of melanoma			x		x		x	
Advanced Therapy	Treatment of knee osteoarthritis			x		x	x	x	
Biological	Treatment of non–small cell lung cancer	x						x	
Chemical	Treatment of graft-versus-host disease				x			x	
Biological	Prevention of respiratory syncytial virus	x					x	x	
Chemical	Treatment of atopic dermatitis	x					x	x	
Biological	Treatment of myasthenia gravis	x						x	
Biological	Treatment of non-small cell lung cancer			x				x	
Chemical	Treatment of chronic kidney disease	x						x	
Chemical	Treatment of mild infections	x						x	
Chemical	Treatment of liver decompensation events	x					x	x	
Chemical	Treatment of pulmonary hypertension	x				x	x	x	
Biological	Treatment of large B-cell lymphoma		x			x			
Biological	Prevention of renal damage	x						x	
Chemical	Treatment of HIV-1 Infection	x				x	x		
Chemical	Treatment of cardiovascular disease			x		x	x	x	
Chemical	Treatment of prostate cancer	x						x	
Biological	Treatment of chronic obstructive pulmonary disease	x					x	x	
Chemical	Treatment of small cell lung cancer	x				x			
Biological	Treatment of Crohn’s disease	x					x	x	
Chemical	Prevention of post-surgery infection	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 neovascular age-related macular degeneration			x		x		x	
Biological	Treatment of thrombocytopenia	x				x	x		
Biological	Prevention of cytomegalovirus infection			x				x	
Biological	Treatment of neovascular age-related macular degeneration	x				x	x	x	
Biological	Prevention of pertussis disease	x				x	x	x	
Biological	Prevention of pneumococcal disease	x				x	x	x	
Chemical	Treatment of urinary tract infections			x		x			
Chemical	Treatment of serious infections	x				x	x	x	
Biological	Treatment of pneumonia	x						x	
Biological	Treatment of myasthenia gravis	x					x	x	
Biological	Treatment of locoregional hepatocellular carcinoma	x						x	
Biological	Treatment of breast cancer	x				x			
Chemical	Treatment of transthyretin-mediated amyloidosis		x					x	
Chemical	Treatment of respiratory disorders	x				x	x	x	
Advanced Therapy	Treatment of solid tumours	x				x			
Qualification	Digital measures in neurodegenerative disorders								
Chemical	Treatment of haematopoietic stem cell transplantation			x			x	x	
Chemical	Treatment of bone and joint infections	x				x	x	x	
Chemical	Treatment of splice switching mutations	x				x	x	x	
Biological	Prevention of migraine	x				x	x	x	

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 72 Scientific Advice letters - 46 Initial Scientific Advice, 14 Follow-up Scientific Advice, 5 Protocol Assistance letters, 6 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 21-24 March 2022 CHMP meeting.

## **New requests for scientific advice procedures**

The Committee accepted 68 new Requests for which the procedure started at the SAWP meeting held on 07-10 March 2022. The new requests are divided as follows: 41 Initial Scientific Advice, 10 Follow-up Scientific Advice, 6 Initial Protocol Assistance, 7 Follow-up Protocol Assistance, 4 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.