



30 March 2023  
EMA/CHMP/SAWP/149934/2023  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 27-30 March 2023

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

	1995-2022	2023	Overall total
Scientific Advice	5684	118	5802
Follow-up to Scientific Advice	1783	34	1817
Protocol Assistance	1268	20	1288
Follow-up to Protocol Assistance	680	8	688
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	210	3	213
	<b>9790</b>	<b>183</b>	<b>9973</b>

### **Outcome of the March 2023 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 age-related macular degeneration			x		x			
Biological	Treatment of age-related macular degeneration (AMD)	x				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 Alzheimer disease	x						x	
Advanced Therapy	Treatment of Stargardt disease	x				x	x	x	
Biological	Treatment of chronic obstructive pulmonary disease	x				x		x	
Biological	Treatment of follicular lymphoma	x					x	x	
Biological	Treatment of large B-cell lymphoma	x					x	x	
Chemical	Treatment of graft-versus-host disease				x			x	
Chemical	Treatment of idiopathic pulmonary fibrosis		x			x	x	x	x
Chemical	Treatment of obesity	x				x	x	x	
Chemical	Treatment of kidney disease	x						x	
Chemical	Treatment of pulmonary fibrosis	x					x	x	
Chemical	Treatment of pulmonary fibrosis	x				x	x	x	
Chemical	Treatment of large B-cell lymphoma	x						x	
Biological	Treatment of type II diabetes	x						x	
Chemical	Treatment of breast cancer	x					x	x	
Biological	Treatment of immune disorders	x				x		x	
Biological	Treatment of rejection in kidney transplant			x				x	
Biological	Treatment of rhinosinusitis	x					x	x	
Chemical	Treatment of macular edema	x						x	
Advanced Therapy	Treatment of haemophilia A				x	x	x	x	
Biological	Treatment of rectal cancer	x						x	
Biological	Treatment of colon cancer	x						x	
Chemical	Prevention of coronary artery disease	x						x	
Chemical	Treatment of vasomotor symptoms	x				x			
Chemical	Treatment of fibrodysplasia ossificans progressiva		x				x	x	
Chemical	Treatment of sickle cell disease	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 myasthenia gravis	x				x		x	
Chemical	Treatment of acute myeloid leukaemia				x			x	
Chemical	Treatment of breast cancer	x					x		
Biological	Treatment of psoriasis	x				x		x	
Chemical	Diagnosis of peripheral arteriography	x				x			
Biological	Treatment of angioedema		x			x		x	
Chemical	Treatment of pruritus	x						x	
Chemical	Treatment of hepatitis	x					x	x	
Advanced Therapy	Treatment of acute myeloid leukaemia	x				x	x	x	
Qualification	Biomarker on acute myeloid leukaemia			x				x	
Chemical	Treatment of septic shock	x				x		x	
Biological	Treatment of cancers			x				x	
Biological	Treatment of cancers			x		x		x	
Chemical	Treatment of idiopathic pulmonary fibrosis		x				x	x	
Chemical	Treatment of breast cancer	x				x	x	x	
Chemical	Treatment of cardiovascular disease			x		x			
Biological	Treatment of melanoma			x		x		x	
Chemical	Treatment of psoriasis	x				x	x	x	
Biological	Prevention of pneumonia			x		x		x	
Biological	Prevention of respiratory syncytial virus			x			x	x	
Chemical	Treatment of gastrointestinal tumour				x			x	x
Chemical	Treatment of myelodysplastic syndrome	x				x	x		
Biological	Treatment of demyelinating polyneuropathy	x				x			
Chemical	Treatment of pulmonary arterial hypertension		x					x	x
Biological	Treatment of kidney injury	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 breast cancer	x				x	x		
Chemical	Treatment of pulmonary hypertension			x				x	
Biological	Treatment of ulcerative colitis	x				x	x	x	
Chemical	Treatment of multiple myeloma				x			x	
Chemical	Treatment of migraine	x					x	x	

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 57 Scientific Advice letters - 37 Initial Scientific Advice, 9 Follow-up Scientific Advice, 5 Protocol Assistance letters, 5 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices were adopted at the 27-30 March 2023 CHMP meeting.

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

The Committee accepted 50 new Requests for which the procedure started at the SAWP meeting held on 13-16 March 2023. The new requests are divided as follows: 24 Initial Scientific Advice, 16 Follow-up Scientific Advice, 5 Initial Protocol Assistance, 3 Follow-up Protocol Assistance, 2 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.