



20 July 2023  
EMA/CHMP/SAWP/333461/2023  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 17-20 July 2023

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

	1995-2022	2023	Overall total
Scientific Advice	5684	230	5914
Follow-up to Scientific Advice	1783	90	1873
Protocol Assistance	1268	38	1306
Follow-up to Protocol Assistance	680	26	706
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	210	10	218
	<b>9790</b>	<b>394</b>	<b>10182</b>

### **Outcome of the July 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				
Chemical	Treatment of blepharoptosis	X						X	
Biological	Treatment of breast cancer	X						X	
Qualification	Modeling and statistical methodology	X							

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Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of vitiligo	X						X	
Qualification	Project to identify and evaluate remote measurement technologies	X							
Chemical	Treatment of narcolepsy	X					X	X	
Chemical	Treatment of breast cancer	X						X	
Biological	Treatment of cancer	X				X	X	X	
Advanced Therapy	Treatment of glycogen storage disease type I				X			X	
Biological	Treatment of lymphomas non-Hodgkin's B-cell	X				X			
Biological	Treatment of non-small cell lung cancer	X						X	
Chemical	Treatment of non-small cell lung cancer	X					X	X	
Biological	Treatment of sclerosis	X						X	
Chemical	Treatment of fibrosis			X			X		
Biological	Treatment of breast carcinoma			X			X		
Chemical	Treatment of leukemia	X						X	
Advanced Therapy	Prevention of leukemia	X					X	X	
Chemical	Treatment of respiratory syncytial virus			X				X	
Biological	Treatment of cardiomyopathy	X					X	X	
Biological	Treatment of Crohn's disease			X				X	
Biological	Treatment of nephropathy	X				X	X	X	
Advanced Therapy	Treatment of Danon disease	X				X		X	
Chemical	Treatment of mycoses	X				X		X	
Biological	Treatment of myeloma	X				X	X	X	
Chemical	Treatment of sclerosis	X				X	X		
Chemical	Treatment of prostate cancer			X				X	
Biological	Treatment of concentrations of factor Xa inhibitors in blood			X		X	X	X	
Biological	Treatment of malignant neoplasms	X						X	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of ulcerative colitis	X					X	X	
Chemical	Treatment of urticaria	X				X	X		
Biological	Treatment of frontotemporal dementia				X		X	X	
Biological	Prevention of Escherichia coli infection			X		X			
Biological	Prevention of Group B streptococcus	X				X	X	X	
Chemical	Treatment of myopathy				X			X	
Chemical	Treatment of spinal muscular atrophy		X					X	
Chemical	Treatment of prostate cancer	X						X	
Biological	Treatment of eosinophilic oesophagitis	X					X	X	
Chemical	Treatment of achondroplasia		X				X	X	X
Chemical	Treatment of dermatitis			X				X	
Advanced Therapy	Treatment of myocardial ischemia	X				X	X	X	
Biological	Prevention of myocardial infarction			X				X	
Biological	Treatment of heart failure			X				X	
Chemical	Treatment of kidney disease			X		X		X	
Advanced Therapy	Treatment of haemophilia				X	X	X	X	
Biological	Prevention of streptococcal disease	X				X			
Biological	Treatment of arterial trauma	X						X	
Biological	Treatment of ischemic stroke	X				X			
Biological	Prevention of meningococcal disease			X		X		X	
Biological	Treatment of dermatitis			X				X	
Chemical	Treatment of short bowel syndrome		X			X		X	
Biological	Treatment of emphysema	X					X	X	
Biological	Treatment of gastritis and duodenitis	X					X	X	
Biological	Treatment of ovarian cancer			X				X	
Chemical	Treatment of obesity	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 myeloma	X				X			
Chemical	Treatment of schizophrenia	X					X	X	
Chemical	Treatment of cardiomyopathy	X				X			
Chemical	Treatment of congenital hyperinsulinism				X			X	
Chemical	Treatment of Alzheimer's disease	X				X		X	
Biological	Treatment of dermatitis	X						X	
Biological	Treatment of steatohepatitis			X				X	
Biological	Treatment of pyrophosphatase/phosphodiesterase 1 deficiency				X		X	X	
Biological	Treatment of giant cell arteritis							X	
Biological	Treatment of pleural effusions	X					X	X	

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 64 Scientific Advice letters - 37 Initial Scientific Advice, 16 Follow-up Scientific Advice, 3 Protocol Assistance letters, 6 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices were adopted at the 19-22 June 2023 CHMP meeting.

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

The Committee accepted 54 new Requests for which the procedure started at the SAWP meeting held on 03-06 July 2023. The new requests are divided as follows: 24 Initial Scientific Advice, 15 Follow-up Scientific Advice, 9 Initial Protocol Assistance, 3 Follow-up Protocol Assistance, 3 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.