



26 January 2023  
EMA/CHMP/SAWP/41275/2023  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 23 – 26 January 2023

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

	1995-2022	2023	Overall total
Scientific Advice	5684	44	5728
Follow-up to Scientific Advice	1783	16	1799
Protocol Assistance	1268	6	1274
Follow-up to Protocol Assistance	680	0	680
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	210	1	211
	<b>9790</b>	<b>67</b>	<b>9857</b>

### **Outcome of the January 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 urinary infection	X					X	X	
Qualification	Acceptability of oral medicines	X						X	
Biological	Treatment of diabetes type II			X		X	X	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 respiratory syncytial virus	X						X	
Chemical	Prevention of cardiovascular risk	X						X	
Chemical	Treatment of aortic stenosis	X					X	X	
Advance Therapy	Treatment of Fanconi anaemia type A		X			X		X	
Advance Therapy	Treatment of stress urinary incontinence	X				X	X	X	
Advance Therapy	Treatment of urothelial carcinoma	X					X	X	
Biological	Treatment of anaemia	X				X		X	
Biological	Treatment of ricin toxicity	X					X	X	
Biological	Treatment of lung cancer	X						X	
Biological	Treatment of sickle cell disease		X			X	X	X	
Chemical	Treatment of amyotrophic lateral sclerosis	X					X	X	
Chemical	Treatment of cholangitis		X			X	X		
Biological	Treatment of lung cancer	X						X	
Advance Therapy	Treatment of radiation syndrome	X					X	X	
Chemical	Treatment of labour induction			X			X	X	
Chemical	Treatment of short bowel syndrome		X					X	X
Chemical	Treatment of macular edema	X				X	X	X	
Chemical	Prevention of stress disorder	X					X	X	
Chemical	Treatment of ischemic stroke	X				X	X	X	
Chemical	Treatment of vaginal infections	X				X		X	
Biological	Treatment of myelin oligodendrocyte glycoprotein disease			X				X	
Chemical	Treatment of urticaria			X				X	
Chemical	Treatment of vitiligo			X			X	X	
Chemical	Treatment of myelodysplastic syndromes			X				X	
Chemical	Treatment of smoking cessation	X				X			

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of inducible urticaria	X						X	
Biological	Treatment of rheumatoid arthritis	X				X			
Chemical	Treatment of diabetes type II	X				X	X	X	
Biological	Treatment of myocardial infarction	X					X	X	
Biological	Treatment of diabetes mellitus			X		X		X	
Chemical	Treatment of galactosaemia		X			X	X	X	
Biological	Prevention of streptococcal disease	X					X		
Biological	Treatment of graft versus host disease			X			X		
Biological	Treatment of Niemann-Pick disease		X			X	X	X	
Biological	Treatment of nephropathy	X					X	X	
Biological	Treatment of Sjogren's syndrome	X						X	
Biological	Treatment of rheumatoid arthritis	X					X	X	
Biological	Treatment of haemoglobinuria	X						X	
Chemical	Treatment of breast cancer	X					X	X	
Biological	Treatment of myeloma	X					X	X	
Biological	Prevention of meningococcal disease			X				X	
Chemical	Treatment of pulmonary arterial hypertension			X				X	
Chemical	Treatment of weight management	X						X	
Biological	Treatment of psoriatic arthritis	X					X	X	
Chemical	Treatment of diabetes type II	X						X	
Biological	Prevention of Lyme disease	X						X	
Chemical	Treatment of autoimmune neuromuscular disease	X					X	X	
Biological	Treatment of autoimmune neuromuscular disease			X		X			
Biological	Treatment of eosinophilic gastritis	X						X	
Chemical	Treatment of lymphatic malformations	X						X	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of lung cancer	X						X	
Chemical	Treatment of stenosis	X						X	
Biological	Treatment of breast cancer	X						X	
Advance Therapy	Treatment of faecal incontinence	X						X	
Chemical	Treatment of hemoglobinuria	X					X	X	
Chemical	Treatment of trypanosomiasis			X		X			
Biological	Treatment of ischaemic stroke	X				X		X	
Chemical	Treatment of spinal muscular atrophy	X				X		X	
Biological	Treatment of adenocarcinoma			X			X		
Chemical	Treatment of gangliosidosis	X						X	
Biological	Treatment of rheumatoid arthritis			X		X		X	
Chemical	Treatment of Niemann-Pick disease	X				X	X	X	
Biological	Prevention of respiratory tract disease			X			X		
Biological	Treatment of multiple sclerosis			X		X			

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 67 Scientific Advice letters - 44 Initial Scientific Advice, 16 Follow-up Scientific Advice, 6 Protocol Assistance letters, 0 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices were adopted at the 23-26 January 2023 CHMP meeting.

## New requests for scientific advice procedures

The Committee accepted 62 new Requests for which the procedure started at the SAWP meeting held on 9-12 January 2023. The new requests are divided as follows: 38 Initial Scientific Advice, 8 Follow-up Scientific Advice, 10 Initial Protocol Assistance, 3 Follow-up Protocol Assistance, 3 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.