



12 October 2023  
EMA/CHMP/SAWP/458078/2023  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 09-12 October 2023

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

	1995-2022	2023	Overall total
Scientific Advice	5684	290	5974
Follow-up to Scientific Advice	1783	115	1898
Protocol Assistance	1268	59	1327
Follow-up to Protocol Assistance	680	30	710
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	210	13	223
	<b>9790</b>	<b>507</b>	<b>10297</b>

### **Outcome of the October 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						
Qualification	Treatment of tuberculosis disease	X					X		
Qualification	Evaluation of oral drug formulations	X					X		
Chemical	Treatment of sclerosis	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 fibrosis	X					X	X	
Chemical	Treatment of anaphylaxis	X					X	X	
Biological	Treatment of head and neck squamous cell cancer	X						X	
Advance Therapy	Treatment of myeloma	X					X	X	
Advance Therapy	Treatment of glioblastoma	X				X	X		
Chemical	Treatment of hypertension	X					X	X	
Biological	Treatment of head and neck squamous cell cancer			X				X	
Chemical	Treatment of Lennox-Gastaut syndrome		X			X			
Chemical	Treatment of vasomotor symptoms			X			X	X	
Chemical	Treatment of postpartum depression	X					X	X	
Advance Therapy	Treatment of retinal dystrophies		X			X	X	X	
Chemical	Treatment of myelodysplastic syndromes		X			X	X	X	
Biological	Treatment of endometrial, NSCLC, ovarian and breast cancer	X					X		
Biological	Treatment of solid tumors	X				X			
Chemical	Prevention of dry age-related macular degeneration	X						X	
Biological	Treatment of large B-cell lymphoma		X					X	
Biological	Treatment of hemophilia A	X					X	X	
Chemical	Treatment of heart failure			X			X	X	
Biological	Treatment of sclerosis	X				X			
Biological	Treatment of chronic inflammatory demyelinating polyneuropathy	X						X	
Biological	Treatment of sclerosis			X		X		X	
Biological	Treatment of transthyretin amyloidosis	X					X	X	
Biological	Treatment of rhinitis	X						X	
Chemical	Treatment of colorectal cancer	X				X		X	
Chemical	Treatment of C3 glomerulopathy		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	
Biological	Prevention of acute otitis and pneumoniae	X				X			
Chemical	Treatment of depressive disorder	X				X			
Chemical	Treatment of asthma			X				X	
Chemical	Treatment of acute myeloid leukemia	X					X		
Chemical	Treatment of respiratory syncytial virus			X				X	
Chemical	Treatment of diabetic retinopathy	X					X	X	
Biological	Treatment of Sjögren's disease	X					X	X	
Chemical	Treatment of Alagille syndrome		X			X		X	
Advance Therapy	Treatment of T cell lymphomas	X						X	
Chemical	Treatment of supranuclear palsy	X						X	
Biological	Treatment of multiple myeloma			X				X	
Biological	Treatment of head and neck squamous cell cancer			X				X	
Chemical	Treatment of leukaemia	X				X	X	X	
Biological	Treatment of hypophosphatasia		X				X	X	
Biological	Treatment of thrombocytopenic purpura			X				X	
Chemical	Treatment of multiple myeloma	X				X			
Biological	Treatment of rheumatoid arthritis	X					X	X	
Chemical	Treatment of soft tissue sarcoma		X					X	X
Biological	Treatment of rheumatoid arthritis			X				X	
Chemical	Treatment of small cell lung cancer	X				X	X	X	
Advance Therapy	Treatment of (wet) age-related macular degeneration	X				X	X	X	
Chemical	Treatment of tuberous sclerosis		X					X	X
Chemical	Treatment of Parkinson's disease	X				X	X	X	
Biological	Treatment of head and neck squamous cell cancer			X				X	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of non-small cell lung cancer	X					X	X	
Chemical	Treatment of sclerosis			X				X	
Biological	Treatment of ulcerative colitis	X					X	X	
Advance Therapy	Treatment of T cell lymphoma	X				X			
Biological	Treatment of biliary tract cancer		X			X			
Biological	Treatment of demyelinating polyneuropathy		X			X		X	
Biological	Prevention of Neisseria meningitidis	X				X		X	
Biological	Treatment of nephritis	X						X	
Biological	Treatment of Priming of labour			X		X		X	

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 62 Scientific Advice letters - 37 Initial Scientific Advice, 14 Follow-up Scientific Advice, 12 Protocol Assistance letters, 0 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices were adopted at the 09-12 October 2023 CHMP meeting.

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

The Committee accepted 80 new Requests for which the procedure started at the SAWP meeting held on 25-28 September 2023. The new requests are divided as follows: 53 Initial Scientific Advice, 15 Follow-up Scientific Advice, 7 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 0 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.