



19 May 2022  
EMA/CHMP/SAWP/284919/2022  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 16– 19 May 2022

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

	1995-2020	2022	Overall total
Scientific Advice	5226	211	5437
Follow-up to Scientific Advice	1623	68	1691
Protocol Assistance	1173	35	1208
Follow-up to Protocol Assistance	634	28	662
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	180	7	187
	<b>9001</b>	<b>349</b>	<b>9265</b>

### **Outcome of the May 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						
Biological	Treatment of neuromyelitis optica spectrum disorders				x			x	
Chemical	Treatment of pulmonary arterial hypertension				x	x			



Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of myelodysplastic syndromes		x					x	x
Biological	Treatment of follicular lymphoma		x			x		x	x
Biological	Treatment of age-related macular degeneration			x		x		x	
Biological	Prevention of bleeding			x				x	
Biological	Treatment of haemophilia A				x			x	
Chemical	Treatment of primary mitochondrial myopathy	x					x	x	
Chemical	Treatment of glycosylation		x				x	x	
Chemical	Treatment of lymphocytic leukemia	x						x	
Chemical	Treatment of lymphocytic leukemia	x						x	
Chemical	Treatment of Fuchs endothelial corneal dystrophy			x				x	
Biological	Treatment of bleeding			x				x	
Biological	Treatment of bladder cancer	x						x	
Biological	Treatment of bladder cancer	x						x	
Chemical	Treatment of lupus erythematosus	x				x		x	
Chemical	Treatment of pneumonia	x					x	x	
Chemical	Treatment of haemophilia B				x			x	
Chemical	Treatment of Prion disease	x					x	x	
Biological	Treatment of colorectal cancer	x						x	
Biological	Treatment of type 2 diabetes mellitus	x					x	x	
Chemical	Treatment of breast cancer	x						x	
Chemical	Treatment of haemoglobinuria				x		x	x	
Chemical	Treatment of haemophilia A				x			x	
Chemical	Treatment of breast cancer	x						x	
Chemical	Treatment of colorectal cancer	x					x		
Advanced Therapy	Treatment of diffuse large B-cell lymphoma	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of osteoporosis			x				x	
Advanced Therapy	Treatment of type 1 diabetes mellitus	x				x			
Biological	Treatment of diffuse large B-cell lymphoma			x				x	
Biological	Prevention of yellow fever			x				x	
Advanced Therapy	Treatment of large B cell lymphoma	x				x	x	x	
Biological	Treatment of growth hormone deficiency		x					x	
Chemical	Prevention of atherothrombotic and thromboembolic disorders	x						x	
Biological	Treatment of atopic dermatitis			x		x		x	
Biological	Treatment of masseter muscle prominence			x				x	
Biological	Treatment of X-linked hypo-hidrotic ectodermal dysplasia				x			x	
Biological	Treatment of rheumatoid arthritis			x		x			
Chemical	Treatment of insomnia in adults			x		x			
Chemical	Treatment of breast cancer	x						x	
Biological	Prevention of Neisseria meningitidis	x				x	x	x	
Biological	Treatment of psoriasis			x				x	
Chemical	Treatment of cholestatic pruritus		x					x	x
Chemical	Treatment of lung diseases			x				x	
Chemical	Treatment of nephropathy	x					x	x	
Biological	Treatment of non-alcoholic steatohepatitis	x				x	x		
Biological	Treatment of multiple myeloma	x						x	
Biological	Treatment of osteosarcoma	x					x	x	
Biological	Prevention of influenza infection	x						x	
Biological	Treatment of small cell lung cancer			x				x	
Biological	Treatment of non-small-cell lung carcinoma	x				x			
Advanced Therapy	Treatment of large B-cell lymphoma	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of sickle cell disease	x						x	
Biological	Treatment of myasthenia gravis	x				x			
Biological	Diagnosis of low endotoxin recovery	x				x			
Biological	Treatment of haematological and solid malignancies	x					x		
Biological	Treatment of squamous cell carcinoma	x						x	
Chemical	Treatment of prostate cancer	x						x	
Advanced Therapy	Treatment of haemophilia B				x	x		x	
Biological	Prevention of atrial fibrillation	x				x	x		
Chemical	Treatment of seizures	x						x	
Biological	Treatment of type 1 diabetes	x					x	x	
Biological	Treatment of large B-cell lymphoma			x				x	
Biological	Prevention of herpes zoster			x		x			
Chemical	Treatment of depressive disorder			x		x			
Biological	Prevention of pertussis disease	x				x	x	x	
Advanced Therapy	Treatment of progressive multifocal leukoencephalopathy	x				x	x	x	
Biological	Prevention of hepatitis B virus			x		x			
Biological	Treatment of multiple myeloma		x					x	x
Biological	Prevention of renal allograft rejection	x				x	x	x	
Chemical	Treatment of thrombotic microangiopathy			x				x	
Chemical	Treatment of interstitial lung diseases	x				x	x	x	
Biological	Treatment of multiple sclerosis	x				x	x	x	
Chemical	Treatment of HIV-1	x					x	x	
Chemical	Treatment of multiple myeloma				x			x	
Chemical	Treatment of vanishing white matter disease	x					x	x	
Chemical	Treatment of urinary infections	x				x	x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Advanced Therapy	Treatment of NGLY1 deficiency		x			x	x	x	
Qualification	Artificial Intelligence for adjudication of clinical events	x							
Qualification	Novel endpoints for use in intermediate age-related macular degeneration	x							
Biological	Treatment of anti adeno-associated virus	x					x	x	
Chemical	Treatment of cardiomyopathy	x						x	
Biological	Diagnosis of cancer patient			x		x	x	x	
Qualification	Patient reported outcome for pulmonary arterial hypertension	x							
Chemical	Treatment of depressive disorder	x					x	x	

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 85 Scientific Advice letters - 46 Initial Scientific Advice, 20 Follow-up Scientific Advice, 7 Protocol Assistance letters, 9 Follow-up Protocol Assistance, 3 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 16-19 May 2022 CHMP meeting.

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

The Committee accepted 77 new Requests for which the procedure started at the SAWP meeting held on 02-05 May 2022. The new requests are divided as follows: 46 Initial Scientific Advice, 12 Follow-up Scientific Advice, 12 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 2 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.