



16 September 2021  
EMA/CHMP/SAWP/519377/2021  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 13 – 16 September 2021

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

	1995-2020	2021	Overall total
Scientific Advice	4766	373	5139
Follow-up to Scientific Advice	1413	174	1587
Protocol Assistance	1076	75	1151
Follow-up to Protocol Assistance	576	38	614
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	161	14	175
	<b>8157</b>	<b>674</b>	<b>8831</b>

### **Outcome of the September 2021 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 hyperphenylalaninemia		X			X	X	X	X
Chemical	Treatment of Acne vulgaris	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 haemophilia A		x			x	x	x	x
Biological	Treatment of COVID-19	x				x	x	x	
Biological	Treatment of neovascular macular degeneration	x				x	x	x	
Biological	Treatment of neovascular macular degeneration	x				x	x	x	
Biological	Treatment of hepatocellular carcinoma	x				x	x	x	
Chemical	Treatment of Cystic fibrosis	x				x	x	x	
Biological	Treatment of spinal muscular atrophy		x			x	x	x	x
Biological	Treatment of exacerbations of COPD	x				x	x	x	
Chemical	Treatment of COVID-19	x				x	x	x	
Advanced Therapy	Treatment of diffuse large B cell lymphoma				x	x	x	x	x
Advanced Therapy	Treatment of diffuse large B cell lymphoma				x	x	x	x	x
Chemical	Treatment of small cell lung cancer	x				x	x	x	
Biological	Treatment of Lupus Nephritis	x				x	x	x	
Biological	Treatment of colon carcinoma	x				x	x	x	
Chemical	Treatment of liposarcoma	x				x	x	x	
Chemical	Treatment of liver fibrosis	x				x	x	x	
Chemical	Treatment of schizophrenia	x				x	x	x	
Chemical	Treatment of glaucoma			x		x	x	x	x
Biological	Treatment of glabellar lines	x				x	x	x	
Chemical	Treatment of non-alcoholic steatosis	x				x	x	x	
Biological	Prevention of COVID-19	x				x	x	x	
Biological	Treatment of osteoporosis			x		x	x	x	x
Chemical	Treatment of osteoporosis			x		x	x	x	x
Advanced Therapy	Treatment of Duchenne muscular dystrophy				x	x	x	x	x

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of ST elevation myocardial infarction			x		x	x	x	x
Biological	Treatment of breast cancer			x		x	x	x	x
Chemical	Treatment of melanoma	x				x	x	x	
Biological	Prevention of cluster headache			x		x	x	x	x
Chemical	Treatment of immune inflammatory disorders	x				x	x	x	
Chemical	Treatment of narcolepsy	x				x	x	x	
Chemical	Treatment of prostate cancer	x				x	x	x	
Chemical	Treatment of biliary tract cancer		x			x	x	x	x
Biological	Treatment of Crohn's disease			x		x	x	x	x
Biological	Treatment of COVID-19	x				x	x	x	
Biological	Treatment of aged-related macular degeneration	x				x	x	x	
Biological	Treatment of Hunter syndrome	x				x	x	x	
Qualification Advice	Patient preferences elicitation	x						x	
Biological	Treatment of rheumatoid arthritis	x				x	x	x	
Biological	Treatment of COVID-19	x				x	x	x	
Chemical	Treatment of lupus nephritis	x				x	x	x	
Chemical	Prevention of HIV-1 infection	x				x	x	x	
Chemical	Treatment of psoriasis	x				x	x	x	
Chemical	Treatment of type 1 diabetes	x				x	x	x	
Advanced Therapy	Treatment of melanoma	x				x	x	x	
Biological	Treatment of type 2 diabetes	x				x	x	x	
Chemical	Treatment of pulmonary arterial hypertension			x		x	x	x	x
Chemical	Prevention of arterial thromboembolism	x				x	x	x	
Chemical	Treatment of bladder cancer	x				x	x	x	
Chemical	Treatment of pulmonary arterial hypertension	x				x	x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Prevention of COVID-19	x				x	x	x	
Chemical	Treatment of septic shock	x				x	x	x	
Biological	Treatment of severe pruritus	x				x	x	x	
Chemical	Treatment of spinal muscular atrophy		x			x	x	x	x
Chemical	Treatment of primary biliary cholangitis	x				x	x	x	
Advanced Therapy	Treatment of Sanfilippo A syndrome		x			x	x	x	x
Chemical	Treatment of Prader-Willi syndrome				x	x	x	x	x
Biological	Treatment of non-small cell lung cancer			x		x	x	x	
Biological	Treatment of melanoma	x				x	x	x	
Biological	Treatment of aged-related macular degeneration	x				x	x	x	
Biological	Treatment of achondroplasia		x			x	x	x	x
Chemical	Treatment of Ulcerative colitis	x				x	x	x	
Chemical	Treatment of polycythaemia vera				x	x	x	x	x
Biological	Prevention of COVID-19	x				x	x	x	
Advanced Therapy	Treatment of sickle cell disease		x			x	x	x	x
Chemical	Treatment of thyroid cancer			x		x	x	x	x
Qualification Advice	Sickle cell disease electronic patient-reported outcome	x						x	
Biological	Prevention of respiratory syncytial infection	x				x	x	x	
Chemical	Treatment of non-small cell lung cancer	x				x	x	x	
Chemical	Prevention of transplant rejection	x				x	x	x	
Biological	Treatment of haemophagocytic lymphohistiocytosis				x	x	x	x	x
Biological	Treatment of celiac disease	x				x	x	x	
Biological	Treatment of breast cancer	x				x	x	x	
Chemical	Treatment of amyotrophic lateral sclerosis		x			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 ovarian cancer	x				x	x	x	
Biological	Treatment of Dupuytren contracture			x		x	x	x	
Biological	Prevention of Lyme borreliosis			x		x	x	x	x
Chemical	Treatment of cutaneous T-cell lymphoma	x				x	x	x	
Chemical	Treatment of squamous cell carcinoma	x				x	x	x	
Biological	Treatment of COVID-19	x				x	x	x	

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 81 Scientific Advice letters - 50 Initial Scientific Advice, 13 Follow-up Scientific Advice, 10 Protocol Assistance letters, 6 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 13-16 September 2021 CHMP meeting.

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

The Committee accepted 81 new Requests for which the procedure started at the SAWP meeting held on 30 August-02 September 2021. The new requests are divided as follows: 41 Initial Scientific Advice, 16 Follow-up Scientific Advice, 10 Initial Protocol Assistance, 9 Follow-up Protocol Assistance, 5 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.