



15 December 2022
EMA/CHMP/SAWP/939122/2022
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 12 – 15 December 2022

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

	1995-2020	2022	Overall total
Scientific Advice	5226	458	5684
Follow-up to Scientific Advice	1623	160	1783
Protocol Assistance	1173	95	1268
Follow-up to Protocol Assistance	634	46	680
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	180	30	210
	9001	789	9790

Outcome of the December 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				
Chemical	Treatment of cystic fibrosis	X				X	X	X	
Biological	Treatment of macular degeneration			X		X		X	
Biological	Treatment of macular degeneration			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 gastrointestinal stromal tumour	x				x	x		
Biological	Treatment of spinal muscular atrophy		x				x	x	
Advanced Therapy	Treatment of adult lymphoblastic leukaemia	x				x		x	
Advanced Therapy	Treatment of Gaucher disease type III		x			x	x	x	
Chemical	Treatment of leprosy			x				x	
Biological	Treatment of fibrosis	x						x	
Chemical	Treatment of obesity	x						x	
Chemical	Treatment of refractory chronic cough	x				x			
Biological	Treatment of respiratory distress syndrome		x			x		x	x
Qualification	Biomarker on white matter in neurological diseases	x							
Chemical	Treatment of type II diabetes	x						x	
Biological	Treatment of upper facial lines	x				x	x		
Biological	Treatment of lupus erythematosus	x					x	x	
Biological	Treatment of breast cancer	x						x	
Chemical	Treatment of epidermolysis bullosa				x			x	
Chemical	Treatment of HIV-1			x			x	x	
Biological	Treatment of atopic dermatitis	x				x	x	x	
Biological	Treatment of steatohepatitis	x						x	
Chemical	Treatment of vasomotor			x				x	
Biological	Treatment of myeloma		x					x	
Chemical	Treatment of liver fibrosis	x					x	x	
Chemical	Treatment of fibrodysplasia		x			x		x	
Advanced Therapy	Treatment of Duchenne muscular dystrophy				x		x	x	
Qualification	Biomarker of cystic fibrosis transmembrane conductance regulator	x							
Chemical	Diagnosis of pathology in MRI	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 non-small cell lung cancer	X				X	X	X	
Biological	Treatment of myopathies	X				X	X	X	
Advanced Therapy	Treatment of Fabry disease		X			X			
Chemical	Treatment of hepatitis	X					X		
Biological	Treatment of amyotrophic lateral sclerosis		X					X	
Chemical	Treatment of epilepsy	X						X	
Qualification	Model on drug exposure in the central nervous system	X							
Advanced Therapy	Treatment of melanoma	X				X	X	X	
Chemical	Treatment of cholangitis		X			X	X		
Chemical	Treatment of obesity	X				X	X	X	
Chemical	Treatment of lung cancer	X						X	
Chemical	Prevention of atherothrombotic and thromboembolic disorders	X						X	
Biological	Treatment of hypercholesterolaemia	X						X	
Biological	Treatment of lymphoma	X						X	
Biological	Treatment of urticaria			X		X		X	
Advanced Therapy	Treatment of glycogen storage disease type I		X			X			
Biological	Treatment of neutropenia			X				X	
Biological	Treatment of lung cancer			X				X	
Biological	Treatment of Crohn's disease	X					X	X	
Chemical	Treatment of poliovirus	X				X	X	X	
Biological	Treatment of Alzheimer's disease	X						X	
Qualification	Biomarker on diabetic kidney disease	X							
Biological	Treatment of cancers	X					X		
Biological	Prevention of Influenza A and B	X				X	X	X	
Chemical	Treatment of limb-girdle muscular dystrophy		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 atopic dermatitis			X				X	
Biological	Treatment of thyroid eye disease (TED)	X						X	
Biological	Treatment of Alzheimer's			X				X	
Biological	Treatment of type II diabetes			X		X		X	
Chemical	Treatment of obesity	X						X	
Biological	Treatment of Solid tumours	X				X	X	X	
Chemical	Treatment of myelodysplastic syndrome		X					X	X
Biological	Treatment of asthma	X						X	
Biological	Prevention of acute respiratory distress syndrome	X						X	
Biological	Treatment of San Filippo syndrome		X				X	X	
Biological	Treatment of breast cancer			X				X	
Biological	Treatment of lung cancer			X				X	
Chemical	Treatment of sickle cell disease		X				X		
Chemical	Treatment of paroxysmal nocturnal haemoglobinuria				X		X	X	X
Chemical	Treatment of myeloid leukemia			X				X	
Chemical	Treatment of HIV-1	X						X	
Biological	Treatment of intracerebral haemorrhage		X			X	X	X	
Advanced Therapy	Treatment of large B cell lymphoma		X			X	X	X	
Chemical	Treatment of Postpartum depression	X				X			

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 72 Scientific Advice letters - 36 Initial Scientific Advice, 14 Follow-up Scientific Advice, 15 Protocol Assistance letters, 3 Follow-up Protocol Assistance, 4 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices were adopted at the 12-15 December 2022 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 65 new Requests for which the procedure started at the SAWP meeting held on 28 November - 1 December 2022. The new requests are divided as follows: 44 Initial Scientific Advice, 17 Follow-up Scientific Advice, 3 Initial Protocol Assistance, 0 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.