



13 October 2022
EMA/CHMP/SAWP/827118/2022
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 10 – 13 October 2022

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

	1995-2020	2022	Overall total
Scientific Advice	5226	380	5606
Follow-up to Scientific Advice	1623	131	1754
Protocol Assistance	1173	71	1244
Follow-up to Protocol Assistance	634	40	674
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	180	24	204
	9001	646	9647

Outcome of the September 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 organ transplantation		x			x	x	x	x
Biological	Treatment of idiopathic pulmonary fibrosis	x				x	x	x	
Biological	Treatment of idiopathic pericarditis		x			x	x	x	

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of hepatitis	x				x	x	x	
Biological	Treatment of psoriasis			x		x			
Biological	Treatment of psoriasis			x		x		x	
Chemical	Treatment of influenza A or B			x				x	
Chemical	Treatment of peripheral neuropathic pain			x				x	
Biological	Treatment of hidradenitis suppurativa	x						x	
Chemical	Treatment of lupus nephritis	x						x	
Biological	Prevention of chikungunya virus			x				x	
Chemical	Treatment of kidney disease	x					x	x	
Advanced Therapy	Treatment of multiple myeloma		x					x	
Biological	Treatment of large B-cell lymphoma	x				x			
Advanced Therapy	Treatment of haematopoietic stem cell transplantations				x			x	
Biological	Treatment of hepatocellular carcinoma	x						x	
Chemical	Treatment of Allan-Herndon-Dudley syndrome		x			x			
Chemical	Treatment of myotonic disorders		x			x	x	x	
Biological	Treatment of osteoporosis			x		x		x	
Biological	Treatment of thrombocythaemia	x						x	
Biological	Treatment of hypercholesterolaemia			x			x		
Biological	Treatment of multiple myeloma	x						x	
Chemical	Treatment of prostate cancer	x				x			
Chemical	Treatment of urinary tract infections			x				x	
Advanced Therapy	Treatment of glycogen storage disease		x				x		
Biological	Treatment of melanoma			x				x	
Chemical	Treatment of inflammatory acne	x					x	x	
Chemical	Treatment of non-small-cell lung carcinoma	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of spinal muscular atrophy	x				x	x	x	
Chemical	Treatment of type I diabetes mellitus	x					x	x	
Advanced Therapy	Treatment of large B cell lymphoma	x					x	x	
Biological	Treatment of lupus erythematosus	x				x			
Biological	Treatment of bowel disorders	x						x	
Biological	Treatment of sclerosis	x					x	x	
Chemical	Treatment of angioedema		x			x	x	x	
Chemical	Treatment of HIV-1 Infection			x		x	x		
Chemical	Treatment of hepatitis B or D			x			x		
Chemical	Treatment of epidermolysis bullosa	x					x	x	
Biological	Treatment of diabetes mellitus	x				x			
Chemical	Treatment of endometrioid ovarian cancer	x						x	
Chemical	Treatment of adrenoleukodystrophy	x				x			
Biological	Treatment of diabetes mellitus	x						x	
Biological	Treatment of Alzheimer's disease	x						x	
Chemical	Treatment of dementia	x					x	x	
Advanced Therapy	Treatment of Duchenne muscular dystrophy			x		x		x	
Biological	Treatment of melanoma	x						x	
Biological	Treatment of lupus erythematosus			x				x	
Chemical	Treatment of seizures	x						x	
Biological	Treatment of systemic sclerosis	x						x	
Biological	Treatment of esophageal carcinoma			x				x	
Biological	Treatment of diabetes mellitus			x		x			
Chemical	Treatment of aspergillosis	x						x	
Chemical	Treatment of glaucoma	x					x	x	
Chemical	Treatment of gliomas	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of seizures	x						x	
Biological	Treatment of non-small-cell lung carcinoma			x				x	
Advanced Therapy	Treatment of leukocyte adhesion deficiency type I		x			x	x	x	
Chemical	Treatment of prostate cancer	x						x	
Chemical	Treatment of cholangiocarcinoma	x					x	x	
Chemical	Treatment of TBR1-related disorder		x					x	x
Advanced Therapy	Treatment of haemophilia B				x	x		x	
Advanced Therapy	Treatment of Duchenne muscular dystrophy			x				x	
Biological	Treatment of osteoarthritis	x					x	x	
Chemical	Treatment of congenital adrenal hyperplasia		x			x			
Biological	Treatment of non-small-cell lung carcinoma	x				x	x	x	
Chemical	Treatment of prostate cancer	x				x	x	x	
Chemical	Treatment of peritoneal carcinomatosis	x				x	x		
Biological	Treatment of psoriasis	x				x		x	
Advanced Therapy	Treatment of follicular lymphoma	x						x	
Biological	Treatment of non-small-cell lung carcinoma			x				x	
Chemical	Treatment of schizophrenia	x				x	x	x	
Chemical	Treatment of myeloid leukemia	x				x			
Biological	Treatment of lymphoblastic leukemia	x						x	
Qualification	Symptoms and Impacts Questionnaire for Ulcerative Colitis and Crohn's disease	x						x	
Qualification	Model-based CTSP for Duchenne Muscular Dystrophy	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 73 Scientific Advice letters - 43 Initial Scientific Advice, 18 Follow-up Scientific Advice, 10 Protocol Assistance letters, 2 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 10-13 October 2022 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 69 new Requests for which the procedure started at the SAWP meeting held on 26-29 September 2022. The new requests are divided as follows: 42 Initial Scientific Advice, 13 Follow-up Scientific Advice, 9 Initial Protocol Assistance, 3 Follow-up Protocol Assistance, 2 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.