



24 February 2022
EMA/CHMP/SAWP/12021
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 21– 24 February 2022

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

	1995-2020	2022	Overall total
Scientific Advice	5226	79	5305
Follow-up to Scientific Advice	1623	23	1646
Protocol Assistance	1173	16	1189
Follow-up to Protocol Assistance	634	7	641
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	180	2	182
	9001	127	9064

Outcome of the February 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 breast cancer	x					x	x	
Chemical	Treatment of melanoma	x				x			
Biological	Treatment of non-small cell lung cancer	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

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Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Prevention of lower respiratory tract disease	x				x		x	
Chemical	Treatment of non-small cell lung cancer			x				x	
Chemical	Treatment of non-small cell lung cancer	x					x	x	
Biological	Prevention of respiratory syncytial virus			x			x	x	
Chemical	Treatment of non-small cell lung cancer	x					x	x	
Biological	Treatment of thrombotic thrombocytopenic purpura				x	x			
Biological	Treatment of chronic idiopathic urticaria	x				x	x	x	
Biological	Treatment of non-small cell lung cancer	x						x	
Chemical	Treatment of malignant hyperthermia			x			x		
Biological	Treatment of glabellar lines			x		x		x	
Biological	Treatment of diabetes mellitus	x					x	x	
Chemical	Treatment of anaemia			x				x	
Biological	Treatment of renal cell carcinoma	x						x	
Biological	Treatment of ulcerative colitis			x		x		x	
Biological	Treatment of breast cancer	x						x	
Biological	Treatment of age-related macular degeneration	x				x	x	x	
Chemical	Treatment of progressing desmoid tumours	x				x	x	x	
Biological	Prevention of streptococcus pneumoniae	x					x	x	
Biological	Treatment of urothelial carcinoma	x						x	
Biological	Treatment of carotid artery stenosis	x					x	x	
Biological	Treatment of tumors			x		x		x	
Biological	Treatment of hidradenitis suppurativa	x						x	
Biological	Treatment of Alzheimer's disease	x					x		
Chemical	Diagnosis of AL amyloidosis				x			x	
Chemical	Prevention of mould disease	x						x	
Biological	Treatment of Crohn's disease			x				x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Prevention of cardiovascular events	x					x	x	
Biological	Treatment of diffuse large B-cell lymphoma		x			x			
Biological	Treatment of bullous pemphigoid	x						x	
Chemical	Treatment of major depressive disorder			x		x			
Biological	Treatment of colorectal cancer	x						x	
Biological	Treatment of glomerulosclerosis	x					x	x	
Biological	Treatment of non-small cell lung cancer	x				x	x	x	
Chemical	Treatment of pulmonary arterial hypertension	x						x	
Biological	Treatment of age-related macular degeneration	x				x	x	x	
Chemical	Treatment of acute myeloid leukaemia	x						x	
Chemical	Treatment of rheumatoid arthritis	x					x	x	
Chemical	Treatment of systemic mastocytosis	x				x	x	x	
Chemical	Treatment of ulcerative colitis	x				x			
Chemical	Treatment of thrombocythaemia		x				x	x	
Chemical	Treatment of ocular surface pain	x				x	x	x	
Biological	Treatment of psoriatic arthritis	x						x	
Chemical	Treatment of unfavourable cervix	x					x	x	
Biological	Treatment of rheumatoid arthritis	x				x		x	
Biological	Treatment of mucopolysaccharidosis type II			x			x	x	
Chemical	Treatment of HIV Infection	x				x			
Advanced Therapy	Treatment of neuronal ceroid lipofuscinosis		x			x	x	x	x
Biological	Active immunization against herpes zoster	x				x	x	x	
Biological	Prevention of bronchopulmonary dysplasia		x			x	x	x	x
Advanced Therapy	Treatment of Hodgkin lymphoma	x				x	x	x	
Chemical	Treatment of cirrhosis	x				x	x	x	
Biological	Treatment of glabellar lines	x				x			

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Detection of cancerous tissue	x						x	
Chemical	Treatment of epithelioid cell tumours		x			x	x	x	
Chemical	Treatment of Parkinson's disease	x						x	
Biological	Treatment of allergic rhinitis	x						x	
Chemical	Treatment of respiratory syncytial virus	x				x	x	x	
Chemical	Treatment of solid tumors	x				x	x	x	
Chemical	Treatment of candidiasis			x			x	x	
Advanced Therapy	Treatment of Krabbe's disease	x				x	x	x	
Chemical	Prevention of cardiovascular events	x				x	x	x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 64 Scientific Advice letters - 46 Initial Scientific Advice, 11 Follow-up Scientific Advice, 5 Protocol Assistance letters, 2 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 21-24 February 2022 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 75 new Requests for which the procedure started at the SAWP meeting held on 07-10 February 2022. The new requests are divided as follows: 45 Initial Scientific Advice, 15 Follow-up Scientific Advice, 7 Initial Protocol Assistance, 6 Follow-up Protocol Assistance, 2 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.