



27 January 2022
EMA/CHMP/SAWP/52892/2022
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 24 – 27 January 2022

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

	1995-2020	2022	Overall total
Scientific Advice	5226	33	5259
Follow-up to Scientific Advice	1623	12	1635
Protocol Assistance	1173	11	1184
Follow-up to Protocol Assistance	634	5	639
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	180	2	182
	9001	63	9064

Outcome of the January 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				
Advanced Therapy	Treatment of glioma		x				x	x	
Chemical	Treatment of Leber's congenital amaurosis				x	x			
Biological	Prevention of respiratory syncytial virus			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				
Advanced Therapy	Treatment of haemophilia A				x	x			
Biological	Treatment of multiple myeloma		x					x	
Chemical	Treatment of pancreatic adenocarcinoma			x			x	x	
Biological	Prevention of papillomatosis			x				x	
Chemical	Treatment of leprosy	x						x	
Advanced Therapy	Treatment of thrombotic thrombocytopenic purpura				x			x	
Advanced Therapy	Treatment of cystic fibrosis		x			x	x	x	x
Chemical	Treatment of diabetic macular oedema			x		x	x	x	
Biological	Prevention of Neisseria meningococcal diseases	x						x	
Chemical	Treatment of cholestatic pruritus			x		x	x	x	
Biological	Prophylaxis of influenza	x				x			
Chemical	Treatment of type II diabetes	x				x	x	x	
Biological	Treatment of Allpega II	x				x	x		
Advanced Therapy	Treatment of amyloidosis		x				x	x	
Biological	Treatment of reversal of anticoagulation	x						x	
Chemical	Treatment of dry eye disease	x				x	x	x	
Biological	Treatment of multiple myeloma				x		x	x	
Biological	Prevention of ETEC diarrhoea			x				x	
Chemical	Treatment of depression	x				x	x		
Biological	Treatment of dengue			x		x			
Advanced Therapy	Treatment of Leber's congenital amaurosis		x			x	x	x	
Advanced Therapy	Treatment of lymphocytic leukaemia	x				x			
Biological	Treatment of hypoparathyroidism		x			x		x	
Biological	Prevention of Neisseria meningococcal diseases	x				x	x	x	
Biological	Treatment of breast cancer	x				x	x	x	
Biological	Prevention of respiratory syncytial virus			x		x			

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of hyperparathyroidism	x				x		x	
Biological	Treatment of lecithin-cholesterol acyltransferase deficiency		x			x	x	x	
Biological	Treatment of solid tumours	x				x		x	
Biological	Treatment of melanoma			x				x	
Biological	Treatment of breast cancer			x		x		x	
Chemical	Treatment of interstitial cystitis	x					x	x	
Chemical	Treatment of acute radiation syndrome		x			x	x	x	
Chemical	Treatment of haemorrhagic diathesis	x					x	x	
Biological	Treatment of uveitic macular oedema	x					x	x	
Chemical	Treatment of Duchenne muscular dystrophy	x						x	
Biological	Treatment of primary IgA nephropathy		x			x	x	x	x
Biological	Treatment of myasthenia gravis	x					x	x	
Biological	Treatment of multiple sclerosis	x						x	
Biological	Treatment of non-alcoholic steatohepatitis	x				x			
Biological	Treatment of adjunctive sealing	x					x	x	
Chemical	Treatment of glioblastoma multiforme	x					x	x	
Chemical	Treatment of polyarticular juvenile idiopathic arthritis	x				x		x	
Chemical	Prevention of Iatrogenic ureteral injury vic Surgeries	x					x	x	
Chemical	Treatment of colorectal cancer	x						x	
Chemical	Treatment of amyotrophic lateral sclerosis	x					x	x	
Biological	Treatment of osteoporosis			x		x		x	
Chemical	Treatment of GM1 gangliosidosis	x					x	x	
Chemical	Treatment of GM2 gangliosidosis		x			x	x	x	
Chemical	Treatment of idiopathic pulmonary fibrosis	x				x	x	x	
Qualification	Biomarkers of drug-induced liver injury	x							
Biological	Treatment of gestational age short stature	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of anti-glomerular basement membrane disease		x					x	
Biological	Prevention of respiratory syncytial virus			x		x		x	
Biological	Treatment of Graft versus host disease				x			x	
Chemical	Treatment of pulmonary arterial hypertension	x				x			
Chemical	Treatment of colorectal cancer	x				x	x	x	
Chemical	Treatment of breast cancer	x				x	x	x	
Advanced Therapy	Treatment of diabetes mellitus	x				x	x	x	
Qualification	Platform on Parkinson's disease	x							

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 63 Scientific Advice letters - 33 Initial Scientific Advice, 12 Follow-up Scientific Advice, 11 Protocol Assistance letters, 5 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 24-27 January 2022 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 66 new Requests for which the procedure started at the SAWP meeting held on 10-13 January 2022. The new requests are divided as follows: 47 Initial Scientific Advice, 10 Follow-up Scientific Advice, 4 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 3 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.