



14 September 2023
EMA/CHMP/SAWP/416080/2023
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 11-14 September 2023

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

	1995-2022	2023	Overall total
Scientific Advice	5684	253	5937
Follow-up to Scientific Advice	1783	101	1884
Protocol Assistance	1268	47	1315
Follow-up to Protocol Assistance	680	30	710
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	210	11	221
	9790	442	10232

Outcome of the September 2023 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 prostate cancer	X					X	X	
Chemical	Induction of anaesthesia			X		X	X	X	
Qualification	Project to identify and evaluate treatment benefit in patients with Crohn's disease	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 prostate cancer	X				X	X	X	
Biological	Treatment of Type 2 mellitus			X				X	
Biological	Treatment of mucopolysaccharidosis			X				X	
Biological	Treatment of non-cystic fibrosis bronchiectasis	X					X	X	
Chemical	Treatment of aldosteronism	X					X	X	
Biological	Treatment of thrombocytopenic purpura	X				X	X	X	
Biological	Treatment of Pompe disease	X				X			
Biological	Treatment of leukaemia		X					X	
Advance Therapy	Treatment of spinal cord injury		X			X	X	X	X
Biological	Treatment of multiple myeloma	X						X	
Chemical	Treatment of Gorlin syndrome		X			X	X	X	
Biological	Treatment of HIV	X					X	X	
Chemical	Treatment of non-small cell lung cancer			X				X	
Biological	Treatment of HIV	X					X	X	
Biological	Treatment of lymphoma			X				X	
Chemical	Treatment of non-cystic fibrosis bronchiectasis	X				X			
Biological	Treatment of colitis			X		X		X	
Chemical	Treatment of septic shock	X				X		X	
Chemical	Treatment of kidney disease	X					X		
Biological	Treatment of myeloid leukemia	X					X		
Chemical	Prevention of stroke			X				X	
Advance Therapy	Treatment of spinal muscular atrophy		X			X			
Chemical	Treatment of supranuclear palsy		X					X	
Chemical	Prevention of cardioembolic stroke			X				X	
Chemical	Prevention of stroke	X				X			

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of asthma	X				X			
Advance Therapy	Treatment of Leber's neuropathy				X			X	
Chemical	Treatment of Alzheimer's disease	X				X	X	X	
Chemical	Treatment of breast cancer	X						X	
Chemical	Treatment of mesothelioma		X					X	X
Advance Therapy	Treatment of retinitis pigmentosa		X			X	X	X	
Biological	Treatment of non-small cell lung cancer	X				X			
Biological	Treatment of dermatomyositis		X					X	
Biological	Prevention of lower respiratory tract disease	X				X	X		
Chemical	Treatment of myasthenia gravis	X						X	
Chemical	Treatment of multiple sclerosis			X				X	
Biological	Treatment of melanoma			X				X	
Advance Therapy	Treatment of respiratory papillomatosis		X			X	X	X	
Advance Therapy	Treatment of beta-thalassemia	X				X	X	X	
Chemical	Prevention of cardiovascular diseases	X				X		X	
Biological	Treatment of urothelial carcinoma			X		X			
Advance Therapy	Treatment of myeloid leukaemia				X	X			
Biological	Treatment of neuromyelitis optica				X			X	
Chemical	Treatment of prostate cancer	X				X		X	
Chemical	Treatment of graft-versus-host disease				X			X	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 48 Scientific Advice letters - 23 Initial Scientific Advice, 11 Follow-up Scientific Advice, 9 Protocol Assistance letters, 4 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices were adopted at the 11-14 September 2023 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 71 new Requests for which the procedure started at the SAWP meeting held on 28-31 August 2023. The new requests are divided as follows: 43 Initial Scientific Advice, 16 Follow-up Scientific Advice, 11 Initial Protocol Assistance, 1 Follow-up Protocol Assistance, 3 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.