



26 April 2019
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Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 22 - 26 April 2019

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

	1995 - 2018	2019	Overall total
Scientific Advice	3866	115	3981
Follow-up to Scientific Advice	1150	46	1196
Protocol Assistance	932	39	971
Follow-up to Protocol Assistance	477	17	494
EMA/EUnetHTA parallel consultation advice	139	9	148
Qualification of novel methodologies	126	2	128
	6689	6689	6918

Outcome of the April 2019 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 biliary atresia		x			x	x	x	
Chemical	Treatment of retinitis pigmentosa				x	x		x	
Biological	Treatment of autoimmune pulmonary alveolar proteinosis		x			x	x		
Biological	Treatment of lysosomal storage disorder				x			x	

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Advanced Therapy	Treatment of synovial sarcoma and non-small cell lung cancer		x			x			
HTA Parallel	Treatment of mucopolysaccharidosis		x			x		x	
Biological	Prevention of bleeding in haemophilia A		x					x	
Biological	Prevention of bleeding in haemophilia B		x					x	
Chemical	Treatment of transthyretin amyloidosis cardiomyopathy		x			x	x		
Chemical	Treatment of amyotrophic lateral sclerosis		x				x	x	x
Chemical	Treatment of cystinuria		x				x	x	x
Biological	Treatment of type 1 Gaucher disease				x		x	x	
Chemical	Treatment of sickle cell syndrome	x						x	
Chemical	Diagnostic agent for MRI	x				x	x	x	
Chemical	Treatment of influenza A or B			x				x	
Chemical	Treatment of acute myelogenous leukaemia			x				x	
Biological	Treatment of psoriasis			x		x		x	
Biological	Treatment of diabetes mellitus			x		x			
Chemical	Treatment of prostate cancer			x				x	
Biological	Treatment of breast cancer	x						x	
Chemical	Treatment of diabetic kidney disease			x				x	
Advanced Therapy	Treatment of rod cone dystrophy	x					x	x	
Chemical	Treatment of respiratory syncytial virus infection			x				x	
Chemical	Treatment of multiple sclerosis	x						x	
Biological	Treatment of neovascular macular degeneration, macular edema, diabetic macular edema, and diabetic retinopathy.			x		x		x	
Biological	Prevention of Chikungunya fever			x		x	x	x	
Biological	Treatment of plaque psoriasis, psoriatic arthritis, rheumatoid arthritis, axial spondyloarthritis, Crohn's disease, ulcerative colitis, polyarticular juvenile idiopathic arthritis and active enthesitis-related arthritis, hidradenitis suppurativa and scarring on the skin and non-infectious uveitis.			x				x	
Chemical	Treatment of non-small cell lung cancer			x				x	
Chemical	Treatment of ulcerative colitis	x						x	

Chemical	Prevention of bronchopulmonary dysplasia	x					x	x	
Chemical	Treatment of cholangiocarcinoma	x					x	x	
Chemical	Treatment of retinopathy	x				x	x	x	
Chemical	Treatment of Parkinson's disease	x						x	
Chemical	Treatment of insomnia	x					x	x	
Biological	Prevention of respiratory syncytial virus infection	x					x	x	
Chemical	Treatment of hepatitis B	x					x	x	
Biological	Treatment of immune thrombocytopenia	x					x	x	
Chemical	Treatment of oral ulcers	x				x		x	
Chemical	Treatment of juvenile psoriatic arthritis	x				x		x	
Chemical	Broad advice on chemically defined active substances.	x				x			
Chemical	Treatment of hypersensitivity reactions	x					x	x	
Chemical	Treatment of prostate cancer	x				x	x	x	
Chemical	Localization of prostate cancer	x					x	x	
Chemical	Surgical anaesthesia and post-surgical pain management	x				x	x	x	
Chemical	Treatment of osteoarthritis	x				x	x	x	
Chemical	Treatment of schizophrenia	x						x	
Biological	Treatment of cancer	x					x	x	
Chemical	Treatment of non-small cell lung cancer	x					x	x	
Biological	Treatment of giant cell tumour of bone, osteoporosis, bone loss and to reduce the risk of bone fractures and bone complications.	x				x	x	x	
Chemical	Treatment of diabetes mellitus	x					x		
Biological	Treatment of bleeding in haemophilia A	x					x	x	
Chemical	Treatment of uterine fibroids	x					x	x	
Biomarker	Neuromuscular disorders	x						x	
Biomarker	Treatment effect measures when using recurrent event endpoints	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 28 Scientific Advice letters, 9 Protocol Assistance letters, 11 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 1 EMA/EUnetHTA parallel consultation advices, were adopted at the 23 - 26 April 2019 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 56 new Requests for which the procedure started at the SAWP meeting held on 8 – 11 aPRIL 2019. The new requests are divided as follows: 32 Initial Scientific Advice, 5 Follow-up Scientific Advice, 13 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 0 Qualification of novel methodologies and 4 EMA/EUnetHTA parallel consultation advices.