



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 25 - 28 March 2019

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

	1995 - 2018	2019	Overall total
Scientific Advice	3866	83	3949
Follow-up to Scientific Advice	1150	41	1191
Protocol Assistance	932	26	958
Follow-up to Protocol Assistance	477	15	492
EMA/EUnetHTA parallel consultation advice	139	5	144
Qualification of novel methodologies	126	2	128
	6689	172	6861

Outcome of the February 2019 CHMP meeting in relation to scientific advice procedures

Final scientific advice procedures

Substance	Intended indication	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of haemophilia A		X			x	x	x	
Biological	Treatment of haemophilia B		X			x	x	x	
Advanced Therapy	Treatment of immunodeficiency due to adenosine deaminase deficiency			x				x	X

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Advanced Therapy	Treatment of multiple myeloma		X					x	
Biological	Treatment of hyperargininaemia				x				X
Chemical	Treatment of ATTR amyloidosis - cardiomyopathy		X				x	x	X
Chemical	Treatment of adrenal insufficiency				x			x	
Chemical	Treatment of adrenal hyperplasia				x			x	X
Chemical	Treatment of oral graft-versus-host disease				x			x	
Chemical	Treatment of severe systemic and/or deep mycoses, treatment of visceral, treatment of fungal infections, treatment of visceral leishmaniasis			x		x		x	
Biological	Treatment of thrombotic thrombocytopenic purpura				x	x		x	
Chemical	Treatment of severe systemic and/or deep mycoses, treatment of visceral, treatment of fungal infections, treatment of visceral leishmaniasis			x				x	
Chemical	Treatment of breast cancer, ovarian cancer, multiple myeloma and AIDS-related Kaposi's sarcoma.			x				x	
Biological	Treatment of melanoma			x				x	
Biological	Treatment of urothelial carcinoma			x				x	
Biological	Treatment of lupus erythematosus	X				x	x	x	
Biological	Treatment of gastric or gastroesophageal junction adenocarcinoma	X						x	
Innovative product or therapy	Prevention of arteriovenous access dysfunction				x	x			
Chemical	Treatment of prostate cancer				X	x		x	
Chemical	Treatment of Parkinson's disease			x				x	
Biological	Treatment of thrombotic microangiopathy	X				x	x	x	
Biological	Prevention of Ebola virus disease			x		x	x	x	
Chemical	Treatment of acute graft-versus-host disease				x	x	x		
Advanced Therapy	Treatment of haemophilia B	X				x		x	
Biological	Treatment of breast cancer, non-small cell lung cancer, renal cell carcinoma and ovarian cancer.			x		x		x	

Chemical	Prevention of recurrent vulvovaginal candidiasis			x				x	
Biological	Treatment of breast cancer	X				x	x	x	
Biological	Treatment of ulcerative colitis	X						x	
Chemical	Treatment of acute pain			x				x	
Biological	Treatment of diabetes mellitus			x		x		x	
Biological	Treatment of neovascular macular degeneration, macular edema, diabetic macular edema, and diabetic retinopathy.			x		x		x	
Biological	Prevention of HIV-1 infection			x		x	x	x	
Biological	Treatment of psoriasis			x		x	x	x	
Chemical	Treatment of actinic keratosis			x		x		x	
Chemical	Treatment of Alzheimer's dementia			x				x	
Biological	Treatment of rejection in kidney transplant	X				x			
Advanced Therapy	Treatment of anorectal malformation anomalies	X					x	x	
Biological	Treatment of multiple sclerosis	X				x		x	
Chemical	Treatment of cystic fibrosis	X				x	x	x	
Chemical	Prevention of myopia	X				x	x	x	
Chemical	Treatment of renal cell carcinoma	X					x	x	
Chemical	Treatment of chronic cough	X						x	
Biological	Prevention of respiratory tract infection	X					x	x	
Advanced Therapy	Treatment of Duchenne muscular dystrophy		X			x	x	x	
Chemical	Treatment of epilepsy and bipolar disorders	X					x		
Chemical	Prevention of respiratory tract infections	X					x	x	
Chemical	Management of pain associated with endometriosis	X					x	x	
Chemical	Treatment of iron deficiency	X				x	x	x	
Chemical/ Biological	Treatment of prostate cancer	X						x	
Chemical	Treatment of cystic fibrosis	X				x			
Biological	Treatment of asthma and chronic idiopathic urticaria.	X				x	x	x	
Chemical	Treatment of multiple system atrophy	X					x	x	

Biological	Treatment of haemophilia A	X				x	x	x	
Chemical	Treatment of acute myeloid leukaemia	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 dementia	X						x	
Chemical	Treatment of Duchenne muscular dystrophy		X					x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 26 Scientific Advice letters, 6 Protocol Assistance letters, 17 Follow-up Scientific Advice, 8 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices, were adopted at the 25 – 28 March 2019 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 47 new Requests for which the procedure started at the SAWP meeting held on 12 – 15 March 2019. The new requests are divided as follows: 26 Initial Scientific Advice, 8 Follow-up Scientific Advice, 8 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 2 EMA/EUnetHTA parallel consultation advices.