



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 16 – 19 September 2019

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

	1995 - 2018	2019	Overall total
Scientific Advice	3866	260	4126
Follow-up to Scientific Advice	1150	90	1240
Protocol Assistance	932	70	1002
Follow-up to Protocol Assistance	477	32	509
EMA/EUnetHTA parallel consultation advice	139	15	154
Qualification of novel methodologies	126	11	137
	6689	478	7167

Outcome of the September 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 IgA nephropathy.				x			x	
Chemical	Eradication of Helicobacter pylori.	x						x	
Biological	Treatment of type 2 diabetes mellitus.			x		x			



Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Chemical	Treatment of type 2 diabetes mellitus.	x				x		x	
Advanced therapy	Treatment of diffuse large B-cell lymphoma and acute lymphoblastic leukaemia.	x				x			
Chemical	Treatment of diffuse large B-cell lymphoma.	x						x	
Biological	Treatment of breast cancer.	x					x	x	
Biological	Treatment of lupus erythematosus.	x					x	x	
Biological	Treatment of plaque psoriasis.	x						x	
Chemical	Treatment of mature B-cell neoplasm and graft-versus-host disease.		x			x			
Chemical	Treatment of cholangiocarcinoma.			x				x	
Advanced therapy	Treatment of multiple myeloma.	x						x	
Advanced therapy	Treatment of multiple myeloma.	x				x	x	x	
Biological	Treatment of atopic dermatitis.	x				x	x	x	
Chemical	Treatment of primary myelofibrosis, post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis.				x			x	x
Biological	Treatment of active axial spondyloarthritis.	x						x	
Chemical	Treatment of mantle cell lymphoma.	x					x	x	
Chemical	Treatment of cholangiocarcinoma.				x	x		x	
Chemical	Treatment of neuroblastoma.			x				x	
Biological	Treatment of breast cancer.	x				x			
Chemical	Treatment of malignant melanoma.	x				x			
Biological	Treatment of plaque psoriasis, active psoriatic arthritis and Crohn’s disease.			x				x	
Chemical	Treatment of chronic lymphocytic leukaemia.			x			x		
Biological	Treatment of warm autoimmune haemolytic anaemia.	x				x	x	x	
Chemical/Biological	Treatment of breast cancer.	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Advanced therapy	Treatment of solid tumours.	x				x	x	x	
Chemical	Treatment of human African trypanosomiasis due to T. b. gambiense.	x				x			
Biological	Treatment and prophylaxis of bleeding in haemophilia A.	x				x	x	x	
Chemical	Treatment of aortic valve stenosis.	x					x	x	
Biological	Treatment of atopic dermatitis.	x				x	x	x	
Advanced therapy	Treatment of epidermolysis bullosa.		x			x	x	x	
Chemical	Treatment of fungal infections.			x			x		
Biological	Broad clinical advice on vaccines.	x						x	
Biological	Broad advice on CMC for vaccines.	x				x			
Biological	Prevention of lower respiratory tract infection due to RSV.			x				x	
Advanced therapy	Treatment of haemorrhagic cystitis.	x				x	x	x	
Biological	Treatment of primary hyperoxaluria type 1.		x				x		
Biological	Treatment of growth failure.	x				x	x	x	
Advanced therapy	Treatment of long bone fractures.			x				x	
Chemical	Treatment of schizophrenia.	x						x	
Chemical	Treatment of epilepsy.	x						x	
Chemical	Treatment of seizures in mitochondrial disease.			x				x	
Chemical	Treatment of infantile neuroaxonal dystrophy.		x				x	x	
Chemical	Treatment of COPD.	x						x	
Chemical	Treatment of asthma.	x					x		
Biological	Treatment of food allergy.	x					x	x	
Chemical	Treatment of chronic obstructive pulmonary disease.			x				x	
Chemical	Treatment of blepharitis.	x				x	x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Biological	Treatment of diabetic macular edema.	x						x	
Biological	Treatment of neovascular age-related macular degeneration.	x				x	x	x	
Advanced therapy	Treatment of haemophilia B.		x					x	
Other innovative	Treatments of celiac disease.	x						x	
Biological	Treatment of paroxysmal nocturnal hemoglobinuria.	x				x	x	x	
Chemical	Treatment of alpha-1 antitrypsin deficiency-associated liver disease.	x					x		
Biological	CMC advice on glass vials.	x				x			
Chemical	Treatment or prevention of encephalopathy.	x					x	x	
Chemical	Treatment of prostate cancer.	x				x	x	x	
EMA/EUnetHTA	Treatment of Duchenne muscular dystrophy.	x					x	x	
Qualification advice	Treatment of osteogenesis imperfecta.	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 39 Scientific Advice letters, 5 Protocol Assistance letters, 10 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 1 EMA/EUnetHTA parallel consultation advices, were adopted at the 16 – 19 September 2019 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 69 new Requests for which the procedure started at the SAWP meeting held on 2 – 5 September 2019. The new requests are divided as follows: 47 Initial Scientific Advice, 6 Follow-up Scientific Advice, 6 Initial Protocol Assistance, 6 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 3 EMA/EUnetHTA parallel consultation advices.