



13 December 2018
EMA/CHMP/SAWP/876120/2018
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 10 – 13 December 2018

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

	1995 - 2017	2018	Overall total
Scientific Advice	3550	316□	3866
Follow-up to Scientific Advice	1052	98□	1150
Protocol Assistance	830	102□	932
Follow-up to Protocol Assistance	413	64□	477
EMA/EUnetHTA parallel consultation advice	115	24□	139
Qualification of novel methodologies	110	16□	126
	6070	619□	6689

Outcome of the December 2018 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 myelodysplastic syndromes and leukemia			x				x	
Advanced Therapy	Treatment of male urethral strictures	x				x			
Chemical	Treatment of neurofibromatosis		x				x	x	
Chemical	Treatment of multiple myeloma		x					x	



Chemical	Treatment of female sexual desire disorder	x						x	
Advanced Therapy	Treatment of Leber Optic Neuropathy				x			x	
Biological	Treatment of Pompe disease		X					x	
Biological	Treatment of non-small cell lung cancer			X				x	
Advanced Therapy	Treatment of synovial sarcoma and non-small cell lung cancer	X						x	
Biological	Treatment of breast cancer	X						x	
Biological	Prevention of Clostridium difficile infection			X		x		x	
Biological	Treatment of metachromatic leukodystrophy				X			x	
Chemical	Treatment of cognitive impairment due to Alzheimer's disease			X				x	
Biological	Treatment of osteoporosis. Treatment of bone loss Prevention of skeletal related events in bone metastases			X		x		x	
Chemical	Treatment of GM2 gangliosidosis			X				x	
Chemical	Treatment of Fabry disease, GM2 gangliosidosis, Gaucher's disease, GBA-Parkinson's disease and autosomal dominant polycystic kidney disease	X				x			
Chemical	Treatment of Duchenne muscular dystrophy		X			x		x	
Biological	Prevention of congenital cytomegalovirus infection	X				x			
Chemical	Treatment of myositis		X				x	x	
Chemical	Treatment of acromegaly, gastro-entero-pancreatic endocrine tumours and TSH-secreting adenomas			X				x	
Chemical	Prevention of migraine	X						x	
Chemical	Treatment of depressive disorder			X				x	
Chemical/Biological	Treatment of non-small cell lung cancer	X						x	
Chemical	Treatment of paroxysmal hemoglobinuria		X			x	x	x	
Chemical	Treatment of urinary tract infections	X				x	x	x	
Advanced Therapy	Repair of articular cartilage defects	X				x	x	x	
Biological	Treatment of glioblastoma	X						x	
Chemical	Treatment of breast cancer	X						x	
Biological	Treatment of rejection in kidney transplant recipients	X					x	x	
Chemical	Treatment of glioma		X				x	x	
Advanced Therapy	Treatment of Epstein-Barr virus-associated				X	x		x	
Chemical	Treatment of schizophrenia	X						x	
Chemical/Innovative product or therapy	Reduction of intraocular pressure	X				x	x	x	

Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis	X				x	x	x	
Chemical/Biological	Treatment of CEA-positive solid tumors	X					x	x	
Chemical	Treatment of breast cancer	X					x	x	
Biological	Treatment of solid tumors	X					x		
Chemical	Detection of glioma		X			x	x	x	
Chemical	Treatment of malignant glioma	X				x		x	
Chemical	Reduction of chemotherapy-induced myelosuppression	X				x	x		
Chemical	Menopausal hormone therapy	X					x	x	
Biological	Treatment of multiple sclerosis	X						x	
Chemical	Treatment of haematological malignancies	X				x	x		
Chemical	Treatment of tuberous sclerosis	X				x	x	x	
Chemical	Treatment of dermatomyositis		X					x	
Biological	Prophylaxis of influenza	X						x	
Biological	Active immunisation against influenza A virus	X						x	
Biological	Prevention of ano-genital lesions, cervical and anal cancers	X						x	
Chemical	Treatment of amyotrophic lateral sclerosis				x			x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 27 Scientific Advice letters, 9 Protocol Assistance letters, 9 Follow-up Scientific Advice, 4 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices, were adopted at the 10 – 13 December 2018 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 55 new Requests for which the procedure started at the SAWP meeting held on 26 – 29 November 2018. The new requests are divided as follows: 34 Initial Scientific Advice, 6 Follow-up Scientific Advice, 11 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 0 Qualification of novel methodologies and 2 EMA/EUnetHTA parallel consultation advices.