



31 May 2018
EMA/CHMP/SAWP/366547/2018
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 28 – 31 May 2018

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

	1995 - 2017	2018	Overall total
Scientific Advice	3550	115	3665
Follow-up to Scientific Advice	1052	48	1100
Protocol Assistance	830	45	875
Follow-up to Protocol Assistance	413	32	445
EMA/EUnetHTA parallel consultation advice	115	9	124
Qualification of novel methodologies	110	12	122
	6070	260	7430

Outcome of the May 2018 CHMP meeting in relation to scientific advice procedures

Final scientific advice procedures

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of Pompe disease				x	x			
Advanced Therapy	Treatment of Leber hereditary optic neuropathy				x	x			
Chemical/Biological	Treatment of Pompe disease	x					x	x	
Chemical/Biological	Treatment of Pompe disease	x					x	x	



Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of polyarticular juvenile idiopathic arthritis, plaque psoriasis, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, axial spondyloarthritis, uveitis, hidradenitis suppurativa, Crohn's disease	x				x		x	
Chemical	Treatment of systemic mastocytosis	x					x	x	
Chemical	Treatment of chronic hepatitis B infection	x					x	x	
EUnetHTA parallel	Treatment of recurrent vulvovaginal candidiasis	x					x	x	
Chemical	Treatment of acute migraine	x					x	x	
Advanced therapy	Treatment of thermal burns	x				x	x	x	
Biological	Treatment of plaque psoriasis, psoriatic arthritis, Crohn's disease	x				x	x	x	
Chemical	Treatment of eosinophilic oesophagitis			x				x	
Chemical	Treatment of diabetic kidney disease			x		x		x	
Chemical	Treatment of chronic obstructive pulmonary disease			x		x		x	
Biological	Treatment of wet (neovascular) age-related macular degeneration, choroidal neovascularization, diabetic macular edema, retinal vein occlusion			x		x		x	
Chemical	Treatment of human immunodeficiency virus type 1 infection			x		x	x		
Chemical	Treatment of Niemann-Pick disease, type C		x			x	x		
EUnetHTA parallel	Treatment of chronic HDV infection		x			x	x	x	
Chemical	Treatment of mycosis fungoides		x				x	x	
Chemical	Treatment of acute myeloid leukaemia		x					x	x
Biological	Treatment of adenocarcinoma of the stomach or the gastroesophageal junction		x					x	
Chemical	Treatment of acute myeloid leukaemia		x					x	x
Advanced therapy	Treatment of acute lymphoblastic leukaemia		x				x	x	
Chemical	Treatment of pemphigus		x			x	x	x	x
Chemical	Treatment of small cell lung cancer		x				x	x	x

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Treatment of acute myeloid leukaemia		x			x	x	x	
Advanced therapy	Treatment of haemophilia A				x	x	x	x	
Biological	Treatment of mitochondrial neurogastrointestinal encephalomyopathy				x	x		x	
Chemical	Treatment of acute myeloid leukaemia				x			x	
Chemical	Prophylaxis of cytomegalovirus disease				x		x		
EUnetHTA parallel	Treatment of haemophilia B	x						x	
Chemical/Biological	Treatment of bladder cancer	x						x	
Biological	Treatment of Alzheimer's disease	x				x	x	x	
Biological	Treatment of breast cancer	x				x			
Biological	Treatment of thrombotic microangiopathy	x					x	x	
Chemical	Treatment of short bowel syndrome	x						x	
Chemical	Treatment of severe chronic anemia	x						x	
Biological	Treatment of Gaucher disease	x				x	x	x	
Chemical	Detection of loss of functional dopaminergic neuron terminals in the striatum	x						x	
Chemical	Treatment of Crohn's disease	x					x	x	
Biological	Treatment of diabetes mellitus	x					x	x	
Advanced therapy	Treatment of localised, full-thickness cartilage defects of the knee joint	x						x	
Biological	Treatment of metastatic melanoma	x					x	x	
Chemical	Treatment of prostate cancer	x				x	x	x	
Chemical	Treatment of major depressive disorder	x				x	x	x	
Chemical	Treatment of insomnia disorder	x				x	x	x	
Biological	Treatment of oesophageal squamous cell carcinoma	x						x	
Biological	Treatment of atopic dermatitis	x				x	x	x	

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Reduction of risk of CV death, myocardial infarction, stroke, coronary revascularisation procedures, or hospitalisation			x				x	
Chemical	Treatment of glioblastoma multiforme			x				x	
Biological	Treatment of cervical dystonia			x				x	
Chemical	Preservation or restoration of sexual function associated with hormonal contraceptive use			x				x	
Chemical	Treatment of cystic fibrosis			x				x	
Biological	Active immunization for the prevention of postoperative invasive disease caused by Staphylococcus aureus			x				x	
Chemical	Treatment of relapsing multiple sclerosis			x		x			
Chemical	Treatment of relapsing multiple sclerosis			x				x	
Biological	Active immunization against poliomyelitis caused by poliovirus types 1, 2 and 3			x		x			
Biological	Adjunct treatment adjunct treatment for haemostasis in general surgery, vascular surgery and neurosurgery.			x		x	x	x	
Qualification opinion	Haematological malignancies	x						x	
Qualification opinion	Chronic obstructive pulmonary disease	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 25 Scientific Advice letters, 9 Protocol Assistance letters, 16 Follow-up Scientific Advice, 6 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 3 EMA/EUnetHTA parallel consultation advices, were adopted at the 28 – 31 May 2018 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 14 – 17 May 2018. The new requests are divided as follows: 32 Initial Scientific Advice, 10 Follow-up Scientific Advice, 12 Initial Protocol Assistance, 8 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 6 EMA/EUnetHTA parallel consultation advices.