



22 February 2018
EMA/CHMP/SAWP/119553/2018
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 19 – 22 February 2018

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

	1995 - 2017	2018	Overall total
Scientific Advice	3550	42	3592
Follow-up to Scientific Advice	1052	14	1066
Protocol Assistance	830	17	847
Follow-up to Protocol Assistance	413	13	426
EMA/EUnetHTA parallel consultation advice	115	2	117
Qualification of novel methodologies	110	6	116
	6070	94	6164

Outcome of the February 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				
Chemical	Treatment of non-small cell lung cancer.			x				x	
Chemical	Treatment of Niemann-Pick disease type C.		x			x	x	x	x
Biological	Treatment of mucopolysaccharidosis type I.						x	x	x



Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharma ceutical	Pre- clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis.	x				x		x	
Chemical	Treatment of castration resistant prostate cancer.	x				x			
Biological	Treatment of epithelial ovarian, fallopian tube, or peritoneal cancer.	x						x	
Biological	Treatment of breast cancer, non-small cell lung cancer, renal cell carcinoma and ovarian cancer.	x				x	x	x	
Biological	Treatment of generalised pustular psoriasis.	x				x	x	x	
Biological	Treatment of non-small cell lung cancer.	x						x	
Chemical	Treatment of systemic lupus erythematosus.	x					x	x	
Biological	Treatment of glioblastoma multiforme.				x			x	
Chemical	Treatment of breast cancer.	x					x	x	
Biological	Treatment of pancreatic cancer.		x					x	
Biological	Multiple oncology indications.	x				x		x	
Advanced therapy	Treatment of adenosine-deaminase-deficient severe combined immunodeficiency.		x			x	x	x	x
Biological	Treatment of breast cancer.	x						x	
Advanced therapy	Treatment of glioblastoma.		x			x	x	x	x
Chemical	Treatment of paroxysmal nocturnal haemoglobinuria.				x			x	x
Chemical	Treatment of anaemia.	x				x			
Chemical	Treatment of prolapsed internal haemorrhoids.			x			x	x	
Biological	Treatment of AL amyloidosis.				x	x			
Chemical	Treatment of naevoid basal-cell carcinoma (Gorlin syndrome).	x				x			
Advanced therapy	Treatment of partial deep dermal and full thickness burns.		x			x	x	x	
Chemical	Treatment of necrotising soft tissue infections.				x		x	x	
Biological	Prevention of influenza disease.	x					x	x	
Chemical	Treatment of adenovirus infection and smallpox.				x	x			
Chemical	Treatment of complicated urinary tract infection.	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 idiopathic inflammatory myopathies.	x					x	x	
Chemical	Treatment of complicated urinary tract infections, hospital acquired and ventilator-associated bacterial pneumonia and carbapenem-resistant Enterobacteriaceae infection.	x				x			
Chemical	Treatment of malignant hyperthermia.	x				x	x	x	
Chemical	Treatment of Duchenne muscular dystrophy.		x				x	x	
Advanced therapy	Treatment of focal chondral defects and osteochondritis dissecans type IV.	x				x	x		
Chemical	Treatment of Duchenne muscular dystrophy.				x			x	
Advanced therapy	Treatment of metachromatic leukodystrophy.				x			x	
Advanced therapy	Treatment of cerebral adrenoleukodystrophy.				x			x	x
Chemical	treatment of anti-MAG neuropathy		x			x	x	x	
Chemical	Treatment of major depressive disorder.		x					x	
Chemical	Treatment of traumatic brain injury.				x		x	x	
Chemical	Treatment of chemotherapy-induced neuropathic pain.	x					x	x	
Chemical	Treatment of cystic fibrosis.	x				x			
Chemical	Treatment of asthma.	x						x	
Advanced therapy	Treatment of dry age-related macular degeneration.	x				x	x	x	
Chemical	Treatment of retinitis pigmentosa.	x					x		
Chemical	Reduction of elevated intra-ocular pressure.			x				x	
Chemical	Treatment of visual impairment due to macular oedema.	x						x	
Advanced therapy	Treatment of haemophilia B.	x				x			
Biological	Treatment of peanut allergy.			x		x	x	x	
Chemical	Treatment of thalassaemia major.			x				x	

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharma ceutical	Pre- clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Advanced therapy	Treatment of haemophilia B.	x					x	x	
Qualification advice	Treatment of Alzheimer's disease.	x						x	
Qualification advice	Treatment of Alzheimer's disease.	x						x	
Qualification advice	Treatment of tuberculosis.	x						x	
EUnetHTA parallel	Treatment of diffuse large B-cell lymphoma.	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 26 Scientific Advice letters, 8 Protocol Assistance letters, 6 Follow-up Scientific Advice, 9 Follow-up Protocol Assistance, 3 Qualifications of novel methodologies and 1 EMA/EUnetHTA parallel consultation advices, were adopted at the 19 – 22 February 2018 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 45 new Requests for which the procedure started at the SAWP meeting held on 5 – 8 February 2018. The new requests are divided as follows: 20 Initial Scientific Advice, 5 Follow-up Scientific Advice, 12 Initial Protocol Assistance, 4 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 2 EMA/EUnetHTA parallel consultation advice.