



14 December 2017
EMA/CHMP/SAWP/833040/2017
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 11 – 14 December 2017

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

	1995 - 2016	2017	Overall total
Scientific Advice	3215	339	3554
Follow-up to Scientific Advice	938	115	1053
Protocol Assistance	735	92	827
Follow-up to Protocol Assistance	355	59	414
EMA/EUnetHTA parallel consultation advice	87	28	115
Qualification of novel methodologies	94	22	116
	5424	655	6079

Outcome of the December 2017 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 seizures in Lennox-Gastaut syndrome.		x					x	x
Chemical	Treatment of enteral feeding intolerance.	x					x	x	
Chemical	Treatment of mantle cell lymphoma.		x				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 breast cancer.			x		x			
Chemical	Treatment of breast cancer.	x						x	
Biological	Treatment of systemic lupus erythematosus.			x				x	
Biological	Treatment of esophageal squamous cell carcinoma.	x						x	
Biological	Treatment of multiple myeloma.		x					x	x
Biological	Treatment of pancreatic ductal carcinoma.	x						x	
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis.			x				x	
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis.			x		x			
Disease-specific	Treatment of multiple myeloma.	x						x	
Advanced therapy	Treatment of malignant pleural mesothelioma.	x				x	x	x	
Biological	Treatment of breast cancer.			x				x	
Chemical	Treatment of cutaneous T-cell lymphoma.	x				x	x		
Biological	Treatment of rheumatoid arthritis, juvenile idiopathic arthritis and giant cell arteritis.	x				x	x	x	
Biological	Treatment of breast cancer.			x				x	
Biological	Treatment of plaque psoriasis, active psoriatic arthritis and Crohn's disease.	x				x	x	x	
Chemical	Treatment of Waldenström's macroglobulinemia.	x						x	
Biological	Treatment of breast cancer.	x					x	x	
Biological	Treatment of atopic dermatitis.	x					x		
Chemical	Treatment of uncomplicated malaria due to Plasmodium falciparum.	x				x	x	x	
Chemical	Treatment of schistosomiasis.	x				x	x	x	
Biological	Treatment of mitochondrial neurogastrointestinal encephalomyopathy.		x			x	x	x	
Chemical	Treatment of sickle cell 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 anaemia due to MDS.		x					x	x
Biological	Treatment and prophylaxis of bleeding in haemophilia B.	x						x	
Biological	Treatment of chemotherapy-induced thrombocytopenia.	x						x	
Chemical	Treatment of chronic heart failure.	x						x	
Chemical	Treatment of diabetic kidney disease.			x				x	
Biological	Treatment of chronic spontaneous urticaria.			x				x	
Chemical	Treatment of dystrophic epidermolysis bullosa.	x						x	
Chemical	Treatment of diabetic foot ulcers.	x					x	x	
Biological	Immunisation against influenza disease.	x				x	x	x	
Biological	Prevention of Chikungunya virus infection.	x				x	x	x	
Chemical	Treatment of uncomplicated and complicated urinary tract infections and complicated intra-abdominal infections.	x				x			
Biological	Prevention of HIV-1 infection.	x				x	x	x	
Advanced therapy	Treatment of spinal muscular atrophy.				x			x	x
Biological	Treatment of osteoporosis, bone metastases from solid tumors, giant cell tumor of the bone and hypercalcemia.	x				x	x	x	
Biological	Treatment of early Alzheimer's disease and progressive supranuclear palsy.	x				x			
Biological	Treatment of early Alzheimer's disease.	x				x			
Chemical	Treatment of acute sensorineural hearing loss.				x	x			
Advanced therapy	Treatment of residual disability following ischemic stroke.			x				x	
Chemical	Treatment of metaphyseal chondrodysplasia, Schmid type.		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 bulbar dysfunction in amyotrophic lateral sclerosis.	x					x	x	
Chemical	Treatment of Lewy body dementia.	x					x	x	
Chemical	Delay of cognitive decline in individuals at risk of developing Alzheimer's dementia.			x				x	
Chemical	Treatment of schizophrenia.			x				x	
Chemical	Treatment of spinal muscular atrophy type 1.			x		x			
Advanced therapy	Treatment of ornithine transcarbamylase deficiency.		x			x	x	x	x
Chemical	Treatment of RARS2 syndrome.	x						x	
Biological	Treatment of impaired vision due to myopic choroidal neovascularisation, impaired vision due to macular oedema and "wet" age-related macular degeneration.	x				x	x	x	
Biological	Treatment of impaired vision due to myopic choroidal neovascularisation, impaired vision due to macular oedema and "wet" age-related macular degeneration.			x				x	
Chemical	Reduction of elevated intraocular pressure in open angle glaucoma and/or ocular hypertension.			x				x	
Advanced therapy	Treatment of Leber hereditary optic neuropathy.				x			x	x
Advanced therapy	Treatment of macular telangiectasia type 2.				x			x	
Biological	Treatment of diabetic macular oedema.	x						x	
Biological	Treatment of neovascular (wet) age-related macular degeneration.	x						x	
Chemical	Treatment of chemotherapy induced neutropenia.	x				x	x	x	
Qualification opinion	Chronic obstructive pulmonary disease.	x						x	
Qualification advice	Autism spectrum disorder.	x						x	
Qualification advice	Autism spectrum disorder.	x						x	

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
EUnetHTA parallel	Treatment of late onset GM2 gangliosidosis (Tay-Sachs and Sandhoff diseases).	x					x	x	
EUnetHTA parallel	Treatment of relapsed or refractory diffuse large B-cell lymphoma.		x						x
EUnetHTA parallel	Treatment of atopic dermatitis.	x					x	x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 33 Scientific Advice letters, 8 Protocol Assistance letters, 15 Follow-up Scientific Advice, 4 Follow-up Protocol Assistance, 3 Qualifications of novel methodologies and 3 EMA/EUnetHTA parallel consultation advices, were adopted at the 11 – 14 December 2017 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 27 – 30 November 2017. The new requests are divided as follows: 16 Initial Scientific Advice, 9 Follow-up Scientific Advice, 13 Initial Protocol Assistance, 4 Follow-up Protocol Assistance, 4 Qualifications of novel methodologies and 1 EMA/EUnetHTA parallel consultation advice.