



20 July 2017
EMA/CHMP/SAWP/466217/2017
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 17 – 20 July 2017

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

	1995 - 2016	2017	Overall total
Scientific Advice	3215	206	3421
Follow-up to Scientific Advice	938	77	1015
Protocol Assistance	735	60	795
Follow-up to Protocol Assistance	355	32	387
HTA parallel advice	87	17	104
Qualification of novel methodologies	94	12	106
	5424	404	5828

Outcome of the July 2017 CHMP meeting in relation to scientific advice procedures

Final scientific advice procedures

Substance	Intended indication(s)	Type of request				Topic			Significant Benefit
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	
		SA	PA	SA	PA				
Advanced therapy	Treatment of type 1 diabetes mellitus.	x				x		x	
Biological	Treatment of type 2 diabetes mellitus.			x			x	x	
Chemical	Treatment of chronic heart failure.	x						x	
Chemical	Treatment of non-alcoholic steatohepatitis.	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 psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis.			x				x	
Biological	Treatment of pleural mesothelioma.		x			x			
Advanced therapy	Treatment of multiple myeloma.	x				x	x	x	
Chemical	Treatment of chronic myelogenous leukaemia.		x					x	
Biological	Treatment of multiple myeloma.				x			x	
Chemical	Treatment of extracranial solid tumours.	x						x	
Biological	Treatment of paroxysmal nocturnal hemoglobinuria and atypical haemolytic uremic syndrome.			x				x	
Chemical	Treatment of acute myeloid leukaemia.				x	x			
Biological	Treatment of B-type lymphocytic tumours.	x				x	x	x	
Chemical	Treatment of breast cancer.	x					x	x	
Biological	Treatment of multiple myeloma.				x			x	
Chemical	Treatment of endometrial carcinoma.	x						x	
Chemical	Treatment of multiple sclerosis.			x		x			
Biological	Treatment of head and neck squamous cell carcinoma.	x						x	
Biological	Treatment of non-small cell lung cancer.	x						x	
Chemical	Treatment of myelodysplastic syndromes.				x			x	
Advanced therapy	Treatment of B-cell acute lymphoblastic leukaemia.	x						x	
Chemical	Treatment of activated PI3Kd syndrome.			x			x	x	
Biological	Treatment of blastic plasmacytoid dendritic cell neoplasm.			x				x	
Biological/ Advanced therapy	Treatment of head and neck squamous cell carcinoma.	x						x	
Chemical	Treatment of breast cancer.			x				x	
Advanced therapy	Treatment of diffuse large B-cell lymphoma and acute lymphoblastic leukaemia.		x			x			
Chemical	Treatment of acute hepatic porphyria.		x				x	x	x
Biological	Prophylaxis of bleeding in haemophilia A.		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 transthyretin amyloidosis cardiomyopathy.	x						x	
Chemical	Treatment of transthyretin amyloidosis cardiomyopathy.	x						x	
Chemical	Treatment of oral lichen planus.			x		x			
Chemical	Treatment of adenovirus infection.		x				x	x	
Chemical	Treatment of respiratory syncytial virus infection.			x				x	
Chemical	Treatment of human metapneumonovirus infection.	x					x	x	
Chemical	Female contraception.	x				x	x	x	
Chemical	Treatment of fibrodysplasia ossificans progressive.		x					x	
Chemical	Treatment of postpartum depression.	x						x	
Chemical	Treatment of C3 glomerulopathy.	x					x	x	
Chemical	Treatment of paroxysmal nocturnal haemoglobinuria.	x					x	x	
Chemical/ Other innovative	Reduction of postoperative pain.	x					x	x	
Chemical	Treatment of Duchenne muscular dystrophy.		x				x	x	
Chemical	Treatment of multiple sclerosis.	x						x	
Chemical	Treatment of hereditary transthyretin amyloidosis with polyneuropathy.		x			x			
Chemical	Treatment of spinal muscular atrophy type 1.	x				x			
Chemical	Treatment of symptomatic TTR cardiomyopathy.			x				x	
Chemical/ Other innovative	Treatment of chronic obstructive pulmonary disease.			x				x	
Biological	Treatment of neovascular (wet) age-related macular degeneration, macular edema, diabetic macular edema and diabetic retinopathy.	x				x	x	x	
Biological	Treatment of choroidal neovascularization associated with wet AMD.	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 elevated intra-ocular pressure in open angle glaucoma or ocular hypertension.			x		x			
Chemical	Reduction of elevated intra-ocular pressure in open angle glaucoma or ocular hypertension.	x						x	
Biological	Treatment of osteoporosis.			x		x	x	x	
Chemical	Treatment of Prader-Willi syndrome.				x			x	x
Biological	Diagnosis of cow's milk allergy.	x				x	x	x	
Chemical	MRI diagnostic.	x				x			
Chemical	Treatment of chronic kidney disease.	x				x	x		
Qualification advice	Treatment of multiple sclerosis, hip fracture, sarcopenia.	x						x	
HTA parallel	Treatment of diabetic gastroparesis.	x						x	
HTA parallel	Symptomatic relief of chronic cough.	x					x	x	
HTA parallel	Treatment of acute myeloid leukaemia.			x				x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 28 Scientific Advice letters, 9 Protocol Assistance letters, 15 Follow-up Scientific Advice, 5 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 3 HTA Parallel advice, were adopted at the 17 – 20 July 2017 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 51 new Requests for which the procedure started at the SAWP meeting held on 3 – 6 July 2017. The new requests are divided as follows: 19 Initial Scientific Advice, 9 Follow-up Scientific Advice, 8 Initial Protocol Assistance, 7 Follow-up Protocol Assistance, 3 Qualifications of novel methodologies and 5 HTA Parallel advices.