



14 September 2017
EMA/CHMP/SAWP/615470/2017
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 11 – 14 September 2017

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

	1995 - 2016	2017	Overall total
Scientific Advice	3215	231	3446
Follow-up to Scientific Advice	938	87	1025
Protocol Assistance	735	68	803
Follow-up to Protocol Assistance	355	39	394
HTA parallel advice	87	18	105
Qualification of novel methodologies	94	19	113
	5424	462	5886

Outcome of the September 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
		SA	PA	SA	PA				
Chemical	Treatment of progressive familial intrahepatic cholestasis.		x			x			
Biological	Treatment of non-alcoholic steatohepatitis.	x					x	x	
Chemical	Treatment of acute pancreatitis.		x				x	x	
Biological	Treatment of diabetes mellitus.	x				x		x	
Biological	Treatment of paroxysmal nocturnal haemoglobinuria.				x		x	x	



Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant
		SA	PA	SA	PA				
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis and ankylosing spondylitis.			x		x	x		
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis and ankylosing spondylitis.	x				x		x	
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis and ankylosing spondylitis.	x						x	
Chemical	Treatment of acute myeloid leukaemia.	x				x		x	
Advanced therapy	Treatment of diffuse large B-cell lymphoma.		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 chronic plaque psoriasis.			x		x		x	
Biological	Reduction in the duration of neutropenia.			x				x	
Advanced therapy	Treatment of diffuse large B-cell lymphoma.	x				x		x	
Chemical	Treatment of polycythaemia vera.	x					x	x	
Chemical	Treatment of tenosynovial giant cell tumour.				x		x		
Advanced therapy	Treatment of pancreatic ductal adenocarcinoma.	x				x	x		
Chemical	Treatment of metastatic castration-resistant prostate cancer.	x						x	
Advanced therapy	Treatment of B-lymphoblastic leukaemia.		x					x	
Chemical	Treatment of paroxysmal nocturnal haemoglobinuria.		x			x	x	x	x
Biological	Treatment of congenital FVII deficiency.				x		x	x	x
Biological	Treatment and prophylaxis of bleeding in haemophilia A.	x				x	x		
Chemical	Treatment of catecholamine-resistant high output shock.	x				x	x	x	
Chemical	Treatment of calciphylaxis.				x		x		
Biological	Treatment of asthma.	x				x			
Biological	Prevention of respiratory syncytial virus 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				
Chemical	Treatment of respiratory syncytial virus disease and human metapneumovirus hMPV infection.	x				x			
Chemical	Treatment of cytomegalovirus disease.		x			x			
Biological	Prevention of respiratory syncytial virus disease.	x					x	x	
Chemical	Prevention of pregnancy.			x			x	x	
Advanced therapy	Treatment of male urethral strictures.			x				x	
Chemical	Treatment of axonal injury in traumatic brain injury.		x				x	x	
Chemical	Treatment of Prader-Willi syndrome.	x					x	x	
Chemical	Improvement of walking in multiple sclerosis.	x						x	
Biological	Treatment of multiple sclerosis.	x				x	x	x	
Biological	Treatment of Crohn's disease.	x				x		x	
Biological	Treatment of neuroblastoma.	x					x	x	
Biological	Prevention of antibody mediated rejection on lung transplantation.		x					x	x
Chemical	Treatment of familial adenomatous polyposis.				x		x	x	
Chemical	Treatment of Alzheimer's disease.	x						x	
Chemical	Treatment of spinal muscular atrophy.				x	x			
Chemical	Treatment of schizophrenia.			x				x	
Chemical	Treatment of autism spectrum disorder.			x			x		
Chemical	Treatment of cystic fibrosis.				x			x	
Biological	Treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy.	x				x	x	x	
Biological	Treatment of geographic atrophy.			x			x	x	
Biological	Treatment of geographic atrophy.	x				x			
Chemical	Treatment of acromegaly.			x				x	
Chemical	Treatment of neuroendocrine tumours.			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	Positron emission tomography diagnostic.			x				x	
Chemical	Treatment of focal segmental glomerulosclerosis.	x					x	x	
Biological	Treatment of hen's egg allergy.	x				x	x	x	
HTA parallel	Treatment of Alzheimer's disease.	x						x	
Qualification advice	Assessment of Crohn's disease activity and severity.	x						x	
Qualification advice	Monitoring of drug-induced liver injury.	x						x	
Qualification opinion	Medicine acceptability assessment.	x						x	
Qualification opinion	Assessment of human metabolism and disposition data.	x						x	
Qualification opinion	Enrichment for clinical trials in Parkinson's disease.	x						x	
Qualification advice	Quality of life measure in plexiform neurofibromas.			x				x	
Qualification advice	Assessment of Crohn's disease activity and severity.	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 26 Scientific Advice letters, 8 Protocol Assistance letters, 11 Follow-up Scientific Advice, 7 Follow-up Protocol Assistance, 7 Qualifications of novel methodologies and 1 HTA Parallel advice, were adopted at the 11 – 14 September 2017 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 59 new Requests for which the procedure started at the SAWP meeting held on 29 August – 1 September 2017. The new requests are divided as follows: 39 Initial Scientific Advice, 3 Follow-up Scientific Advice, 6 Initial Protocol Assistance, 8 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 2 HTA Parallel advices.