



25 June 2015
EMA/CHMP/SAWP/428252/2015
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 22 – 25 June 2015

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

	1995 - 2014	2015	Overall total
Scientific Advice	2653	135	2788
Follow-up to Scientific Advice	758	42	800
Protocol Assistance	566	63	629
Follow-up to Protocol Assistance	267	23	290
HTA parallel advice	34	14	48
Qualification of novel methodologies	60	8	68
	4338	285	4623

FDA Parallel Scientific Advice	2006 - 2014	2015	Overall total
Completed	26	2	28

Outcome of the June 2015 CHMP meeting in relation to scientific advice procedures

Final scientific advice procedures

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Treatment of Niemann-Pick type C disease.		x			x	x	x	x
Biological	Treatment of Farber disease.		x			x	x	x	



Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of aspartylglucosaminuria.		x				x	x	
Biological	Treatment of type 2 diabetes mellitus.	x				x	x	x	
Chemical	Treatment of NSCLC.								
Biological	Treatment of mesothelioma.		x				x	x	
Chemical	Treatment of prostate cancer.	x						x	
Biological	Treatment of breast cancer.			x				x	
Chemical	Treatment of acute myeloid leukaemia.		x			x			
Biological	Treatment of pancreatic ductal adenocarcinoma.		x			x	x	x	x
Biological	Reduction in the duration of neutropenia and incidence of febrile neutropenia.	x						x	
Advanced therapy	Treatment of acute immunosuppressant-refractory GvHD.		x				x	x	x
Chemical	Treatment of myelodysplastic syndromes.				x			x	
Biological	Treatment of blastic plasmacytoid dendritic cell neoplasm.	x				x	x	x	
Chemical	Treatment of anaemia.	x					x	x	
Chemical	Treatment of anaemia.	x				x	x		
Biological	Treatment of neuromyelitis optica spectrum disorder.	x					x	x	
Biological	Prevention of bleeding in hemophilia A.		x			x	x		
Chemical	Treatment of diabetic kidney disease.	x				x	x	x	
Chemical	Treatment of chronic heart failure.	x						x	
Chemical	Treatment of pulmonary arterial hypertension.	x					x	x	
Advanced therapy	Treatment of critical limb ischemia.			x		x			
Advanced therapy	Treatment of recessive dystrophic epidermolysis bullosa.		x					x	
Chemical	Treatment of pruritus due to psoriasis vulgaris.	x					x		
Chemical	Treatment of bacterial infections.	x					x	x	
Biological	Prevention of dengue disease.			x				x	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Treatment of respiratory syncytial virus infection.	x				x	x	x	
Chemical	Treatment of hepatitis delta virus infection.	x				x	x	x	
Chemical	Treatment of <i>pseudomonas aeruginosa</i> infections.	x					x	x	
Biological	Active immunisation against <i>pseudomonas aeruginosa</i> .	x						x	
Biological	Treatment of Duchenne muscular dystrophy.	x						x	
Chemical	Management of fibromyalgia.	x				x	x	x	
Chemical	Treatment of osteoporosis.	x				x			
Chemical	Treatment of schizophrenia.	x						x	
Chemical	Treatment of Dravet syndrome.		x			x	x	x	x
Chemical/ Other innovative	Treatment of Alzheimer's disease.	x						x	
Chemical	Treatment of Parkinson's disease.	x						x	
Chemical	Treatment of schizophrenia.			x				x	
Chemical	Treatment of Wolfram syndrome.		x					x	
Chemical	Treatment of Parkinson's disease.	x						x	
Chemical	Treatment of Alzheimer's dementia.	x					x	x	
Chemical	Treatment of behavioral variant frontotemporal dementia.	x					x	x	
Chemical	Treatment of multiple sclerosis.	x						x	
Biological	Treatment of osteoporosis.	x				x	x	x	
Biological	Prevention of ischemia reperfusion injury.		x				x		
Biological	Treatment of asthma and chronic spontaneous urticaria.	x				x			
Chemical	Treatment of mastocytosis.				x			x	
Qualification opinion	Prognostic imaging biomarker.	x						x	
Qualification advice	Ulcerative colitis.	x						x	
Qualification advice	Ulcerative colitis.	x						x	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
HTA parallel advice	Treatment of Urea Cycle Disorders.		x					x	x
HTA parallel advice	Treatment of acute myeloid leukaemia.	x				x	x	x	
HTA parallel advice	Treatment of B-thalassemia.	x					x	x	
HTA parallel advice	Treatment of asthma.	x					x	x	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 27 Scientific Advice letters, 12 Protocol Assistance letters, 6 Follow-up Scientific Advice, 2 Follow-up Protocol Assistance letters, 4 HTA parallel advice letters and 3 Qualifications of novel methodologies letters were adopted at the 22 – 25 June 2015 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 48 new Requests for which the procedure started at the SAWP meeting held on 1 – 4 June 2015. The new requests are divided as follows: 18 Initial Scientific Advice, 16 Follow-up Scientific Advice, 8 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 2 HTA parallel advices and 2 Qualifications of novel methodologies.