



23 April 2015
EMA/CHMP/SAWP/210613/20155
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 20 – 23 April 2015

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

	1995 - 2014	2015	Overall total
Scientific Advice	2653	94	2747
Follow-up to Scientific Advice	758	28	786
Protocol Assistance	566	38	604
Follow-up to Protocol Assistance	267	17	284
HTA parallel advice	34	9	43
Qualification of novel methodologies	60	4	64
	4338	190	4528

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

Outcome of the April 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 nonalcoholic steatohepatitis.	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 acid sphingomyelinase deficiency.		x			x			
Biological	Treatment of type 2 diabetes mellitus.	x				x	x	x	
Chemical	Treatment of acute myeloid leukaemia.	x					x	x	
Chemical	Treatment of non-small cell lung cancer.	x					x	x	
Biological	Biosimilar to Avastin			x		x		x	
Biological	Biosimilar to Avastin	x				x	x	x	
Biological	Treatment of Still's disease.	x						x	
Biological	Treatment of multiple myeloma.				x	x			x
Advanced therapy	Treatment of chronic lymphocytic leukaemia.	x					x	x	
Chemical	Treatment of acute myeloid leukaemia.		x			x			
Biological	Treatment of squamous non-small cell lung cancer.			x				x	
Biological	Treatment of glioblastoma multiforme.		x					x	
Chemical	Treatment of early myelofibrosis.				x			x	
Biological	rheumatoid arthritis.			x				x	
Advanced therapy	Treatment of haematological malignancies.	x				x	x		
Chemical	Treatment of breast cancer.	x				x			
Advanced therapy	Prevention and control of lung transplant rejection, rheumatoid arthritis and scleroderma.	x				x			
Chemical	Treatment of paroxysmal nocturnal haemoglobinuria.		x				x	x	x
Biological	Treatment of bleeding episodes and prevention of bleeding in surgery.	x				x	x	x	
Biological	Treatment of major bleeding.	x					x	x	
Chemical	Treatment of hypertrophic cardiomyopathy.	x					x	x	
Chemical	Treatment of epidermolysis bullosa.		x				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 infections caused by susceptible Gram-negative bacteria.	x				x			
Chemical	Treatment of infections caused by susceptible Gram-negative bacteria.			x			x	x	
Biological	Prevention of invasive disease caused by N. meningitidis serogroup B.			x		x			
Biological	Prophylaxis against Ebola virus infection.	x				x	x	x	
Biological	Stimulation of spermatogenesis and multifollicular development, anovulation.	x				x		x	
Chemical	Treatment of malignant hyperthermia.		x			x	x	x	x
Chemical	Treatment of hip and knee osteoarthritis.			x		x			
Biological	Treatment of muscle wasting syndromes.			x				x	
Advanced therapy	Treatment of metachromatic leukodystrophy.				x			x	
Chemical	Treatment of major depressive disorder.	x						x	
Biological	Treatment of neuromyelitis optica and NMO spectrum disorders.			x				x	
Advanced therapy	Treatment of chronic motor deficit.	x					x	x	
Biological/Chemical	Treatment of myasthenia gravis.	x						x	
Chemical/Other innovative	Treatment of asthma.	x						x	
Chemical/Other innovative	Treatment of COPD.	x				x		x	
Chemical/Other innovative	Treatment of asthma.	x						x	
Biological	Treatment of asthma.	x						x	
Biological	Treatment of asthma.	x						x	
Biological	Treatment of growth hormone deficiency.				x			x	
Chemical	Diagnosis of gastroenteropancreatic neuroendocrine tumours.		x			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				
Advanced therapy	Treatment of placental insufficiency.		x			x	x	x	
Chemical	Treatment of mastocytosis.				x			x	
Biological	Immunotherapy for peanut allergy.	x				x	x		
Qualification	Treatment of endometriosis.	x						x	
Qualification	Treatment of endometriosis.	x						x	
HTA parallel	Treatment of Schnitzler syndrome.		x					x	
HTA parallel	treatment of infections due to aerobic Gram-negative pathogens	x						x	
HTA parallel	Treatment of beta-thalassaemia major.		x					x	
HTA parallel	Treatment of gastric/GEJ cancer.	x						x	
HTA parallel	Treatment of Alzheimer's disease	x				x		x	
HTA parallel	Treatment of Alzheimer's disease	x					x	x	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 25 Scientific Advice letters, 8 Protocol Assistance letters, 8 Follow-up Scientific Advice, 5 Follow-up Protocol Assistance letters, 6 HTA parallel advice letters and 2 Qualification of novel methodologies letters were adopted at the 20 – 23 April 2015 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 49 new Requests for which the procedure started at the SAWP meeting held on 7 – 10 April 2015. The new requests are divided as follows: 19 Initial Scientific Advice, 9 Follow-up Scientific Advice, 11 Initial Protocol Assistance, 3 Follow-up Protocol Assistance, 4 HTA parallel advices and 3 Qualification of novel methodologies.