



28 June 2013
EMA/CHMP/SAWP/389179/2013
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 24 – 27 June 2013

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

	1995 - 2012	2013	Overall total
Scientific Advice	1848	119	1967
Follow-up to Scientific Advice	496	52	548
Protocol Assistance	396	26	422
Follow-up to Protocol Assistance	189	13	202
HTA parallel advice	16	2	18
Qualification of novel methodologies	28	7	35
	2973	219	3192

FDA Parallel Scientific Advice	2006 - 2012	2013	Overall total
Completed	19	1	20

Outcome of the June 2013 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 functional dyspepsia.			x				x	
Chemical	Treatment of irritable bowel syndrome.			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 ulcerative colitis.	x					x	x	
Chemical	Treatment of type-2 diabetes mellitus.	x				x			
Chemical	Treatment of type-2 diabetes mellitus.			x				x	
Chemical	Treatment of opioid-induced constipation.	x						x	
Biological	Treatment of nail psoriasis.	x						x	
Biological	Treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, psoriasis and Crohn's disease.			x		x	x	x	
Chemical	Treatment of paediatric solid tumours.	x				x	x	x	
Chemical	Treatment of breast cancer.	x					x	x	
Chemical	Treatment of melanoma.	x				x		x	
Advanced therapy	Treatment of prostate cancer.			x				x	
Chemical/ Other innovative	Treatment of non-small cell lung cancer.			x				x	
Chemical	Treatment of diffuse large B cell lymphoma.	x						x	
Biological	Treatment of resectable non-small cell lung cancer.			x				x	
Biological	Treatment of melanoma.			x				x	
Chemical	Treatment of colorectal cancer.			x				x	
Chemical	Treatment of breast cancer.	x					x	x	
Chemical	Treatment of non-Hodgkin lymphoma.	x					x	x	
Biological	Treatment of breast cancer.			x		x		x	
Biological	Treatment of systemic lupus erythematosus.	x				x	x	x	
Chemical	Treatment of thrombocytopenia.			x			x	x	
Chemical	Treatment of primary pulmonary hypertension.		x			x		x	
Biological	Treatment and prevention of bleeding in haemophilia B.	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	Prevention of stroke and systemic embolic events.	x						x	
Chemical	Prevention of recurrent venous thromboembolism.	x						x	
Chemical	Reduction of cardiovascular mortality and morbidity.	x				x			
Chemical	Treatment of chronic plaque psoriasis.	x					x	x	
Biological	Active immunization against <i>N. meningitidis</i> .			x				x	
Biological	Active immunisation against <i>S. pneumoniae</i> and <i>H. influenzae</i> .	x				x		x	
Chemical	Treatment of HIV-1 infection.	x				x	x	x	
Other innovative	Treatment of inflammatory bowel disease.	x				x	x	x	
Biological	Stimulation of multifollicular development.	x						x	
Chemical	Medical expulsive therapy of ureteral calculi.	x					x	x	
Biological	Treatment of osteoporosis.			x				x	
Chemical	Treatment of migraine.	x				x		x	
Chemical	Treatment of Alzheimer's disease.	x						x	
Chemical	Treatment of pain associated with diabetic neuropathy.	x						x	
Biological	Treatment of Alzheimer's disease.			x		x	x	x	
Biological	Treatment of Alzheimer's disease	x				x	x	x	
Chemical	Treatment of COPD.	x					x		
Chemical	Treatment of cystic fibrosis.		x			x			
Biological/Advanced therapy	Treatment of retinitis pigmentosa.		x			x	x	x	
Chemical	Treatment of Leber congenital amaurosis and retinitis pigmentosa.				x		x		
Chemical	Treatment of symptoms from neuroendocrine tumors.	x						x	
Biological	Treatment of GHD.			x				x	

SA: scientific advice
PA: protocol assistance

The above-mentioned 27 Scientific Advice letters, 3 Protocol Assistance letters, 15 Follow-up Scientific Advice, 1 Follow-up Protocol Assistance letters, 0 HTA parallel advice letters and 0 Qualification of novel methodologies letters were adopted at the 24 – 27 June 2013 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 46 new Requests for which the procedure started at the SAWP meeting held on 03 – 06 June 2013. The new requests are divided as follows: 21 Initial Scientific Advice, 11 Follow-up Scientific Advice, 7 Initial Protocol Assistance, 7 Follow-up Protocol Assistance, 0 HTA parallel advices and 0 Qualification of novel methodologies.