



30 May 2013
EMA/CHMP/SAWP/332193/2013
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 27 – 30 May 2013

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

	1995 - 2012	2013	Overall total
Scientific Advice	1848	92	1940
Follow-up to Scientific Advice	496	37	533
Protocol Assistance	396	23	419
Follow-up to Protocol Assistance	189	12	201
HTA parallel advice	16	2	18
Qualification of novel methodologies	28	5	33
	2973	171	3144

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

Outcome of the May 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 diarrhoea-predominant irritable bowel syndrome.	x					x	x	
Chemical	Treatment of mild-to-moderate 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				
Biological	Treatment of type 2 diabetes.			x			x		
Chemical	Treatment of follicular lymphoma.	x					x	x	
Biological	Treatment of generalized myasthenia gravis.	x						x	
Chemical	Treatment of metastatic triple negative breast cancer.			x				x	
Chemical	Treatment of systemic light-chain amyloidosis.		x				x	x	
Biological	Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia and rheumatoid arthritis.			x		x		x	
Advanced therapy	Treatment of melanoma.			x		x	x	x	
Chemical	Treatment of thrombocytopenia.			x				x	
Biological	Supportive treatment in surgery for improvement of haemostasis, promotion of tissue sealing and suture support.	x						x	
Chemical	Treatment of symptomatic transthyretin (TTR) amyloid cardiomyopathy.			x				x	
Chemical	Treatment of hypertension.	x				x	x	x	
Chemical/ Biological	Treatment of acute myocardial infarction.	x					x	x	
Chemical	Treatment of acute coronary syndrome.	x					x	x	
Chemical	Treatment of HIV 1.			x		x		x	
Chemical	Treatment of HSV infections, genital herpes, ocular HSV, chickenpox.	x				x	x	x	
Biological	Treatment of medical conditions associated with loss of muscle mass.	x						x	
Chemical	Treatment of prodromal and mild Alzheimer's 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 in moderate to severe traumatic brain injury.			x			x	x	
Biological	Treatment of asthma.	x				x	x	x	
Chemical	Treatment of sodium and fluid overload in end stage renal disease.	x						x	
Chemical	Treatment of lead toxicity.		x				x	x	
Chemical	Enhancement of the dissolution rate of poorly water-soluble active pharmaceutical ingredients.	x				x	x	x	
Chemical	Treatment of calciphylaxis.		x					x	

SA: scientific advice
PA: protocol assistance

The above-mentioned 13 Scientific Advice letters, 4 Protocol Assistance letters, 8 Follow-up Scientific Advice, 0 Follow-up Protocol Assistance letters, 0 HTA parallel advice letters and 0 Qualification of novel methodologies letters were adopted at the 27 – 30 May 2013 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 57 new Requests for which the procedure started at the SAWP meeting held on 06 – 08 May 2013. The new requests are divided as follows: 32 Initial Scientific Advice, 13 Follow-up Scientific Advice, 4 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 0 HTA parallel advice and 6 Qualification of novel methodologies.