



13 December 2012
EMA/CHMP/SAWP/800282/2012
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 10 – 13 December 2012

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

	1995 - 2011	2012	Overall total
Scientific Advice	1627	223	1850
Follow-up to Scientific Advice	400	96	496
Protocol Assistance	342	52	394
Follow-up to Protocol Assistance	162	28	190
HTA parallel advice	8	9	17
Qualification of novel methodologies	14	14	28
	2553	422	2975

FDA Parallel Scientific Advice	2006 - 2011	2012	Overall total
Completed	17	1	18

Outcome of the December 2012 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 irritable bowel syndrome.			x				x	
Chemical/Biological	Treatment of Fabry disease.		x				x		



Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Prevention of cytomegalovirus complications in hematopoietic cell transplant.				x			x	
Chemical	Treatment of non-small cell lung cancer.	x						x	
Biological	Intended for patients with kidney transplantation.	x					x	x	
Chemical	Treatment of mantle cell lymphoma.	x						x	
Chemical	Treatment of gastrointestinal stromal tumour.				x			x	
Chemical	Treatment of metastatic colorectal cancer.	x						x	
Chemical	Treatment of metastatic non-small cell lung cancer.	x						x	
Chemical	Treatment of metastatic Castrate Resistant Prostate Cancer.	x						x	
Biological	Treatment of melanoma.	x					x	x	
Chemical/ Biological	Treatment of non-small cell lung cancer.	x				x			
Biological	Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia and rheumatoid arthritis.	x				x	x	x	
Chemical	Treatment of gastric cancer.	x						x	
Biological	Treatment of breast cancer and gastric cancer.			x				x	
Chemical	Treatment of acute myeloid leukaemia.				x			x	x
Chemical	Treatment of acute myeloid leukaemia.		x			x	x	x	
Chemical	Treatment of thrombocytopenia.	x				x	x	x	
Biological	Treatment and prophylaxis of bleeding in hemophilia A.		x			x	x	x	
Chemical	Treatment of peripheral arterial disease.	x				x	x	x	
Chemical	Treatment of heart failure.	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	Reduction of atherothrombotic events.	x				x	x	x	
Chemical	Treatment of essential hypertension.			x		x		x	
Chemical	Treatment of acute coronary syndrome.			x				x	
Chemical	Treatment of non-permanent Atrial Fibrillation.	x						x	
Chemical	Treatment of calciphylaxis.		x				x	x	
Biological	Prevention of cholera.	x				x	x	x	
Chemical	Prophylaxis of kidney injury in patients undergoing surgery.	x					x	x	
Biological	Treatment of symptomatic osteoarthritis	x					x	x	
Biological	Treatment of pain in osteoarthritis.	x						x	
Advanced therapy	Treatment of spinal cord injury.	x				x	x		
Chemical	Treatment of Lambert-Eaton myasthenic syndrome (LEMS).		x					x	
Other innovative	Intended for monitoring treatment adherence in schizophrenic patients.	x				x			
Chemical/ Other innovative	Maintenance treatment of schizophrenia.	x				x	x	x	
Biological	Treatment of diabetic peripheral neuropathic pain.	x						x	
Chemical	Treatment of spinal muscular atrophy.		x				x	x	
Chemical	Treatment of Fragile X Syndrome.	x					x	x	
Chemical	Treatment of asthma and chronic obstructive pulmonary disease.	x				x		x	
Biological	Treatment of severe asthma.			x		x			
Chemical	Reduction in progression of diabetic retinopathy.	x						x	
HTA	Treatment of pouchitis.		x					x	x

SA: scientific advice

PA: protocol assistance

The above-mentioned 26 Scientific Advice letters, 6 Protocol Assistance letters, 5 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance letters, 1 HTA parallel advice letters and 0 Qualification of novel methodologies letters were adopted at the 10 – 13 December 2012 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 34 new Requests for which the procedure started at the SAWP meeting held on 26 – 29 November 2012. The new requests are divided as follows: 20 Initial Scientific Advice, 5 Follow-up Scientific Advice, 4 Initial Protocol Assistance, 3 Follow-up Protocol Assistance, 1 HTA parallel advice and 1 Qualification of novel methodologies.