



21 November 2013
EMA/CHMP/SAWP/718027/2013
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 18 – 21 November 2013

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

	1995 - 2012	2013	Overall total
Scientific Advice	1848	226	2047
Follow-up to Scientific Advice	496	86	571
Protocol Assistance	396	58	447
Follow-up to Protocol Assistance	189	33	217
HTA parallel advice	16	4	18
Qualification of novel methodologies	28	13	40
	2973	420	3340

FDA Parallel Scientific Advice	2006 - 2012	2013	Overall total
Completed	19	3	22

Outcome of the November 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 Wilson's disease.		x			x	x	x	
Chemical	Treatment of diarrhoea-predominant 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				
Chemical	Treatment of non-small cell lung cancer.	x					x	x	
Chemical	Treatment of non-small cell lung cancer.	x				x	x	x	
Biological	Prevention of delayed graft function.	x						x	
Biological/ Advanced therapy	Treatment of hepatocellular carcinoma.				x		x	x	
Biological/ Advanced therapy	Treatment of pancreatic cancer.				x			x	
Chemical	Treatment of pancreatic neuroendocrine tumors.	x						x	
Biological	Treatment of rheumatoid arthritis, non-Hodgkin lymphoma and chronic lymphocytic leukaemia			x				x	
Chemical	Reduction of mortality in patients with severe sepsis.	x						x	
Advanced therapy	Treatment of chronic lymphocytic leukaemia.	x				x			
Chemical	Treatment of severe and/or complicated malaria.				x	x	x	x	
Chemical	Treatment of malaria.				x	x	x	x	
Biological	Treatment of thromboembolic events and myocardial infarction.	x				x	x	x	
Biological	Treatment of thromboembolic events and myocardial infarction.			x		x	x	x	
Advanced therapy	Treatment of heart failure.	x				x	x	x	
Chemical	Treatment of hypercholesterolaemia and reduction of cardiovascular mortality and morbidity			x			x	x	
Advanced therapy	Treatment of chronic heart failure.			x			x		
Biological	Treatment of hyperlipidemia.			x			x	x	
Chemical	Treatment of pre-eclampsia.		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 neuropathic diabetic foot ulcers.			x		x		x	
Chemical	Broad advice on generic topical dermatological products.	x				x	x	x	
Chemical	Prophylaxis of omphalitis.	x				x	x	x	
Chemical	Treatment of chronic plaque psoriasis.			x			x	x	
Chemical	Treatment of chronic plaque psoriasis.	x				x			
Chemical	Treatment of chronic plaque psoriasis.	x				x	x	x	
Chemical/ Other innovative	Relief of pain or discomfort and prevention of infection in burns.	x					x	x	
Chemical	Treatment of atopic dermatitis.	x						x	
Chemical	Treatment of hepatitis C viral infection.	x						x	
Chemical	Treatment of hepatitis C viral infection.			x		x			
Chemical	Treatment of <i>Acinetobacter baumannii</i> infections.	x				x	x	x	
Biological	Treatment of adult-onset Still's disease.	x				x	x	x	
Chemical	Treatment of relapsing-remitting forms of multiple sclerosis.	x						x	
Chemical	Treatment of pain associated with diabetic neuropathy.	x				x			
Chemical	Treatment of pain associated with fibromyalgia.	x						x	
Chemical	Treatment of Parkinson's disease.	x						x	
Biological	Treatment of neuromyelitis optica.	x				x	x	x	
Biological	Treatment of relapsing remitting multiple sclerosis.	x					x	x	
Chemical	Maintenance treatment of schizophrenia.	x					x	x	
Chemical	Treatment of asthma.	x					x	x	
Chemical	Treatment of cystic fibrosis.		x			x	x	x	
Chemical	Treatment of cystic fibrosis.	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				
Other innovative	Prevention of allergic rhinitis/rhinoconjunctivitis and of allergic asthma.	x					x	x	
Chemical	Treatment of acromegaly.				x	x	x	x	x
Biological	Prevention of bleeding.			x				x	
Biological	Prevention of bleeding.			x			x		
HTA	Treatment of chronic non-infectious uveitis.		x					x	
Biomarker	Prediction, detection, monitoring of clinical drug-induced kidney injury.	x						x	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 27 Scientific Advice letters, 3 Protocol Assistance letters, 11 Follow-up Scientific Advice, 5 Follow-up Protocol Assistance letters, 1 HTA parallel advice letters and 1 Qualification of novel methodologies letters were adopted at the 18 – 21 November 2013 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 38 new Requests for which the procedure started at the SAWP meeting held on 4 – 7 November 2013. The new requests are divided as follows: 18 Initial Scientific Advice, 9 Follow-up Scientific Advice, 3 Initial Protocol Assistance, 6 Follow-up Protocol Assistance, 1 HTA parallel advice and 1 Qualification of novel methodologies.