



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 January 2013
EMA/CHMP/SAWP/29382/2013
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 14 – 17 January 2013

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

	1995 - 2012	2013	Overall total
Scientific Advice	1848	24	1872
Follow-up to Scientific Advice	496	7	503
Protocol Assistance	396	2	398
Follow-up to Protocol Assistance	189	5	194
HTA parallel advice	16	0	16
Qualification of novel methodologies	28	1	29
	2973	39	3012

FDA Parallel Scientific Advice	2006 - 2012	2013	Overall total
Completed	19	0	19

Outcome of the January 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/ Other innovative	Prevention of post-operative nausea and vomiting.			x				x	
Biological	Treatment of type 1 diabetes.	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 Fabry disease.				x		x	x	
Biological	Treatment of primary hyperoxaluria.		x			x	x	x	
Chemical	Treatment of Chronic lymphocytic leukaemia.	x					x	x	
Advanced therapy	Treatment of inflammatory bowel disease.	x					x		
Chemical	Treatment of breast cancer and head and neck squamous cell carcinoma.	x					x		
Biological	Treatment of non-small cell lung cancer, renal cell carcinoma and melanoma.	x				x			
Chemical	Treatment of advanced ovarian cancer, AIDS related Kaposi's sarcoma, metastatic breast cancer and progressive multiple myeloma.			x			x		
Biological	Treatment of relapsing neuromyelitis optica.	x						x	
Chemical	Treatment of prostate cancer.			x			x	x	
Biological	Treatment of rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis.	x				x	x	x	
Chemical	Treatment of prostate cancer.	x						x	
Chemical	Treatment of granulomatosis with polyangiitis (Wegener Granulomatosis).				x			x	x
Chemical	Treatment melanoma.	x						x	
Biological	Treatment of acute lymphoblastic leukaemia.	x						x	
Biological	Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia and rheumatoid arthritis.			x				x	
Biological	Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia and rheumatoid arthritis.			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 high grade glioma.		x			x		x	
Biological	Treatment of rheumatoid arthritis.	x					x	x	
Chemical	Conditioning treatment prior to haemotopoietic progenitor cell transplantation.				x			x	
Chemical	Treatment of sickle-cell patients experiencing a painful vaso-occlusive event.	x					x	x	
Chemical	Treatment of diabetic retinopathy.	x						x	
Chemical	Treatment of coronary artery disease and chronic heart failure.	x						x	
Chemical	Treatment of hypertension.	x						x	
Biological	Treatment of neuroischemic diabetic foot ulcer.	x				x	x	x	
Biological	Treatment of pemphigus vulgaris.	x					x	x	
Chemical	Treatment of genotype 1 chronic hepatitis C.			x		x			
Chemical	Treatment of Gram-negative infections caused by pathogens with known or suspected MBL resistance.	x					x	x	
Biological	Treatment of early pseudomonas aeruginosa pulmonary infection/pulmonary colonisation.			x				x	
Chemical	Treatment of overactive bladder syndrome.	x					x	x	
Chemical	Treatment of secondary hypogonadism.	x					x	x	
Chemical	Treatment of Duchenne muscular dystrophy.				x	x			
Chemical	Treatment of Autism Spectrum Disorder.	x					x		
Chemical	Treatment of mild-to-moderate pain of osteoarthritis.	x						x	
Chemical	Treatment of dystonia in children.	x				x	x	x	
Biological	Treatment of polycythaemia vera.				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 allergic rhinoconjunctivitis including SAR and PAR.	x					x	x	
Biomarker	Alzheimer's disease.	x						x	

SA: scientific advice

PA: protocol assistance

The above-mentioned 24 Scientific Advice letters, 2 Protocol Assistance letters, 7 Follow-up Scientific Advice, 5 Follow-up Protocol Assistance letters, 0 HTA parallel advice letters and 1 Qualification of novel methodologies letters were adopted at the 14 – 17 January 2013 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 35 new Requests for which the procedure started at the SAWP meeting held on 17 – 19 December 2012. The new requests are divided as follows: 15 Initial Scientific Advice, 8 Follow-up Scientific Advice, 7 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 0 HTA parallel advice and 0 Qualification of novel methodologies.