



21 June 2012
EMA/CHMP/SAWP/420418/2012
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 18 - 21 June 2012

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

	1995 - 2011	2012	Overall total
Scientific Advice	1627	114	1741
Follow-up to Scientific Advice	400	53	453
Protocol Assistance	342	27	369
Follow-up to Protocol Assistance	162	16	178
HTA parallel advice	8	3	11
Qualification of novel methodologies	14	10	24
	2553	223	2776

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

Outcome of the June 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				
Advanced therapy	Treatment of mucopolysaccharidosis type IIIA (Sanfilippo A syndrome).		x			x	x	x	
Biological	Treatment of DM type 2.			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 mucopolysaccharidosis IV type A (Morquio A syndrome, MPS IVA).		x					x	
Advanced therapy	Treatment of Acute Alcoholic Hepatitis.			x				x	
Biological	Enzyme replacement therapy for mucopolysaccharidosis VII (Sly syndrome).	x					x	x	
Chemical	Treatment of glioma.		x			x	x	x	
Biological	Treatment of active and progressive psoriatic arthritis.	x						x	
Biological	Treatment of active lupus nephritis.	x						x	
Chemical	Treatment of high-risk non-metastatic castration-resistant prostate cancer (CRPC).	x					x	x	
Biological	Treatment of SLE.	x				x	x	x	
Biological/Other innovative	Treatment of locally advanced NSCLC.			x		x	x		
Biological	Treatment of ALL.	x						x	
Biological	Treatment of resectable nSCLC and resected cutaneous melanoma expressing MAGE-A3.			x		x			
Biological	Treatment of locally advanced / metastatic pancreatic cancer.				x			x	
Biological	Treatment of HER2-positive advanced gastric cancer.	x						x	
Chemical	Treatment of carcinoid tumours.		x			x	x	x	
Chemical	Treatment of patients with unresectable or metastatic cMET (+) hepatocellular carcinoma.	x						x	
Chemical	Treatment of high-risk BRAF V600-mutant melanoma.	x					x	x	
Biological	Treatment of HER2-overexpressing breast cancer and metastatic gastric cancer.			x				x	
Biological	Prophylaxis and treatment of bleeding in haemophilia A.	x				x	x	x	
Biological	Treatment of Sickle Cell Disease.		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	Reduction of major cardiac events including death in acute myocardial infarction patients undergoing primary PCI.	x						x	
Advanced therapy	Treatment of Chronic Heart Failure.	x				x			
Chemical	Treatment of symptomatic transthyretin (TTR) amyloid cardiomyopathy.	x					x	x	
Chemical	Treatment of chronic hepatitis C.			x				x	
Chemical	Treatment of HIV 1.	x				x	x	x	
Biological	Immunization of pregnant women to passively protect neonates and infants against RSV.	x						x	
Biological	Immunization against severe RSV disease in infants.	x				x	x	x	
Biological	Protection of infants and children living in malaria-endemic regions.			x		x		x	
Advanced therapy	Treatment of urethral stricture.	x						x	
Biological	Treatment of Alzheimer's disease.			x				x	
Chemical/ Other innovative	Treatment of Parkinson's disease.			x				x	
Chemical	Treatment of Alzheimer's disease.	x						x	
Chemical	Treatment of major depressive disorder.			x				x	
Biological/ Other innovative	Treatment of traumatic spinal cord injury.		x				x	x	x
Chemical	Treatment of asthma and rhinitis.	x					x	x	
Chemical	Treatment of COPD and asthma.			x		x			
Chemical	Treatment of COPD and asthma.			x				x	
Biological	Treatment of asthma.			x		x			
Chemical	Treatment of chronic non-infectious uveitis.		x				x	x	x
Biological	Diagnosis of Mycobacterium tuberculosis infection.	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				
Biological	Treatment of Parkinson's Disease of moderate to severe stage.	x					x	x	
Biomarker	CT image analysis	x						x	
HTA	Treatment of diabetic gastroparesis.	x						x	

SA: scientific advice

PA: protocol assistance

The above-mentioned 21 Scientific Advice letters, 7 Protocol Assistance letter, 13 Follow-up Scientific Advice, 1 Follow-up Protocol Assistance letters, 1 HTA parallel advice letters and 1 Qualification of novel methodologies letters were adopted at the 18 – 21 June 2012 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 44 new Requests for which the procedure started at the SAWP meeting held on 29 May – 1 June 2012. The new requests are divided as follows: 24 Initial Scientific Advice, 14 Follow-up Scientific Advice, 2 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 1 HTA parallel advice and 1 Qualification of novel methodologies.