



19 July 2012
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Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 16 - 19 July 2012

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

	1995 - 2011	2012	Overall total
Scientific Advice	1627	132	1759
Follow-up to Scientific Advice	400	67	467
Protocol Assistance	342	33	375
Follow-up to Protocol Assistance	162	18	180
HTA parallel advice	8	4	12
Qualification of novel methodologies	14	11	25
	2553	265	2818

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

Outcome of the July 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 type 2 diabetes mellitus and hypercholesterolaemia.	x						x	
Biological	Treatment of moderate to severe ulcerative colitis.	x						x	



Substance	Intended indications(s)	Type of request				Topic			
		Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
SA	PA	SA	PA						
Chemical	Treatment of non-alcoholic steato-hepatitis.			x			x	x	
Chemical	Treatment of familial chylomicronemia.		x				x	x	
Chemical	Treatment of type II diabetes mellitus.			x				x	
Biological	Replacement therapy for patients with Lysosomal Acid Lipase (LAL) deficiency.		x			x	x	x	
Biological	Treatment of Crohn's disease.			x			x		
Biological	Treatment of rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, Crohn's disease, ulcerative colitis and polyarticular juvenile idiopathic arthritis.	x				x	x	x	
Biological	Treatment of pancreatic cancer.	x					x	x	
Biological	Treatment of NSCLC.			x				x	
Chemical	Treatment of second-line non-small cell lung cancer.	x				x		x	
Chemical	Treatment of myelofibrosis.		x				x	x	
Biological	Treatment of Rheumatoid Arthritis (RA), Polyarticular Juvenile Idiopathic Arthritis (JIA), Psoriatic Arthritis (PsA), Ankylosing Spondylitis (AS) and Plaque Psoriasis (PsO).			x			x	x	
Chemical	Treatment of adult RA patients.	x				x		x	
Chemical	Treatment of CLL.	x						x	
Biological	Treatment of Rheumatoid Arthritis (RA), Crohn's Disease (CD), Ankylosing Spondylitis (AS), Psoriatic Arthritis (PsA), Ulcerative Colitis (UC) and Plaque Psoriasis (PsO).			x				x	
Chemical	Treatment of colorectal carcinoma.	x						x	
Biological	Treatment of severe	x				x	x		

		Type of request				Topic			
	allergic asthma and food allergies.								
Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of rheumatoid arthritis, non-Hodgkin's lymphoma and chronic lymphocytic leukaemia.			x		x			
Chemical	Treatment of locally advanced or metastatic KRAS mutation positive NSCLC.	x					x	x	
Chemical	Treatment of NSCLC and HCC.	x				x			
Biological	Treatment of mild to moderately active RA.	x					x		
Chemical	Treatment of leishmaniasis.	x					x	x	
Biological	Supportive treatment for improvement of haemostasis and as suture support for haemostasis in vascular surgery.			x		x	x	x	
Biological	Prevention and treatment of haemorrhage or surgical bleeding in von Willebrand Disease.		x					x	
Chemical	Treatment of chronic thromboembolic pulmonary hypertension.				x			x	
Chemical	Prevention of cardiovascular mortality, MI, stroke, and symptomatic venous thromboembolic events in patients with heart failure.			x				x	
Chemical	Prevention of oral mucositis in head and neck cancer patients undergoing radiation therapy.		x				x	x	x
Chemical	Treatment of chronic HCV infection.	x				x	x	x	
Biological	Prevention of invasive meningococcal disease.			x				x	
Chemical	Treatment of chronic hepatitis C.			x			x	x	
Biological	Adjunctive immunotherapy to standard AB treatment of latent TB.	x				x	x	x	

Substance	Intended indications(s)	Type of request				Topic			
		Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
SA	PA	SA	PA						
Biological	Prevention of shiga toxin-mediated complications.				x	x	x	x	
Chemical	Treatment of schizophrenia.	x						x	
Chemical	Treatment of ALS.		x					x	x
Chemical	Treatment of Inner ear tinnitus.			x				x	
Chemical	Management of pain and opioid-induced constipation.	x				x	x	x	
Chemical	Treatment of Duchenne muscular dystrophy.	x					x	x	
Chemical/Other innovative	Treatment of severe, oral corticosteroid dependent asthma.			x				x	
Biological	Active (prophylactic) immunization against Lyme Borreliosis.			x		x		x	
Biomarker	Alzheimer's disease	x						x	
HTA	Treatment of MDD	x						x	

SA: scientific advice

PA: protocol assistance

The above-mentioned 18 Scientific Advice letters, 6 Protocol Assistance letter, 14 Follow-up Scientific Advice, 2 Follow-up Protocol Assistance letters, 1 HTA parallel advice letters and 1 Qualification of novel methodologies letters were adopted at the 16 – 19 July 2012 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 31 new Requests for which the procedure started at the SAWP meeting held on 25 - 27 June 2012. The new requests are divided as follows: 14 Initial Scientific Advice, 7 Follow-up Scientific Advice, 5 Initial Protocol Assistance, 3 Follow-up Protocol Assistance, 1 HTA parallel advice and 1 Qualification of novel methodologies.