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Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 16-19 January 2012

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

	1995 - 2011	2012	Overall total
Scientific Advice	1627	23	1650
Follow-up to Scientific Advice	400	6	406
Protocol Assistance	342	3	345
Follow-up to Protocol Assistance	162	4	166
HTA parallel advice	8	1	9
Qualification of novel methodologies	14	2	16
	2553	39	2592

FDA Parallel Scientific Advice	2006 - 2011	2012	Overall total
Completed	17	0	17

Outcome of the January 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				
Biological	Improvement of growth in preterm infants.	x				x		x	
Biological	Treatment of mucopolysaccharidosis IIIA (MPSIIIA, Sanfillipo A syndrome).		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 opioid-induced bowel dysfunction.			x				x	
Biological	Treatment of non-small cell lung cancer.	x						x	
Biological	Treatment of renal cell carcinoma.	x						x	
Chemical	Treatment of Chronic Lymphocytic Leukaemia.		x				x	x	x
Chemical	Treatment of advanced ovarian cancer, AIDS related Kaposi's sarcoma, metastatic breast cancer and progressive multiple myeloma.			x		x		x	
Biological	Treatment of Rheumatoid Arthritis (RA), Polyarticular Juvenile Idiopathic Arthritis (JIA), Psoriatic Arthritis (PsA), Ankylosing Spondylitis (AS), moderate to severe plaque psoriasis.	x				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 Chronic myeloid leukemia (CML).				x		x	x	x
Biological	Adjuvant used in prophylactic and therapeutic vaccines.	x					x		
Biological	Treatment of systemic Juvenile Idiopathic Arthritis (sJIA).	x						x	
Biological	Treatment of Polyarticular-course Juvenile Idiopathic Arthritis (pcJIA).	x						x	
Chemical	Treatment of myelodysplastic syndromes.	x						x	
Chemical	Treatment of brain metastases from non-small cell lung cancer (NSCLC).	x						x	
Biological	Treatment of emphysema.				x	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 and prophylaxis of bleeding in hemophilia A.				x			x	x
Chemical	Prevention of the risk of Stroke/Systemic Embolic Events (SEE) in patients with Atrial Fibrillation (AF) and acute treatment and long-term prevention of venous thromboembolism (VTE).			x		x			
Biological	Treatment of haemophilia A or B in patients with inhibitors to Factor VIII or Factor IX.			x		x			
Chemical	Treatment of Chronic thromboembolic pulmonary hypertension (CTEPH).		x					x	
Chemical	Reduction of aneurysm growth rate.	x						x	
Chemical	Treatment of haemodynamic insufficiency in newborn infants.	x					x	x	
Chemical	Radio-imaging and delineation of lymphatic vessels/nodes.	x						x	
Chemical	Treatment of Alopecia Universalis.				x		x		
Chemical	Treatment of short-term and intermittent long-term therapy of flares of moderate to severe atopic dermatitis and as maintenance therapy for the prevention of flares.	x					x	x	
Chemical	Treatment of nosocomial pneumonia.	x						x	
Chemical	Treatment of community acquired pneumonia.	x					x	x	
Chemical	Treatment of complicated skin and skin structure infections.	x						x	
Chemical	Treatment of chronic HCV 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				
Advanced therapy	Treatment of non union fractures.	x				x	x	x	
Chemical	Treatment of cancer-related cachexia.			x			x	x	
Biological	Treatment of Alzheimer's disease.			x		x			
Biological	Treatment of disability and maintenance of function in multifocal motor neuropathy (MMN).	x						x	
Chemical	Adjunctive therapy in Parkinson's disease.	x				x	x	x	
Chemical	Intended for intravenous contrast-enhanced computed tomography (CECT) for visualisation of normal and abnormal structures.	x					x	x	
Chemical	Treatment of anorexia/cachexia in patients with cancer.	x				x	x	x	
Biomarker	Quantitative disease progression model applicable for the design of Alzheimer's Disease.	x						x	
Biomarker	Patient-reported outcome instrument for patients with gastro-oesophageal reflux disease (GORD).	x						x	
Biological	Prophylactic treatment of IgE mediated poly-food allergy patients.	x						x	

SA: scientific advice

PA: protocol assistance

The above-mentioned 23 Scientific Advice letters, 3 Protocol Assistance letter, 6 Follow-up Scientific Advice, 4 Follow-up Protocol Assistance letters, 1 HTA parallel advice letters and 2 Qualification of novel methodologies letters were adopted at the 16 – 19 January 2012 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 3 – 5 January 2012. The new requests are divided as follows: 15 Initial Scientific Advice, 10 Follow-up Scientific Advice, 5 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 0 HTA parallel advice and 3 Qualification of novel methodologies.