



20 April 2012  
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Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 16-19 April 2012

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

	1995 - 2011	2012	Overall total
Scientific Advice	1627	76	1703
Follow-up to Scientific Advice	400	31	431
Protocol Assistance	342	17	359
Follow-up to Protocol Assistance	162	12	174
HTA parallel advice	8	2	10
Qualification of novel methodologies	14	9	23
	<b>2553</b>	<b>147</b>	<b>2700</b>

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

### ***Outcome of the April 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.			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	Reduction of LDL-C level in circulation.			x			x	x	
Chemical	Treatment of Wilson's disease.				x		x	x	x
Chemical	Treatment of hormone-naïve metastatic prostate cancer.	x						x	
Chemical	Treatment of primary IgA nephropathy.	x					x	x	
Biological	Treatment of Progressive Multifocal Leukoencephalopathy (PML) caused by Polyomavirus JC (JCV).	x						x	
Chemical	Treatment of advanced ovarian cancer, AIDS related Kaposi's sarcoma, metastatic breast cancer and progressive multiple myeloma.	x					x	x	
Chemical	Treatment of HER2 negative lymph node-positive early stage breast cancer.	x				x	x	x	
Biological	Treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, moderate to severe plaque psoriasis.			x		x	x	x	
Chemical	Treatment of lung cancer.	x						x	
Biological	Treatment of pulmonary metastasizing renal cell carcinoma.		x			x	x	x	x
Chemical	First line treatment extensive-stage small-cell lung cancer (ES-SCLC).	x					x	x	
Biological	Prevention of ischaemia reperfusion injury associated with solid organ transplantation.		x					x	
Biological	Reduction in the duration of neutropenia and the incidence of febrile neutropenia.	x						x	
Biological	Treatment of various solid tumours.			x		x			

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	First line treatment of MET-positive locally advanced or metastatic gastric, lower esophageal, or gastroesophageal junction adenocarcinoma.	x					x	x	
Chemical	Treatment of prostate carcinoma.			x				x	
Biological	Treatment of haemophilia A or B.			x				x	
Advanced therapy/ Other innovative	Treatment of chronic critical limb ischemia.	x				x	x	x	
Chemical	Treatment of HIV-1 infection.	x				x	x	x	
Chemical	Substitution therapy for treatment of human immunodeficiency virus-1 (HIV-1) infection.	x				x	x	x	
Biological	Treatment of osteoporosis.	x				x	x	x	
Chemical	Treatment of severe chronic pain.	x						x	
Chemical	Treatment of Familial Amyloid Polyneuropathy (FAP).	x					x	x	
Chemical	Treatment of insomnia.	x						x	
Chemical	Treatment of peripheral neuropathic pain.			x				x	
Chemical	Treatment of Alzheimer's disease.			x				x	
Chemical	Treatment of epilepsy.	x					x	x	
Chemical	Treatment of chronic obstructive pulmonary disorder.			x				x	
Chemical	Treatment of chronic obstructive pulmonary disorder.	x				x			
Chemical	Regular treatment of asthma and symptomatic treatment of COPD in adults.	x						x	
Chemical	Regular treatment of asthma and symptomatic treatment of COPD in children.	x						x	
Chemical/ Other innovative	Treatment of active severe vernal keratoconjunctivitis with severe keratitis.				x			x	
Biological	Treatment of growth hormone deficiency.	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	Substitutive therapy in hypothyroidism.	x					x		
Qualification of novel methodology	Assess brain amyloid plaque burden in subjects with mild to moderate Alzheimer's disease.	x						x	
Qualification of novel methodology	Assess impact of brain amyloid removal on the rate of brain atrophy in subjects with mild to moderate Alzheimer's disease.	x						x	
Qualification of novel methodology	Assess impact of brain amyloid removal on downstream disease pathological processes that reflect neurodegeneration in subjects with mild to moderate Alzheimer's disease.	x						x	

**SA: scientific advice**  
**PA: protocol assistance**

The above-mentioned 22 Scientific Advice letters, 2 Protocol Assistance letter, 9 Follow-up Scientific Advice, 2 Follow-up Protocol Assistance letters, 0 HTA parallel advice letters and 3 Qualification of novel methodologies letters were adopted at the 16 – 19 April 2012 CHMP meeting.

### **New requests for scientific advice procedures**

The Committee accepted 36 new Requests for which the procedure started at the SAWP meeting held on 26 – 28 March 2012. The new requests are divided as follows: 16 Initial Scientific Advice, 10 Follow-up Scientific Advice, 6 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 1 HTA parallel advice and 1 Qualification of novel methodologies.