



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 17 - 20 September 2012

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

	1995 - 2011	2012	Overall total
Scientific Advice	1627	151	1778
Follow-up to Scientific Advice	400	75	475
Protocol Assistance	342	36	378
Follow-up to Protocol Assistance	162	20	182
HTA parallel advice	8	5	13
Qualification of novel methodologies	14	11	25
	<b>2553</b>	<b>298</b>	<b>2851</b>

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

### ***Outcome of the September 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	Prevention of nausea and vomiting associated with chemotherapy.			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 low HER2-expressing metastatic breast cancer.	x						x			
Chemical	Treatment of rheumatoid arthritis.	x				x	x	x			
Chemical	Treatment of unresectable malignant pleural mesothelioma.	x					x	x			
Biological	Reduction in the duration of severe neutropenia and the incidence of febrile neutropenia.			x		x	x	x			
Chemical	Treatment of thyroid cancer.	x					x	x			
Advanced therapy	Treatment of haemophilia B.		x					x			
Biological	Treatment of emphysema secondary to congenital AAT deficiency.				x			x			
Advanced therapy	Treatment of various haematological malignancies (AML, ALL, CML, HD, MDS).				x			x	x		
Biological	Reduction of elevated cholesterol and lipoprotein levels.	x						x			
Chemical	Treatment of abdominal aortic aneurysm.	x						x			
Chemical	Treatment of complicated skin and soft tissue infections.	x					x	x			
Biological	Prevention of herpes zoster.			x				x			
Chemical	Treatment of HIV-1.	x				x	x	x			
Chemical	Treatment of hyperuricemia in patients with gout.	x				x	x	x			
Biological	Treatment of lateral canthal lines.	x				x	x	x			
Chemical	Treatment of major depressive episodes.			x				x			
Chemical	Treatment of major depressive disorder.			x				x			
Biological	Treatment of sporadic inclusion body myositis.	x					x	x			
Chemical	Treatment of PGTC seizures in IGE.	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 partial onset seizures in epilepsy.			x		x			
Chemical	Treatment of cognitive impairment in Down syndrome.			x			x		
Chemical	Treatment of cognitive impairment in Down syndrome.	x						x	
Biological	Treatment of COPD and severe asthma.	x					x	x	
Chemical / Biological	Treatment of cystic fibrosis.		x			x			
Biological	Treatment of visual impairment due to choroidal neovascularisation or macular edema.	x						x	
Biological	Treatment of visual impairment due to choroidal neovascularization or macular edema in children.	x						x	
Chemical	Detection of loss of functional dopaminergic neurons in adult patients with clinically uncertain Parkinsonian Syndromes.	x					x	x	
Chemical	For use with ultrasound imaging to enhance the echogenicity of the blood.	x						x	
Biological	Treatment of human growth hormone deficiency.			x			x		
Advanced therapy	Treatment of acute myeloid leukaemia.		x			x	x	x	
Biological	Treatment of chronic anaemia in children.	x					x		
HTA	Treatment of heart failure.	x				x		x	

**SA: scientific advice**

**PA: protocol assistance**

The above-mentioned 19 Scientific Advice letters, 3 Protocol Assistance letter, 8 Follow-up Scientific Advice, 2 Follow-up Protocol Assistance letters, 1 HTA parallel advice letters and 0 Qualification of novel methodologies letters were adopted at the 17 – 20 September 2012 CHMP meeting.

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

The Committee accepted 39 new Requests for which the procedure started at the SAWP meeting held on 22 - 24 August 2012. The new requests are divided as follows: 22 Initial Scientific Advice, 8 Follow-up Scientific Advice, 5 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 2 HTA parallel advice and 0 Qualification of novel methodologies.