



15 November 2012  
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Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 12 – 15 November 2012

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

	1995 - 2011	2012	Overall total
Scientific Advice	1627	197	1824
Follow-up to Scientific Advice	400	91	491
Protocol Assistance	342	46	388
Follow-up to Protocol Assistance	162	25	187
HTA parallel advice	8	8	16
Qualification of novel methodologies	14	14	28
	<b>2553</b>	<b>382</b>	<b>2935</b>

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

### ***Outcome of the November 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/Other innovative	Prevention of post-operative nausea and vomiting.	x					x	x	
Chemical	Treatment of type II diabetes mellitus.			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 type II diabetes mellitus.			x				x	
Chemical	Treatment of type II diabetes mellitus.	x					x	x	
Chemical	Treatment of alkaptonuria.	x						x	
Chemical	Treatment of multiple myeloma.		x					x	
Chemical	Treatment of hepatocellular carcinoma.	x				x	x	x	
Chemical	Treatment of advanced breast cancer.	x					x	x	
Chemical	Treatment of advanced/metastatic soft tissue sarcoma.	x						x	
Chemical	Treatment of pancreatic cancer.		x			x	x		
Biological	Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia and rheumatoid arthritis.			x		x		x	
Biological	Treatment of multiple myeloma.				x			x	
Biological	Treatment of moderate to severe rheumatoid arthritis.	x				x	x	x	
Chemical	Treatment of pancreatic cancer.		x					x	x
Chemical	Treatment of metastatic breast cancer.			x				x	
Chemical	Treatment of non-metastatic castrate resistant prostate cancer.	x					x	x	
Chemical	Treatment of hormone-sensitive prostate cancer with bone metastases.	x					x	x	
Chemical	Treatment of secondary progressive multiple sclerosis.			x				x	
Chemical	Prevention of atherothrombotic events in adult patients with acute ischaemic stroke or TIA.	x						x	

  

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Advanced	Treatment of refractory	x				x	x	x	

	Intended indications(s)	Type of request				Topic			
therapy	angina.								
Chemical	Treatment of plaque psoriasis.	x				x	x	x	
Chemical	Treatment of non-CF bronchiectasis patients with respiratory bacterial pathogens.			x				x	
Biological	Vaccine for infants against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and Haemophilus influenzae type b.	x				x			
Biological	Active immunization against invasive disease, pneumonia and otitis media caused by Streptococcus pneumoniae.	x				x	x		
Chemical	Treatment of overactive bladder syndrome.	x					x	x	
Chemical	Treatment of overactive bladder.	x					x	x	
Chemical	Treatment of nicotine or cocaine addictions.	x						x	
Chemical/Other innovative	Treatment of major depression.	x				x	x	x	
Chemical	Treatment of severe chronic pain.			x				x	
Chemical	Treatment of schizophrenia.	x				x	x	x	
Chemical	Treatment of Alzheimer's disease.	x						x	
Chemical	Treatment of multiple sclerosis.	x						x	
Chemical	Treatment of idiopathic Parkinson's disease.	x						x	
Chemical	Treatment of spinal muscular atrophy.			x				x	x
Chemical	Treatment of cystic fibrosis.					x		x	x
Chemical	Treatment of Chronic obstructive pulmonary disease.	x				x	x	x	

Substance	Intended indications(s)	Type of request				Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		New		Follow-up					
		SA	PA	SA	PA				
Chemical	Treatment of inflammation of the mucosa of the mouth and throat.	x				x		x	
Chemical/Biological	Treatment for cystic fibrosis.		x					x	
Chemical	Sentinel lymph node	x					x	x	

	Intended indications(s)	Type of request					Topic		
	mapping.								
Chemical/Other innovative	Treatment of acute hyperkalemia.	x					x	x	
Biomarker	Prediction of risk of developing Mild cognitive impairment due to Alzheimer's disease.	x						x	
HTA	Treatment of major depressive disorder	x						x	
HTA	Treatment of malignant pleural mesothelioma.	x						x	
HTA	Treatment of metastatic or locally advanced unresectable pancreatic adenocarcinoma.	x					x	x	

**SA: scientific advice**

**PA: protocol assistance**

The above-mentioned 26 Scientific Advice letters, 5 Protocol Assistance letter, 7 Follow-up Scientific Advice, 2 Follow-up Protocol Assistance letters, 3 HTA parallel advice letters and 1 Qualification of novel methodologies letters were adopted at the 12 – 15 November 2012 CHMP meeting.

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

The Committee accepted 45 new Requests for which the procedure started at the SAWP meeting held on 22 – 24 October 2012. The new requests are divided as follows: 24 Initial Scientific Advice, 6 Follow-up Scientific Advice, 8 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 0 HTA parallel advice and 0 Qualification of novel methodologies.