



21 February 2013  
EMA/CHMP/SAWP/78103/2013  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 18 – 21 February 2013

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

	1995 - 2012	2013	Overall total
Scientific Advice	1848	41	1889
Follow-up to Scientific Advice	496	14	510
Protocol Assistance	396	10	406
Follow-up to Protocol Assistance	189	6	195
HTA parallel advice	16	1	17
Qualification of novel methodologies	28	2	30
	<b>2973</b>	<b>74</b>	<b>3047</b>

FDA Parallel Scientific Advice	2006 - 2012	2013	Overall total
Completed	19	0	19

### ***Outcome of the February 2013 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	Treatment of Fabry disease.	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 of diabetes mellitus.	x				x	x	x	
Biological	Treatment of multiple myeloma.	x					x	x	
Chemical/ Other innovative	Treatment of acute myeloid leukemia.		x			x		x	
Biological	Treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis and paediatric plaque psoriasis.	x				x		x	
Chemical	Treatment of Crohn's disease.	x						x	
Chemical	Treatment of malignant pleural mesothelioma and non-small cell lung cancer.	x				x			
Chemical	Treatment of neuroblastoma.		x				x		
Chemical	Treatment of thyroid cancer.			x				x	
Biological	Treatment of bleeding episodes in congenital haemophilia.		x			x	x	x	
Biological	Treatment of acute ischaemic stroke.	x				x	x		
Biological	Treatment of congenital hypotransferrinaemia.		x					x	
Biological	Treatment of bleeding episodes in haemophilia A.		x					x	x
Biological	Prophylaxis and treatment of bleeding in hemophilia A.			x		x		x	
Biological	Treatment of haemophilia A or B.				x			x	
Chemical	PET myocardial perfusion imaging for detecting coronary artery disease.	x				x		x	
Chemical	Treatment of impetigo.	x				x	x	x	
Other innovative	Prevention and treatment of infected diabetic foot ulcers.			x				x	
Chemical	Treatment of complicated urinary tract infections.	x						x	
Chemical	Treatment of Community Acquired Bacterial Pneumonia.			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 complicated skin and skin structure infections caused by Staphylococcus aureus or Streptococcus pyogenes.			x				x	
Chemical	Treatment of Community Acquired Bacterial Pneumonia.	x				x			
Biological	Intended for assisted reproductive technologies or treatment of infertility.	x				x	x	x	
Chemical	Treatment of renal tubular acidosis.	x				x	x	x	
Chemical	Treatment of cystinuria.	x				x	x	x	
Chemical	Treatment of postmenopausal osteoporosis.			x				x	
Chemical	Treatment of major depressive disorder.	x				x	x	x	
Chemical	Treatment of cystic fibrosis.		x				x	x	
Biological	Chronic treatment of idiopathic pulmonary fibrosis.	x					x	x	
Chemical	Treatment for endogenous Cushing's syndrome.		x			x	x	x	
Biological	Treatment of growth hormone deficiency.	x				x	x	x	
Chemical	Treatment of acromegaly.		x			x	x	x	
Chemical	Delay of renal disease progression in type 2 diabetes mellitus and nephropathy.			x			x	x	
Biomarker	A predictive biomarker for IL-13 activity in order to select high risk asthma patients.	x						x	
HTA	Treatment of Chronic Obstructive Pulmonary Disease (COPD).	x					x	x	

**SA: scientific advice**

**PA: protocol assistance**

The above-mentioned 18 Scientific Advice letters, 8 Protocol Assistance letters, 7 Follow-up Scientific Advice, 1 Follow-up Protocol Assistance letters, 1 HTA parallel advice letters and 1 Qualification of novel methodologies letters were adopted at the 18 – 21 February 2013 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 28 – 31 January 2013. The new requests are divided as follows: 21 Initial Scientific Advice, 6 Follow-up Scientific Advice, 4 Initial Protocol Assistance, 3 Follow-up Protocol Assistance, 1 HTA parallel advice and 1 Qualification of novel methodologies.