



20 February 2014  
EMA/CHMP/SAWP/105255/2014  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 17 – 20 February 2014

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

	1995 - 2013	2014	Overall total
Scientific Advice	2091	49	2140
Follow-up to Scientific Advice	594	11	605
Protocol Assistance	460	5	465
Follow-up to Protocol Assistance	236	8	244
HTA parallel advice	23	0	23
Qualification of novel methodologies	43	0	43
	<b>3447</b>	<b>73</b>	<b>3520</b>

FDA Parallel Scientific Advice	2006 - 2013	2014	Overall total
Completed	22	0	22

### ***Outcome of the February 2014 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 1 diabetes mellitus.	x						x	
Chemical	Treatment of gastrointestinal symptoms associated with carcinoid syndrome.				x			x	



Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical/ Other innovative	Treatment of moderate to severe allergic rhinoconjunctivitis to birch pollen.	x				x	x	x	
Chemical	Treatment of non-metastatic castration-resistant prostate cancer.	x				x			
Biological	Treatment of multiple myeloma.				x			x	
Biological	Treatment of multiple myeloma.		x			x			
Biological	Treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, moderate to severe plaque psoriasis.	x				x	x	x	
Biological	Prevention of cardiovascular events.	x						x	
Chemical	Treatment of follicular lymphoma and small lymphocytic lymphoma.		x					x	x
Chemical	Treatment acute myeloid leukaemia.				x			x	
Biological	Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia and rheumatoid arthritis.			x				x	
Chemical	Treatment of adjuvant pancreatic cancer.	x						x	
Chemical	Treatment of gastrointestinal stromal tumour, metastatic renal cell carcinoma and pancreatic neuroendocrine tumours.	x				x			
Chemical	Treatment of NSCLC brain metastases.			x				x	
Biological	Treatment of emphysema secondary to congenital AAT deficiency.				x	x		x	
Chemical	Reduction of risk of cardiovascular events including death, myocardial infarction and stroke.			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 haemophilia A and B.	x					x	x	
Biological	Treatment of neutropenia.	x				x	x	x	
Biological	Treatment of hyperlipidaemia.			x		x		x	
Advanced therapy/ Other innovative	Treatment of post-acute myocardial infarction.	x				x		x	
Chemical	Treatment of venous leg ulcers.	x				x	x	x	
Chemical	Treatment of influenza infection type A and B.	x					x	x	
Biological	Prevention of ventilator-associated <i>S aureus</i> pneumonia.	x						x	
Biological	Treatment of adult T-cell leukaemia.	x					x	x	
Biological	Treatment of lateral canthal lines.			x				x	
Chemical	Treatment of cognitive impairment associated with schizophrenia and symptomatic treatment of mild to moderately severe Alzheimer's dementia.	x				x			
Chemical	Treatment of severe chronic pain.			x				x	
Chemical	Treatment of major depressive disorder.	x					x	x	
Chemical	Treatment of Fragile X syndrome.				x			x	
Chemical	Treatment of pain in patients with primary erythromelalgia.	x					x	x	
Chemical/ Other innovative	Treatment of chronic obstructive pulmonary disease.	x					x	x	
Chemical	Treatment of asthma and COPD.	x						x	
Biological	Treatment of asthma.	x				x	x	x	
Chemical	Treatment of atopic keratoconjunctivitis.				x			x	
Chemical	Treatment of the wet age-related macular degeneration.			x				x	
Biological	Treatment of dry eye disease.	x					x	x	
Biological	Treatment of allergic conjunctivitis.	x						x	
Biological	Treatment of oesophageal cancer.				x			x	

**SA: Scientific Advice**  
**PA: Protocol Assistance**

The above-mentioned 22 Scientific Advice letters, 2 Protocol Assistance letters, 7 Follow-up Scientific Advice, 7 Follow-up Protocol Assistance letters, 0 HTA parallel advice letters and 0 Qualification of novel methodologies letters were adopted at the 17 – 20 February 2014 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 3 – 6 January 2014. The new requests are divided as follows: 27 Initial Scientific Advice, 10 Follow-up Scientific Advice, 1 Initial Protocol Assistance, 0 Follow-up Protocol Assistance, 1 HTA parallel advice and 6 Qualification of novel methodologies.