



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

24 October 2013  
EMA/CHMP/SAWP/657916/2013  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 21 – 24 October 2013

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

	1995 - 2012	2013	Overall total
Scientific Advice	1848	199	2047
Follow-up to Scientific Advice	496	75	571
Protocol Assistance	396	51	447
Follow-up to Protocol Assistance	189	28	217
HTA parallel advice	16	2	18
Qualification of novel methodologies	28	12	40
	<b>2973</b>	<b>367</b>	<b>3340</b>

FDA Parallel Scientific Advice	2006 - 2012	2013	Overall total
Completed	19	3	22

### ***Outcome of the October 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 hypophosphatasia.		x					x	
Chemical	Treatment of renal disease.	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 ulcerative colitis.	x				x	x	x	
Chemical	Treatment of Fabry disease.		x				x	x	
Biological	Treatment of osteoarthritis.	x				x	x	x	
Chemical	Treatment of chronic plaque psoriasis.	x						x	
Biological	Treatment of colorectal, breast, lung and renal cell cancer.			x		x	x	x	
Chemical	Treatment of follicular lymphoma.	x						x	
Advanced therapy	Treatment of graft-versus-host disease.		x			x	x	x	
Biological	Treatment of ALL.				x	x			
Chemical	Treatment of melanoma.	x						x	
Chemical	Treatment of CRPC.	x				x	x	x	
Chemical	Treatment of breast cancer.			x				x	
Chemical	Treatment of anaplastic large-cell lymphoma.	x						x	
Biological	Prevention of group C meningococcal infection.	x				x	x	x	
Biological	Treatment of arterial ischemic stroke.	x					x	x	
Chemical	Treatment of hypertension.			x				x	
Chemical	Treatment of HCV infection.	x					x		
Biological	Prophylaxis of influenza.	x				x		x	
Chemical	Treatment of bacteremia, hospital-acquired bacterial pneumonia, and ventilator-associated bacterial pneumonia.	x						x	
Chemical	Prevention of HIV-1 transmission.			x				x	
Biological	Prophylaxis of diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and <i>Haemophilus influenzae</i> type b.	x				x		x	
Biological	Prophylaxis of influenza.	x						x	
Chemical	Prevention of CMV viremia and/or 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				
Chemical	Prevention of CMV viremia and/or disease.		x				x		
Biological	Prophylaxis of seasonal influenza.	x				x	x	x	
Biological	Prophylaxis of seasonal influenza.	x					x	x	
Chemical	Treatment of uterine fibroids.	x					x	x	
Biological	Treatment of infertility and deficient spermatogenesis.	x				x		x	
Chemical	Treatment of pain.	x				x	x	x	
Chemical	Treatment of acute sensorineural hearing loss.				x	x	x	x	
Chemical	Treatment of Alzheimer's disease.	x						x	
Chemical	Treatment of cognitive impairment associated with schizophrenia.	x					x	x	
Chemical	Treatment of multiple sclerosis.	x					x	x	
Chemical	Treatment of opioid dependence.	x				x	x	x	
Chemical	Treatment of convulsive seizures.	x				x		x	
Biological	Treatment of neuromyelitis optica.	x					x	x	
Chemical	Treatment of 5q Spinal Muscular Atrophy.				x	x	x	x	
Chemical	Treatment of autism spectrum disorders.			x			x		
Chemical	Treatment of asthma and COPD.			x				x	
Chemical/Biological	Treatment of asthma.	x					x	x	
Chemical	Treatment of COPD.			x				x	
Chemical	Treatment of COPD.	x					x		
Chemical	Treatment of wet age-related macular degeneration.	x				x	x	x	
Biological	Treatment of chronic non-infectious uveitis.				x		x	x	
Biological	Treatment of chronic non-infectious uveitis.		x			x			
Chemical	Treatment of dry age-related macular degeneration.	x					x	x	
Chemical	Treatment of severe hypoglycaemia.	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				
Chemical	Treatment of Cushing's disease.	x					x	x	
Chemical	Treatment of chronic iron overload in patients with transfusion-dependent anaemia.				x			x	

**SA: Scientific Advice**

**PA: Protocol Assistance**

The above-mentioned 32 Scientific Advice letters, 6 Protocol Assistance letters, 7 Follow-up Scientific Advice, 5 Follow-up Protocol Assistance letters, 0 HTA parallel advice letters and 0 Qualification of novel methodologies letters were adopted at the 21 – 24 October 2013 CHMP meeting.

### New requests for scientific advice procedures

The Committee accepted 51 new Requests for which the procedure started at the SAWP meeting held on 30 September – 3 November 2013. The new requests are divided as follows: 28 Initial Scientific Advice, 14 Follow-up Scientific Advice, 3 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 1 HTA parallel advice and 0 Qualification of novel methodologies.