



18 October 2012  
EMA/CHMP/SAWP/667462/2012  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 15 - 18 October 2012

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

	1995 - 2011	2012	Overall total
Scientific Advice	1627	171	1798
Follow-up to Scientific Advice	400	84	484
Protocol Assistance	342	41	383
Follow-up to Protocol Assistance	162	23	185
HTA parallel advice	8	5	13
Qualification of novel methodologies	14	13	27
	<b>2553</b>	<b>337</b>	<b>2890</b>

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

### **Outcome of the October 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				
Biological	Treatment of arthritis, Crohn's disease, psoriasis, ankylosing spondylitis.			x		x	x	x	
Biological	Treatment of moderate to severe rheumatoid arthritis.	x				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						
Biological	Treatment of melanoma.	x						x	
Chemical	Treatment of multiple myeloma.				x			x	
Chemical	Treatment of (Ph+) acute lymphoblastic leukaemia.		x			x		x	
Chemical	Treatment of chronic myeloid leukaemia.		x			x		x	
Chemical/ Other innovative	Treatment of lung cancer (SCLC and NSCLC).	x				x			
Biological	Treatment of paroxysmal nocturnal haemoglobinuria.				x			x	
Biological	Treatment of HER2-Met+ gastroesophageal cancer.	x						x	
Chemical	Treatment of hepatocellular carcinoma.		x					x	
Biological	Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukemia and rheumatoid arthritis.			x			x	x	
Chemical	Treatment of ovarian cancer.	x					x	x	
Chemical/ Other innovative	Treatment of hepatocellular carcinoma.				x		x		
Chemical	Prevention of colorectal cancer.	x						x	
Chemical	Treatment of anaemia due to chronic kidney disease.	x						x	
Chemical	Treatment of dyslipidaemia and primary hypercholesterolaemia.			x		x		x	
Chemical	Treatment of psoriasis and local inflammatory conditions.	x						x	
Advanced therapy	Treatment of chronic venous or arteriovenous leg ulcers.	x				x	x	x	
Chemical	Treatment of HIV infection.	x					x		
Biological	Prevention of herpes zoster.			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						
Biological	Broad advice on the D antigen of several vaccines.	x				x			
Chemical	Treatment of chronic hepatitis C infection.			x		x			
Chemical	Intended for contraception.	x				x	x	x	
Chemical	Treatment of overactive bladder syndrome.	x				x	x	x	
Chemical	Treatment of schizophrenia.	x					x	x	
Chemical	Treatment of behavioural symptoms of Fragile X syndrome.			x				x	
Biological	Intended for tobacco cessation.	x				x	x	x	
Chemical	Treatment of Parkinson's disease.			x		x	x	x	
Chemical	Treatment of chronic obstructive pulmonary disease.	x				x	x	x	
Biological	Treatment of Churg-Strauss syndrome.	x						x	
Biological	Treatment of asthma.	x					x		
Chemical	Treatment of corneal cystine crystals deposits in cystinosis.		x			x		x	x
Chemical	Treatment of ocular signs and symptoms of seasonal and perennial allergic conjunctivitis.	x				x	x	x	
Biological	Treatment of growth hormone deficiency, Turner Syndrome, chronic renal insufficiency, small for gestational age, Prader Willi syndrome.			x		x	x	x	
Biological	Prevention of bleeding in emergency situations and bleeding episodes.			x				x	
Biological	Prevention of bleeding in emergency situations and bleeding episodes.	x					x		
Chemical	Treatment of mercury poisoning.		x				x	x	x
Biomarker	Brain metastasis symptom and impact questionnaire.	x						x	
Biomarker	Companion diagnostic immunoassay.	x						x	

**SA: scientific advice**  
**PA: protocol assistance**

The above-mentioned 20 Scientific Advice letters, 5 Protocol Assistance letter, 9 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance letters, 0 HTA parallel advice letters and 2 Qualification of novel methodologies letters were adopted at the 15 – 18 October 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 24 – 26 September 2012. The new requests are divided as follows: 31 Initial Scientific Advice, 8 Follow-up Scientific Advice, 3 Initial Protocol Assistance, 1 Follow-up Protocol Assistance, 1 HTA parallel advice and 1 Qualification of novel methodologies.