



20 October 2011  
EMA/CHMP/SAWP/840907/2011  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 17-20 October 2011

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

	1995 - 2010	2011	Overall total
Scientific Advice	1368	217	1585
Follow-up to Scientific Advice	320	66	386
Protocol Assistance	297	35	332
Follow-up to Protocol Assistance	133	20	153
	<b>2118</b>	<b>338</b>	<b>2456</b>

FDA Parallel Scientific Advice	2006 - 2010	2011	Overall total
Completed	9	5	14
<b>Ongoing</b>	0	1	1
Foreseen	0	2	2
	<b>9</b>	<b>8</b>	<b>17</b>

### **Outcome of the October 2011 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	Biostaging in colon cancer.	x				x	x	x	
Advanced therapy	Treatment of acute alcoholic hepatitis.	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 chylomicronemia.	x					x	x	
Chemical	Treatment of cystinosis.		x			x	x	x	x
Chemical	Prevention of recurrence of diverticulitis.			x				x	
Chemical/ Other innovative	Treatment of inflammatory bowel disease.	x					x	x	
Biological	Treatment of anti-neutrophil cytoplasmic antibody associated vasculitis.	x					x	x	
Chemical	Treatment of non small cell lung cancer.	x						x	
Biological	Treatment of small cell lung cancer.	x						x	
Biological	Treatment of chronic lymphocytic leukaemia.		x			x	x	x	
Chemical	Treatment of metastatic breast cancer.	x				x	x	x	
Chemical	Treatment of myelodysplastic syndrome.	x						x	
Biological	Treatment of non-Hodgkin's lymphoma, and rheumatoid arthritis.			x				x	
Biological	Treatment of rheumatoid arthritis.			x			x		
Biological	Treatment of rheumatoid arthritis.			x				x	
Biological	Treatment of psoriatic arthritis.	x						x	
Biological	Treatment of HER2-overexpressing breast cancer and metastatic gastric cancer.	x				x	x	x	
Biological/ Chemical	Treatment of gastric cancer.	x						x	
Chemical	Treatment of melanoma.	x					x	x	
Chemical	Treatment of mastocytosis.				x			x	
Biological	Treatment of haemophilia.	x					x	x	
Biological	Treatment and prophylaxis of bleeding in haemophilia B.	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 atherothrombotic events.	x						x	
Chemical	Prevention of cardiovascular mortality & morbidity.	x						x	
Chemical	Treatment of mixed dyslipidaemia.	x						x	
Chemical	Elimination of nasal colonization in carriers of methicillin sensitive and resistant Staphylococcus aureus.			x				x	
Chemical	Treatment of congenital ichthyosis.	x					x	x	
Biological	Prevention of congenital CMV infection.	x						x	
Chemical	Reduction of acute exacerbations in non-CF bronchiectasis.	x				x	x	x	
Chemical	Treatment of nosocomial pneumonia.	x						x	
Biological	Prevention of zoster and related post-herpetic neuralgia.			x				x	
Biological	Prevention of zoster and related post-herpetic neuralgia.	x				x	x		
Chemical	Treatment of chronic HCV infection.			x				x	
Chemical	Treatment of chronic HCV infection.	x				x			
Chemical	Treatment of chronic HCV infection.			x				x	
Chemical	Treatment of amyotrophic lateral sclerosis.		x			x	x	x	
Chemical	Maintenance treatment of schizophrenia.			x			x	x	
Chemical	Treatment of excessive daytime sleepiness.				x		x	x	x
Advanced therapy	Treatment of Parkinson's disease.	x				x			
Chemical	Treatment of Fragile X Syndrome.		x				x	x	
Chemical	Treatment of chronic obstructive pulmonary disease.	x						x	
Biological	Treatment of severe asthma.			x				x	
Chemical	Treatment of cystic fibrosis.				x			x	
Biological	Treatment of neurotrophic keratitis.	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 acromegaly.	x				x	x	x	
Biological	Broad quality advice on replacement of culture and indicator cell culture method.	x				x			
Chemical	Treatment of chronic plaque psoriasis.	x					x		

**SA: scientific advice**

**PA: protocol assistance**

The above-mentioned 30 Scientific Advice letters, 4 Protocol Assistance letter, 10 Follow-up Scientific Advice and 3 Follow-up Protocol Assistance letters were adopted at the 17 – 20 October 2011 CHMP meeting.

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

The Committee accepted 40 new Requests for which the procedure started at the SAWP meeting held on 26 – 29 September 2011. The new requests are divided as follows: 23 Initial Scientific Advice, 10 Follow-up Scientific Advice, 2 Initial Protocol Assistance and 5 Follow-up Protocol Assistance.