



23 October 2014  
EMA/CHMP/SAWP/659072/2014  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 20 – 23 October 2014

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

	1995 - 2013	2014	Overall total
Scientific Advice	2091	234	2325
Follow-up to Scientific Advice	594	87	681
Protocol Assistance	460	43	503
Follow-up to Protocol Assistance	236	32	268
HTA parallel advice	23	7	30
Qualification of novel methodologies	43	15	58
	<b>3447</b>	<b>418</b>	<b>3865</b>

FDA Parallel Scientific Advice	2006 - 2013	2014	Overall total
Completed	22	2	24

### ***Outcome of the October 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	Induction of remission of pouchitis.		x					x	
Chemical	Treatment of type 2 diabetes mellitus.			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 type 1 diabetes mellitus.	x					x	x	
Biological	Treatment of ulcerative colitis.	x				x		x	
Chemical	Rectal evacuation.	x				x	x	x	
Biological	Treatment of ulcerative colitis.			x		x		x	
Chemical	Treatment of gastroparesis.	x					x	x	
Biological	Treatment of systemic lupus erythematosus.	x				x	x	x	
Chemical	Treatment of myelodysplastic syndromes, chronic myelomonocytic leukaemia, acute myeloid leukaemia.	x				x		x	
Chemical	Treatment of breast cancer.	x				x			
Biological	Treatment of glioblastoma, metastatic colorectal cancer, non-small cell lung cancer, metastatic kidney cancer	x						x	
Biological	Treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer, non-small cell lung cancer and metastatic renal cell cancer.	x				x	x	x	
Chemical/Biological	Treatment of Hodgkin's lymphoma.				x			x	
Chemical/Biological	Treatment of T-cell lymphoma.			x				x	
Biological	Treatment of neutropenia.	x				x	x	x	
Biological	Treatment of metastatic colorectal cancer and squamous cell carcinoma of the head and neck.	x				x	x	x	
Advanced therapy	Treatment of prostate cancer.			x		x		x	
Advanced therapy	Treatment of malignant glioma.		x					x	x
Chemical	Treatment of castrate resistant prostate cancer.			x			x		
Chemical	Prevention of acute rejection of liver and renal transplant.	x						x	
Chemical	Treatment of oncology indications.	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 angioimmunoblastic-T-cell lymphoma.	x						x	
Chemical	Treatment of mastocytosis.				x		x	x	
Chemical	Treatment of Sjogren's syndrome.	x						x	
Chemical	Treatment of ovarian cancer.				x			x	
Biological	Treatment of systemic lupus erythematosus.	x				x		x	
Biological	Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis and granulomatosis with polyangiitis and microscopic polyangiitis.	x				x	x	x	
Chemical	Treatment of non-small cell lung cancer.			x		x		x	
Chemical	Treatment of non-small cell lung cancer.	x						x	
Chemical	Treatment of deep vein thrombosis and secondary prevention of venous thromboembolism.			x				x	
Biological	Treatment of haemophilia.	x				x			
Chemical	Reduction of major adverse cardiovascular events.	x				x			
Chemical	Prevention of HIV-1 transmission.			x				x	
Biological	Prevention of dengue fever.	x				x	x	x	
Biological	Prevention of gastro-enteritis.			x		x		x	
Biological	Prevention of acute otitis media and pneumonia.			x				x	
Chemical	Treatment of pre-term labour.			x			x	x	
Chemical	Treatment of absence seizures.			x		x		x	
Chemical/ Biological	Treatment of Alzheimer's disease.	x					x	x	
Chemical	Treatment of Parkinson's disease.	x				x	x	x	
Chemical	Treatment of schizophrenia.			x			x		
Chemical	Treatment of asthma and COPD.			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 asthma and COPD.	x				x	x	x	
Chemical	Treatment of cystic fibrosis.	x					x	x	
Chemical	Prevention of scarring post glaucoma filtration surgery.		x			x	x	x	
Chemical	Treatment of neovascular age-related macular degeneration.	x					x		
Chemical	Treatment of multiple sclerosis.	x				x	x	x	
Chemical/ Other innovative	Treatment of rheumatoid arthritis.	x				x	x	x	
Biological	Treatment of growth hormone deficiency.		x				x	x	
Biological	Reversal of anticoagulation due to fXa inhibitors in emergency situations.			x				x	
Biological	Treatment of Ebola.	x				x		x	
HTA Parallel advice	Treatment of Niemann-Pick A and B.	x						x	

**SA: Scientific Advice**

**PA: Protocol Assistance**

The above-mentioned 29 Scientific Advice letters, 4 Protocol Assistance letters, 15 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance letters, 1 HTA parallel advice letters and 0 Qualification of novel methodologies letters were adopted at the 20 – 23 October 2014 CHMP meeting.

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

The Committee accepted 57 new Requests for which the procedure started at the SAWP meeting held on 6 – 9 October 2014. The new requests are divided as follows: 28 Initial Scientific Advice, 12 Follow-up Scientific Advice, 12 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 3 HTA parallel advice and 0 Qualification of novel methodologies.