



26 June 2014  
EMA/CHMP/SAWP/382409/2014  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 23 – 26 June 2014

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

	1995 - 2013	2014	Overall total
Scientific Advice	2091	139	2230
Follow-up to Scientific Advice	594	51	645
Protocol Assistance	460	24	484
Follow-up to Protocol Assistance	236	20	256
HTA parallel advice	23	4	27
Qualification of novel methodologies	43	12	55
	<b>3447</b>	<b>250</b>	<b>3697</b>

FDA Parallel Scientific Advice	2006 - 2013	2014	Overall total
Completed	22	1	23

### ***Outcome of the June 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 eosinophilic oesophagitis.		x				x	x	
Advanced therapy	Treatment of acute liver failure.		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				
Biological	Treatment of Crohn's disease.	x					x	x	
Biological	Treatment of type 2 diabetes mellitus.			x				x	
Biological	Treatment of diabetes.	x				x	x	x	
Biological	Treatment of systemic lupus erythematosus.			x				x	
Chemical	Treatment of myelodysplastic syndromes, chronic myelomonocytic leukaemia and acute myeloid leukaemia.	x				x		x	
Chemical	Treatment of rheumatoid arthritis.	x				x			
Chemical	Treatment of non-small cell lung cancer.	x				x	x	x	
Biological	Treatment of plaque psoriasis.			x				x	
Biological	Treatment of acute lymphoblastic leukaemia.				x	x	x	x	
Biological	Treatment of rheumatoid arthritis, adult Crohn's disease, paediatric Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis.	x				x	x	x	
Chemical	Treatment of multiple myeloma.		x					x	
Biological	Treatment of urothelial bladder cancer.	x						x	
Chemical	Treatment of acute myelogenous leukaemia.				x			x	
Biological	Treatment of hairy cell leukaemia.		x			x			
Biological	Reduction in the duration of severe neutropenia and incidence of febrile neutropenia.			x		x	x	x	
Chemical	Treatment of acute myeloid leukaemia.	x					x	x	
Biological	Treatment of non-Hodgkin's lymphoma and rheumatoid arthritis.			x		x	x	x	
Chemical	Treatment of secondary progressive multiple sclerosis.			x				x	
Chemical	Treatment of African trypanosomiasis.			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 acute coronary syndrome.	x				x	x	x	
Advanced therapy	Treatment of glioblastoma.		x					x	
Biological	Treatment of sickle cell disease.				x			x	
Biological	Treatment and prophylaxis of bleeding in haemophilia B.		x			x	x	x	
Biological	Treatment of indolent B-cell lymphoma.	x					x		
Chemical	Treatment of anaemia associated with chronic kidney disease.	x				x			
Advanced therapy	Treatment of transfusion-dependent beta-thalassemia.	x						x	
Chemical	Treatment of essential hypertension.	x				x		x	
Chemical	Treatment of vasopressor-dependent septic shock.	x					x	x	
Chemical	Treatment of acne vulgaris.	x				x	x	x	
Chemical	Treatment of HIV-1 infection.	x					x	x	
Chemical	Treatment HIV-1 infection.	x						x	
Chemical	Treatment of HIV-1 infection.	x					x	x	
Chemical	Treatment of HIV-1 infection.			x		x		x	
Biological/ Other innovative	Foot and ankle fusion procedures requiring supplemental graft material.	x				x	x	x	
Chemical	Treatment of acute sensorineural hearing loss.				x			x	
Chemical	Treatment of neonatal seizures.	x						x	
Biological	Treatment of prodromal Alzheimer's disease.			x			x	x	
Chemical	Treatment of uremic pruritus.	x					x	x	
Biological	Treatment of chronic obstructive pulmonary disease.	x						x	
Biological	Treatment of neovascular (wet) age-related macular degeneration.			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 visual impairment due to diabetic macular oedema.			x				x	
Biological	Treatment of visual impairment due to retinal vein occlusion.			x				x	
Chemical	Treatment of nocturia.	x				x	x	x	
Chemical	Treatment of acromegaly.				x	x			
Chemical	Treatment of symptoms associated with neuroendocrine tumours.			x				x	
Chemical	Treatment of HCV infection.	x					x	x	
Biomarker	Tuberculosis	x						x	
Biomarker	Dried blood spot test	x						x	
Biomarker	Alzheimer's disease	x						x	
Biomarker	Database for identifying entry in clinical trials	x						x	

**SA: Scientific Advice**

**PA: Protocol Assistance**

The above-mentioned 24 Scientific Advice letters, 6 Protocol Assistance letters, 13 Follow-up Scientific Advice, 5 Follow-up Protocol Assistance letters, 0 HTA parallel advice letters and 4 Qualification of novel methodologies letters were adopted at the 23 – 26 June 2014 CHMP meeting.

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

The Committee accepted 54 new Requests for which the procedure started at the SAWP meeting held on 2 – 5 June 2014. The new requests are divided as follows: 30 Initial Scientific Advice, 8 Follow-up Scientific Advice, 7 Initial Protocol Assistance, 8 Follow-up Protocol Assistance, 1 HTA parallel advice and 0 Qualification of novel methodologies.