



27 February 2015  
EMA/CHMP/SAWP/139113/20155  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 23 – 26 February 2015

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

	1995 - 2014	2015	Overall total
Scientific Advice	2653	52	2705
Follow-up to Scientific Advice	758	15	773
Protocol Assistance	566	19	585
Follow-up to Protocol Assistance	267	9	276
HTA parallel advice	34	1	35
Qualification of novel methodologies	60	1	61
	<b>4338</b>	<b>97</b>	<b>4435</b>

FDA Parallel Scientific Advice	2006 - 2014	2015	Overall total
Completed	26	0	26

### ***Outcome of the February 2015 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 Prader-Willi syndrome.		x			x	x	x	
Chemical	Treatment of nausea and vomiting.	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 liver failure.				x			x	
Chemical	Treatment of Crigler-Najjar syndrome.		x				x	x	
Chemical	Treatment of type II diabetes.	x						x	
Chemical	Treatment of type II diabetes.	x					x	x	
Chemical	Treatment of neuroblastoma.	x				x	x	x	
Biological	Treatment of breast cancer, NSCLC, RCC and ovarian cancer.			x				x	
Biological	Treatment of breast cancer.			x		x			
Biological	Treatment of atopic dermatitis.	x				x			
Biological	Treatment of paroxysmal nocturnal haemoglobinuria.	x					x	x	
Biological	Treatment of Guillian-Barre syndrome.	x						x	
Biological	Treatment of chronic myelomonocytic leukemia.	x					x	x	
Biological	Treatment of bladder cancer.	x						x	
Chemical	Treatment of metastatic colorectal cancer.			x				x	
Chemical	Treatment of asthma.			x			x	x	
Biological	Treatment of non-Hodgkin's lymphoma.	x						x	
Chemical	Treatment of trypanosomiasis.		x					x	
Chemical	Treatment of pyruvate kinase deficiency.	x					x	x	
Biological	Treatment of rejection in kidney transplant.	x					x	x	
Chemical	Treatment of anaemia.			x				x	
Chemical	Treatment of cerebral vasospasm.				x			x	
Chemical	Treatment of Ebola virus disease.	x					x	x	
Chemical	Treatment of pulmonary arterial hypertension.	x						x	
Chemical	Treatment of atopic dermatitis.	x				x	x	x	
Chemical	Treatment of pemphigus.	x					x	x	x
Chemical	Treatment of diabetic foot ulcers.	x				x		x	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Other innovative	Treatment of cystic fibrosis.		x			x	x	x	x
Chemical	Treatment of acute haematogenous osteomyelitis.								
Biological	Prevention of dengue disease.	x				x			
Chemical	Treatment of hepatitis C virus.	x				x			
Chemical	Treatment of HIV-1.			x				x	
Chemical	Treatment of carbapenem-resistant infections.	x					x	x	
Other innovative	Treatment of hospital-acquired and ventilator-associated bacterial pneumonia.	x						x	
Other innovative	Treatment of acute bacterial skin and skin structure infections.	x				x	x	x	
	Treatment of overactive bladder.			x				x	
Other innovative	Treatment of sarcopenia.	x						x	
	Treatment of Duchenne muscular dystrophy.		x					x	
Biological	Treatment of rheumatoid arthritis.	x					x	x	
Biological	Treatment of Alzheimer's disease.	x				x	x	x	
Chemical	Treatment of schizophrenia.	x						x	
Chemical	Treatment of seizures in epilepsy.	x						x	
Chemical	Induction of general anaesthesia.			x		x	x	x	
Chemical	Treatment of spinal muscular atrophy.	x				x	x	x	
Chemical	Treatment of spinal muscular atrophy.	x				x	x	x	
Chemical	Treatment of Alzheimer's dementia.	x				x			
Chemical	Treatment of asthma.			x				x	
Chemical	Treatment of cystic fibrosis.		x					x	
Biological	Treatment of wet macular degeneration.	x				x			
Chemical	Keratoplasty.	x						x	
Chemical	Treatment of Stargardt's disease.		x			x	x	x	x
Chemical	Treatment of mastocytosis.				x			x	
Biological	Treatment of mastocytosis.	x				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				
Qualification advice	Skeletal muscle injury.	x						x	
HTA parallel advice	Treatment of prostate cancer.	x						x	

**SA: Scientific Advice**

**PA: Protocol Assistance**

The above-mentioned 31 Scientific Advice letters, 10 Protocol Assistance letters, 9 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance letters, 1 HTA parallel advice letters and 1 Qualification of novel methodologies letters were adopted at the 23 – 26 February 2015 CHMP meeting.

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

The Committee accepted 49 new Requests for which the procedure started at the SAWP meeting held on 2 – 5 February 2015. The new requests are divided as follows: 23 Initial Scientific Advice, 7 Follow-up Scientific Advice, 7 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 6 HTA parallel advices and 1 Qualification of novel methodologies.