



28 April 2016  
EMA/CHMP/SAWP/304744/2016  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 25 – 28 April 2016

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

	1995 - 2015	2016	Overall total
Scientific Advice	2899	97	2996
Follow-up to Scientific Advice	846	27	873
Protocol Assistance	662	23	685
Follow-up to Protocol Assistance	310	14	324
HTA parallel advice	63	5	68
Qualification of novel methodologies	83	6	89
	<b>4863</b>	<b>172</b>	<b>5035</b>

### ***Outcome of the April 2016 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	Prevention of nausea and vomiting.	x						x	
Biological	Treatment of intestinal malabsorption.	x						x	
Chemical	Treatment of type 2 diabetes mellitus.	x				x			
Chemical/ Other innovative	Treatment of acute hyperammonaemia.	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 breast cancer, non-small cell lung cancer, renal cell carcinoma and ovarian cancer.	x				x	x	x	
Chemical/ Biological	Treatment B-cell lymphoma.	x						x	
Advanced therapy	Treatment of diffuse large B-cell lymphoma.	x				x	x	x	
Advanced therapy	Treatment of acute lymphoblastic leukaemia.		x			x	x	x	
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile idiopathic arthritis, plaque psoriasis, ankylosing spondylitis.			x		x			
Chemical	Treatment of biliary tract cancer.		x					x	
Biological/ Other innovative	Prophylaxis of organ rejection.	x					x	x	
Biological	Treatment of acute myeloid leukaemia.		x			x			
Chemical	Treatment of myelofibrosis.	x					x		
Chemical	Treatment of non-small cell lung cancer.	x						x	
Biological	Treatment of severe eosinophilic asthma, COPD, EGPA, HES.	x				x	x	x	
Chemical	Treatment of colorectal cancer.	x						x	
Advanced therapy	Treatment of soft tissue sarcoma.	x						x	
Biological	Reduction in incidence of febrile neutropenia.			x		x	x	x	
Chemical	Treatment of castration-resistant prostate cancer.	x					x	x	
Biological	Treatment of diffuse cutaneous systemic sclerosis.	x					x	x	
Chemical	Prophylaxis of transplant rejection and treatment of allograft rejection.	x				x			
Biological	Treatment of rheumatoid arthritis.	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				
Chemical	Intravenous nutrition.	x				x			
Advanced therapy	Treatment of ischemic chronic cardiomyopathy.	x				x	x	x	
Biological	Treatment of atopic dermatitis.	x				x		x	
Chemical	Treatment of HIV-1.			x				x	
Chemical	Prevention of HIV-1 infection.			x		x			
Biological	Treatment of Ebola virus.			x		x		x	
Chemical	Treatment of invasive aspergillosis.	x						x	
Chemical	Purge of HIV reservoir.	x					x	x	
Chemical	Prophylaxis of GVH disease.	x					x	x	
Chemical	Treatment of Dravet syndrome.				x	x			
Advanced therapy	Treatment of metachromatic leukodystrophy.				x		x		
Advanced therapy	Treatment of metachromatic leukodystrophy.		x			x			
Chemical	Treatment of spinal cord injury.		x			x	x	x	
Chemical	Treatment of Parkinson's disease.	x						x	
Chemical	Treatment of schizophrenia.	x					x	x	
Chemical	Treatment of symptomatic TTR cardiomyopathy.	x						x	
Chemical	Treatment of asthma.	x				x		x	
Biological	Treatment of nasal polyps.	x					x	x	
Advanced therapy/ Other innovative	Treatment of retinitis pigmentosa.	x					x		
Biological	Treatment of achondroplasia.		x			x	x	x	
Qualification opinion	Treatment of epilepsy.	x							
Qualification advice	Treatment of epilepsy.	x							
Qualification advice	Treatment of epilepsy.	x							
Qualification advice	Treatment of epilepsy.	x							
HTA parallel advice	Treatment of soft tissue sarcoma.	x				x		x	
HTA parallel advice	Treatment of non-Hodgkins' lymphoma.	x						x	

**SA: Scientific Advice**

**PA: Protocol Assistance**

The above-mentioned 29 Scientific Advice letters, 6 Protocol Assistance letters, 5 Follow-up Scientific Advice, 2 Follow-up Protocol Assistance letters, 2 HTA parallel advice letters and 4 Qualifications of novel methodologies letters were adopted at the 25 - 28 April 2016 CHMP meeting.

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

The Committee accepted 59 new Requests for which the procedure started at the SAWP meeting held on 11 – 14 April 2016. The new requests are divided as follows: 40 Initial Scientific Advice, 6 Follow-up Scientific Advice, 8 Initial Protocol Assistance, 4 Follow-up Protocol Assistance, 1 HTA parallel advices and 0 Qualifications of novel methodologies.