

23 March 2017  
EMA/CHMP/SAWP/206041/2017  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 20 – 23 March 2017

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

	1995 - 2015	2017	Overall total
Scientific Advice	3215	86	3301
Follow-up to Scientific Advice	938	30	968
Protocol Assistance	735	29	764
Follow-up to Protocol Assistance	355	11	366
HTA parallel advice	87	5	92
Qualification of novel methodologies	94	5	99
	<b>5424</b>	<b>166</b>	<b>5590</b>

### ***Outcome of the March 2017 CHMP meeting in relation to scientific advice procedures***

#### **Final scientific advice procedures**

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Advanced therapy	Treatment of Gaucher disease.		x			x	x	x	x
Chemical	Treatment of metabolic diseases including hyperphagia and food-related behavior in Prader-Willi syndrome.	x					x	x	
Chemical/ Other innovative	Treatment of acute liver failure.		x				x	x	

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of diabetes mellitus.			x		x	x	x	
Advanced therapy	Treatment of ornithine transcarbamylase deficiency.	x				x	x	x	
Chemical	Treatment of obesity and hyperphagia.		x			x	x	x	
Chemical	Treatment of rheumatoid arthritis.			x				x	
Chemical	Treatment of rheumatoid arthritis.	x				x			
Chemical	Treatment of breast cancer.	x					x	x	
Chemical	Treatment of breast cancer.	x					x	x	
Chemical	Treatment of castration resistant prostate cancer.			x		x			
Chemical/Other innovative	Treatment of malignant mesothelioma.		x			x	x	x	
Biological	Treatment of soft tissue sarcoma.		x			x	x		
Advanced therapy	Treatment of soft tissue sarcoma.		x			x	x		
Biological	Treatment of renal cell carcinoma.	x						x	
Biological	Treatment of multiple myeloma.		x			x	x	x	
Chemical	Treatment of sickle cell disease.		x			x	x	x	
Advanced therapy	Treatment of synovial sarcoma.		x			x			
Biological	Reduction in incidence of febrile neutropenia.			x				x	
Biological	Treatment of adenocarcinoma of the esophagus and Siewert type 1 adenocarcinoma of the esophagogastric junction.	x						x	
Biological	Treatment of gastric cancer.	x						x	
Chemical	Treatment of tenosynovial giant cell tumour.				x		x	x	
Chemical	Treatment of tenosynovial giant cell tumour.				x	x			
Biological	Treatment of melanoma.	x				x	x	x	
Chemical	Treatment of acute myeloid leukaemia and malignant pleural mesothelioma.		x			x			
Biological	Treatment of paroxysmal nocturnal haemoglobinuria.				x	x	x	x	x
Chemical	Treatment of Langerhans' cell histiocytosis.		x			x	x	x	x

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Treatment of active lupus nephritis.	x				x	x	x	
Biological/ Advanced therapy	Treatment of periventricular leukomalacia.		x					x	
Biological	Treatment of homozygous familial hypercholesterolemia.	x					x	x	
Chemical	Treatment of myotonic disorders.	x					x	x	
Chemical	Treatment of obstructive hypertrophic cardiomyopathy.	x				x	x	x	
Advanced therapy	Treatment of critical limb ischemia.	x				x	x		
Biological	Treatment of community-acquired pneumonia.	x				x	x	x	
Chemical/ Other innovative	Prevention of sternal wound infections.	x				x	x	x	
Chemical	Treatment of hepatitis C.	x					x	x	
Chemical	Prevention of breast cancer.	x					x	x	
Advanced therapy	Treatment of glycogen storage disorder type II.	x					x		
Advanced therapy	Treatment of X-linked myotubular myopathy.	x					x		
Biological	Treatment of mild Alzheimer's disease.	x				x	x	x	
Chemical	Treatment of narcolepsy.		x				x	x	x
Chemical	Treatment of pantothenate kinase associated neurodegeneration.				x			x	
Chemical	Treatment of breast cancer.			x				x	
Chemical	Treatment of epithelial ovarian, fallopian tube or primary peritoneal cancer.		x			x			
Chemical	Treatment of pulmonary tuberculosis.				x		x		
Biological	Treatment of chronic obstructive pulmonary disease.	x				x	x	x	
Biological	Treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy.	x				x	x	x	

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Tumour control in neuroendocrine tumours of lung origin.	x						x	
Biological	Treatment of hypoparathyroidism.		x			x	x	x	
Biological	Treatment of eosinophilic oesophagitis.	x					x	x	
Qualification advice	Treatment of epilepsy.	x						x	
Qualification advice	Treatment of epilepsy.	x						x	
Qualification advice	Treatment of multiple sclerosis, hip fracture, sarcopenia.	x						x	
HTA parallel advice	Treatment of Crohn's disease	x				x	x	x	
HTA parallel advice	Treatment of ulcerative colitis.	x				x	x	x	
HTA parallel advice	Treatment of non-small cell lung cancer.	x						x	
HTA parallel advice	Treatment of active rheumatoid arthritis.	x						x	

**SA: Scientific Advice**

**PA: Protocol Assistance**

The above-mentioned 25 Scientific Advice letters, 14 Protocol Assistance letters, 6 Follow-up Scientific Advice, 5 Follow-up Protocol Assistance, 3 Qualifications of novel methodologies and 4 HTA Parallel advice, were adopted at the 20 – 23 March 2017 CHMP meeting.

## New requests for scientific advice procedures

The Committee accepted 53 new Requests for which the procedure started at the SAWP meeting held on 6 – 9 March 2017. The new requests are divided as follows: 30 Initial Scientific Advice, 8 Follow-up Scientific Advice, 10 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 2 HTA Parallel advices.