



23 February 2017  
EMA/CHMP/SAWP/135817/2017  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 20 – 23 February 2017

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

	1995 - 2015	2017	Overall total
Scientific Advice	3215	61	3276
Follow-up to Scientific Advice	938	24	962
Protocol Assistance	735	15	750
Follow-up to Protocol Assistance	355	6	361
HTA parallel advice	87	1	88
Qualification of novel methodologies	94	2	96
	<b>5424</b>	<b>109</b>	<b>5533</b>

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

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

Substance	Intended indication(s)	Type of request				Topic			Significant Benefit
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	
		SA	PA	SA	PA				
Chemical	Screening of colon cancer.	x				x	x	x	
Chemical	Pain management due to primary dysmenorrhoea.	x						x	
Biological	Treatment of diabetes mellitus.	x				x			
Chemical	Treatment of type 2 diabetes mellitus.			x			x	x	
Chemical	Treatment of type 2 diabetes mellitus.	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 acute myeloid leukaemia.	x				x	x	x	
Biological	Treatment of systemic lupus erythematosus.			x				x	
Biological	Treatment of breast cancer, non-small cell lung cancer, renal cell carcinoma and ovarian cancer.	x				x	x	x	
Chemical	Treatment of non-alcoholic steatohepatitis.	x					x	x	
Biological	Treatment of paroxysmal nocturnal haemoglobinuria atypical haemolytic uremic syndrome.			x		x		x	
Biological	Treatment of primary haemophagocytic lymphohistiocytosis.		x					x	
Chemical	Treatment of cholangiocarcinoma.		x			x	x	x	
Chemical	Treatment of metastatic castration-resistant prostate cancer.	x				x			
Biological	Desensitization of sensitized renal transplant patients.	x						x	
Biological	Treatment of myelodysplastic syndromes.	x						x	
Advanced therapy	Treatment of diffuse large B-cell lymphoma, primary mediastinal B-cell lymphoma and transformed follicular lymphoma.				x	x	x		
Advanced therapy	Treatment of Merkel cell carcinoma.	x						x	
Biological	Treatment of follicular lymphoma.	x						x	
Biological	Treatment of non-small cell lung cancer.	x						x	
Biological	Treatment of rheumatoid arthritis, chronic lymphocytic leukaemia and non-Hodgkin lymphoma.			x				x	
Biological	Treatment of haemophilia A.				x		x	x	
Biological	Treatment of emphysema in alpha1-proteinase inhibitor deficiency.			x				x	
Biological	Management of congenital haemophilia A.	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 haemophilia A.	x				x	x	x	
Chemical	Treatment of epidermolysis bullosa.				x		x	x	
Chemical	Treatment of atopic dermatitis.	x					x	x	
Chemical	Treatment of psoriasis.	x					x	x	
Chemical	Treatment of primary focal segmental glomerulosclerosis.		x					x	
Biological	Replacement therapy for primary immunodeficiency syndromes.	x				x		x	
Biological	Prophylaxis of influenza.	x				x	x	x	
Biological	Prevention of invasive <i>E. coli</i> disease.	x				x			
Biological	Prevention of invasive meningococcal disease caused by <i>N. meningitidis</i> .			x				x	
Biological	Prophylaxis of seasonal influenza.			x		x	x	x	
Chemical/ Other innovative	Treatment of glioma.			x		x	x	x	x
Biological/ Other innovative	Treatment of glioma.	x						x	
Chemical	Treatment of Dravet syndrome.	x				x	x	x	
Chemical	Treatment of amyotrophic lateral sclerosis.				x			x	x
Chemical	Treatment of type 1A Charcot-Marie-Tooth disease.		x				x	x	
Chemical	Treatment of schizophrenia.	x						x	
Chemical	Treatment of schizophrenia.			x			x	x	
Chemical	Treatment of schizophrenia.	x				x			
Chemical	Management of overweight and obesity in Prader-Willi syndrome.	x						x	
Chemical	Treatment of Alzheimer's disease.	x				x	x	x	
Chemical	Treatment of Leigh syndrome.		x			x	x	x	
Chemical	Treatment of amyotrophic lateral sclerosis.	x					x	x	
Chemical	Treatment of influenza A and B.	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 visual impairment due to diabetic macular oedema.			x				x	
Chemical/ Other innovative	Treatment of retinitis pigmentosa.		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	
Advanced therapy	Treatment of Usher syndrome.		x				x	x	
Biological	Treatment of osteoporosis.	x				x	x	x	

**SA: Scientific Advice**

**PA: Protocol Assistance**

The above-mentioned 29 Scientific Advice letters, 8 Protocol Assistance letters, 10 Follow-up Scientific Advice, 4 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 1 HTA Parallel advice, were adopted at the 20 – 23 February 2017 CHMP meeting.

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

The Committee accepted 42 new Requests for which the procedure started at the SAWP meeting held on 6 – 9 February 2017. The new requests are divided as follows: 21 Initial Scientific Advice, 6 Follow-up Scientific Advice, 8 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 2 HTA Parallel advices.