



22 June 2017  
EMA/CHMP/SAWP/395099/2017  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 19 – 22 June 2017

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

	1995 - 2016	2017	Overall total
Scientific Advice	3215	178	3393
Follow-up to Scientific Advice	938	62	1000
Protocol Assistance	735	51	786
Follow-up to Protocol Assistance	355	27	382
HTA parallel advice	87	14	101
Qualification of novel methodologies	94	11	105
	<b>5424</b>	<b>343</b>	<b>5767</b>

### ***Outcome of the June 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	Treatment of hyperammonemia due to isovaleric acidaemia.		x				x	x	
Chemical	Treatment hyperammonaemia due to methymalonic acidaemia.		x				x	x	
Chemical	Treatment of hyperammonaemia due to propionic acidaemia.		x				x	x	
Chemical	Treatment of type 2 diabetes mellitus.	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 cutaneous systemic sclerosis.		x					x	
Biological	Treatment of systemic lupus erythematosus.			x				x	
Biological	Treatment of systemic lupus erythematosus.	x					x		
Biological	Treatment of non-small cell lung cancer.	x					x		
Biological	Treatment of breast cancer, non-small cell lung cancer, renal cell carcinoma and ovarian cancer.			x				x	
Biological	Treatment of breast cancer, non-small cell lung cancer, renal cell carcinoma and ovarian cancer.			x		x	x	x	
Biological	Treatment of myasthenia gravis.				x		x	x	x
Chemical	Treatment of peripheral T-cell lymphoma.	x						x	
Biological	Treatment of smouldering multiple myeloma.				x			x	
Biological	Treatment of primary haemophagocytic lymphohistiocytosis.				x	x			
Chemical	Treatment of non-small cell lung cancer.	x						x	
Biological	Treatment of multiple myeloma.				x			x	
Biological	Treatment of multiple myeloma.				x	x		x	
Biological	Treatment of sepsis.	x					x	x	
Biological	Treatment of renal cell carcinoma.	x						x	
Biological	Treatment of head and neck squamous cell carcinoma.	x						x	
Biological	Treatment of breast cancer.	x					x	x	
Chemical	Treatment of myelodysplastic syndromes, chronic myelomonocytic leukaemia or low-blast acute myelogenous leukaemia.	x					x	x	
Biological	Treatment of non-small cell lung cancer.	x						x	
Chemical	Treatment of activated PI3Kd syndrome.			x		x			
Biological	Treatment of steroid-resistance acute graft-vs-host disease.				x		x	x	x
Biological	Treatment of endometrial cancer.	x					x	x	
Chemical	Treatment of breast cancer.			x				x	
Chemical	Treatment of breast cancer.			x		x			

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharma ceutical	Pre- clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Treatment of non-small cell lung cancer.			x				x	
Chemical	Treatment of breast carcinoma.	x					x	x	
Biological	Treatment of rheumatoid arthritis.	x				x			
Biological	Treatment of plasminogen deficiency.				x	x		x	x
Biological	Treatment of cold agglutinin disease.		x				x	x	
Biological	Treatment and prophylaxis of bleeding episodes in congenital haemophilia A and B.				x	x	x	x	
Chemical	Treatment of acute heart failure.	x					x	x	
Advanced therapy	Treatment of ischaemic stroke.	x				x	x	x	
Advanced therapy	Derma regeneration.	x				x		x	
Biological	Treatment of Ebola virus disease.			x			x	x	
Biological	Treatment of Ebola virus disease.	x					x	x	
Chemical	Treatment of chronic hepatitis B infection.	x					x	x	
Biological	Prevention of nosocomial pneumonia caused by S. aureus.			x				x	
Chemical	Treatment of Gram-negative bacterial infections.	x					x	x	
Chemical	Treatment of nosocomial infections due to P. aeruginosa.			x				x	
Chemical	Treatment of nosocomial infections due to P. aeruginosa.	x					x		
Chemical	Treatment of chronic hepatitis C infection.	x				x			
Biological	Prevention of seasonal influenza disease.			x		x		x	
Biological	Prevention of seasonal influenza disease.	x						x	
Biological	Broad advice on Hepatitis A.	x				x			
Chemical	Treatment of Clostridium difficile infection.			x				x	
Chemical	Treatment of Clostridium difficile infection.	x				x			
Chemical	Prevention of mobility-disability in age-related sarcopenia.	x						x	
Chemical	Treatment of McArdle disease.		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 McArdle disease.		x				x	x	
Chemical	Treatment of complement 3 glomerulopathy.	x						x	
Advanced therapy	Treatment of metachromatic leukodystrophy.				x		x	x	
Advanced therapy	Treatment of metachromatic leukodystrophy.				x	x			
Chemical	Treatment of treatment-resistant depression.	x						x	
Chemical	Treatment of major depressive episodes.	x						x	
Biological	Treatment of asthma.	x					x	x	
Biological	Treatment of asthma.			x			x	x	
Advanced therapy	Treatment of Leber's hereditary optic neuropathy.				x	x			
Biological	Treatment of peanut allergy.	x						x	
Chemical	Treatment of inorganic mercury toxicity.				x		x	x	x
HTA parallel advice	Treatment of castrate-resistant prostate cancer.	x						x	
HTA parallel advice	Treatment of Crohn's disease.	x					x	x	
HTA parallel advice	Treatment of ulcerative colitis.	x					x	x	
HTA parallel advice	Treatment of psoriasis.	x					x	x	
HTA parallel advice	Treatment of insomnia.	x						x	

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 32 Scientific Advice letters, 7 Protocol Assistance letters, 12 Follow-up Scientific Advice, 12 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 5 HTA Parallel advice, were adopted at the 19 – 22 June 2017 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 6 – 9 June 2017. The new requests are divided as follows: 30 Initial Scientific Advice, 14 Follow-up Scientific Advice, 8 Initial Protocol Assistance, 4 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 2 HTA Parallel advices.