



15 December 2016  
EMA/CHMP/SAWP/864003/2016  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 12 – 15 December 2016

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

	1995 - 2015	2016	Overall total
Scientific Advice	2899	317	3216
Follow-up to Scientific Advice	846	92	938
Protocol Assistance	662	73	735
Follow-up to Protocol Assistance	310	45	355
HTA parallel advice	63	22	85
Qualification of novel methodologies	83	11	94
	<b>4863</b>	<b>560</b>	<b>5423</b>

### ***Outcome of the December 2016 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				
Biological	Treatment of short bowel syndrome.	x						x	
Chemical	Treatment of non-alcoholic steatohepatitis.	x						x	
Chemical	Treatment of opioid-induced constipation.	x						x	
Chemical/ Other innovative	Treatment of acute sensorineural hearing loss.	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	Frontline treatment of acute myeloid leukaemia.		x			x			
Chemical	Treatment of acute ischaemic stroke or TIA.	x						x	
Biological	Treatment of anaemia.	x						x	
Biological	Treatment of acute graft-versus-host disease.		x				x	x	
Chemical/ Other innovative	Treatment of post-cardiac arrest syndrome.				x			x	
Chemical	Intermittent treatment of symptoms of uterine fibroids.	x				x			
Chemical	Intermittent treatment of symptoms of uterine fibroids.			x			x	x	
Biological	Prevention of retinopathy.				x	x			
Chemical	Treatment of acromegaly.				x			x	
Chemical	Treatment of infection due to aerobic Gram-negative bacteria.	x					x	x	
Chemical	Treatment of HIV-1 infection.	x				x			
Chemical	Treatment of serious bacterial infections, hospital acquired bacterial pneumonia and ventilator-associated bacterial pneumonia.			x		x			
Biological	Prevention of RSV-associated pneumonia.	x				x	x	x	
Chemical	Treatment of HIV-1 infection.			x		x			
Biological	Prevention of dengue virus disease.			x		x	x	x	
Biological	Treatment of active polyarticular juvenile idiopathic arthritis.	x					x	x	
Biological	Treatment of metastatic melanoma.			x				x	
Chemical/ Other innovative	Treatment of recurrent ovarian cancer.	x				x	x	x	
Chemical	Treatment of thyroid carcinoma.		x					x	
Chemical	Treatment of castration resistant prostate cancer.	x						x	
Chemical	Treatment of non-small cell lung cancer.			x				x	
Chemical	Treatment of breast cancer.			x				x	

Substance	Intended indication(s)	Type of request				Topic			Significant Benefit
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	
		SA	PA	SA	PA				
Chemical	Treatment of WHIM syndrome.	x					x	x	
Chemical	Treatment of chronic myeloid leukaemia.	x					x	x	
Chemical	Treatment of lymphoplasmacytic lymphoma, mantle cell lymphoma and chronic lymphocytic lymphoma.		x			x			
Biological	Treatment of ovarian, fallopian tube, or primary peritoneal cancer.	x					x	x	
Biological	Treatment of urothelial carcinoma.			x				x	
Chemical	Treatment of melanoma.			x		x			
Biological	Treatment of acute respiratory distress syndrome.		x			x			
Chemical	Treatment of multiple myeloma.				x			x	
Chemical	Treatment of breast cancer.			x				x	
Chemical	Treatment of postoperative pain and acute renal colic.	x					x	x	
Biological/Chemical	Treatment of Alzheimer's disease.	x						x	
Chemical	Treatment of type 2 and 3 spinal muscular atrophy.				x	x		x	
Chemical	Treatment of chronic obstructive pulmonary disease.	x				x		x	
Chemical	Treatment of asthma.	x				x		x	
Chemical	Treatment of neurotrophic keratitis.		x			x	x	x	
Biological	Treatment of chronic anterior uveitis.	x						x	
Biological	Treatment of thyroid eye disease.	x						x	
Biological	Treatment of neovascular (wet) age-related macular degeneration, visual impairment due to diabetic macular oedema, diabetic macular oedema and choroidal neovascularisation secondary to pathological myopia.	x				x	x	x	
Chemical	Treatment of cystic fibrosis.	x				x			
Biological	Broad advice on CMC.	x				x			
Biological	Treatment of peanut allergy.			x			x		
Chemical	Treatment of asthma.	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 light chain amyloidosis.				x			x	
Chemical	Reduction of elevated intra-ocular pressure.			x		x		x	
Biological	Treatment of neovascular (wet) age-related macular degeneration, visual impairment due to diabetic macular oedema and choroidal neovascularisation secondary to pathological myopia.			x				x	
Biological	Prevention of cytomegalovirus disease.				x	x			
Chemical	Treatment of diffuse intrinsic pontine glioma.	x					x	x	

**SA: Scientific Advice**  
**PA: Protocol Assistance**

The above-mentioned 27 Scientific Advice letters, 6 Protocol Assistance letters, 13 Follow-up Scientific Advice, 7 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 3 HTA Parallel advice, were adopted at the 12 – 15 December 2016 CHMP meeting.

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

The Committee accepted 60 new Requests for which the procedure started at the SAWP meeting held on 28 November – 1 December 2016. The new requests are divided as follows: 34 Initial Scientific Advice, 12 Follow-up Scientific Advice, 9 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 1 HTA Parallel advice.