



19 November 2015  
EMA/CHMP/SAWP/776856/2015  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 16 – 19 November 2015

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

	1995 - 2014	2015	Overall total
Scientific Advice	2653	226	2879
Follow-up to Scientific Advice	758	81	839
Protocol Assistance	566	90	656
Follow-up to Protocol Assistance	267	34	301
HTA parallel advice	34	28	62
Qualification of novel methodologies	60	19	79
	<b>4338</b>	<b>478</b>	<b>4816</b>

FDA Parallel Scientific Advice	2006 - 2014	2015	Overall total
Completed	26	3	29

### ***Outcome of the November 2015 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 type 2 diabetes mellitus.	x						x	
Biological	Treatment of Pompe disease.		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	Treatment of type 1 diabetes mellitus.			x				x	
Chemical	Treatment of irritable bowel syndrome with constipation.	x					x	x	
Chemical	Treatment of rheumatoid arthritis.	x					x	x	
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis.	x						x	
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis.			x		x	x	x	
Biological	Treatment of breast cancer, non-small cell lung cancer, renal cell carcinoma, ovarian cancer.	x				x	x	x	
Chemical	Broad advice on clinical trials.	x						x	
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile idiopathic arthritis, plaque psoriasis, ankylosing spondylitis.			x		x		x	
Chemical	Treatment of primary myelofibrosis.	x					x	x	
Chemical	Treatment of acute graft-versus-host disease.	x				x	x	x	
Chemical	Treatment of urothelial carcinoma.	x				x			
Biological/ Advanced therapy	Treatment of metastatic castrate resistant prostate cancer.			x		x			
Chemical	Treatment of thrombocytopenia.	x				x			
Biological	Treatment of haemophilia A.	x				x			
Chemical	Treatment of allergic reactions.	x						x	
Advanced therapy	Treatment of heart failure.			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 acute heart failure.	x						x	
Chemical	Treatment of african trypanosomiasis.	x					x	x	
Chemical	Treatment of HIV-1.	x				x	x	x	
Chemical	Treatment of <i>Clostridium difficile</i> infection.	x					x	x	
Chemical	Prevention of pregnancy.			x				x	
Biological	Treatment of chronic musculoskeletal pain.			x				x	
Chemical	Treatment of major depressive disorder.	x						x	
Chemical/ Other innovative	Treatment of major depressive disorder.			x		x			
Biological	Treatment of prodromal Alzheimer's disease and mild dementia.			x		x		x	
Advanced therapy	Treatment of haematological malignancies.			x				x	
Chemical	Treatment of subarachnoid haemorrhage.	x					x	x	
Chemical	Treatment of Huntington's disease.				x			x	
Chemical	Treatment of Huntington's disease.		x			x			
Chemical	Treatment of Alzheimer's dementia.			x			x		
Chemical	Treatment of asthma.	x						x	
Chemical	Treatment of acromegaly, gastroenteropancreatic neuroendocrine tumors, carcinoid syndrome.	x				x		x	
Biological	Treatment of growth hormone deficiency.				x			x	x
Chemical	Treatment of Prader-Willi syndrome.		x					x	x
Chemical	Treatment of Parkinson's disease.	x				x	x	x	
Chemical	Reversal of respiratory depression.	x					x	x	
Chemical	Detection of vesicoureteral reflux.	x						x	
Qualification advice	Treatment of functional dyspepsia.	x						x	
Qualification advice	Treatment of Parkinson's disease.	x						x	
Qualification advice	Treatment of autism spectrum disorder.	x						x	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Qualification advice	Treatment of autism spectrum disorder.	x						x	
Qualification advice	Treatment of autism spectrum disorder.	x						x	
Qualification advice	Treatment of autism spectrum disorder.	x						x	
Qualification advice	Treatment of autism spectrum disorder.	x							
HTA parallel advice	Treatment of hormone-sensitive prostate cancer.	x						x	
HTA parallel advice	Treatment of early Alzheimer's disease.	x						x	

**SA: Scientific Advice**

**PA: Protocol Assistance**

The above-mentioned 23 Scientific Advice letters, 3 Protocol Assistance letters, 11 Follow-up Scientific Advice, 2 Follow-up Protocol Assistance letters, 2 HTA parallel advice letters and 8 Qualifications of novel methodologies letters were adopted at the 16 – 19 November 2015 CHMP meeting.

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

The Committee accepted 47 new Requests for which the procedure started at the SAWP meeting held on 3 – 6 November 2015. The new requests are divided as follows: 22 Initial Scientific Advice, 8 Follow-up Scientific Advice, 5 Initial Protocol Assistance, 9 Follow-up Protocol Assistance, 2 HTA parallel advices and 1 Qualification of novel methodologies.