



22 October 2015
EMA/CHMP/SAWP/701884/2015
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 19 – 22 October 2015

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

	1995 - 2014	2015	Overall total
Scientific Advice	2653	203	2856
Follow-up to Scientific Advice	758	70	828
Protocol Assistance	566	87	653
Follow-up to Protocol Assistance	267	32	299
HTA parallel advice	34	26	60
Qualification of novel methodologies	60	12	72
	4338	430	4768

FDA Parallel Scientific Advice	2006 - 2014	2015	Overall total
Completed	26	2	28

Outcome of the October 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	Treatment of ulcerative colitis.				x		x	x	
Biological	Treatment of type 2 diabetes.	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 Pompe disease.		x			x			
Biological	Treatment of diabetes mellitus.			x				x	
Chemical	Treatment of irritable bowel syndrome.	x						x	
Biological	Treatment of paroxysmal nocturnal haemoglobinuria and atypical haemolytic uremic syndrome.	x				x	x	x	
Advanced therapy	Treatment of systemic sclerosis.		x			x	x	x	x
Biological	Treatment of gastric cancer.	x					x	x	
Biological	Treatment of bladder cancer.	x						x	
Biological	Treatment of renal cell carcinoma.	x						x	
Biological	Treatment of hereditary haemorrhagic telangiectasia.		x					x	
Biological	Treatment of psoriasis.	x				x	x	x	
Biological	Treatment of psoriatic arthritis.	x						x	
Biological	Treatment of breast cancer, non-small cell lung cancer, renal cell carcinoma and ovarian cancer.			x				x	
Advanced therapy	Treatment of mesothelioma.	x				x	x	x	
Chemical	Treatment of non-small cell lung cancer.	x						x	
Biological	Treatment of myasthenia gravis.		x			x	x	x	
Chemical	Treatment of colorectal carcinoma.	x						x	
Chemical	Treatment of non-small cell lung cancer.	x					x	x	
Chemical	Treatment of breast cancer.	x					x	x	
Chemical	Treatment of endometrial adenocarcinoma.	x				x		x	
Biological	Treatment of colorectal carcinoma.	x						x	
Chemical	Treatment of hepatocellular carcinoma .				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 rheumatoid arthritis, chronic lymphocytic leukaemia and non-Hodgkin lymphoma.			x		x		x	
Biological	Treatment of neuromyelitis optica.	x				x			
Advanced therapy	Treatment of haemophilia B.		x			x	x		
Advanced therapy	Treatment of metastatic melanoma.	x				x	x		
Chemical	Treatment of hepatitis C.	x				x			
Chemical	Treatment of HIV.	x					x	x	
Biological	Treatment of sporadic inclusion body myositis.		x			x			
Chemical	Postoperative analgesia.	x						x	
Chemical	Treatment of opioid drug dependence.	x				x	x	x	
Biological	Treatment of asthma.	x				x		x	
Advanced therapy	Treatment of choroideremia.		x			x	x	x	
Biological	Treatment of neurotrophic keratitis.	x				x		x	
Biological	Treatment of type 2 diabetes.	x					x	x	
Chemical	Treatment of severe hypoglycaemia.	x				x	x	x	
Chemical	treatment of acromegaly.	x				x	x	x	
Chemical	Treatment of acromegaly, gastroenteropancreatic neuroendocrine tumours, advanced neuroendocrine tumours and TSH-secreting adenomas.	x				x		x	
Qualification opinion	Prognostic imaging biomarker.	x						x	
Qualification advice	Neuropathic pain.	x						x	
HTA parallel advice	Treatment of rare tumors.	x						x	
HTA parallel advice	Treatment of multiple myeloma.	x						x	
HTA parallel advice	Treatment of retinitis pigmentosa.	x					x	x	
HTA parallel advice	Treatment of open-angle glaucoma and ocular hypertension.	x				x	x	x	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 27 Scientific Advice letters, 7 Protocol Assistance letters, 3 Follow-up Scientific Advice, 2 Follow-up Protocol Assistance letters, 4 HTA parallel advice letters and 2 Qualifications of novel methodologies letters were adopted at the 19 – 22 October 2015 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 49 new Requests for which the procedure started at the SAWP meeting held on 5 – 8 October 2015. The new requests are divided as follows: 23 Initial Scientific Advice, 9 Follow-up Scientific Advice, 3 Initial Protocol Assistance, 6 Follow-up Protocol Assistance, 1 HTA parallel advices and 7 Qualifications of novel methodologies.