



13 October 2016
EMA/CHMP/SAWP/681417/2016
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 10 – 13 October 2016

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

	1995 - 2015	2016	Overall total
Scientific Advice	2899	260	3159
Follow-up to Scientific Advice	846	69	915
Protocol Assistance	662	57	719
Follow-up to Protocol Assistance	310	35	345
HTA parallel advice	63	15	78
Qualification of novel methodologies	83	9	92
	4863	445	5308

Outcome of the October 2016 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 non-alcoholic steatohepatitis and non-alcoholic fatty liver disease.	x					x		
Biological	Treatment of breast cancer.	x					x	x	
Chemical	Treatment of Wilson disease.				x	x	x	x	
Biological	Treatment of giant cell arteritis.	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 cholangiocarcinoma.	x						x	
Chemical	Treatment of C3 glomerulopathy.		x				x	x	
Biological	Treatment of prostate cancer.	x						x	
Biological	Treatment of colon cancer.	x						x	
Biological	Treatment of ovarian cancer.			x				x	
Biological	Treatment of diffuse large B-cell lymphoma.	x						x	
Chemical	Treatment of chronic lymphocytic leukaemia.	x						x	
Chemical	Treatment of Waldenström's macroglobulinaemia.	x						x	
Chemical	Treatment of severe oral mucositis.	x					x	x	
Chemical/Biological	Treatment of multiple symmetric lipomatosis.		x				x	x	
Biological	Treatment of neutropenia.	x					x	x	
Chemical	Treatment of multiple sclerosis.	x						x	
Chemical	Treatment of glomerular sickle cell nephropathy.		x					x	
Biological	Treatment of multiple myeloma.				x			x	
Biological	Treatment of ovarian cancer.		x			x			
Biological	Treatment of ovarian cancer.		x				x	x	
Biological	Treatment of solid tumours.	x						x	
Biological	Treatment of rheumatoid arthritis, chronic lymphocytic leukaemia and non-Hodgkin lymphoma.			x		x	x	x	
Biological	Treatment of rheumatoid arthritis, chronic lymphocytic leukaemia and non-Hodgkin lymphoma.			x		x		x	
Chemical	Treatment of chronic graft vs host disease.	x						x	
Biological	Treatment of ankylosing spondylitis.	x						x	
Chemical	Treatment of activated PI3Kd syndrome.	x				x			
Chemical	Treatment of beta thalassaemia intermedia and major.		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 interstitial lung disease.	x						x	
Biological/ Advanced therapy	Treatment of metastatic melanoma.	x				x	x	x	
Biological/ Other innovative	Treatment of cervical squamous intraepithelial lesions.	x				x	x	x	
Biological	Treatment of paroxysmal nocturnal haemoglobinuria.	x				x	x	x	
Biological	Treatment of atypical haemolytic uremic syndrome.	x						x	
Biological	Treatment of alpha1-proteinase inhibitor deficiency.	x						x	
Advanced therapy	Treatment of haemophilia B.	x					x	x	
Biological	Treatment of plasminogen deficiency.		x			x	x	x	
Chemical	Treatment of acute coronary syndrome.	x						x	
Chemical	Treatment of pulmonary arterial hypertension.	x						x	
Chemical	Treatment of pulmonary arterial hypertension.	x					x	x	
Chemical	Delay of renal disease progression.	x				x	x		
Advanced therapy	Treatment of critical limb ischemia.			x		x		x	
Chemical	Treatment of urinary tract infections.			x				x	
Chemical/ Biological	Treatment of hospital acquired bacterial pneumonia.	x				x	x		
Chemical	Treatment of tuberculosis.	x				x		x	
Chemical	Treatment of serious bacterial infections.	x					x	x	
Chemical	Preservation or restoration of sexual function.			x			x	x	
Chemical	Treatment of osteoporosis.	x				x	x	x	
Chemical	Treatment of gout.	x						x	
Chemical	Treatment of Duchenne muscular dystrophy.				x			x	
Advanced therapy	Intended for faecal incontinence.	x						x	
Biological	Treatment of osteoporosis.	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 super-refractory status epilepticus.	x					x	x	
Chemical/Other innovative	Treatment of progressive supranuclear palsy.		x					x	
Chemical	Treatment of adrenoleukodystrophy.			x			x	x	
Chemical	Treatment of adrenoleukodystrophy.	x				x			
Chemical	Treatment of paediatric epilepsy.	x					x		
Biological	Treatment of asthma and chronic idiopathic urticaria.	x				x	x		
Chemical	Treatment of drug resistant pulmonary tuberculosis in adults.				x		x	x	x
Chemical	Treatment of drug resistant pulmonary tuberculosis.				x	x			
Chemical	Treatment of primary graft dysfunction.				x			x	
Chemical	Treatment of acanthamoeba keratitis.		x				x	x	
Chemical	Treatment of Leber's congenital amaurosis.		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	
Chemical	Intended for nocturia.			x		x		x	
Biological	Treatment of growth hormone deficiency.		x			x		x	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 38 Scientific Advice letters, 11 Protocol Assistance letters, 9 Follow-up Scientific Advice, 6 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 6 HTA Parallel advice, were adopted at the 10 - 13 October 2016 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 48 new Requests for which the procedure started at the SAWP meeting held on 26 – 29 September 2016. The new requests are divided as follows: 25 Initial Scientific Advice, 11 Follow-up Scientific Advice, 6 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 4 HTA Parallel advices.