



23 June 2016
EMA/CHMP/SAWP/436366/2016
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 20 – 23 June 2016

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

	1995 - 2015	2016	Overall total
Scientific Advice	2899	162	3061
Follow-up to Scientific Advice	846	41	887
Protocol Assistance	662	38	700
Follow-up to Protocol Assistance	310	23	333
HTA parallel advice	63	6	69
Qualification of novel methodologies	83	7	90
	4863	225	5088

Outcome of the June 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				
Biological	Treatment of hypophosphatasia.				x	x			
Other innovative	Treatment of Gaucher disease.		x					x	
Chemical	Treatment of type II diabetes mellitus.			x				x	
Chemical	Treatment of type II diabetes mellitus.	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 diabetes mellitus.	x				x	x	x	
Biological	Treatment of diabetes mellitus.	x				x	x	x	
Biological	Treatment of mucopolysaccharidosis type IIIA.	x				x	x	x	
Biological	Treatment of juvenile idiopathic arthritis and paediatric plaque psoriasis.	x				x		x	
Biological	Treatment of metastatic Merkel cell carcinoma.				x			x	
Biological	Treatment of paroxysmal nocturnal haemoglobinuria.	x					x	x	
Biological	Treatment of systemic lupus erythematosus.	x					x	x	
Biological	Treatment of systemic amyloid light-chain amyloidosis.	x						x	
Biological	Treatment of melanoma.	x				x		x	
Biological	Treatment of light chain amyloidosis.		x			x			
Chemical	Treatment of interstitial lung disease.	x					x	x	
Chemical/Biological	Treatment of ovarian cancer.	x						x	
Biological	Treatment of rheumatoid arthritis.			x				x	
Chemical	Treatment of breast cancer.			x				x	
Chemical	Treatment of liposarcoma.	x						x	
Chemical	Treatment of familial adenomatous polyposis.				x		x	x	
Chemical	Treatment of small cell lung cancer.	x						x	
Chemical	Treatment of acute myeloid leukaemia.		x					x	
Biological	Prevention of congenital cytomegalovirus infection.	x					x	x	
Chemical	Treatment of chronic pulmonary infection.			x			x	x	
Chemical	Treatment of chronic pulmonary infection.	x				x			

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Prevention of primary Clostridium difficile infection.	x				x	x	x	
Biological	Prophylaxis of seasonal influenza.			x				x	
Biological	Immunization against influenza disease.			x				x	
Advanced Therapy	Prophylaxis of bleeding in haemophilia B.		x			x	x	x	
Biological	Bleeding prophylaxis in haemophilia A.				x		x	x	
Biological	Bleeding prophylaxis in haemophilia A.				x	x			
Chemical	Treatment of bleeding prophylaxis in haemophilia A&B.		x			x	x	x	
Biological	Treatment of systemic sclerosis.		x				x	x	
Chemical	Treatment of hyperuricemia.	x				x		x	
Advanced Therapy	Treatment of articular cartilage defects of the knee.	x						x	
Chemical	Treatment of amyotrophic lateral sclerosis.				x			x	
Chemical	Prevention of first episode of psychosis in attenuated psychosis syndrome.	x					x	x	
Chemical	Prevention of first episode of psychosis in attenuated psychosis syndrome.	x					x	x	
Chemical	Treatment of Parkinson's disease.	x					x	x	
Chemical	Treatment of opioid use disorder.			x				x	
Chemical	Treatment of cognitive impairment associated with schizophrenia.	x						x	
Chemical	Treatment of type 1 spinal muscular atrophy.	x					x	x	
Chemical	Treatment of types 2&3 spinal muscular atrophy.	x					x	x	
Chemical	Treatment of uncontrolled asthma.			x				x	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Prevention of acute exacerbations in COPD.	x					x	x	
Chemical	Treatment of severe keratitis in dry eye disease.			x			x	x	
Chemical	Treatment of acanthamoeba keratitis.				x		x	x	
Biological	Treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion and diabetic macular edema.			x		x		x	
Biological	Treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion and diabetic macular edema.	x				x	x	x	
Biological	Treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion and diabetic macular edema.	x				x	x	x	
Biological	Treatment of growth hormone deficiency.				x			x	x
Biological	Treatment of chronic kidney disease.	x					x	x	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 29 Scientific Advice letters, 6 Protocol Assistance letters, 9 Follow-up Scientific Advice and 8 Follow-up Protocol Assistance letters were adopted at the 6 - 9 June 2016 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 38 new Requests for which the procedure started at the SAWP meeting held on 6 – 9 June 2016. The new requests are divided as follows: 24 Initial Scientific Advice, 6 Follow-up Scientific Advice, 4 Initial Protocol Assistance, 2 Follow-up Protocol Assistance and 2 Qualifications of novel methodologies.