



1 April 2016
EMA/CHMP/SAWP/236499/2016
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 29 March – 1 April 2016

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

	1995 - 2015	2016	Overall total
Scientific Advice	2899	68	2967
Follow-up to Scientific Advice	846	22	868
Protocol Assistance	662	17	679
Follow-up to Protocol Assistance	310	12	322
HTA parallel advice	63	3	66
Qualification of novel methodologies	83	2	85
	4863	124	4944

Outcome of the March 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 recurrent Clostridium difficile infection.	x				x	x	x	
Chemical	Treatment of hyperargininaemia.		x			x	x	x	x
Chemical	Treatment of argininosuccinic aciduria.		x			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				
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis.			x				x	
Biological	Treatment of small-cell lung cancer.	x						x	
Advanced therapy	Treatment of severe combined immunodeficiency due to adenosine deaminase deficiency.		x			x			
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile idiopathic arthritis, plaque psoriasis, ankylosing spondylitis.			x		x		x	
Chemical	Treatment of rheumatoid arthritis.			x		x		x	
Chemical	Prevention of recurrent painful vaso-occlusive crises in sickle cell disease.	x				x	x	x	
Chemical	Treatment of myelodysplastic syndrome.	x						x	
Chemical	Treatment of renal cell carcinoma.	x						x	
Chemical/Biological	Treatment of non-small cell lung cancer.	x					x	x	
Biological	Treatment of multiple sclerosis.			x				x	
Chemical	Treatment of neuroblastoma.		x				x	x	
Biological	Reduction of incidence of febrile neutropenia.	x				x	x	x	
Biological	Treatment of rheumatoid arthritis, chronic lymphocytic leukaemia, non-Hodgkin's lymphoma.			x				x	
Biological	Treatment of triple-negative breast cancer.	x					x	x	
Biological	Treatment of breast cancer.	x					x	x	
Chemical	Treatment of anaemia.	x					x		
Chemical	Treatment of anaemia.			x				x	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Advanced therapy	Treatment of pyruvate kinase deficiency.		x			x	x	x	
Chemical	Reduction of risk of cardiovascular death and heart failure events.	x					x	x	
Chemical	Treatment of actinic keratosis.	x				x	x	x	
Chemical	Treatment of hepatitis C.			x				x	
Chemical	Treatment of hepatitis C.			x		x			
Biological	Prevention of herpes zoster in adults.	x						x	
Chemical	Treatment of pain associated with interstitial cystitis/bladder pain syndrome.	x				x	x	x	
Chemical	Treatment of perinatal asphyxia.		x			x	x	x	
Chemical	Treatment of mild-to-moderate agitation in schizophrenia or bipolar disorder.	x						x	
Chemical	Treatment of moderate to severe acute pain.			x		x			
Chemical	Treatment of multiple sclerosis.			x				x	
Advanced therapy	Improvement in hematopoietic reconstitution.		x			x			
Chemical	Treatment of pantothenate kinase associated neurodegeneration.	x					x	x	
Biological	Prophylaxis of bleeding in haemophilia A.		x			x	x	x	x
Biological	Treatment of mucopolysaccharidosis VII.		x			x			
Chemical	Treatment of COPD.	x					x	x	
Chemical	Treatment of asthma.			x				x	
Chemical	Treatment of primary graft dysfunction following lung transplantation.		x					x	
Chemical	Treatment of TSH-secreting adenomas, acromegaly, advanced neuroendocrine tumours and gastroenteropancreatic neuroendocrine tumours.			x				x	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Prevention and treatment of postpartum haemorrhage.	x				x	x	x	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 18 Scientific Advice letters, 10 Protocol Assistance letters, 12 Follow-up Scientific Advice, 0 Follow-up Protocol Assistance letters, 1 HTA parallel advice letters and 0 Qualifications of novel methodologies letters were adopted at the 29 March – 1 April 2016 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 43 new Requests for which the procedure started at the SAWP meeting held on 14 – 17 March 2016. The new requests are divided as follows: 29 Initial Scientific Advice, 4 Follow-up Scientific Advice, 7 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 1 HTA parallel advices and 0 Qualifications of novel methodologies.