



21 May 2015
EMA/CHMP/SAWP/344744/20155
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 18 – 21 May 2015

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

	1995 - 2014	2015	Overall total
Scientific Advice	2653	108	2761
Follow-up to Scientific Advice	758	36	794
Protocol Assistance	566	51	617
Follow-up to Protocol Assistance	267	21	288
HTA parallel advice	34	10	44
Qualification of novel methodologies	60	5	65
	4338	231	4569

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

Outcome of the May 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 familial adenomatous polyposis.		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 II diabetes mellitus.			x				x	
Biological	Treatment of type I diabetes.	x				x	x	x	
Chemical	Treatment of chronic lymphocytic leukaemia.	x				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	
Advanced therapy	Treatment of Wiskott-Aldrich syndrome.		x			x	x	x	
Chemical/Biological	Treatment of multiple myeloma.		x			x	x	x	
Biological	Treatment of breast cancer.	x					x	x	
Chemical	Treatment of idiopathic pulmonary fibrosis.		x			x		x	
Biological/Other innovative	Treatment of non-small cell lung cancer.	x						x	
Chemical	Treatment of pancreatic cancer.		x				x	x	
Chemical	Treatment of haemophilia A.		x			x	x	x	x
Biological	Treatment of congenital FVII deficiency.		x				x	x	
Biological	Treatment of congenital haemophilia.		x					x	
Chemical	Treatment of mucopolysaccharidosis type I.		x				x	x	
Chemical	Treatment of familial amyloid cardiomyopathy.		x					x	x
Biological	Treatment of atopic dermatitis.			x				x	
Chemical	Treatment of seborrhic keratosis.	x				x	x	x	
Chemical	Treatment of diabetic foot ulcers.	x						x	
Chemical	Treatment of skin and soft tissue infections.	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 congenital ichthyosis.		x				x	x	
Chemical/Other innovative	Treatment of Gram-negative pneumonia.			x				x	
Chemical	Treatment of non-tuberculous mycobacterial lung disease.				x			x	
Chemical	Treatment of community-acquired pneumonia.			x				x	
Chemical	Treatment of acute bacterial skin and skin-structure infections.	x						x	
Chemical	Treatment of hypoactive sexual desire disorder.			x				x	
Chemical	Treatment of overactive bladder.	x				x			
Biological	Treatment of X-linked hypophosphataemia.		x			x			
Chemical	Treatment of Parkinson's disease.	x				x	x	x	
Chemical	Treatment of partial-onset seizures.	x						x	
Chemical	Treatment of tonic-clonic seizures.	x						x	
Chemical	Treatment of familial amyloidotic polyneuropathy.		x					x	
Chemical	Treatment of amyotrophic lateral sclerosis.				x			x	
Chemical	Treatment of asthma and COPD.			x				x	
Chemical	Treatment of Leber hereditary optic neuropathy.				x			x	
Chemical	Diagnosis of GH deficiency.			x		x	x	x	
Chemical	Prevention of oral mucositis.				x			x	
Biological	Treatment of chronic venous leg ulcers.	x						x	
Qualification advice	Treatment of dysmenorrhea.	x						x	
HTA parallel advice	Treatment of prostate cancer.	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 14 Scientific Advice letters, 13 Protocol Assistance letters, 8 Follow-up Scientific Advice, 4 Follow-up Protocol Assistance letters, 1 HTA parallel advice letter and 1 Qualification of novel methodologies letter were adopted at the 18 – 21 May 2015 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 55 new Requests for which the procedure started at the SAWP meeting held on 4 – 7 May 2015. The new requests are divided as follows: 29 Initial Scientific Advice, 5 Follow-up Scientific Advice, 10 Initial Protocol Assistance, 4 Follow-up Protocol Assistance, 6 HTA parallel advices and 1 Qualification of novel methodologies.