



21 September 2011
EMA/CHMP/SAWP/768314/2011
Press Office

Scientific advice and protocol assistance

Adopted during the CMHP meeting 19-22 September 2011

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

	1995 - 2010	2011	Overall total
Scientific Advice	1368	187	1555
Follow-up to Scientific Advice	320	56	376
Protocol Assistance	297	31	328
Follow-up to Protocol Assistance	133	17	150
	2118	291	2409

FDA Parallel Scientific Advice	2006 - 2010	2011	Overall total
Completed	9	5	14
Ongoing	0	1	1
Foreseen	0	2	2
	9	8	17

Outcome of the September 2011 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 diabetes mellitus.	x				x	x	x	
Chemical	Treatment of type 2 diabetes mellitus.	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 2 diabetes mellitus.	x					x	x	
Biological	Treatment of chronic, moderate to severe plaque psoriasis.	x				x			
Chemical	Treatment of pain and bone metastases resulting from castration-resistant prostate cancer.	x						x	
Chemical	Treatment of multiple myeloma.				x			x	
Chemical	Treatment of acute myeloid leukaemia.	x				x	x	x	
Chemical	Treatment of Crohn's disease.			x				x	
Biological	Treatment of rheumatoid arthritis and psoriatic arthritis.	x					x		
Biological	Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia and rheumatoid arthritis.			x		x		x	
Chemical	Prevention of acute rejection of kidney allografts.	x				x	x	x	
Chemical	Treatment of moderately to severely active ulcerative colitis.	x						x	
Chemical	Prevention of kidney transplant rejection.			x				x	
Advanced therapy	Prevention of transplant related mortality caused by Graft vs Host Disease and/or infections.				x			x	
Biological	Prophylaxis and treatment of bleeding episodes in patients with haemophilia A.			x		x	x	x	
Chemical	Treatment of post-myocardial infarction or hypertriglyceridaemia.	x					x		
Chemical	Treatment of heterozygous familial hypercholesterolemia.			x		x			
Chemical	Treatment of pulmonary arterial hypertension.	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 hypertension.			x				x	
Chemical	Treatment of atopic dermatitis.	x					x	x	
Chemical	Treatment of hepatitis C virus (HCV) genotype 1 infection.			x			x	x	
Other innovative	Management of non-CF bronchiectasis patients with respiratory infections with pseudomonas aeruginosa.	x					x	x	
Biological	Active immunisation against pseudomonas aeruginosa.			x				x	
Chemical	Prevention of recurrent hepatitis C in liver transplant recipients.		x				x	x	
Chemical	Reduction of COPD exacerbations risk.	x					x	x	
Chemical	Treatment of L-dopa induced dyskinesia in Parkinson's's.			x			x	x	
Chemical	Treatment of negative symptoms of schizophrenia.	x					x	x	
Chemical	Treatment of multiple sclerosis.	x				x	x	x	
Chemical	Treatment of clinically isolated syndrom (multiple sclerosis).	x						x	
Chemical	Treatment of idiopathic Parkinson's disease.			x				x	
Chemical	Treatment of asthma and COPD.			x		x		x	
Chemical	Treatment of chronic obstructive pulmonary disorder.	x					x	x	
Chemical	Treatment of allergic rhinitis.			x				x	
Biological	Treatment of growth hormone deficiency.	x				x	x	x	
Biological	Treatment of growth hormone deficiency.	x					x	x	
Chemical	Treatment of osteoporosis.	x						x	
Chemical	A diagnostic imaging agent.	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	Intended for the neutralization of the anticoagulant effect of rivaroxaban in emergency situations.	x					x	x	
Chemical	Treatment of hyperphosphataemia.	x				x		x	

SA: scientific advice

PA: protocol assistance

The above-mentioned 24 Scientific Advice letters, 1 Protocol Assistance letter, 12 Follow-up Scientific Advice and 2 Follow-up Protocol Assistance letters were adopted at the 19 – 22 September 2011 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 62 new Requests for which the procedure started at the SAWP meeting held on 30 August – 1 September 2011. The new requests are divided as follows: 35 Initial Scientific Advice, 14 Follow-up Scientific Advice, 8 Initial Protocol Assistance and 5 Follow-up Protocol Assistance.