



19 September 2013
EMA/CHMP/SAWP/573231/2013
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 16 – 19 September 2013

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

	1995 - 2012	2013	Overall total
Scientific Advice	1848	146	1994
Follow-up to Scientific Advice	496	61	557
Protocol Assistance	396	34	430
Follow-up to Protocol Assistance	189	19	208
HTA parallel advice	16	2	18
Qualification of novel methodologies	28	9	37
	2973	271	3244

FDA Parallel Scientific Advice	2006 - 2012	2013	Overall total
Completed	19	2	21

Outcome of the September 2013 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	Lipid lowering agent.			x				x	
Biological	Treatment of hypophosphatasia.				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 neuronal ceroid lipofuscinosis type 2.	x					x	x	
Biological	Treatment of Pompe disease.		x				x	x	
Chemical	Treatment of type 2 diabetes mellitus.	x				x			
Biological	Prevention of cytomegalovirus related complications in hematopoietic cell transplant and Solid Organ Transplant recipients.				x	x	x	x	
Biological	Treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, psoriasis and Crohn's disease.	x			x	x	x		
Chemical	Treatment of peripheral T-cell lymphoma.		x				x	x	
Chemical	Treatment of breast cancer.	x						x	
Biological	Treatment of rheumatoid arthritis.	x				x		x	
Biological	Treatment of diabetic nephropathy.	x						x	
Chemical	Treatment of Chronic lymphocytic leukemia.		x				x	x	
Chemical	Treatment of multiple myeloma.		x				x	x	
Chemical	Treatment of myelofibrosis.				x			x	
Biological	Treatment of renal cell carcinoma.				x			x	
Chemical	Treatment of ovarian cancer.		x				x	x	
Chemical	Treatment of breast cancer.	x						x	
Biological	Treatment of non-small cell lung cancer.	x						x	
Biological	Treatment of Duchenne muscular dystrophy.		x			x	x	x	
Biological	Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia and rheumatoid arthritis.	x				x	x	x	
Biological	Treatment of neuromyelitis optica.	x					x	x	
Chemical	Treatment of sickle cell disease.			x				x	
Biological	Treatment of sepsis.			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 chronic HCV GT1 infection.	x				x			
Chemical	Treatment of complicated intra-abdominal infections.	x				x	x	x	
Chemical	Treatment of complicated urinary tract infections.	x						x	
Chemical	Treatment of complicated intra-abdominal infections and complicated urinary tract infections in children.	x						x	
Biological	Active immunisation against invasive meningococcal diseases caused by Neisseria meningitidis.			x				x	
Chemical	Emergency contraception.	x					x	x	
Biological	Treatment of osteoporosis, prostate cancer and prevention of skeletal related events of bone metastases from solid tumors.	x				x		x	
Chemical	Treatment of partial onset seizures.	x						x	
Chemical	Treatment of Alzheimer's dementia.	x				x		x	
Chemical	Treatment of chronic pain.			x				x	
Chemical	Treatment of sore throat.	x				x		x	
Biological	Treatment of chronic obstructive pulmonary disease.	x						x	
Biological	Treatment of neovascular (wet) age-related macular degeneration.	x				x	x	x	
Chemical	Treatment of chronic non-infectious uveitis.		x					x	
Chemical	Detection of colorectal cancer.			x				x	
Chemical	Treatment of mercury toxicity.				x		x	x	
Chemical/Other innovative	Treatment of acute hyperkalaemia.			x			x	x	
Biomarker	Statistical methodology for model-based design.	x							

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biomarker	Treatment of Alzheimer's disease.	x							

SA: scientific advice
PA: protocol assistance

The above-mentioned 21 Scientific Advice letters, 8 Protocol Assistance letters, 7 Follow-up Scientific Advice, 4 Follow-up Protocol Assistance letters, 0 HTA parallel advice letters and 2 Qualification of novel methodologies letters were adopted at the 16 – 19 September 2013 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 54 new Requests for which the procedure started at the SAWP meeting held on 02 – 05 September 2013. The new requests are divided as follows: 27 Initial Scientific Advice, 6 Follow-up Scientific Advice, 6 Initial Protocol Assistance, 7 Follow-up Protocol Assistance, 5 Protocol Assistance with significant benefit only, 2 HTA parallel advices and 1 Qualification of novel methodologies.