



18 December 2014
EMA/CHMP/SAWP/794686/2014
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 15 – 18 December 2014

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

	1995 - 2013	2014	Overall total
Scientific Advice	2091	299	2390
Follow-up to Scientific Advice	594	111	705
Protocol Assistance	460	63	523
Follow-up to Protocol Assistance	236	37	273
HTA parallel advice	23	10	33
Qualification of novel methodologies	43	17	60
	3447	537	4044

FDA Parallel Scientific Advice	2006 - 2013	2014	Overall total
Completed	22	4	26

Outcome of the December 2014 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 type 2 diabetes mellitus.			x		x		x	
Biological	Treatment of type 2 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				
Chemical	Intended for nausea and vomiting symptoms.	x						x	
Chemical	Treatment of type 1 diabetes mellitus.	x						x	
Biological	Intended for local haemostasis during surgery.	x				x	x	x	
Biological	Prevention of necrotising enterocolitis.	x				x	x	x	
Chemical/Other innovative	Treatment of type 2 diabetes mellitus.	x						x	
Chemical	Treatment of type 1 diabetes mellitus.	x						x	
Chemical	Treatment of malignant glioma.		x				x	x	x
Chemical	Treatment of adrenocortical carcinoma.		x					x	
Chemical	Treatment of soft tissue sarcoma.		x					x	x
Chemical	Treatment of melanoma.	x				x			
Biological	Treatment of IgA nephropathy and persistent proteinuria.	x						x	
Chemical	Treatment of multiple myeloma.	x				x	x	x	
Chemical	Treatment of multiple sclerosis.	x						x	
Advanced therapy	Treatment of graft versus host disease.	x				x	x		
Chemical	Treatment of metastatic breast cancer, advanced ovarian cancer, progressive multiple myeloma, Kaposi's sarcoma.			x				x	
Chemical	Treatment of CRPC.	x					x	x	
Chemical	Treatment of Crohn's disease.	x					x	x	
Chemical	Treatment of prostate cancer	x						x	
Chemical	Treatment of NSCLC	x				x			
Biological	Treatment of Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis	x				x	x	x	
Chemical	Treatment of breast cancer.	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 pancreatic cancer.		x					x	
Biological	Treatment of HNSCC.	x						x	
Biological	Treatment of HNSCC.	x						x	
Biological	Treatment of NSCLC.	x					x	x	
Advanced therapy	Prevention of graft versus host disease.		x			x		x	x
Biological	Treatment of NSCLC.			x				x	
Biological	Treatment of NSCLC.	x					x		
Chemical	Treatment of myelofibrosis.	x					x	x	
Biological	Treatment of gastric cancer.				x			x	
Biological	Treatment of NSCLC.	x						x	
Biological	Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis and polyangiitis			x		x	x	x	
Biological	Quality Broad Advice.	x				x			
Chemical	Prophylaxis of hereditary angioedema.	x					x	x	
Biological	Treatment of haemophilia.			x			x	x	
Biological	Treatment of indolent B-cell lymphoma.	x						x	
Chemical	Reduction of risk of major thrombotic vascular events.	x						x	
Chemical	Myocardial protection strategy for cardiac ischaemia-reperfusion injury.	x					x	x	
Biological/ Other innovative	Treatment of acute bacterial skin and skin structure infections caused by Staphylococcus aureus.	x				x	x	x	
Chemical	Treatment of HCV.	x				x			
Biological	Treatment of Ebola.			x		x		x	
Biological	Prevention of fetal and neonatal alloimmune thrombocytopenia.		x			x	x	x	
Biological	Prevention of serious lower respiratory tract disease.	x					x	x	
Biological	Prevention of bronchopulmonary dysplasia.		x				x	x	
Chemical	Contraception.	x					x	x	
Chemical	Treatment of primary dysmenorrhea.	x						x	
Biological	Treatment of AML.	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 hereditary inclusion body myopathy.		x				x	x	
Biological	Treatment of mild AD.	x					x	x	
Other innovative	Minimization of the impact of placebo response.	x						x	
Chemical	Treatment of non-24-hour sleep-wake disorder.		x					x	
Chemical	Treatment of COPD.	x					x	x	
Chemical	Treatment of COPD.	x					x	x	
Advanced therapy	Treatment of Leber Hereditary Optic Neuropathy.		x			x	x	x	
Biological	Treatment of neovascular (wet) age-related macular degeneration, macular oedema following RVO and diabetic macular oedema	x				x	x	x	
Biological	Treatment of neovascular (wet) age-related macular degeneration, macular oedema following RVO and diabetic macular oedema			x				x	
Advanced therapy	Treatment of Stargardt disease.		x			x	x		
Chemical	Prophylaxis for acute kidney injury.			x				x	
Chemical	Treatment of Duchenne muscular dystrophy.	x					x	x	
Chemical	Treatment of type 2 diabetes mellitus nephropathy.	x						x	
Qualification advice.	Mild cognitive impairment.								
Qualification advice.	Multiple Sclerosis.								
HTA parallel advice	Treatment of myasthenia gravis.	x						x	
HTA parallel advice	Treatment of basal cell carcinoma.	x						x	
HTA parallel advice	Prophylaxis for migraine.	x					x	x	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 41 Scientific Advice letters, 11 Protocol Assistance letters, 9 Follow-up Scientific Advice, 1 Follow-up Protocol Assistance letters, 3 HTA parallel advice letters and 2 Qualification of novel methodologies letters were adopted at the 15 – 18 December 2014 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 51 new Requests for which the procedure started at the SAWP meeting held on 1 – 4 December 2014. The new requests are divided as follows: 25 Initial Scientific Advice, 7 Follow-up Scientific Advice, 11 Initial Protocol Assistance, 4 Follow-up Protocol Assistance, 1 HTA parallel advice and 3 Qualification of novel methodologies.