



20 March 2014
EMA/CHMP/SAWP/166871/2014
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 17 – 20 March 2014

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

	1995 - 2013	2014	Overall total
Scientific Advice	2091	70	2161
Follow-up to Scientific Advice	594	22	616
Protocol Assistance	460	5	465
Follow-up to Protocol Assistance	236	10	246
HTA parallel advice	23	0	23
Qualification of novel methodologies	43	1	44
	3447	108	3555

FDA Parallel Scientific Advice	2006 - 2013	2014	Overall total
Completed	22	0	22

Outcome of the March 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				
Chemical	Treatment of irritable bowel syndrome.	x				x			
Biological	Treatment of alpha-mannosidosis.	x				x	x		
Biological	Treatment of hormone-naive metastatic prostate cancer.			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 rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, Crohn's disease, ulcerative colitis and polyarticular juvenile idiopathic arthritis.			x		x		x	
Biological	Prevention of delayed graft function after renal transplantation.			x				x	
Chemical	Treatment of locally recurrent or metastatic breast cancer.	x				x	x	x	
Biological	Treatment of multiple myeloma.				x			x	
Chemical	Treatment of breast cancer.	x						x	
Biological	Treatment of advanced non-small cell lung cancer (NSCLC).	x				x	x	x	
Chemical	Treatment of colorectal carcinoma.	x						x	
Biological	Treatment of relapsing-remitting multiple sclerosis.			x				x	
Chemical	Treatment of soft tissue sarcoma.			x		x			
Chemical/Biological	Treatment of advanced HER2-positive gastric adenocarcinoma.			x				x	
Chemical	Treatment of non-small cell lung cancer.	x						x	
Biological	Prophylaxis of thromboembolic disorders, unstable angina and non-Q-wave myocardial infarction and acute ST-segment Elevation Myocardial Infarction (STEMI).			x		x			
Biological	Treatment and prophylaxis of bleeding in haemophilia B.			x		x			
Chemical	Treatment of primary and secondary hypertension in children.	x					x	x	
Chemical	Treatment of heart failure in children.	x						x	
Chemical	Prophylaxis of DVT and PE.	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 bile acid induced diarrhoea.	x				x	x	x	
Chemical	Treatment of hypercholesterolaemia or mixed hyperlipidaemia.	x				x		x	
Advanced therapy	Treatment of chronic lower extremity ulcers in diabetic patients.	x						x	
Biological	Treatment of atopic dermatitis.	x						x	
Chemical	Prevention of respiratory infection in cystic fibrosis.	x				x	x	x	
Biological	Prevention of herpes zoster and post-herpetic neuralgia.			x				x	
Biological	Prevention of herpes zoster.	x				x			
Chemical/ Other innovative	Management of cystic fibrosis patients with P. aeruginosa.	x					x	x	
Chemical	Treatment of calciphylaxis.				x			x	
Chemical	Treatment of swelling, inflammation and pain and mild arthritis.	x				x	x	x	
Chemical	Treatment of severe chronic pain.			x				x	
Biological	Treatment of relapsing remitting multiple sclerosis.	x				x		x	
Chemical	Treatment of schizophrenia.	x				x		x	
Chemical	Treatment of pulmonary tuberculosis.	x					x	x	
Biological	Treatment of GH deficiency (AGHD) and GH failure due to inadequate secretion of endogenous GH (GHD).			x		x	x		

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 21 Scientific Advice letters, 0 Protocol Assistance letters, 11 Follow-up Scientific Advice, 2 Follow-up Protocol Assistance letters, 0 HTA parallel advice letters and 1 Qualification of novel methodologies letters were adopted at the 17 – 20 March 2014 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 39 new Requests for which the procedure started at the SAWP meeting held on 3 – 6 March 2014. The new requests are divided as follows: 22 Initial Scientific Advice, 8 Follow-up Scientific Advice, 4 Initial Protocol Assistance, 1 Follow-up Protocol Assistance, 1 HTA parallel advice and 3 Qualification of novel methodologies.