



25 July 2014
EMA/CHMP/SAWP/430613/2014
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 21 – 24 July 2014

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

	1995 - 2013	2014	Overall total
Scientific Advice	2091	168	2259
Follow-up to Scientific Advice	594	60	654
Protocol Assistance	460	34	494
Follow-up to Protocol Assistance	236	27	262
HTA parallel advice	23	5	28
Qualification of novel methodologies	43	14	58
	3447	308	3755

FDA Parallel Scientific Advice	2006 - 2013	2014	Overall total
Completed	22	1	23

Outcome of the July 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 type 1 diabetes mellitus.			x				x	
Biological	Treatment of rotavirus gastroenteritis.	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	Reduction in recurrence of hepatic encephalopathy.	x						x	
Chemical	Treatment of type 1 diabetes mellitus.	x					x	x	
Biological	Treatment of rheumatoid arthritis and polyarticular juvenile idiopathic arthritis.	x				x	x	x	
Biological	Treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, psoriasis and Crohn's disease.			x				x	
Advanced therapy	Treatment of glioblastoma multiforme.		x			x		x	x
Advanced therapy	Treatment of graft-versus-host disease.				x			x	
Biological	Treatment of CRC, breast cancer, NSCLC and renal cell cancer.	x						x	
Chemical	Prevention of graft rejection.		x			x	x	x	
Chemical	Treatment iNHL.	x				x			
Biological	Treatment of multiple myeloma.				x	x			
Biological	Treatment of multiple myeloma.		x					x	
Chemical	Treatment of prostate cancer.			x				x	
Chemical	Treatment of breast cancer.	x						x	
Chemical	Treatment of AML.				x			x	
Biological	Treatment of rheumatoid arthritis, adult and paediatric Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis.			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 endometrioid adenocarcinoma.	x					x	x	
Advanced	Treatment of soft-		x				x	x	

	Intended indications(s)	Type of request				Topic			
therapy	tissue sarcoma.								
Chemical	Treatment of pigmented villonodular synovitis or giant-cell tumor of the tendon sheath.	x					x	x	
Chemical	Treatment of early breast cancer.			x				x	
Chemical	Treatment of diffuse cutaneous systemic sclerosis.	x						x	
Chemical	Treatment of DLBCL.	x				x	x	x	
Other innovative	Prevention of arteriovenous access dysfunction.		x					x	
Chemical	Treatment of breast cancer.	x					x	x	
Chemical	Treatment of varicose veins.	x				x			
Chemical	Treatment of uncomplicated gonorrhoea.	x						x	
Chemical	Prophylaxis and treatment of infections due to inhaled biothreat pathogens.	x					x	x	
Chemical	Treatment of acute bacterial infections caused by <i>Staphylococcus aureus</i> and <i>Streptococcus pneumoniae</i> .	x						x	
Chemical/ Other innovative	Treatment of HIV infection.	x						x	
Chemical	Treatment of CMV infection.		x				x	x	x
Biological	Treatment of multi-drug resistant tuberculosis (MDR-TB).	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	Treatment HIV infection.	x				x	x	x	
Chemical	Treatment of benign prostatic hyperplasia.	x					x	x	
Biological	Treatment of sarcopenia.	x						x	
Biological	Treatment of symptomatic osteoarthritis of the knee and the hip.			x				x	
Biological	Treatment of glabellar and lateral canthal lines.	x				x	x	x	
Chemical	Treatment of Charcot-		x				x	x	

	Intended indications(s)	Type of request				Topic			
	Marie-Tooth disease Type 1A (CMT 1A).								
Chemical/ Other innovative	Treatment of depression.			x		x		x	
Chemical	Treatment of refractory seizures in Dravet syndrome.		x					x	x
Chemical	Treatment of multiple sclerosis.			x			x	x	
Chemical	Treatment of multiple sclerosis.	x						x	
Biological	Treatment of Alzheimer's disease.	x						x	
Biological	Treatment of asthma.	x					x	x	
Chemical	Treatment of COPD.	x					x	x	
Biological	Treatment of geographic atrophy due to AMD.	x					x	x	
Chemical	Treatment of <i>Acanthamoeba</i> keratitis.		x			x		x	x
Biological	Treatment of macular oedema.	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 congenital adrenal hyperplasia.		x			x		x	x
Chemical	Diagnostic for use with PET.	x					x	x	
Chemical	Treatment of lead toxicity.				x		x		
Chemical	Prevention of graft loss in transplantation.				x			x	
Chemical/ Other innovative	Treatment of hyperkalaemia.			x				x	
Biomarker	Drug-induced kidney injury.								
HTA parallel	Treatment of asthma.	x						x	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 29 Scientific Advice letters, 10 Protocol Assistance letters, 9 Follow-up Scientific Advice, 6 Follow-up Protocol Assistance letters, 1 HTA parallel advice letters and 2 Qualification of novel methodologies letters were adopted at the 21 – 24 July 2014 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 53 new Requests for which the procedure started at the SAWP meeting held on 7 – 10 July 2014. The new requests are divided as follows: 32 Initial Scientific Advice, 12 Follow-up Scientific Advice, 5 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 1 HTA parallel advice and 1 Qualification of novel methodologies.