



22 May 2014
EMA/CHMP/SAWP/312025/2014
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 19 – 22 May 2014

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

	1995 - 2013	2014	Overall total
Scientific Advice	2091	116	2207
Follow-up to Scientific Advice	594	38	632
Protocol Assistance	460	17	477
Follow-up to Protocol Assistance	236	15	251
HTA parallel advice	23	4	27
Qualification of novel methodologies	43	8	51
	3447	198	3645

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

Outcome of the May 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 molybdenum cofactor deficiency type A.		x				x	x	
Chemical	Treatment of Fabry disease.				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 type 1 Gaucher's disease & Niemann-Pick Type C disease.	x				x		x	
Chemical	Treatment of primary biliary cirrhosis.		x			x	x	x	
Biological	Treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, psoriasis and Crohn's disease.			x				x	
Biological	Treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer, non-small cell lung cancer and metastatic renal cell cancer.	x				x	x	x	
Chemical/Biological	Treatment of cutaneous T-cell lymphoma.				x			x	
Chemical	Treatment of castration-resistant prostate cancer.			x				x	
Chemical	Treatment of castration-resistant prostate cancer.	x				x			
Biological	Treatment of multiple myeloma.		x				x	x	
Chemical	Treatment of breast cancer, ovarian cancer, multiple myeloma, AIDS-related Kaposi's sarcoma.	x				x	x	x	
Chemical	Treatment of non-small cell adenocarcinoma of the lung.			x				x	
Biological	Treatment of Merkel cell carcinoma.	x						x	
Chemical	Treatment of non-small cell lung cancer.	x				x	x	x	
Chemical	Treatment of nasopharyngeal carcinoma.	x						x	
Biological	Treatment of breast cancer.	x				x	x	x	
Chemical	Treatment of ovarian cancer.		x					x	x
Chemical	Treatment of hairy cell leukaemia.	x						x	
Chemical	treatment of non-small cell lung 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 polycythaemia vera.				x	x		x	
Chemical	Treatment of hypovolaemia.	x						x	
Biological	Treatment and prevention of bleeding.			x		x		x	
Biological	Treatment of von Willebrand Disease.				x			x	
Chemical	Treatment of familial chylomicronemia syndrome.	x						x	
Chemical	Treatment of severe hypertriglyceridemia.	x					x	x	
Chemical	Prevention of cytomegalovirus infection.	x					x	x	
Chemical	Prevention of cytomegalovirus infection in children.	x					x	x	
Chemical	Treatment of influenza A or B infection.			x			x	x	
Chemical	Treatment of Alzheimer's dementia.	x					x	x	
Chemical	Treatment of Alzheimer's disease.	x					x	x	
Chemical	Treatment of major depressive episodes.	x						x	
Chemical	Treatment of major depressive episodes in children.	x						x	
Chemical	Treatment of cystic fibrosis.		x			x	x	x	
Biological	Treatment of idiopathic pulmonary fibrosis.	x					x	x	
Advanced therapy	Treatment of uveitis.	x					x	x	
Biological	Treatment of neovascular age related macular oedema, diabetic macular oedema, macular oedema secondary to retinal vein occlusion and choroidal neovascularisation secondary to pathologic myopia.	x				x	x	x	
Biological	Treatment of neovascular (wet) age-related macular degeneration.			x		x			
Chemical	Treatment of Stargardt's disease.		x				x	x	
Chemical	Treatment of retinitis pigmentosa.		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 acromegaly.			x				x	
Biological	Treatment of growth hormone deficiency.		x			x			
Chemical	Prophylaxis of acute kidney injury.			x				x	
Qualification advice	Autism spectrum disorder.	x						x	
Qualification advice	Autism spectrum disorder.	x						x	
Qualification advice	Autism spectrum disorder.	x						x	
Qualification advice	Autism spectrum disorder.	x						x	
Qualification advice	Autism spectrum disorder.	x						x	
HTA Parallel advice	Treatment of cancer cachexia.	x						x	
HTA Parallel advice	Treatment of osteoporosis.			x				x	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 22 Scientific Advice letters, 8 Protocol Assistance letters, 8 Follow-up Scientific Advice, 4 Follow-up Protocol Assistance letters, 2 HTA parallel advice letters and 6 Qualification of novel methodologies letters were adopted at the 19 – 22 May 2014 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 56 new Requests for which the procedure started at the SAWP meeting held on 5 – 8 May 2014. The new requests are divided as follows: 29 Initial Scientific Advice, 12 Follow-up Scientific Advice, 8 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 1 HTA parallel advice and 1 Qualification of novel methodologies.