



15 December 2011
EMA/CHMP/SAWP/974493/2011
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 12-15 December 2011

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

	1995 - 2010	2011	Overall total
Scientific Advice	1368	259	1627
Follow-up to Scientific Advice	320	80	400
Protocol Assistance	297	45	342
Follow-up to Protocol Assistance	133	29	162
	2118	413	2531

FDA Parallel Scientific Advice	2006 - 2010	2011	Overall total
Completed	9	8	17
Ongoing	0	4	4
Foreseen	0	2	2
	9	14	23

Outcome of the December 2011 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 alpha-mannosidosis.				x			x	
Chemical	Treatment of advanced endometrial cancer.	x						x	



Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Advanced therapy	Treatment of advanced renal cell carcinoma.	x				x	x	x	
Chemical	Treatment of advanced ovarian cancer.	x					x	x	
Chemical	Treatment of various solid tumours.	x				x	x		
Chemical	Treatment of multiple myeloma.				x			x	
Chemical	Treatment of advanced ovarian cancer, AIDS related Kaposi's sarcoma, metastatic breast cancer and progressive multiple myeloma.			x				x	
Chemical	Treatment of ovarian cancer.				x		x	x	
Chemical	Adjuvant treatment of soft-tissue sarcoma.	x						x	
Biological	Treatment of various solid tumours.	x				x			
Biological	Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia and rheumatoid arthritis.	x				x	x	x	
Biological	Treatment of non-Hodgkin's lymphoma, and rheumatoid arthritis.	x				x	x	x	
Chemical	Treatment of hepatocellular carcinoma.		x			x	x	x	
Biological	Treatment of thrombotic thrombocytopenic purpura (TTP).				x	x	x	x	
Chemical	Treatment of relapsed and/or refractory multiple myeloma.		x					x	
Biological	Treatment of bleeding episodes in haemophilia A.		x			x		x	
Chemical	Prevention of cardiovascular mortality, MI, stroke, and symptomatic venous thromboembolic events.	x						x	
Biological	Treatment of hepatitis C.			x		x		x	
Chemical	Prevention of male-to-female sexual transmission of HIV-1.			x				x	
Chemical	Prevention of influenza.	x						x	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Advanced therapy	Treatment for partial chondral defects of articular joints.	x				x	x	x	
Chemical	Treatment of Duchenne muscular dystrophy.				x			x	
Chemical	Treatment of relapsing multiple sclerosis.			x				x	
Biological	Treatment of Alzheimer's disease.	x				x			
Chemical	Treatment of Parkinson's disease (PD).	x					x	x	
Chemical	Treatment of major depressive disorder.	x					x	x	
Chemical	Treatment of partial onset seizures.	x				x			
Chemical	Treatment of Leber congenital amaurosis (LCA) and retinitis pigmentosa (RP).	x				x	x		
Advanced therapy	Prevention of oral mucositis in head and neck cancer.	x				x	x	x	

SA: scientific advice

PA: protocol assistance

The above-mentioned 17 Scientific Advice letters, 3 Protocol Assistance letter, 4 Follow-up Scientific Advice and 5 Follow-up Protocol Assistance letters were adopted at the 12 – 15 December 2011 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 37 new Requests for which the procedure started at the SAWP meeting held on 28 – 30 November 2011. The new requests are divided as follows: 21 Initial Scientific Advice, 4 Follow-up Scientific Advice, 8 Initial Protocol Assistance and 4 Follow-up Protocol Assistance.