



24 May 2012
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Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 21-24 May 2012

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

	1995 - 2011	2012	Overall total
Scientific Advice	1627	93	1720
Follow-up to Scientific Advice	400	40	440
Protocol Assistance	342	20	362
Follow-up to Protocol Assistance	162	15	177
HTA parallel advice	8	2	10
Qualification of novel methodologies	14	9	23
	2553	179	2732

FDA Parallel Scientific Advice	2006 - 2011	2012	Overall total
Completed	17	0	17

Outcome of the May 2012 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				
Advanced therapy	Treatment of Cridler Najjar syndrome.				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 type 1 and type 2 Diabetes Mellitus.	x				x	x	x	
Chemical	Treatment of diarrhea-predominant irritable bowel syndrome.	x				x	x	x	
Chemical	Treatment of type II diabetes mellitus.			x			x	x	
Biological	Prevention of ischemia reperfusion injury associated with solid organ transplantation.		x					x	x
Biological	Treatment of CD30-positive mature T-cell lymphomas.			x				x	
Chemical	Treatment of chronic lymphocytic leukaemia.	x						x	
Chemical	Treatment of chronic lymphocytic leukaemia.	x					x	x	
Chemical	Treatment of mantle cell lymphoma.	x						x	
Biological	Treatment of psoriasis.			x		x	x	x	
Advanced therapy	Treatment of pancreatic cancer.		x			x	x	x	
Chemical	Treatment of non-small cell lung cancer.	x						x	
Chemical	Treatment of breast cancer.	x						x	
Chemical	Treatment of acute myeloid leukaemia .	x					x	x	
Biological	Prevention and treatment of life-threatening thromboembolic events	x				x	x	x	
Chemical	Reduction of cardiovascular mortality and morbidity in patients with stable CVD, and T2D or pre-diabetes.			x				x	
Advanced therapy	Treatment of Chronic Heart Failure.	x					x	x	
Chemical/ Other innovative	Monitor the compliance of celiac disease patients to a gluten-free diet.	x						x	
Advanced therapy	Treatment of of epidermolysis bullosa.		x				x	x	
Chemical	Treatment of genotype 1 chronic hepatitis C.			x				x	
Chemical	Treatment of genotype 1 chronic hepatitis C.	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 complicated bacterial skin and skin structure infections.	x				x	x	x	
Chemical	Treatment of influenza A and B virus infection.			x				x	
Chemical	Treatment of nonsense mutation Duchenne muscular Dystrophy.				x			x	
Chemical	Treatment of chronic central neuropathic pain related to multiple sclerosis.	x						x	
Chemical	Treatment of ADHD.			x				x	
Chemical	Treatment of Parkinson's disease.			x				x	
Chemical	Treatment of cystic fibrosis.				x			x	
Chemical	Maintenance treatment of chronic obstructive pulmonary disease.	x				x		x	
Chemical	Intended for peripheral neuropathic pain associated with chemotherapy.	x					x	x	
Chemical	Treatment of anorexia/cachexia in patients with NSCLC.			x		x			
Chemical	Treatment of colorectal cancer.	x						x	

SA: scientific advice

PA: protocol assistance

The above-mentioned 17 Scientific Advice letters, 3 Protocol Assistance letter, 9 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance letters, 0 HTA parallel advice letters and 0 Qualification of novel methodologies letters were adopted at the 21 – 24 May 2012 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 47 new Requests for which the procedure started at the SAWP meeting held on 23 – 25 April 2012. The new requests are divided as follows: 24 Initial Scientific Advice, 13 Follow-up Scientific Advice, 7 Initial Protocol Assistance, 1 Follow-up Protocol Assistance, 0 HTA parallel advice and 2 Qualification of novel methodologies.