



25 April 2014
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Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 22 – 25 April 2014

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

	1995 - 2013	2014	Overall total
Scientific Advice	2091	94	2185
Follow-up to Scientific Advice	594	30	624
Protocol Assistance	460	9	469
Follow-up to Protocol Assistance	236	11	247
HTA parallel advice	23	2	25
Qualification of novel methodologies	43	2	45
	3447	148	3595

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

Outcome of the April 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				
Biological	Treatment of type 2 diabetes.			x				x	
Biological	Treatment of diabetes mellitus.			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				
Biological	Treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, psoriasis and Crohn's disease.			x		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	
Advanced therapy	Treatment of B cell acute lymphoblastic leukemia in adults.	x						x	
Advanced therapy	Treatment of B cell acute lymphoblastic leukemia in children.	x						x	
Chemical	Treatment of melanoma.			x		x		x	
Chemical	Treatment of ovarian cancer.		x					x	
Chemical	Treatment of neuroblastoma.				x	x	x		
Chemical	Treatment of transitional cell carcinoma of the urinary tract.	x						x	
Chemical	Treatment of primary myelofibrosis.		x			x	x	x	x
Biological	Reduction in the duration of neutropenia and the incidence of febrile neutropenia.	x				x	x	x	
Chemical	Treatment of relapsing multiple sclerosis.	x				x	x	x	
Chemical	Treatment of hairy cell leukaemia and non-small cell lung cancer.			x			x		
Chemical	Treatment of complicated intra-abdominal infections.			x				x	
Chemical	Treatment of complicated urinary tract infections.			x				x	
Chemical	Treatment of nosocomial pneumonia including ventilator-associated pneumonia.			x				x	
Chemical	Treatment of chronic hepatitis C.	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 hospital and ventilatory acquired pneumonia.	x				x	x	x	
Advanced therapy	Treatment of glioblastoma multiforme.		x			x	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	
Biological	Treatment of acute lymphoblastic leukaemia.		x				x	x	x
Chemical	Treatment of allograft rejection.	x				x	x	x	
Chemical	Treatment of triple-negative breast cancer.	x						x	
Chemical	Treatment of squamous non-small cell lung cancer.	x					x	x	
Chemical	Treatment of small cell lung cancer.	x						x	
Chemical	Treatment of diabetic foot ulcer.	x				x	x	x	
Biological	Treatment of severe influenza A (B) infection.	x					x	x	
Chemical	Treatment of polycystic ovary syndrome.	x					x	x	
Chemical/Biological	Slowing progressive loss of renal function in patients with diabetic kidney disease.	x					x	x	
Chemical	Treatment of treatment resistant depression.	x					x	x	
Chemical	Treatment of autism spectrum disorders.	x						x	
Chemical	Treatment of moderate to severe idiopathic Restless Legs Syndrome.	x						x	
Biological	Treatment of Alzheimer's disease.	x					x	x	
Other innovative	Treatment of house dust mite allergen-induced rhinoconjunctivitis.	x				x	x	x	
Chemical	Treatment of moderate to severe asthma.			x				x	
Chemical	Treatment of chronic obstructive pulmonary disease.	x						x	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Reversal of anticoagulation in serious uncontrolled bleeding or requiring urgent or emergent surgery.	x				x	x	x	
Qualification advice	Clinical outcome assessment in multiple sclerosis.	x							
Qualification advice	Clinical outcome assessment in autism.	x							
HTA Parallel advice	Treatment of breast cancer.	x						x	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 24 Scientific Advice letters, 4 Protocol Assistance letters, 9 Follow-up Scientific Advice, 1 Follow-up Protocol Assistance letters, 1 HTA parallel advice letters and 2 Qualification of novel methodologies letters were adopted at the 22 – 25 April 2014 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 45 new Requests for which the procedure started at the SAWP meeting held on 31 March – 3 April 2014. The new requests are divided as follows: 16 Initial Scientific Advice, 11 Follow-up Scientific Advice, 11 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 1 HTA parallel advice and 1 Qualification of novel methodologies.