

22 January 2015
EMA/CHMP/SAWP/54035/2015
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 19 – 22 January 2015

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

	1995 - 2014	2015	Overall total
Scientific Advice	2653	21	2674
Follow-up to Scientific Advice	758	6	764
Protocol Assistance	566	9	575
Follow-up to Protocol Assistance	267	6	273
HTA parallel advice	34	0	34
Qualification of novel methodologies	60	0	60
	4338	42	4380

FDA Parallel Scientific Advice	2006 - 2014	2015	Overall total
Completed	24	0	26

Outcome of the January 2015 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 type 1 diabetes mellitus.	x				x	x		
Chemical	Treatment of primary biliary cirrhosis.				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 actinic keratosis.	x						x	
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis.			x				x	
Chemical	Treatment of chronic lymphocytic leukaemia.				x			x	
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis.	x				x	x	x	
Biological	Treatment of breast cancer.	x						x	
Advanced therapy	Treatment of Wiskott Aldrich syndrome.	x					x	x	
Chemical	Treatment of acute respiratory distress syndrome.		x				x	x	
Advanced therapy	Treatment of mesothelioma.		x			x	x	x	
Chemical	Treatment of acute myeloid leukaemia.				x			x	
Biological	Treatment of pulmonary alveolar proteinosis.		x				x	x	
Biological/ Other innovative	Treatment of mNSCLC.	x						x	
Chemical	Treatment of cancer cachexia.	x				x	x	x	
Chemical	Treatment of primary myelofibrosis.		x			x	x	x	
Biological	Treatment of non-small cell lung cancer.	x						x	
Chemical	Treatment of myelodysplastic syndrome.				x			x	
Biological	Treatment of multiple myeloma.		x			x	x	x	
Biological	Reduction in duration of neutropenia.	x					x	x	
Chemical	Treatment of rheumatoid arthritis.			x			x	x	
Biological	Prevention of cytomegalovirus infection.				x	x			
Advanced therapy	Treatment of advanced systolic heart failure.			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 cryptococcal meningitis and tularemia.	x					x	x	
Biological	Treatment of chronic inflammatory demyelinating polyradiculoneuropathy			x				x	
Biological	Treatment of chronic inflammatory demyelinating polyradiculoneuropathy			x				x	
Biological	Treatment of avian influenza virus H5N1.	x				x	x	x	
Biological	Immunisation against poliomyelitis.	x				x			
Biological	Prophylaxis against Ebola virus disease.	x				x		x	
Chemical	Treatment of HIV-1 infection.			x			x		
Biological/ Other innovative	Labour induction, treatment of labour arrest and treatment of post partum haemorrhage.	x				x	x	x	
Biological	Treatment of acute pancreatitis.		x			x	x	x	
Biological	Treatment of sporadic inclusion body myositis, hip fracture recovery, sarcopenia, cancer-related muscle wasting.	x				x			
Biological	Treatment of X-linked hypophosphatemia.		x				x	x	
Chemical	Treatment of Duchenne muscular dystrophy.	x				x	x	x	
Chemical	Treatment of amyotrophic lateral sclerosis.	x						x	
Chemical	Treatment of Alzheimer's disease.	x						x	
Chemical	Treatment of chronic obstructive pulmonary disease.	x					x	x	
Chemical	Treatment of acute respiratory distress syndrome.		x				x	x	
Chemical	Treatment of cystic fibrosis.				x			x	
Biological	Treatment of allergic rhinoconjunctivitis.	x						x	
Chemical	Treatment of diabetic kidney disease.	x					x	x	
Chemical	Treatment of uraemic pruritis.		x			x		x	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 21 Scientific Advice letters, 9 Protocol Assistance letters, 6 Follow-up Scientific Advice, 6 Follow-up Protocol Assistance letters, 0 HTA parallel advice letters and 0 Qualification of novel methodologies letters were adopted at the 19 – 22 January 2015 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 48 new Requests for which the procedure started at the SAWP meeting held on 6 – 9 January 2015. The new requests are divided as follows: 24 Initial Scientific Advice, 7 Follow-up Scientific Advice, 13 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 2 HTA parallel advices and 0 Qualification of novel methodologies.