



17 December 2015
EMA/CHMP/SAWP/857429/2015
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 14 – 17 December 2015

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

	1995 - 2014	2015	Overall total
Scientific Advice	2653	244	2897
Follow-up to Scientific Advice	758	89	847
Protocol Assistance	566	96	662
Follow-up to Protocol Assistance	267	43	310
HTA parallel advice	34	29	63
Qualification of novel methodologies	60	23	83
	4338	524	4862

FDA Parallel Scientific Advice	2006 - 2014	2015	Overall total
Completed	26	3	29

Outcome of the December 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				
Chemical	Treatment of NASH.	x				x	x	x	
Chemical	Treatment of type 2 diabetes mellitus.	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 Fabry disease.	x				x	x	x	
Advanced therapy	Treatment of mucopolysaccharidosis type IIIA.				x		x	x	
Biological	Treatment of systemic sclerosis.	x						x	
Chemical	Treatment of ovarian cancer.		x			x		x	x
Biological	Treatment of ovarian cancer.	x						x	
Biological	Treatment of breast cancer, NSCLC, RCC, ovarian cancer.			x		x		x	
Chemical	Treatment of AML.				x		x		
Chemical	Treatment of breast cancer, ovarian cancer, multiple myeloma, AIDS-related Kaposi's sarcoma.	x				x	x		
Chemical	Treatment of breast cancer.	x						x	
Chemical	Treatment of hepatocellular carcinoma.	x				x	x	x	
Chemical	Treatment of acute myeloid leukaemia.				x		x		
Chemical	Treatment of acute myeloid leukaemia.				x	x			
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis.			x				x	
Advanced therapy	Treatment of DLBCL.		x			x	x	x	
Advanced therapy	Treatment of acute lymphoblastic leukaemia.	x				x	x	x	
Chemical	Treatment of mesothelioma.	x						x	
Biological	Treatment of melanoma.			x				x	
Chemical	Treatment of advanced ovarian cancer.		x			x			
Chemical	prevention and treatment of allograft rejection. Scientific Advice is sought on clinical development								
Chemical	Treatment of NSCLC.	x					x	x	
Biological	Treatment of acute myeloid leukaemia.		x					x	x
Biological	Treatment of hyperlipidemia.			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 hepatitis C.			x		x			
Biological	Prevention of diphtheria and tetanus.	x				x			
Chemical	Hormone replacement therapy and combined oral contraception.	x				x	x		
Biological	Treatment of chronic kidney disease.	x					x	x	
Chemical	Treatment of pre-term labour.			x				x	
Biological	Treatment of muscle wasting syndromes/conditions.			x				x	
Chemical	Treatment of Duchenne muscular dystrophy.				x	x	x	x	
Chemical	Treatment of mild to moderate ALS.		x			x	x	x	x
Biological	Treatment of primary hyperoxaluria.				x			x	
Chemical	Treatment of asthma.	x				x	x	x	
Biological	Treatment of eosinophilic granulomatosis with polyangiitis.		x					x	
Advanced therapy	Treatment of Leber's congenital amaurosis.				x	x	x	x	
Chemical	Prevention of severe oral mucositis.				x			x	x
Chemical	treatment of Duchenne muscular dystrophy.				x			x	
Biological	Treatment of sepsis.	x				x	x	x	
Chemical/Biological	Reconstitution of vaccines.	x				x			
Qualification opinion	Treatment of ulcerative colitis.	x						x	
Qualification opinion	Medication adherence.	x						x	
Qualification advice	Treatment of plexiform neurofibromas.	x						x	
Qualification advice	Treatment of autism spectrum disorder.	x						x	
HTA Parallel advice	Treatment of diabetic nephropathy.	x						x	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 18 Scientific Advice letters, 6 Protocol Assistance letters, 8 Follow-up Scientific Advice, 9 Follow-up Protocol Assistance letters, 1 HTA parallel advice letters and 4 Qualifications of novel methodologies letters were adopted at the 14 – 17 December 2015 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 30 November – 3 December 2015. The new requests are divided as follows: 21 Initial Scientific Advice, 6 Follow-up Scientific Advice, 6 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 0 HTA parallel advices and 1 Qualifications of novel methodologies.