



26 May 2016
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Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 23 – 26 May 2016

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

	1995 - 2015	2016	Overall total
Scientific Advice	2899	133	3032
Follow-up to Scientific Advice	846	32	878
Protocol Assistance	662	32	694
Follow-up to Protocol Assistance	310	15	325
HTA parallel advice	63	6	69
Qualification of novel methodologies	83	7	90
	4863	225	5088

Outcome of the May 2016 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 postoperative ileus	x						x	
Chemical	Improvement of glycemic control	x					x	x	
Chemical	Treatment of primary sclerosing cholangitis		x					x	x
Chemical	Treatment of hyperphenylalaninemia		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 gastric neuroendocrine tumours		x				x	x	
Chemical	Treatment of ulcerative colitis	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 Sjogren's syndrome	x						x	
Biological	Treatment of triple negative breast cancer	x						x	
Biological	Treatment of renal cell carcinoma	x						x	
Biological	Treatment of SSCHN	x						x	
Chemical	Treatment of thymic epithelial tumors		x					x	
Biological	Treatment of breast cancer, NSCLC, RCC, ovarian cancer	x						x	
Biological	Treatment of breast cancer, NSCLC, RCC, ovarian cancer			x				x	
Biological	Treatment of chronic plaque psoriasis	x				x	x	x	
Chemical	Treatment of breast cancer	x				x	x	x	
Chemical	Treatment of active rheumatoid arthritis	x					x	x	
Chemical	Treatment of multiple myeloma		x					x	
Chemical	Treatment of Ph+ acute lymphoblastic leukaemia and Ph+ chronic myelogenous leukaemia	x						x	
Chemical	Treatment of recurrent anaplastic astrocytoma	x				x	x	x	
Chemical	Treatment of colorectal cancer			x				x	
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile idiopathic arthritis, plaque psoriasis, ankylosing spondylitis.			x		x		x	
Chemical	Treatment of myelodysplastic 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 acute myeloid leukaemia	x						x	
Biological	Treatment of renal cell carcinoma	x						x	
Biological	Treatment of urothelial cancer	x						x	
Chemical	Treatment of tenosynovial giant cell tumor		x			x			
Chemical	Treatment of relapsing remitting multiple sclerosis	x						x	
Biological	Treatment of rheumatoid arthritis, juvenile idiopathic arthritis and juvenile idiopathic polyarthritis.	x				x		x	
Biological	Treatment of primary Sjogren's Syndrome	x					x	x	
Biological/ Advanced Therapy	Treatment of immunodeficiency	x				x	x	x	
Chemical	Treatment of iron overload in transfusion-dependent beta thalassaemia		x				x	x	x
Chemical	Reduction of LDL-C and cardiovascular risk	x						x	
Chemical	Prevention of clinical sequelae of acute lung injury induced by cardiopulmonary bypass	x						x	
Chemical	Treatment of chronic kidney disease	x						x	
Chemical	Treatment of chronic heart failure	x						x	
Advanced Therapy	Treatment of critical limb ischemia	x				x		x	
Chemical	Treatment of pain in oral lichen planus	x				x	x	x	
Biological	Treatment of chronic hepatitis B	x				x	x	x	
Biological	Prevention of primary Clostridium difficile infection	x						x	
Biological	Prevention of HZ-related complications			x		x			
Advanced Therapy	Treatment of non-traumatic osteonecrosis				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 psoriatic arthritis	x					x	x	
Biological	Treatment of ankylosing spondylitis	x					x	x	
Chemical	Treatment resistant depression	x					x	x	
Chemical	Acute treatment of migraine	x						x	
Chemical	Treatment of ovarian cancer		x			x	x	x	
Biological	Treatment of age-related macular degeneration	x				x	x	x	
Biological	Treatment of osteoporosis	x				x	x	x	
Biological	Treatment of acute radiation syndrome		x			x	x	x	
Chemical	Treatment of graft versus host disease	x				x	x	x	
Qualification opinion	Treatment of COPD	x							
HTA parallel advice	Prevention of chemotherapy-induced peripheral neuropathy	x				x	x	x	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 37 Scientific Advice letters, 9 Protocol Assistance letters, 4 Follow-up Scientific Advice, 1 Follow-up Protocol Assistance letter, 1 HTA parallel advice letter and 1 Qualifications of novel methodologies letter were adopted at the 23 - 26 May 2016 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 57 new Requests for which the procedure started at the SAWP meeting held on 10 – 13 May 2016. The new requests are divided as follows: 32 Initial Scientific Advice, 8 Follow-up Scientific Advice, 6 Initial Protocol Assistance, 6 Follow-up Protocol Assistance, 3 HTA parallel advices and 2 Qualifications of novel methodologies.