



21 July 2016
EMA/CHMP/SAWP/508519/2016
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 18 – 21 July 2016

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

	1995 - 2015	2016	Overall total
Scientific Advice	2899	193	3092
Follow-up to Scientific Advice	846	47	893
Protocol Assistance	662	42	704
Follow-up to Protocol Assistance	310	26	336
HTA parallel advice	63	9	72
Qualification of novel methodologies	83	9	92
	4863	326	5189

Outcome of the July 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				
Advanced therapy	Promotion of wound healing.	x				x	x	x	
Chemical	Treatment and prevention of juvenile polyposis syndrome.	x				x	x	x	
Biological	Treatment of Sjögren's syndrome.	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 psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis.			x		x		x	
Biological	Treatment of breast cancer, non-small cell lung cancer, renal cell carcinoma, ovarian cancer.	x				x	x	x	
Biological	Treatment of non-small cell lung cancer.	x				x			
Biological	Treatment of psoriatic arthritis.	x						x	
Biological	Treatment of axial spondyloarthritis.	x						x	
Chemical	Treatment of microscopic polyangiitis		x			x	x	x	
Chemical	Treatment of granulomatosis with polyangiitis.		x			x	x	x	
Chemical	Treatment of non-small cell lung cancer and castration resistant prostate cancer.	x						x	
Chemical	Treatment of angiosarcoma.	x						x	
Chemical	Treatment of chronic myelomonocytic leukaemia.	x						x	
Chemical	Treatment of acute myeloid leukaemia.		x					x	
Biological	Treatment of atypical haemolytic uremic syndrome.	x					x	x	
Chemical	Treatment of breast cancer.	x						x	
Biological	Reduction in incidence of febrile neutropenia.			x		x		x	
Chemical	Treatment of acute myeloid leukaemia.				x	x			
Biological	Treatment of breast cancer, non-small cell lung cancer, renal cell carcinoma, ovarian cancer.			x				x	
Biological	Treatment of small cell lung cancer.	x				x	x	x	
Chemical	Treatment of renal cell carcinoma.	x					x	x	
Biological	Treatment of breast cancer.	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 breast cancer and gastric cancer.	x				x	x	x	
Biological	Prophylaxis of bleeding in hemophilia A.				x	x			
Biological	Treatment of haemophilia A and B.	x					x		
Chemical/ Other innovative	Treatment of post cardiac arrest syndrome.	x				x	x	x	
Biological	Treatment of diabetic foot ulcer.			x		x	x	x	
Chemical	Treatment of invasive candidiasis.	x						x	
Chemical	Treatment of influenza.	x					x	x	
Chemical	Treatment of HIV-1 infection.	x				x			
Biological	Prevention of diarrhoea	x						x	
Biological	Broad clinical advice.			x				x	
Biological	Prevention of seasonal influenza disease.	x				x	x	x	
Chemical/ Other innovative	Treatment of acute influenza infection.	x						x	
Biological	Treatment of sepsis-associated acute kidney injury.			x		x		x	
Biological	Treatment of primary hyperoxaluria.				x			x	
Chemical	Treatment of pulmonary arterial hypertension and persistent pulmonary hypertension.	x						x	
Advanced therapy	Treatment of primary osteoarthritis of the knee.	x				x	x	x	
Chemical	Treatment of Parkinson's disease.	x						x	
Advanced therapy	Treatment of disability following ischaemic stroke.	x				x	x	x	
Chemical	Treatment of focal (partial) epilepsy.	x					x		
Biological	Treatment of metachromatic leukodystrophy.		x				x	x	
Chemical	Treatment of cystic fibrosis.	x					x	x	
Biological	In-vivo diagnostic of tuberculosis.	x				x	x	x	
HTA parallel advice	Treatment of Crohn's disease.	x				x	x	x	
HTA parallel advice	Prophylaxis of headaches in migraine.			x			x	x	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
HTA parallel advice	Treatment of wet age related macular degeneration.	x						x	
Qualification advice	Treatment of Crohn's disease.	x						x	
Qualification advice	Treatment of Parkinson's disease.	x						x	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 31 Scientific Advice letters, 4 Protocol Assistance letters, 6 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance, 3 HTA Parallel advice and 2 Qualification advice letters were adopted at the 18 - 21 July 2016 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 64 new Requests for which the procedure started at the SAWP meeting held on 4 – 7 July 2016. The new requests are divided as follows: 33 Initial Scientific Advice, 12 Follow-up Scientific Advice, 8 Initial Protocol Assistance, 6 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 5 HTA Parallel advice.