



21 April 2017
EMA/CHMP/SAWP/253962/2017
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 18 – 21 April 2017

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

	1995 - 2015	2017	Overall total
Scientific Advice	3215	112	3327
Follow-up to Scientific Advice	938	36	974
Protocol Assistance	735	34	769
Follow-up to Protocol Assistance	355	14	369
HTA parallel advice	87	7	94
Qualification of novel methodologies	94	9	103
	5424	212	5636

Outcome of the April 2017 CHMP meeting in relation to scientific advice procedures

Final scientific advice procedures

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of colorectal cancer.	x						x	
Biological	Maintenance treatment in colorectal cancer.	x						x	
Chemical	Treatment of chronic lymphocytic leukaemia.			x				x	
Chemical	Treatment of secondary hyperparathyroidism.	x					x	x	
Biological	Treatment of rheumatoid arthritis.	x					x	x	



Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Management of cystic fibrosis.	x						x	
Chemical	Treatment of ovarian cancer, AIDS-related Kaposi's sarcoma and multiple myeloma.			x			x	x	
Biological	Treatment of atypical haemolytic uremic syndrome and paroxysmal nocturnal haemoglobinuria.	x				x		x	
Chemical/ Other innovative	Treatment of treatment-resistant major depressive disorder			x				x	
Chemical	Treatment of vasomotor symptoms due to menopause or hormone therapy.	x					x	x	
Chemical	Treatment of asthma.	x				x		x	
Chemical	Treatment of asthma.	x					x	x	
Chemical	Treatment of acute myeloid leukaemia.	x						x	
Chemical	Treatment and management of Rett Syndrome.	x					x	x	
Chemical	Treatment and management of Fragile X syndrome.	x					x	x	
Chemical	Prevention of heart attack and stroke.	x				x	x	x	
Biological	Active immunization to prevent invasive disease caused by <i>Neisseria meningitides</i> .	x				x	x	x	
Chemical	Treatment of alkaptonuria.		x					x	
Biological	Treatment of autoimmune pulmonary alveolar proteinosis.		x				x	x	
Biological	Treatment of relapsing-remitting multiple sclerosis.	x				x	x	x	
Biological	Treatment of nasal polyps .	x					x	x	
Chemical	Maintenance treatment of schizophrenia.			x				x	
Biological	Treatment of breast cancer.	x				x			
Chemical	Treatment of dystrophic epidermolysis bullosa.	x				x	x		
Biological	Treatment of cervical carcinoma.	x						x	
Other innovative	Treatment of mastocytosis.	x					x	x	
Chemical	Treatment of mastocytosis.		x			x	x	x	

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of paroxysmal nocturnal haemoglobinuria.		x			x	x	x	
Biological	Treatment of neuromyelitis optica and neuromyelitis optica spectrum disorders.				x		x	x	
Biological	Treatment of neuromyelitis optica and neuromyelitis optica spectrum disorders.				x	x			
Biological	Treatment of giant cell arthritis.	x						x	
Biological	Treatment of polymyalgia rheumatic.	x						x	
Chemical	Treatment of invasive candidiasis.	x					x	x	
Biological	Treatment of breast cancer.			x				x	
Chemical	Treatment of amyotrophic lateral sclerosis.		x					x	
Chemical	Treatment of hepatocellular carcinoma.	x				x			
Chemical	Treatment of non-small cell lung cancer.	x				x			
Biological	Prevention of tick born encephalitis.	x				x	x	x	
Chemical	Treatment of Wolfram syndrome.		x					x	
Chemical	Treatment of Wolfram syndrome.				x			x	
Chemical	Treatment of breast cancer.			x				x	
Qualification advice	Treatment of epilepsy.			x				x	
Qualification advice	Treatment of epilepsy.	x						x	
Qualification advice	Treatment of age-related macular degeneration.	x						x	
Qualification advice	Treatment of multiple sclerosis, hip fracture and sarcopenia.	x						x	
HTA parallel advice	Treatment of non-alcoholic steatohepatitis.	x					x	x	
HTA parallel advice	Treatment of β -thalassaemia.		x			x	x	x	x

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 26 Scientific Advice letters, 5 Protocol Assistance letters, 6 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance, 4 Qualifications of novel methodologies and 2 HTA Parallel advice, were adopted at the 18 – 21 April 2017 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 59 new Requests for which the procedure started at the SAWP meeting held on 3 – 6 April 2017. The new requests are divided as follows: 32 Initial Scientific Advice, 12 Follow-up Scientific Advice, 5 Initial Protocol Assistance, 3 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 5 HTA Parallel advices.