



26 January 2017  
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Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 23 – 26 January 2017

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

	1995 - 2015	2017	Overall total
Scientific Advice	3215	32	3247
Follow-up to Scientific Advice	938	14	952
Protocol Assistance	735	7	742
Follow-up to Protocol Assistance	355	2	357
HTA parallel advice	87	0	87
Qualification of novel methodologies	94	2	96
	<b>5424</b>	<b>57</b>	<b>5481</b>

### ***Outcome of the December 2016 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 type 2 diabetes mellitus.			x			x	x	
Chemical	Treatment of psoriatic arthritis.	x						x	
Advanced therapy	Treatment of advanced renal cell carcinoma.			x		x	x	x	
Biological	Treatment of paroxysmal nocturnal haemoglobinuria.				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			
Chemical	Treatment of metastatic breast cancer.			x		x			
Biological	Treatment of multiple myeloma.	x						x	
Biological	Treatment of breast cancer, non-small cell lung cancer, renal cell carcinoma, ovarian cancer.	x				x	x	x	
Biological	Treatment of Ewing sarcoma.	x					x	x	
Chemical	Treatment of non-small cell lung cancer.	x						x	
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis.	x				x			
Biological	Treatment of diffuse large B-cell lymphoma and chronic and chronic lymphocytic leukaemia.		x				x		
Biological	Treatment of breast cancer.			x				x	
Biological	Treatment of pancreatic cancer.	x						x	
Chemical	Treatment of Crohn's disease.	x						x	
Biological	Treatment of renal cell carcinoma.	x						x	
Chemical	Treatment of breast cancer.	x					x	x	
Chemical	Treatment of ulcerative colitis.			x				x	
Biological	Treatment of anaemia due to chronic kidney disease and chemotherapy.	x				x	x	x	
Advanced therapy	Treatment of severe haemophilia B.	x				x	x	x	
Chemical	Chronic anticoagulation.	x					x	x	
Chemical	Treatment of atopic dermatitis.	x				x	x	x	
Chemical	Treatment of epidermolysis bullosa simplex.				x		x	x	
Biological	Treatment of atopic dermatitis.			x			x	x	
Chemical	Prevention and treatment of HIV-1.	x				x			

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Treatment of nosocomial pneumonia, including ventilator-associated pneumonia.			x				x	
Chemical	Treatment of nosocomial pneumonia, including ventilator-associated pneumonia.	x					x		
Chemical	Treatment of invasive aspergillosis and scedosporiosis.		x			x			
Chemical	Treatment of complicated intraabdominal infections.	x						x	
Chemical	Treatment of complicated urinary tract infections	x					x	x	
Biological	Immunisation against invasive meningococcal disease caused by Neisseria meningitides.	x				x			
Biological	Immunisation against hepatitis B virus.	x				x	x	x	
Chemical	Treatment of chronic hepatitis C infection.	x					x	x	
Chemical	Treatment of Duchenne muscular dystrophy.		x					x	
Biological	Treatment of osteoporosis.			x				x	
Biological	Treatment of multiple sclerosis.	x						x	
Advanced therapy	Treatment of type 1 spinal muscular atrophy.		x					x	
Chemical	Treatment of hypoxic-ischemic encephalopathy.	x				x	x	x	
Biological	Treatment of Alzheimer's disease and prodromal Alzheimer's disease.	x				x			
Chemical	Treatment of acute inner ear tinnitus.	x				x			
Chemical	Treatment of autosomal dominant polycystic kidney disease.	x					x	x	
Chemical	Treatment of mitochondrial encephalomyopathy, lactic acidosis, and stroke-like episodes.		x					x	
Chemical	Treatment of Parkinson's disease.			x			x	x	
Chemical	Treatment of schizophrenia.			x				x	
Chemical	Treatment of schizophrenia.			x				x	
Chemical	Treatment of schizophrenia.	x				x			

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Advanced therapy	Treatment of tracheal stenosis.		x			x	x		
Chemical	Treatment of facioscapulohumeral muscular dystrophy.	x						x	
Chemical	Treatment of TTR cardiomyopathy.			x				x	
Chemical	Treatment of eosinophilic asthma.	x				x			
Advanced therapy	Treatment of retinitis pigmentosa.	x				x	x		
Biological	Treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy.			x				x	
Chemical	Treatment of autosomal dominant polycystic kidney disease.		x					x	x
Chemical/ Other innovative	Treatment of rheumatoid arthritis.			x				x	
Biological	Treatment of peanut allergy.	x				x	x	x	
Qualification advice	Treatment of cystic fibrosis.	x						x	
Qualification opinion	Treatment of paediatric tumours.	x						x	

**SA: Scientific Advice**

**PA: Protocol Assistance**

The above-mentioned 32 Scientific Advice letters, 7 Protocol Assistance letters, 14 Follow-up Scientific Advice, 2 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 0 HTA Parallel advice, were adopted at the 23 – 26 January 2017 CHMP meeting.

### **New requests for scientific advice procedures**

The Committee accepted 62 new Requests for which the procedure started at the SAWP meeting held on 9 – 12 January 2017. The new requests are divided as follows: 31 Initial Scientific Advice, 10 Follow-up Scientific Advice, 12 Initial Protocol Assistance, 3 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 4 HTA Parallel advice.