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Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 9 – 12 October 2017

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

	1995 - 2016	2017	Overall total
Scientific Advice	3215	262	3477
Follow-up to Scientific Advice	938	92	1030
Protocol Assistance	735	76	811
Follow-up to Protocol Assistance	355	46	401
HTA parallel advice	87	23	110
Qualification of novel methodologies	94	19	113
	<b>5424</b>	<b>518</b>	<b>5942</b>

### ***Outcome of the October 2017 CHMP meeting in relation to scientific advice procedures***

#### **Final scientific advice procedures**

Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharma- ceutical	Pre- clinical	Clinical	Significant
		SA	PA	SA	PA				
Chemical	Treatment of Niemann-Pick type C disease.				x	x	x	x	
Chemical	Treatment of primary biliary cholangitis.	x						x	
Chemical	Chronic management of urea cycle disorders.	x						x	
Advanced therapy	Treatment of Wilson's disease.		x			x	x	x	
Chemical	Treatment of relapsing multiple sclerosis.	x					x	x	



Substance	Intended indication(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant
		SA	PA	SA	PA				
Chemical	Treatment of chronic myeloid leukaemia.	x				x			
Biological	Treatment of head and neck squamous cell carcinoma.	x						x	
Chemical	Treatment of follicular lymphoma.	x						x	
Biological	Treatment of bladder cancer.	x						x	
Biological	Treatment of paroxysmal nocturnal haemoglobinuria and atypical haemolytic uremic syndrome.	x				x	x	x	
Chemical	Treatment of haematologic malignancies and cGVHD.	x						x	
Biological	Treatment of adenocarcinoma of the stomach or gastroesophageal junction.	x				x		x	
Chemical	Treatment of myelodysplastic syndromes.	x				x			
Biological	Treatment of acute respiratory distress syndrome.		x			x	x	x	
Chemical	Treatment of multiple myeloma.				x		x	x	
Biological	Treatment of myelodysplastic syndromes.		x				x		
Chemical	Treatment of pulmonary arterial hypertension.	x				x	x	x	
Biological	Treatment of active psoriatic arthritis.			x				x	
Biological	Treatment of rheumatoid arthritis, chronic lymphocytic leukaemia and non-Hodgkin lymphoma.			x		x		x	
Biological	Treatment of hidradenitis suppurativa.	x						x	
Chemical	Treatment of hereditary angioedema.	x					x	x	
Chemical	Treatment of transfusion-dependent beta thalassemia.				x			x	
Biological	Removal on non-viable tissue in diabetic foot ulcers and venous leg ulcers.	x				x	x	x	
Chemical	Treatment of atopic dermatitis.	x				x	x	x	
Chemical	Prevention of atopic dermatitis.	x						x	
Chemical	Treatment of adenovirus infection and smallpox.		x			x	x		
Biological	Immunisation against invasive meningococcal disease caused by Neisseria meningitidis group B.	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 hospital-associated pneumonia and ventilator-associated pneumonia due to P. aeruginosa.	x				x			
Chemical	Treatment of acute influenza A.			x			x	x	
Chemical	Treatment of uncomplicated urinary tract infections.	x						x	
Chemical	Treatment of complicated urinary tract infections.	x						x	
Chemical	Treatment of complicated intra-abdominal infections.	x					x	x	
Biological	Immunisation against poliomyelitis.	x				x	x	x	
Biological	Immunisation for prevention of congenital cytomegalovirus infection and disease.	x					x	x	
Advanced therapy	Treatment of Asherman's syndrome.		x			x	x	x	
Biological	Treatment of diffuse large B-cell lymphoma.		x			x		x	
Biological	Treatment of achondroplasia.		x				x		
Chemical	Treatment of Alzheimer's disease.	x				x			
Chemical	Treatment of cerebral amyloid angiopathy.	x					x	x	
Biological/ Other innovative	Treatment of multiple sclerosis.	x					x		
Advanced therapy	Hematopoietic reconstitution in allogeneic hematopoietic stem cell transplantation.		x				x		
Chemical	Treatment of Huntington disease.				x		x	x	
Chemical/ Other innovative	Treatment of acute migraine.	x					x	x	
Chemical	Treatment of autism spectrum disorder.			x				x	
Chemical	Treatment of glioblastoma multiforme.	x						x	
Biological	Treatment of neovascular age-related macular degeneration.			x		x	x	x	
Advanced therapy	Treatment of choroideremia.				x			x	
Biological	Treatment of achondroplasia.				x	x		x	

Substance	Intended indication(s)	Type of request				Topic			Significant Benefit
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	
		SA	PA	SA	PA				
Other innovative	Treatment of IgA nephropathy.				x			x	
Chemical	Treatment of thalassaemia major.	x				x		x	
Chemical	Hysterosalpingo-contrast sonography agent.	x						x	
HTA parallel	Treatment of resistant hypertension.	x					x	x	
HTA parallel	Treatment of lupus erythematosus and lupus nephritis.	x						x	
HTA parallel	Treatment of osteogenesis imperfecta.		x			x	x	x	
HTA parallel	Prevention of chemotherapy-induced peripheral neuropathy.			x				x	
HTA parallel	Treatment of Alzheimer's disease.	x						x	

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 32 Scientific Advice letters, 8 Protocol Assistance letters, 5 Follow-up Scientific Advice, 7 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 5 HTA Parallel advice, were adopted at the 9 – 12 October 2017 CHMP meeting.

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

The Committee accepted 79 new Requests for which the procedure started at the SAWP meeting held on 25 – 28 September 2017. The new requests are divided as follows: 45 Initial Scientific Advice, 9 Follow-up Scientific Advice, 12 Initial Protocol Assistance, 10 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 3 HTA Parallel advices.