



25 July 2019  
EMA/CHMP/SAWP/420885/2019  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 22 – 25 July 2019

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

	1995 - 2018	2019	Overall total
Scientific Advice	3866	221	4087
Follow-up to Scientific Advice	1150	80	1230
Protocol Assistance	932	65	997
Follow-up to Protocol Assistance	477	29	506
EMA/EU netHTA parallel consultation advice	139	14	153
Qualification of novel methodologies	126	10	136
	<b>6689</b>	<b>419</b>	<b>7108</b>

### **Outcome of the July 2019 CHMP meeting in relation to scientific advice procedures**

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

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of actinic keratosis	X						X	
Biological	Treatment of chronic spontaneous or inducible urticaria	X				X		X	
Biological	Treatment of Fabry disease	X				X	X	X	



Chemical	Treatment of obesity and hyperphagia		X			X			
Chemical	Treatment and maintenance of healed erosive reflux oesophagitis and relief of heartburn	X					X	X	
Chemical	Treatment of anaemia			X				X	
Biological	Treatment of myelodysplastic syndrome and transfusion dependent beta-thalassemia		X			X			
Chemical	Reduction/prevention of myocardial necrosis	X					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 NSCLC			X				X	
Chemical	Treatment of myelodysplastic syndromes		X			X		X	
Biological	Treatment of hidradenitis suppurativa		X					X	
Biological	Treatment of biliary tract cancer				X			X	X
Chemical	Treatment of renal cell carcinoma	X						X	
Biological	Treatment of urothelial carcinoma	X						X	
Advanced Therapy	Treatment of atopic dermatitis			X		X		X	
Chemical	Treatment of acute graft vs host disease				X	X			
Biological	Broad clinical advice in various oncology indications	X						X	
Advanced Therapy	Immunosuppression in living donor kidney transplantation	X				X		X	
Advanced Therapy	Treatment of steroid-refractory acute graft-versus-host disease		X			X	X		
Chemical	Treatment of rheumatoid arthritis	X					X	X	
Biological	Cross-indication advice for new sub-cutaneous route of administration	X				X			
Biological	Treatment of classical Hodgkin lymphoma	X						X	
Chemical	Treatment of breast cancer	X					X	X	
Biological	Treatment of rheumatoid arthritis, chronic lymphocytic leukaemia, non-Hodgkin lymphoma			X		X			
Chemical	Treatment of lymphoplasmacytic lymphoma		X			X			
Chemical	Broad advice on early stage development for multiple oncology indications	X						X	
Chemical	Treatment of splenomegaly				X			X	
Chemical	Treatment of thyroid cancer		X			X	X	X	X
Chemical	Treatment of non-small cell lung cancer	X						X	

Chemical	Treatment of glioma	X					X	X	
Chemical	Treatment of basal cell carcinoma				X		X	X	X
Biological	Immunisation against tuberculosis	X					X	X	
Biological	Prevention of rabies			X		X		X	
Biological	Prevention of pneumococcal disease caused by strains of S.pneumoniae			X		X			
Chemical	Treatment of schizophrenia and bipolar disorder	X						X	
Chemical/ Biological	Treatment of Alzheimer's disease	X						X	
Biological	Treatment of headache	X						X	
Chemical	Treatment of acute peripheral tinnitus			X				X	
Chemical	Treatment of vasomotor symptoms associated with menopause	X				X			
Chemical	Treatment of neurodegeneration.		X			X	X		
Biological	Treatment of chronic obstructive pulmonary disease			X				X	
Chemical	Treatment of insomnia	X						X	
Advanced Therapy	Treatment of GM1 gangliosidosis	X				X	X	X	
Chemical	Treatment of pyruvate kinase deficiency			X			X	X	
Chemical	Treatment of cystic fibrosis	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	X	X	
Chemical	Treatment of Stargardt's disease		X				X	X	
Advanced Therapy	Treatment of X-linked retinitis pigmentosa		X				X	X	
Chemical	Symptomatic treatment of urgency.	X				X		X	
Biological	Treatment of sepsis-associated kidney injury	X						X	
Other innovative	Diagnostic markers	X					X	X	
Chemical	Oncology diagnostic	X				X	X	X	
Biological	Treatment of head and neck squamous cell carcinoma	X				X	X	X	
Biological	Treatment of ectonucleotide pyrophosphatase/phosphodiesterase 1 deficiency		X				X	X	
Qualification Advice	Treatment of Parkinson's disease	X						X	
Qualification Advice	Treatment of Parkinson's disease	X						X	

Qualification Advice	Treatment of osteogenesis imperfecta	X					X	
EMA/EUnetHTA	Treatment of ovarian, fallopian tube, and primary peritoneal carcinoma		X			X	X	
EMA/EUnetHTA	Treatment of graft-versus-host disease		X				X	

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 33 Scientific Advice letters, 9 Protocol Assistance letters, 9 Follow-up Scientific Advice, 4 Follow-up Protocol Assistance, 3 Qualifications of novel methodologies and 2 EMA/EUnetHTA parallel consultation advices, were adopted at the 22 – 25 July 2019 CHMP meeting.

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

The Committee accepted 63 new Requests for which the procedure started at the SAWP meeting held on 8 – 11 July 2019. The new requests are divided as follows: 41 Initial Scientific Advice, 12 Follow-up Scientific Advice, 4 Initial Protocol Assistance, 4 Follow-up Protocol Assistance, 0 Qualification of novel methodologies and 2 EMA/EUnetHTA parallel consultation advices.