



25 June 2020  
EMA/CHMP/SAWP/347887/2020  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 22 – 25 June 2020

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

	1995 - 2019	2020	Overall total
Scientific Advice	4258	238	4496
Follow-up to Scientific Advice	1277	71	1348
Protocol Assistance	1003	29	1032
Follow-up to Protocol Assistance	525	28	553
EMA/EU netHTA parallel consultation advice	159	5	164
Qualification of novel methodologies	142	12	154
	<b>7364</b>	<b>229</b>	<b>7747</b>

### **Outcome of the June 2020 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 thymidine kinase 2 deficiency				x			x	
Chemical	Treatment of ulcerative colitis	x						x	
Biological	Treatment of membranous nephropathy	x					x	x	
Biological	Prevention of COVID-19 disease	x				x	x	x	

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Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of infections caused by COVID-19.	x				x	x	x	
Biological	Treatment of infections caused by COVID-19	x				x	x	x	
Chemical	Treatment of allergic bronchopulmonary aspergillosis	x					x	x	
Chemical	Treatment of primary ERT	x					x	x	
Chemical	Treatment of Alexander disease				x			x	
Chemical	Treatment of Huntington's disease		x					x	
Biological	Treatment of eosinophilic oesophagitis	x				x			
Biological	Treatment of eosinophilic oesophagitis			x			x	x	
Biological	Treatment of type 2 diabetes mellitus	x				x	x	x	
Chemical	Treatment of thymidine kinase 2 deficiency				x	x			
Chemical	Treatment of Alagille syndrome		x					x	
Chemical	Treatment of gastroparesis	x				x	x	x	
Chemical	Treatment of primary biliary cholangitis	x				x	x	x	
Chemical	Treatment of Wilson disease				x		x		
Biological	Treatment of NSCLC	x						x	
Chemical	Treatment of paroxysmal nocturnal haemoglobinuria		x			x			
Biological	Treatment of esophageal squamous cell carcinoma	x						x	
Biological	Treatment of large B-cell lymphoma	x					x	x	
Biological	Treatment of follicular lymphoma	x					x	x	
Biological	Treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and ulcerative colitis	x				x	x	x	
Chemical	Prevention of painful vaso-occlusive crises	x				x		x	
Biological	Treatment of squamous cell carcinoma	x				x			
Chemical	Treatment of graft versus host disease				x			x	
Advanced Therapy	Treatment of lymphocytic leukaemia or small lymphocytic lymphoma	x						x	
Biological	Treatment of solid tumors	x				x	x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of breast cancer			x				x	
Biological	Treatment of rheumatoid arthritis, chronic lymphocytic leukaemia, non-Hodgkin lymphoma			x		x		x	
Biological	Treatment of esophageal squamous cell carcinoma	x						x	
Biological	Treatment of melanoma	x						x	
Chemical	Treatment of neuroendocrine tumours	x				x	x	x	
Biological	Treatment of lymphoma	x						x	
Chemical	Treatment of breast cancer	x						x	
Biological	Treatment of breast cancer and gastric cancer			x				x	
Biological	Treatment of plaque psoriasis and active psoriatic arthritis	x						x	
Biological	Treatment of plaque psoriasis and active psoriatic arthritis			x		x		x	
Chemical	Treatment of multiple myeloma				x			x	
Biological	Treatment of adenocarcinoma of the stomach and gastroesophageal junction				x	x			
Chemical	Treatment of onchocerciasis			x				x	
Advanced Therapy	Treatment of $\beta$ -thalassaemia intermedia and major				x			x	x
Advanced Therapy	Treatment of $\beta$ -thalassaemia intermedia and major		x			x			
Biological	Treatment of beta-thalassaemia intermedia and major				x			x	
Chemical	Treatment of sickle cell disease		x			x			
Chemical	Treatment of chylomicronemia	x					x	x	
Chemical	Treatment of chronic thromboembolic pulmonary hypertension	x						x	
Chemical	Local anaesthesia of dermal lacerations	x					x	x	
Chemical	Treatment of mycobacterium avium complex and mycobacterium abscessus complex lung infection		x					x	
Chemical	Treatment of HIV-1 infection	x				x			
Chemical	Treatment of infections caused by Covid-19	x				x	x	x	
Chemical	Treatment of non-cystic fibrosis bronchiectasis	x					x	x	
Chemical	Treatment of human respiratory syncytial virus infection			x			x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of human respiratory syncytial virus infection			x				x	
Chemical	Treatment of hepatitis B or hepatitis B & D co-infection	x				x			
Biological	Prevention of chronic obstructive pulmonary disease	x				x		x	
Chemical	Treatment of invasive candidiasis			x				x	
Biological	Prevention of yellow fever	x				x	x	x	
Biological	Treatment of primary hyperoxaluria				x			x	
Chemical	Treatment of Duchenne muscular dystrophy	x					x	x	
Chemical	Treatment of postmenopausal osteoporosis	x				x	x	x	
Biological	Treatment of osteoporosis or increase of bone mass in osteoporosis at high risk of fracture	x				x		x	
Biological	Quality broad Advice	x				x			
Chemical	Treatment of amyotrophic lateral sclerosis		x			x			
Biological	Prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae	x				x			
Innovative product or therapy	Treatment of amyotrophic lateral sclerosis	x						x	
Chemical	Treatment of Parkinson's disease	x						x	
Advanced Therapy	Treatment of Parkinson's disease	x				x	x	x	
Chemical	Treatment of schizophrenia	x						x	
Chemical	Treatment of amyotrophic lateral sclerosis				x			x	x
Chemical	Treatment of Leber's congenital amaurosis				x	x	x		
Chemical	Treatment of Friedreich's ataxia	x					x	x	
Biological	Treatment of severe wheeze	x					x	x	
Biological	Treatment of autoimmune pulmonary alveolar proteinosis				x			x	
Biological	Prevention of respiratory tract infections.	x						x	
Biological	Treatment of chronic obstructive pulmonary disease	x						x	
Biological	Treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema and diabetic			x				x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
	retinopathy								
Chemical	Treatment of prostate cancer	x				x		x	
Chemical	Treatment of pneumoniae caused by COVID-19	x						x	
Chemical	Treatment of prostate cancer			x		x	x	x	
Chemical	Treatment of prostate cancer	x				x		x	
Qualification Advice	Treatment of Autism spectrum disorder	x							
Qualification Advice	Treatment of Autism spectrum disorder	x							
Qualification Advice	Treatment of endometriosis-related pain	x							
Parallel EUnetHta	Treatment of Huntington's disease				x			x	

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 51 Scientific Advice letters, 7 Protocol Assistance letters, 12 Follow-up Scientific Advice, 12 Follow-up Protocol Assistance, 3 Qualifications of novel methodologies and 1 EMA/EUnetHTA parallel consultation advices, were adopted at the 22-25 June 2020 CHMP meeting.

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

The Committee accepted 68 new Requests for which the procedure started at the SAWP meeting held on 08-11 June 2020. The new requests are divided as follows: 47 Initial Scientific Advice, 11 Follow-up Scientific Advice, 4 Initial Protocol Assistance, 3 Follow-up Protocol Assistance, 3 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.