



12 November 2020  
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Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 09 – 12 November 2020

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

	1995 - 2019	2020	Overall total
Scientific Advice	4258	450	4708
Follow-up to Scientific Advice	1277	126	1403
Protocol Assistance	1003	61	1064
Follow-up to Protocol Assistance	525	44	569
EMA/EUnetHTA parallel consultation advice	159	5	164
Qualification of novel methodologies	142	16	158
	<b>7364</b>	<b>542</b>	<b>8066</b>

### **Outcome of the November 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 myocardial infarction	x						x	
Advanced Therapy	Treatment of intrahepatic cholestasis		x				x	x	
Chemical/Biological	Treatment of urothelial carcinoma	x						x	
Biological	Treatment of bladder cancer	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				
Chemical	Treatment of breast cancer	x						x	
Biological	Treatment of large B-cell lymphoma	x						x	
Biological	Treatment of large B-cell lymphoma	x					x	x	
Biological	Treatment of mantle cell lymphoma	x				x	x	x	
Chemical	Treatment of severe hyperglyceridemia	x				x	x	x	
Chemical	Treatment of cardiovascular outcome trial	x				x	x	x	
Biological	Treatment of frontotemporal dementia	x					x	x	
Chemical	Detection of prostate carcinoma			x				x	
Biological	Treatment of NASH			x			x		
Biological	Treatment of NASH		x			x	x	x	
Chemical	Treatment of Pompe disease	x					x	x	
Chemical	Treatment of type I diabetes		x					x	
Biological	Treatment of Bardet Biedl and Alström syndromes	x					x		
Biological	Treatment of myeloid leukaemia	x					x	x	
Chemical	Treatment of multiple myeloma	x						x	
Biological	Treatment of breast cancer	x					x	x	
Biological	Treatment of nonn small cell lung cancer			x			x		
Chemical	Treatment of paroxysmal nocturnal hemoglobinuria and atypical haemolytic uremic syndrome		x				x		
Biological	Treatment of myeloid leukaemia			x				x	
Biological	Treatment of ulcerative colitis	x					x	x	
Biological	Treatment of hepatocellular carcinoma	x					x	x	
Chemical	Treatment of Sjogren's syndrome	x				x		x	
Biological	Treatment of atypical haemolytic uremic syndrome	x				x			
Chemical	Treatment of solid tumors	x						x	
Chemical	Treatment of systemic sclerosis		x					x	x

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Advanced Therapy	Treatment of desmoid tumours		x			x	x	x	
Chemical	Treatment of Wiskott Aldrich syndrome			x			x	x	
Biological	Treatment of prostate cancer	x					x	x	
Chemical	Treatment of dermatomyositis	x				x	x	x	
Chemical	Prevention of COVID-19 disease		x					x	x
Chemical	Treatment of marginal zone lymphoma	x					x	x	
Biological	Treatment of neuroblastoma	x				x	x	x	
Chemical	Treatment of rheumatoid arthritis, chronic lymphocytic leukaemia, non-Hodgkin lymphoma.	x					x	x	
Chemical	Treatment of breast cancer				x			x	
Biological	Treatment of pulmonary arterial hypertension			x		x		x	
Chemical	Treatment of plaque psoriasis and active psoriatic arthritis			x				x	
Biological	Treatment of myelodysplastic syndromes	x						x	
Chemical	Treatment of gastroesophageal adenocarcinomas			x				x	
Chemical	Treatment of human African trypanosomiasis	x				x			
Chemical	Treatment of sickle cell disease	x						x	
Chemical	Treatment of sickle cell disease		x						x
Chemical	Treatment of diffused large B-cell lymphoma			x			x	x	
Chemical	Treatment of atopic dermatitis			x				x	
Chemical	Treatment of atopic dermatitis	x						x	
Chemical	Treatment of chronic hand eczema	x						x	
Biological	Treatment of S.aureus infections	x						x	
Biological	Treatment of chronic spontaneous urticaria	x						x	
Chemical	Treatment of atopic dermatitis	x						x	
Biological	Treatment of HIV-1	x				x			
Biological	Prevention of lower respiratory tract infection			x				x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Prevention of Streptococcus pneumoniae diseases	x					x	x	
Chemical	Treatment of Acinetobacter infections		x				x	x	
Chemical	Treatment of Alport syndrome	x				x	x	x	
Chemical	Treatment of overactive bladder		x			x	x		
Chemical	Treatment of anti-MAG neuropathy	x					x		
Chemical	Treatment of alcohol use disorder			x		x		x	
Biological	Treatment of major depressive disorder	x						x	
Advanced Therapy	Treatment of X-linked retinitis pigmentosa				x			x	
Chemical	Treatment of prostate cancer	x						x	
Biological	Treatment or prophylaxis of graft rejection	x				x		x	
Biological	Treatment of mantle cell lymphoma	x						x	
Biological	Prevention of COVID 19			x				x	
Biological	Prevention of COVID 19	x					x	x	
Biological	Prevention of COVID 19			x				x	
Biological	Prevention of COVID 19	x					x		
Biological	Treatment of COVID 19	x				x	x		
Biological	Treatment of COVID 19	x					x		
Qualification Advice	Drug-induced Vascular Injury	x							
Qualification Advice	Drug-induced Kidney Injury	x							

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 73 Scientific Advice letters - 48 Initial Scientific Advice, 11 Follow-up Scientific Advice, 9 Protocol Assistance letters, 3 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 09-12 November 2020 CHMP meeting.

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

The Committee accepted 78 new Requests for which the procedure started at the SAWP meeting held on 26-29 October 2020. The new requests are divided as follows: 49 Initial Scientific Advice, 10 Follow-up Scientific Advice, 10 Initial Protocol Assistance, 8 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.