



28 May 2020
EMA/CHMP/SAWP//2020
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 25 – 28 May 2020

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

	1995 - 2019	2020	Overall total
Scientific Advice	4258	187	4445
Follow-up to Scientific Advice	1277	59	1336
Protocol Assistance	1003	22	1025
Follow-up to Protocol Assistance	525	16	541
EMA/EU netHTA parallel consultation advice	159	4	163
Qualification of novel methodologies	142	9	151
	7364	229	7661

Outcome of the May 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				
Advanced Therapy	Treatment of acute liver failure	x				x	x	x	
Biological	Treatment of diabetes mellitus	x				x	x	x	
Chemical	Treatment of irritable bowel syndrome	x						x	
Biological	Treatment of type 2 diabetes mellitus			x				x	



Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of celiac disease	x					x	x	
Biological	Prevention of major bleeding	x				x	x	x	
Chemical	Treatment of intrahepatic cholestasis	x					x	x	
Chemical	Treatment of myeloid leukaemia	x					x	x	
Biological	Treatment of melanoma			x				x	
Advanced Therapy	Treatment of cryptoglandular fistulas		x				x	x	
Chemical	Treatment of ovarian tumors	x					x		
Biological	Treatment of non-small cell lung cancer			x			x	x	
Biological	Treatment of small cell lung cancer			x				x	
Chemical	Treatment of mature B-cell neoplasm and graft-versus-host disease				x	x	x	x	
Advanced Therapy	Treatment of renal cell carcinoma.			x		x	x	x	
Chemical, Biological	Treatment of metastatic NSCLC.			x				x	
Chemical	Treatment of myelofibrosis		x				x	x	
Biological	Treatment of oesophageal cancer	x						x	
Biological	Treatment of urothelial cancer	x						x	
Biological	Treatment of advanced melanoma			x				x	
Biological	Treatment of papillary tumours	x				x			
Biological	Treatment of chronic inflammatory demyelinating polyneuropathy	x					x		
Chemical	Treatment of myelofibrosis	x				x	x	x	
Biological	Treatment of thrombotic microangiopathy			x				x	
Chemical	Treatment of breast cancer	x				x			
Chemical	Treatment of active psoriatic arthritis			x				x	
Chemical	Treatment of ulcerative colitis			x				x	
Chemical	Treatment of active psoriatic arthritis and ulcerative colitis	x				x			
Chemical	Prevention and treatment of soil-transmitted helminths infections			x				x	
Chemical	Treatment of immunoglobulin A nephropathy	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 IgA nephropathy			x				x	
Chemical	Treatment of IgA nephropathy	x					x		
Chemical	Treatment of pulmonary arterial hypertension				x			x	
Biological	Treatment of prurigo nodularis	x				x		x	
Chemical	Treatment of atopic dermatitis	x				x	x	x	
Chemical	Treatment of psoriasis	x				x	x	x	
Chemical	Treatment of human immunodeficiency virus 1	x						x	
Chemical	Treatment of endometriosis			x		x			
Advanced Therapy	Treatment of Duchenne muscular dystrophy		x			x	x	x	x
Biological	Treatment of osteoporosis			x				x	
Chemical	Treatment of fibrodysplasia ossificans progressiva	x				x	x	x	
Chemical	Treatment of Charcot-Marie-Tooth disease Type 1A		x			x	x	x	
Chemical	Treatment of bipolar disorder	x				x	x	x	
Chemical	Treatment of schizophrenia	x				x	x	x	
Biological	Treatment of idiopathic intracranial hypertension		x				x	x	
Chemical	Treatment of bronchial asthma	x						x	
Chemical	Treatment of severe asthma			x				x	
Biological	Treatment of asthma and chronic idiopathic urticaria.			x				x	
Biological	Treatment of allergic asthma and chronic spontaneous urticaria	x				x		x	
Biological	Treatment of asthma and chronic idiopathic urticaria.	x						x	
Chemical	Treatment of chronic obstructive pulmonary disease			x				x	
Chemical	Prevention of myopic progression			x			x	x	
Biological	Treatment of diabetic macular oedema and neovascular macular degeneration			x		x			
Biological	Prevention of respiratory syncytial virus infection	x					x	x	
Biological	Treatment of mucopolysaccharidosis type II (Hunter syndrome)		x					x	x
Chemical	Treatment of hepatocellular carcinoma		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 severe refractory heterozygous familial hypercholesterolaemia	x						x	
Advanced Therapy	Treatment of dystrophic epidermolysis bullosa				x	x	x	x	
Chemical	Treatment of pseudoxanthoma elasticum	x					x	x	
Biological	Treatment of fibrodysplasia ossificans progressiva		x					x	
Chemical	Treatment of amyotrophic lateral sclerosis		x				x	x	
Chemical	Treatment of hypoactive sexual desire disorder	x					x	x	
Chemical	Treatment of multiple sclerosis	x					x	x	
Advanced Therapy	Treatment of retinitis pigmentosa		x				x	x	
Chemical	Treatment of breast cancer			x				x	
Biological	Treatment and prevention of COVID-19	x				x	x	x	
Biological	Treatment and prevention of COVID-19	x				x			
Biological	Treatment of pneumonia caused by COVID-19	x				x		x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 36 Scientific Advice letters, 10 Protocol Assistance letters, 19 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance, x Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices, were adopted at the 25 - 28 May 2020 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 89 new Requests for which the procedure started at the SAWP meeting held on 11 - 14 May 2020. The new requests are divided as follows: 58 Initial Scientific Advice, 13 Follow-up Scientific Advice, 12 Initial Protocol Assistance, 6 Follow-up Protocol Assistance, 0 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.