



27 April 2020
EMA/CHMP/SAWP/232798/2020
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 28 – 30 April 2020

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

	1995 - 2019	2020	Overall total
Scientific Advice	4258	151	4409
Follow-up to Scientific Advice	1277	40	1317
Protocol Assistance	1003	12	1015
Follow-up to Protocol Assistance	525	13	538
EMA/EU netHTA parallel consultation advice	159	4	163
Qualification of novel methodologies	142	9	151
	7364	229	7593

Outcome of the April 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 Niemann-Pick disease type C		x					x	
Biological	Treatment of diabetes mellitus	x				x	x	x	
Chemical	Treatment of breast cancer			x				x	
Biological	Treatment of papillary tumours	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				
Chemical	Treatment of paroxysmal nocturnal haemoglobinuria	x				x	x	x	
Biological	Treatment of multiple myeloma	x					x		
Biological	Treatment of biliary tract cancer				x			x	
Biological	Treatment of breast cancer	x					x	x	
Chemical	Treatment of prostate cancer	x						x	
Biological	Treatment of ulcerative colitis			x				x	
Biological	Treatment of rheumatoid arthritis, chronic lymphocytic leukaemia, non-Hodgkin lymphoma	x				x		x	
Biological	Treatment of diffuse large B-cell lymphoma				x			x	x
Chemical	Treatment of prostate cancer	x					x	x	
Biological	Treatment of postoperative adhesions	x				x	x	x	
Biological	Treatment of angioedema	x					x	x	
Biological	Treatment of paroxysmal nocturnal haemoglobinuria	x						x	
Advanced Therapy	Treatment of leukocyte adhesion deficiency-I	x				x		x	
Chemical	Treatment of hypertension	x					x		
Biological	COVID-19 vaccine	x				x	x		
Chemical	Treatment of complicated urinary tract infections			x		x		x	
Chemical	Treatment of HIV-1 infection			x		x	x	x	
Biological	Treatment of chronic hepatitis B virus infection	x				x	x	x	
Biological	Prevention of invasive disease caused by Neisseria meningitidis serogroup B	x				x	x	x	
Biological	Prevention of respiratory syncytial virus lower respiratory tract disease	x				x			
	Prevention of chikungunya virus			x				x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
	infection								
Biological	Prevention of influenza disease			x				x	
Chemical	Treatment of HIV	x						x	
Chemical	Treatment of dermatomycoses	x				x		x	
Biological	Treatment of X-linked hypophosphataemia		x			x		x	
Biological	Treatment of osteoporosis or increase of bone mass			x				x	
Biological	Treatment of Duchenne muscular dystrophy		x				x	x	
Chemical	Treatment of acute ischaemic stroke	x					x	x	
Chemical	Prevention of relapse in schizophrenia	x						x	
Chemical	Treatment of hypoactive sexual desire disorder			x				x	
Chemical	Treatment of epilepsy		x			x		x	
Chemical	Treatment of behavioural variant frontotemporal dementia			x				x	
Biological	Treatment of membranous nephropathy	x						x	
Chemical	Treatment of somatic acute pain			x				x	
Biological	Treatment of non-cystic fibrosis bronchiectasis	x						x	
Chemical	Treatment of asthma			x				x	
Biological	Treatment of chronic rhinosinusitis with nasal polyps	x						x	
Chemical	Treatment of idiopathic pulmonary fibrosis				x		x	x	
Biological	Treatment of choroidal neovascularisation	x				x			
Chemical	Treatment of sensorineural hearing loss	x				x	x	x	
Biological	Treatment of plaque psoriasis and active psoriatic arthritis	x				x		x	
Biological	Treatment of follicular lymphoma	x					x	x	
Qualification Advice	Patient preference studies	x							

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Qualification Advice	Treatment of liver fibrosis	x						x	
Qualification Advice	Treatment of ulcerative colitis	x							

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 29 Scientific Advice letters, 10 Protocol Assistance letters, 4 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance, 3 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices, were adopted at the 28 - 30 April 2020 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 13 – 16 April 2020. The new requests are divided as follows: 34 Initial Scientific Advice, 17 Follow-up Scientific Advice, 5 Initial Protocol Assistance, 4 Follow-up Protocol Assistance, 2 Qualification of novel methodologies and 1 EMA/EUnetHTA parallel consultation advices.