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EMA/CHMP/SAWP//2020
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 20 – 23 July 2020

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

	1995 - 2019	2020	Overall total
Scientific Advice	4258	283	4541
Follow-up to Scientific Advice	1277	87	1364
Protocol Assistance	1003	34	1037
Follow-up to Protocol Assistance	525	31	556
EMA/EUnetHTA parallel consultation advice	159	5	164
Qualification of novel methodologies	142	12	154
	7364	452	7816

Outcome of the July 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 sickle cell disease				x			x	
Chemical	Treatment of mucopolysaccharidosis type VI				x			x	
Biological	Treatment of hemolytic uremic syndrome	x						x	
Biological	Treatment of non small cell lung cancer	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 solid tumors	x						x	
Advanced Therapy	Treatment of large B cell lymphoma	x						x	
Chemical	Treatment of multiple sclerosis			x				x	
Chemical	Treatment of multiple sclerosis			x				x	
Biological	Treatment of solid tumors	x						x	
Biological	Treatment of Crohn's disease	x						x	
Biological	Treatment of pulmonary arterial hypertension	x						x	
Biological	Treatment of Crohn's disease	x						x	
Chemical	Treatment of major depressive disorder	x					x	x	
Chemical	Treatment of acromegaly	x					x	x	
Chemical	Treatment of short bowel syndrome		x			x	x	x	x
Chemical	Treatment of eosinophilic esophagitis		x					x	
Chemical	Treatment of type 2 diabetes mellitus	x				x		x	
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis			x		x			
Advanced Therapy	Treatment of organ dysfunction associated with sepsis	x					x	x	
Chemical	Treatment of chronic myelogenous leukaemia				x			x	x
Biological	Treatment of Crohn's disease, rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis	x					x	x	
Biological	Treatment of non small cell lung cancer and small cell lung cancer	x						x	
Chemical	Treatment of colorectal cancer	x						x	
Chemical	Treatment of breast cancer			x			x	x	
Biological	Treatment of hidradenitis suppurativa	x					x	x	
Advanced Therapy	Treatment of large B cell lymphoma	x					x	x	
Chemical	Treatment of von-Hippel Lindau syndrome	x					x	x	
Biological	Treatment of lupus nephritis			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 non small cell lung cancer	x				x	x	x	
Biological	Treatment of lupus erythematosus	x					x	x	
Biological	Treatment of breast cancer	x						x	
Chemical	Treatment of acute myeloid leukaemia	x						x	
Chemical	Broad Advice on a new formulation	x				x		x	
Chemical	Treatment of anaemia			x				x	
Chemical	Treatment of pneumonia caused by Covid-19	x					x	x	
Chemical	Treatment of sickle cell disease	x					x	x	
Chemical	Treatment of pulmonary arterial hypertension	x					x		
Chemical	Treatment of chronic kidney disease			x				x	
Biological	Treatment of lupus erythematosus	x					x	x	
Chemical	Treatment of alopecia areata			x				x	
Chemical	Treatment of infection caused by COVID-19	x						x	
Biological	Broad Advice on new manufacturing	x				x			
Chemical	Prevention of A and B strains of influenza	x				x		x	
Biological	Treatment of infection caused by COVID-19	x				x	x	x	
Biological	Prevention of primary Clostridium difficile infection			x				x	
Biological	Prevention of diseases caused by haemophilus influenzae type b	x				x			
Biological	Prevention of chikungunya virus			x				x	
Advanced Therapy	Treatment of Duchenne muscular dystrophy				x	x		x	
Chemical	Treatment of amyotrophic lateral sclerosis		x			x	x	x	
Chemical	Treatment for essential tremor	x				x	x	x	
Chemical	Prevention of urogenital infection	x				x	x	x	
Biological	Treatment of large B cell lymphoma			x				x	
Chemical	Treatment of multiple sclerosis			x				x	
Chemical	Treatment of ischemic stroke	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of Parkinson's disease	x						x	
Chemical	Treatment of Parkinson's disease	x					x	x	
Chemical	Treatment of cystic fibrosis				x		x		
Chemical	Treatment of primary ciliary dyskinesia	x					x	x	
Biological	Treatment of tympanic membrane perforation	x				x	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	
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	
Biological	Treatment of neovascular macular	x					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			
Chemical	Treatment of phototoxic reactions	x				x	x	x	
Biological	Prevention of COVID-19 disease			x			x	x	
Biological	Prevention and Treatment of COVID-19 disease	x				x	x	x	
Biological	Treatment of pulmonary disease caused by COVID19	x				x	x	x	
Biological	Prevention of COVID-19 disease	x				x	x	x	
Biological	Treatment of infections caused by Covid19			x		x	x	x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 45 Scientific Advice letters, 16 Follow-up Scientific Advice, 5 Protocol Assistance letters, 3 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices, were adopted at the 20-23 July 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 06-09 July 2020. The new requests are divided as follows: 40 Initial Scientific Advice, 11 Follow-up

Scientific Advice, 7 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.