



27 February 2020
EMA/CHMP/SAWP/98532/2020
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 24 – 27 February 2020

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

	1995 - 2019	2020	Overall total
Scientific Advice	4258	92	4350
Follow-up to Scientific Advice	1277	26	1303
Protocol Assistance	1003	2	1005
Follow-up to Protocol Assistance	525	5	528
EMA/EU netHTA parallel consultation advice	159	3	162
Qualification of novel methodologies	142	3	145
	7364	129	7493

Outcome of the February 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				
Biological	Treatment of diabetes mellitus	x						x	
Chemical	Treatment of acromegaly			x		x		x	
Chemical	Treatment of diabetes mellitus			x		x	x	x	
Chemical	Treatment of ulcerative colitis	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 glioma				x			x	
Chemical	Treatment of PIK3CA-related overgrowth spectrum	x						x	
Biological	Treatment of squamous cell carcinoma of the head and neck	x						x	
Biological	Treatment of breast cancer, non-small cell lung cancer, renal cell carcinoma and ovarian cancer	x						x	
Biological	Treatment of acute lymphoblastic leukaemia	x				x	x	x	
Biological	Treatment of no-small cell lung cancer	x						x	
Biological	Treatment of non-small cell lung cancer	x						x	
Biological	Treatment of non-small cell lung cancer			x				x	
Advanced Therapy	Treatment of multiple myeloma			x				x	
Biological	Treatment of active axial spondyloarthritis			x				x	
Chemical	Treatment of prostate cancer	x				x		x	
Chemical	Treatment of desmoid tumours	x				x	x		
Chemical	Treatment of non-small cell lung cancer			x				x	
Biological	Treatment of juvenile idiopathic arthritis			x				x	
Biological	Treatment of breast cancer and gastric cancer	x						x	
Biological	Treatment of non-small cell lung cancer	x						x	
Chemical	Treatment of epithelial ovarian, fallopian tube or primary peritoneal cancer			x				x	
Chemical	Treatment of glioblastoma			x				x	
Advanced Therapy	Treatment of multiple myeloma	x						x	
Chemical	Treatment of non-small cell lung cancer	x						x	
Chemical	Treatment of multiple sclerosis	x						x	
Chemical	Treatment of Ewing sarcoma	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 non-small cell lung cancer and advanced solid tumours	x				x	x	x	
Biological	Treatment of ulcerative colitis and Crohn's disease	x				x	x	x	
Advanced Therapy	Treatment of haemophilia B				x	x	x	x	
Advanced Therapy	Treatment of transfusion-dependent beta thalassaemia				x	x			
Chemical	Treatment of elevated LDL-cholesterol	x						x	
Chemical	Treatment of suspected acute myocardial infarction			x		x			
Biological	Treatment of prurigo nodularis	x						x	
Chemical	Treatment of axillary hyperhidrosis	x						x	
Biological	Treatment of invasive pneumococcal disease, acute otitis media and pneumonia caused by Streptococcus pneumoniae	x						x	
Chemical	Treatment of fungal infections	x				x			
Biological	Treatment of endocarditis			x				x	
Biological	Prevention of invasive disease, pneumonia and acute otitis media	x					x	x	
Biological	Treatment of chronic Staphylococcus aureus prosthetic joint infection of knee or hip	x				x	x	x	
Biological	Prevention of influenza disease	x				x		x	
Biological	Prevention of RSV-associated lower respiratory tract disease	x				x	x	x	
Biological	Treatment of ExPEC disease	x					x	x	
Chemical	Treatment of acute sensorineural hearing loss				x			x	
Chemical	Treatment of osteoarthritis	x					x		
Chemical	Treatment of multiple sclerosis, rheumatoid arthritis and systemic lupus erythematosus	x				x			

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of tonic-clonic seizures in epilepsy	x						x	
Biological	Treatment of neuromyelitis optica spectrum disorder			x				x	
Chemical	Treatment of treatment-resistant depression in major depressive disorder	x					x	x	
Chemical	Treatment of treatment-resistant bipolar depression	x						x	
Chemical	Treatment of Sanfilippo syndrome	x				x	x	x	
Chemical	Treatment of severe asthma	x						x	
Biological	Treatment of bullous pemphigoid	x						x	
Chemical	Treatment of chronic cough	x				x			
Advanced Therapy	Treatment of retinitis pigmentosa		x			x			
Biological	Treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema	x				x	x	x	
Biological	Treatment of macular neovascularization	x				x		x	
Chemical	Treatment of keratitis in Sjogren's syndrome	x							
Biological	Treatment of retinal vein occlusion	x						x	
Biological	Treatment of diabetic retinopathy	x						x	
INNOVATIVE	Broad advice on contrast agent	x				x	x		
Qualification Opinion	Treatment effect measures for efficient statistical analyses.	x						x	
EUnetHTA parallel	Treatment of transfusion dependent beta-thalassaemia				x			x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 43 Scientific Advice letters, 1 Protocol Assistance letters, 12 Follow-up Scientific Advice, 1 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 1 EMA/EUnetHTA parallel consultation advices, were adopted at the 24 - 27 February 2020 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 58 new Requests for which the procedure started at the SAWP meeting held on 10 – 13 February 2020. The new requests are divided as follows: 32 Initial Scientific Advice, 4 Follow-up Scientific Advice, 4 Initial Protocol Assistance, 1 Follow-up Protocol Assistance, 2 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.