



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 October 2021
EMA/CHMP/SAWP/586853/2021
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 11 – 14 October 2021

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

	1995-2020	2021	Overall total
Scientific Advice	4766	420	5186
Follow-up to Scientific Advice	1413	189	1602
Protocol Assistance	1076	85	1161
Follow-up to Protocol Assistance	576	47	623
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	161	14	175
	8157	755	8912

Outcome of the October 2021 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 acne			x		x	x	x	
Chemical	Treatment of glioma				x	x	x	x	x
Chemical	Prevention of ischaemic events.			x		x	x	x	

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Chemical	Treatment of pancreatic adenocarcinoma	x				x	x	x	
Advanced Therapy	Treatment of soft tissue sarcoma		x			x	x	x	x
Advanced Therapy	Treatment of myeloid leukaemia				x	x	x	x	x
Biological	Prevention of transplant-related complications	x				x	x	x	
Advanced Therapy	Treatment of myeloid leukaemia				x	x	x	x	
Advanced Therapy	Treatment of COVID-19 infection	x				x	x	x	
Chemical	Treatment of PIK3CA related overgrowth spectrum		x			x	x	x	
Advanced Therapy	Treatment of thrombotic thrombocytopenic purpura				x	x	x	x	
Chemical	Treatment of Alzheimer's disease	x				x	x	x	
Chemical	Treatment of non-small cell lung cancer	x				x	x	x	
Chemical	Treatment of non-small cell lung cancer	x				x	x	x	
Advanced Therapy	Treatment of multiple myeloma	x				x	x	x	
Chemical	Treatment of hepatitis B	x				x	x	x	
Advanced Therapy	Treatment of epidermolysis bullosa				x	x	x	x	
Biological	Treatment of atopic dermatitis	x				x	x	x	
Biological	Treatment of neurologic disorders	x				x	x	x	
Chemical	Treatment of tuberous sclerosis		x			x	x	x	
Chemical	Treatment of Lennox-Gastaut syndrome		x			x	x	x	
Chemical	Treatment of Dravet syndrome		x			x	x	x	
Chemical	Treatment of urinary tract infections	x				x	x	x	
Biological	Prevention of Chikungunya disease			x		x	x	x	
Advanced Therapy	Treatment of multiple myeloma		x			x	x	x	
Biological	Prevention of Clostridium difficile infection			x		x	x	x	
Biological	Prevention of COVID-19 infection	x				x	x	x	
Biological	Prevention of COVID-19 infection	x				x	x	x	
Similar biological	Treatment of osteoporosis or increase of bone mass in			x		x	x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
	osteoporosis at high risk of fracture								
Similar biological	Treatment of osteoporosis or increase of bone mass in osteoporosis at high risk of fracture			x		x	x	x	
Chemical	Treatment of Prader-Willi syndrome		x			x	x	x	
Chemical	Treatment of multiple sclerosis	x				x	x	x	
Biological	Treatment of Alzheimer's disease	x				x	x	x	
Chemical	Treatment of chronic obstructive pulmonary disease			x		x	x	x	
Biological	Treatment of Alzheimer's disease	x				x	x	x	
Biological	Treatment of haemophilia A		x			x	x	x	x
Biological	Treatment of septic shock	x				x	x	x	
Advanced Therapy	Treatment of melanoma	x				x	x	x	
Biological	Treatment of type 1 diabetes	x				x	x	x	
Chemical	Treatment of iron deficiency	x				x	x	x	
Chemical	Treatment of cholangiocarcinoma	x				x	x	x	
Chemical	Treatment of hyperglycemia			x		x	x	x	
Chemical	Treatment of glioma				x	x	x	x	x
Biological	Treatment of COVID-19 infection	x				x	x	x	
Biological	Treatment of chronic obstructive pulmonary disease	x				x	x	x	
Biological	Treatment of thromboembolic events			x		x	x	x	
Chemical	Prevention of cardiovascular risk	x				x	x	x	
Biological	Treatment of sepsis-associated acute kidney injury			x		x	x	x	
Biological	Treatment of COVID-19	x				x	x	x	
Biological	Treatment of chronic obstructive pulmonary disease			x		x	x	x	
Chemical	Treatment of prostate cancer	x				x	x	x	
Advanced Therapy	Treatment of GM1 gangliosidosis				x	x	x	x	
Biological	Treatment of obstructive pulmonary disease	x				x	x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Biological	Prevention of cytomegalovirus infection	x				x	x	x	
Biological	Treatment of mucosal melanoma	x				x	x	x	
Biological	Treatment of ovarian cancer	x				x	x	x	
Biological	Treatment of chronic inflammatory demyelinating polyneuropathy	x				x	x	x	
Biological	Treatment of non-small lung cancer	x				x	x	x	
Advanced Therapy	Treatment of spinal muscular atrophy		x			x	x	x	
Biological	Prevention of thromboembolic events	x				x	x	x	
Biological	Treatment of primary hyperoxaluria				x	x	x	x	
Advanced Therapy	Treatment of haemophilia A		x			x	x	x	
Chemical	Treatment of age-related macular degeneration	x				x	x	x	
Biological	Treatment of breast cancer	x				x	x	x	
Biological	Treatment of diabetic macular edema			x		x	x	x	
Chemical	Treatment of chronic spontaneous urticaria	x				x	x	x	
Biological	Prevention of lower respiratory tract disease			x		x	x	x	
Chemical	Treatment of acinetobacter baumannii infections	x				x	x	x	
Biological	Treatment of psoriasis			x		x	x	x	
Advanced Therapy	Treatment of non Hodgkin's lymphoma	x				x	x	x	
Biological	Treatment of bladder cancer	x				x	x	x	
Biological	Treatment of eosinophilic esophagitis	x				x	x	x	
Biological	Treatment of small cell lung cancer	x				x	x	x	
Chemical	Treatment of solid tumors	x				x	x	x	
Chemical	Treatment of hyperparathyroidism	x				x	x	x	
Similar biological	Treatment of plaque psoriasis and active psoriatic arthritis			x		x	x	x	
Chemical	Treatment of Gaucher disease				x	x	x	x	
Biological	Treatment of COVID-19	x				x	x	x	
Biological	Treatment of non-small cell lung cancer	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 large B-cell lymphoma	x				x	x	x	
Chemical	Treatment of insomnia	x				x	x	x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 81 Scientific Advice letters - 47 Initial Scientific Advice, 15 Follow-up Scientific Advice, 10 Protocol Assistance letters, 9 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 11-14 October 2021 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 80 new Requests for which the procedure started at the SAWP meeting held on 27-30 September 2021. The new requests are divided as follows: 38 Initial Scientific Advice, 18 Follow-up Scientific Advice, 11 Initial Protocol Assistance, 11 Follow-up Protocol Assistance, 2 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.