



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 November 2019
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Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 11 – 14 November 2019

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

	1995 - 2018	2019	Overall total
Scientific Advice	3866	338	4204
Follow-up to Scientific Advice	1150	113	1362
Protocol Assistance	932	82	1014
Follow-up to Protocol Assistance	477	43	520
EMA/EUnetHTA parallel consultation advice	139	20	159
Qualification of novel methodologies	126	13	139
	6689	609	7298

Outcome of the November 2019 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 polycythaemia vera		x				x	x	x
Chemical	Treatment of neurofibromatosis				x		x	x	
Chemical	Treatment of pulmonary arterial hypertension		x					x	
Chemical	Treatment of acute myeloid leukemia		x					x	



Chemical	Treatment of sickle cell disease		x					x	
Biological	Treatment of epithelial ovarian, fallopian tube, or primary peritoneal cancer				x			x	
Advanced Therapy	Treatment of haemophilia B				x			x	
Biological	Treatment of chronic inflammatory demyelinating polyradiculoneuropathy			x				x	
Biological	Treatment of multifocal motor neuropathy	x						x	
Biological	Rewording of secondary immunodeficiency	x						x	
Chemical	Treatment of acute peripheral tinnitus			x				x	
Biological	Treatment of breast cancer	x						x	
Chemical	Treatment of acute myeloid leukemia	x						x	
Chemical	Detection of coronary artery disease	x				x	x	x	
Biological	Treatment of metastatic colorectal cancer			x				x	
Chemical	Treatment of acute myeloid leukemia	x						x	
Chemical	Treatment of chronic obstructive pulmonary disease	x				x	x	x	
Biological	Treatment of bullous pemphigoid	x						x	
Chemical	Treatment of Parkinson's disease			x				x	
Chemical/ Innovative product or therapy	Treatment of breast cancer	x						x	
Biological	Treatment of spinal muscular atrophy	x				x	x	x	
Biological	Treatment of gastric cancer and breast cancer			x		x		x	
Biological	Treatment of type-2 diabetes mellitus			x				x	
Biological	Treatment of paroxysmal nocturnal hemoglobinuria, atypical hemolytic uremic syndrome and generalized myasthenia gravis			x		x		x	
Biological	Treatment of Crohn's disease			x		x		x	
Chemical	Prevention of postpartum haemorrhage			x				x	
Biological	Treatment of colorectal cancer	x						x	
Biological	Treatment of non-small cell lung cancer	x						x	
Chemical	Treatment of heterozygous GBA mutation and PD	x						x	
Biological	Treatment of lupus	x					x	x	

	nephritis								
Chemical	Treatment of depression	x					x	x	
Chemical	Treatment of major depressive disorder	x				x			
Chemical	Treatment of mixed urinary incontinence			x				x	
Biological	Treatment of non-small cell lung cancer and biliary tract cancer	x				x			
Chemical/Biological	Treatment of hepatocellular carcinoma	x						x	
Chemical	Treatment of HIV-1 infection			x				x	
Chemical	Treatment of urothelial carcinoma	x						x	
Chemical	Treatment of common cold symptoms			x				x	
Chemical	Treatment of hypotension	x				x		x	
Chemical	Treatment of chronic kidney disease	x						x	
Advanced Therapy	Treatment of diffuse large B-cell lymphoma	x					x	x	
Advanced Therapy	Treatment of chronic granulomatous disease	x					x		
Biological	Treatment of breast cancer and cancer of the stomach or gastroesophageal junction.	x				x	x	x	
Chemical	Reduction of hepatic injury	x						x	
Biological	Treatment of acute myeloid leukemia	x				x	x	x	
Advanced Therapy	Treatment of acute myeloid leukemia	x					x	x	
Biological	Treatment of AL amyloidosis	x					x	x	
Chemical	Treatment of Alexander disease	x					x	x	
Chemical	Treatment of cholestatic pruritus	x				x	x	x	
Biological	Treatment of thrombocytopenia	x				x		x	
Chemical	Treatment of acute ST-segment elevation myocardial infarction	x				x		x	
Chemical	Treatment of urea cycle disorders	x					x	x	
Chemical	Treatment of nausea and vomiting	x					x	x	
Chemical	Treatment of hyperammonemia	x						x	
Chemical	Treatment of amyotrophic lateral sclerosis	x						x	
Biological	Prevention of influenza disease	x				x		x	
Chemical	Treatment of acute ischaemic stroke	x					x	x	
Biological	Treatment of non-small cell lung cancer	x				x	x	x	

Biological	Treatment of small cell lung cancer	x						x	
Biological	Treatment of giant cell tumour of bone, osteoporosis and bone loss	x				x	x	x	
Biological	Treatment of type 1 diabetes	x				x	x	x	
Chemical	Treatment of multiple sceloris	x						x	
Chemical	Treatment of Wilson's disease			x				x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 38 Scientific Advice letters, 4 Protocol Assistance letters, 14 Follow-up Scientific Advice, 4 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 3 EMA/EUnetHTA parallel consultation advices, were adopted at the 11 – 14 November 2019 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 28 – 31 October 2019. The new requests are divided as follows: 39 Initial Scientific Advice, 13 Follow-up Scientific Advice, 4 Initial Protocol Assistance, 4 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 2 EMA/EUnetHTA parallel consultation advices.