



17 October 2019
EMA/CHMP/SAWP/571393/2019
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 14 – 17 October 2019

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

	1995 - 2018	2019	Overall total
Scientific Advice	3866	300	4166
Follow-up to Scientific Advice	1150	99	1249
Protocol Assistance	932	78	1010
Follow-up to Protocol Assistance	477	39	516
EMA/EU netHTA parallel consultation advice	139	17	156
Qualification of novel methodologies	126	13	139
	6689	546	7235

Outcome of the October 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 familial adenomatous polyposis				X			X	
Chemical	Treatment of glioblastoma				X	X	X	X	
Chemical	Treatment of Duchenne muscular dystrophy				X	X	X	X	X
Chemical	Treatment of pulmonary arterial hypertension		X				X	X	
Biological	Treatment of multiple myeloma				X		X	X	

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Chemical	Treatment of gastrointestinal cancer		x					x	x
Chemical	Treatment of cholangiocarcinoma		x				x	x	
Chemical	Treatment of Graft versus Host disease				X			x	
Advanced Therapy	Treatment of Duchenne muscular dystrophy	x						x	
Chemical	Treatment of familial intrahepatic cholestasis				X	x			
Advanced Therapy	Treatment of Leber's amaurosis		x			x	x	x	
Chemical	Treatment of Angelman Syndrome		x					x	
Biological	Treatment of congenital hyperinsulinism		x			x			
Chemical	Treatment of adrenal hyperplasia		x					x	x
Biological	Treatment of amyotrophic lateral sclerosis		x					x	x
Biological	Treatment of graft-versus-host Disease				X			x	x
Chemical	Treatment of idiopathic gastroparesis			X			x	x	
Chemical	Treatment of biliary cholangitis	x						x	
Biological	Prevention of pneumococcal disease			X		x			
Chemical	Treatment of metastatic breast cancer, advanced ovarian cancer, Kaposi's sarcoma and multiple myeloma.			X				x	
Chemical/ Biological	Treatment of cervical cancer			X				x	
Biological	Treatment of bladder cancer	x						x	
Biological	Treatment of hepatocellular carcinoma	x						x	
Advanced Therapy	Treatment of leukemia			x				x	
Chemical	Treatment of non-small cell lung cancer	x						x	
Biological	Treatment of hidradenitis suppurativa	x						x	
Chemical/ Biological	Treatment of endometrial cancer	x						x	
Biological	Treatment of neuromyelitis optica spectrum disorder	x						x	
Biological	Treatment of ovarian cancer, epithelial ovarian, fallopian tube, or primary peritoneal cancer, cervical cancer, renal cell carcinoma, glioblastoma, non-small cell lung cancer and colorectal cancer	x				x	x	x	
Advanced Therapy	Treatment of articular cartilage defects	x				x	x		
Biological	Treatment of breast cancer	x				x	x		

Biological	Prophylaxis against delayed-graft-function	x					x	x	
Chemical	Treatment and prevention of vulvovaginal candidiasis	x				x			
Biological	Prevention of congenital CMV infection and disease	x				x		x	
Chemical	Treatment of myeloid or lymphoid neoplasm	x						x	
Biological	Treatment of non-small cell lung cancer			x				x	
Chemical/Innovative product or therapy	Treatment of breast cancer.	x					x	x	
Chemical	Treatment of cholangiocarcima	x				x			
Biological	Treatment of asthma and chronic idiopathic urticaria			x		x	x	x	
Chemical	Treatment of non-small cell lung cancer	x						x	
Chemical/ Biological	Treatment of osteoarthritis	x						x	
Biological	Treatment of respiratory distress syndrome	x					x	x	
Chemical	Treatment of ovarian cancer	x				x	x	x	
Chemical	Treatment of graft versus host Disease	x				x	x	x	
Chemical	Treatment of diabetic retipathy	x						x	
Biological	To decrease the incidence of infection in non-myeloid malignancies and increase survival in acute exposure to myelosuppressive doses of radiation.	x				x	x	x	
Biological	Treatment of osteoarthritis	x					x	x	
Biological	Treatment of carcinoma in situ and papillary tumors	x					x	x	
Chemical	Treatment of myocardial infarction	x				x		x	
Biological	Treatment of urothelial cancer	x						x	
Chemical	Treatment of autoimmune diseases	x				x			
Innovative product or therapy	Treatment of acromegaly	x						x	
Biological	Treatment of rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis	x				x			
Biological	Prevention of invasive pneumococcal disease and pneumococcal pneumonia	x					x	x	
Advanced Therapy	Treatment of ulcerative colitis	x				x	x	x	
Chemical	Treatment of Alzheimer's disease	x						x	
Chemical	Treatment of Prader-Willi Syndrome	x					x	x	

Biological	Treatment of homocystinuria	x					x	x	
Biological	Prevention of invasive pneumococcal disease and pneumococcal pneumonia	x				x	x	x	
Biological	Treatment of multiple sclerosis	x					x	x	
Biological	Treatment of soft tissue sarcoma	x				x			
Advanced Therapy	Treatment of hemophilia A	x				x	x	x	
Chemical	Localization of tumors	x				x	x	x	
Biological	Prevention of herpes zoster and post-herpetic neuralgia			x				x	
Chemical	Treatment of seizures			x				x	
Chemical	Prevention and treatment of soil-transmitted helminths infections	x				x	x	x	
Biomarker	Treatment of nonalcoholic fatty liver disease and nonalcoholic steatohepatitis	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 40 Scientific Advice letters, 8 Protocol Assistance letters, 9 Follow-up Scientific Advice, 7 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 2 EMA/EUnetHTA parallel consultation advices, were adopted at the 14 – 17 October 2019 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 61 new Requests for which the procedure started at the SAWP meeting held on 30 September – 3 October 2019. The new requests are divided as follows: 36 Initial Scientific Advice, 14 Follow-up Scientific Advice, 2 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 2 Qualification of novel methodologies and 2 EMA/EUnetHTA parallel consultation advices.