



25 July 2024
EMA/CHMP/SAWP/373208/2024
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 22-25 July 2024

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

	1995-2023	2024	Overall total
Scientific Advice	6072	256	6328
Follow-up to Scientific Advice	1928	93	2021
Protocol Assistance	1343	53	1396
Follow-up to Protocol Assistance	719	29	748
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	228	15	243
	10455	447	10901

Outcome of the July 2024 CHMP meeting in relation to scientific advice procedures

Final scientific advice procedures

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
ATMP	Treatment of mucopolysaccharidosis				x	x		x	
Biological	Treatment of cancer	x					x		
Biological	Treatment of cancer	x						x	



Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Biological	Treatment of atopic dermatitis			x		x			
Biological	Treatment of adenocarcinoma	x					x	x	
Biological	Treatment of neovascularization			x		x		x	
Biological	Treatment of glabellar lines	x				x	x	x	
Biological	Treatment of myeloma			x				x	
Biological	Treatment of arthritis			x		x		x	
Biological	Treatment of cancer.	x						x	
Biological	Treatment of hypophosphatasia	x					x	x	
Biological	Prevention of kidney transplant rejection			x				x	
Biological	Treatment of herpes	x						x	
Biological	Treatment of atrophy		x				x	x	
Biological	Treatment of vasculitis	x						x	
Biological	Prevention of thrombotic cardiovascular	x					x		
Biological	Treatment of asthma	x						x	
Biological	Treatment of CDI	x				x	x	x	
Biological	Treatment of thrombocytopenia	x				x	x	x	
Biological	Treatment of immune system	x						x	
Biological	Treatment of adenocarcinoma	x				x			
Biological	Treatment of Non-Small Cell Lung cancer	x						x	
Biological	Treatment of melanoma	x				x		x	
Biological	Treatment of cirrhosis	x				x			
Biological	Treatment of cirrhosis			x			x	x	
Biological	Prevention of pneumonia	x						x	
Biological	Treatment of tumours	x						x	
Biological	Treatment of sclerosis	x					x		

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Biological	Treatment of tumour			x				x	
Biological	Treatment of pulmonary arterial hypertension		x			x		x	
Biological	Treatment of obstructive pulmonary disease	x						x	
Biological	Treatment of carcinoma	x						x	
Biological	Treatment of cancer	x						x	
Biological	Treatment of diabetes	x				x	x		
Biological	Treatment of psoriasis	x				x			
Biological	Treatment of ulcerates	x						x	
Biological	Treatment of lymphoma	x						x	
Biological	Treatment of yellow fever			x		x	x	x	
Chemical	Treatment of cancer	x						x	
Chemical	Treatment of glioblastoma	x					x	x	
Chemical	Treatment of carcinoma	x						x	
Chemical	Treatment of cancer	x				x		x	
Chemical	Treatment of arthritis	x				x	x	x	
Chemical	Treatment of tumour	x				x			
Chemical	Treatment of sclerosis	x				x			
Chemical	Treatment of HCV	x					x	x	
Chemical	Treatment of sclerosing cholangitis		x					x	x
Chemical	Treatment of leukemia	x						x	
Chemical	Treatment of obstructive pulmonary disease			x		x		x	
Chemical	Treatment of cancer		x					x	
Chemical	Treatment of achondroplasia		x			x			
Chemical	Treatment of ALS			x				x	
Chemical	Treatment of encephalopathy		x				x	x	x

Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Chemical	Treatment of calciphylaxis		x					x	
Chemical	Treatment of lymphoma				x			x	
Chemical	Treatment of cancer			x				x	
Chemical	Treatment of weight management	x						x	
Chemical	Treatment of inflammatory diseases	x				x	x	x	
Chemical	Treatment of Neovascular age-related macular degeneration	x				x	x	x	
Chemical	Treatment of dermatitis	x						x	
Chemical	Treatment of ischaemic stroke	x				x		x	
Chemical	Treatment of glioma		x			x	x	x	x
Chemical	Treatment of epilepsy		x					x	x

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 63 Scientific Advice letters – 41 Initial Scientific Advice, 11 Follow-up Scientific Advice, 9 Protocol Assistance letters, 2 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 22-25 July 2024.

New requests for scientific advice procedures

The Committee accepted 71 new Requests for which the procedure started at the SAWP meeting held on 8-11 July 2024. The new requests are divided as follows: 42 Initial Scientific Advice, 18 Follow-up Scientific Advice, 3 Protocol Assistance letters, 6 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.