



22 February 2024
EMA/CHMP/SAWP/85681/2024
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 19-22 February 2024

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

	1995-2023	2024	Overall total
Scientific Advice	6072	68	6140
Follow-up to Scientific Advice	1928	23	1951
Protocol Assistance	1343	15	1358
Follow-up to Protocol Assistance	719	9	728
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	228	6	234
	10455	122	10576

Outcome of the February 2024 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 cutaneous T-cell lymphoma		x				x	x	
Biological	Treatment of sickle cell				x	x	x	x	x
Advanced Therapy	Treatment of methylmalonic acidemia				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 acromegaly			x			x	x	
Chemical	Treatment of ovarian cancer	x						x	
Chemical	Treatment of heart failure			x				x	
Biological	Treatment of AMD			x		x		x	
Chemical	Treatment of lysosomal storage disorder		x					x	x
Chemical	Treatment of Hidradenitis Suppurativa	x						x	
Chemical	Treatment of COVID-19	x				x			
Biological	Treatment of myelodysplastic syndromes		x					x	
Biological	Treatment of myelodysplastic syndromes		x					x	
Biological	Treatment of Neoplasm			x		x			
Advanced Therapy	Treatment of optic neuropathy				x	x			
Biological	Treatment of Crohn's Disease	x					x	x	
Biological	Treatment of Crohn's Disease	x					x	x	
Advanced Therapy	Treatment of Relapsed/refractory multiple myeloma	x						x	
Chemical	Treatment of non-small cell lung cancer			x				x	
Chemical	Treatment of complicated urinary tract infections (cUTI)			x				x	
Biological	Treatment of pulmonary disease	x						x	
Chemical	Treatment of iron deficiency	x				x	x	x	
Chemical	Treatment of weight management	x				x			
Chemical	Treatment of amyotrophic lateral sclerosis		x			x	x	x	
Biological	Treatment of Immune system disease		x				x	x	
Chemical	Treatment of seizure		x					x	
Chemical	Treatment of nephropathy	x						x	
Biological	Treatment of Weight Management	x				x	x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Qualification	Medical Tool								
Qualification	Medical Tool							x	
Qualification	Medical Tool								

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 55 Scientific Advice letters – 26 Initial Scientific Advice, 8 Follow-up Scientific Advice, 11 Protocol Assistance letters, 5 Follow-up Protocol Assistance, 5 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 19-22 February 2024.

New requests for scientific advice procedures

The Committee accepted 56 new Requests for which the procedure started at the SAWP meeting held on 5-8 Feb 2024. The new requests are divided as follows: 30 Initial Scientific Advice, 14 Follow-up Scientific Advice, 5 Protocol Assistance letters, 5 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.