



30 May 2024  
EMA/CHMP/SAWP/252273/2024  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 27-30 May 2024

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

	1995-2023	2024	Overall total
Scientific Advice	6072	170	6242
Follow-up to Scientific Advice	1928	72	2000
Protocol Assistance	1343	34	1377
Follow-up to Protocol Assistance	719	22	741
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	228	14	242
	10455	313	10767

### Outcome of the May 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
Advanced Therapy	Treatment of sickle cell disease			x		x			
Advanced Therapy	Treatment of chronic granulomatous disease	x				x	x	x	
Advanced Therapy	Treatment of pyruvate kinase deficiency		x			x	x	x	x



Substance	Intended indications	Type of request				Topic			
		New		Follow-up					
		SA	PA	SA	PA	Quality	Preclinical	Clinical	Significant benefit
Biological	Treatment of adenocarcinoma	x						x	
Biological	Treatment of adenocarcinoma	x						x	
Biological	Treatment of thrombotic thrombocytopenic purpura		x			x			
Biological	Treatment of plasma cell myeloma		x					x	
Biological	Treatment of solid tumor			x		x		x	
Biological	Treatment of haemophilia A				x	x			
Biological	Prevention of exacerbations chronic obstructive pulmonary disease	x				x	x	x	
Biological	Treatment of emphysema			x				x	
Biological	Prevention of lower respiratory tract disease	x				x	x	x	
Biological	Prevention of cervical cancer			x				x	
Biological	Prevention of influenza	x						x	
Biological	Treatment of Hidradenitis Suppurativa	x					x		
Biological	Treatment of HNSCC			x				x	
Biological	Treatment of NSCLC	x						x	
Biological	Treatment of psoriasis	x				x		x	
Biological	Treatment of osteogenesis				x			x	
Biological	Treatment of psoriatic	x						x	
Biological	Treatment of colitis			x		x		x	
Biological	Treatment of colitis			x		x		x	
Chemical	Treatment of NSCLC	x						x	
Chemical	Treatment of Prader-Willi syndrome		x			x	x	x	x
Chemical	Prevention of Transthyretin Amyloidosis	x					x	x	
Chemical	Prevention of heart failure	x					x	x	
Chemical	Treatment of weight management	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 idiopathic pulmonary fibrosis (IPF)	x					x		
Chemical	Prevention of angioedema			x			x	x	
Chemical	Treatment of NSCLC			x			x	x	
Chemical	Treatment of ABCC6 deficiency		x				x	x	
Chemical	Treatment of Head and Neck Cancer	x						x	
Chemical	Diagnosis of AL amyloidosis		x				x	x	
Chemical	Treatment of overweight			x		x		x	
Chemical	Treatment of hypertension	x					x	x	
Chemical	Treatment of schizophrenia	x					x	x	
Chemical	Treatment of organ transplantation		x				x	x	
Chemical	Treatment of MGMT	x						x	
Chemical	Treatment of Niemann-Pick disease			x				x	
Chemical	Treatment of gangliosidosis			x				x	
Chemical	Treatment of kidney disease	x						x	
Chemical	Treatment of muscular atrophy			x				x	
Chemical	Treatment of muscular atrophy				x			x	
Chemical	Treatment of heart failure	x						x	
Chemical	Treatment of hyperplasia	x					x	x	
Chemical	Treatment of hidradenitis suppurativa			x		x			
Chemical	Treatment of adenocarcinoma	x				x	x	x	
Chemical	Treatment of acute myeloid leukaemia (AML)			x				x	
Chemical	Treatment of infections			x				x	
Chemical	Treatment of polycythaemia vera		x			x	x		
Chemical	Treatment of pulmonary arterial hypertension		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 NSCLC			x				x	
Chemical	Treatment of Non-alcoholic steatohepatitis	x				x	x	x	
Chemical	Treatment of non-small-cell lung cancer	x						x	
Chemical	Treatment of non-small-cell lung cancer	x						x	
Chemical	Treatment of colitis	x				x	x	x	
Chemical	Treatment of follicular lymphoma		x					x	
Chemical	Treatment of TiO2	x					x		
Chemical	Treatment of insomnia	x				x		x	
Qualification	Medical tool								
Qualification	Medical tool								

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 61 Scientific Advice letters – 29 Initial Scientific Advice, 17 Follow-up Scientific Advice, 10 Protocol Assistance letters, 10 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 27-30 May 2024.

## New requests for scientific advice procedures

The Committee accepted 66 new Requests for which the procedure started at the SAWP meeting held on 13-16 May 2024. The new requests are divided as follows: 41 Initial Scientific Advice, 12 Follow-up Scientific Advice, 8 Protocol Assistance letters, 5 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.