



27 June 2024  
EMA/CHMP/SAWP/332435/2024  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 24-27 June 2024

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

	1995-2023	2024	Overall total
Scientific Advice	6072	215	6287
Follow-up to Scientific Advice	1928	82	2010
Protocol Assistance	1343	44	1387
Follow-up to Protocol Assistance	719	27	746
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	228	15	243
	<b>10455</b>	<b>384</b>	<b>10838</b>

### **Outcome of the June 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				
ATMP	Treatment of non-small cell lung cancer			x		x			
ATMP	Treatment of head and neck squamous cell carcinoma	x						x	



Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
ATMP	Treatment of Crohn's Disease	x					x	x	
Biological	Treatment of arthritis			x		x			
Biological	Treatment of non-small cell lung cancer	x						x	
Biological	Treatment of cancer	x						x	
Biological	Treatment of osteoporosis	x					x	x	
Biological	Treatment of blood disease	x				x		x	
Biological	Treatment of cancer	x						x	
Biological	Treatment of atrophy	x						x	
Biological	Treatment of chronic graft versus host disease			x				x	
Biological	Prevention of staphylococcus	x				x	x	x	
Biological	Treatment of chronic spontaneous urticaria	x				x			
Biological	Treatment of non-small cell lung cancer	x						x	
Biological	Treatment of cancer	x				x	x	x	
Biological	Treatment of multiple myeloma				x			x	
Biological	Prevention of gastroenteritis	x						x	
Biological	Treatment of myeloma	x				x		x	
Biological	Treatment of NSCLC	x						x	
Biological	Treatment of dermatomyositis and polymyositis			x		x		x	
Biological	Prevention of blood disease	x						x	
Biological	Treatment of lymphoma		x					x	
Biological	Treatment of cancer	x					x	x	
Biological	Treatment of dysplasia				x	x			
Biological	Treatment of carcinoma	x						x	
Biological	Treatment of psoriasis	x				x		x	
Biological	Treatment of ovarian cancer	x				x			

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of melanoma	x				x			
Biological	Treatment of fibrosing interstitial lung disease	x				x		x	
Biological	Treatment of melanoma	x				x	x	x	
Biological	Treatment of melanoma	x						x	
Biological	Treatment of rheumatoid arthritis	x				x		x	
Biological	Treatment of acute myeloid leukaemia		x					x	x
Biological	Treatment of patients with trichuriasis, mansonellosis, onchocerciasis and loiasis	x						x	
Biological	Treatment of mucopolysaccharidosis				x			x	
Biological	Prevention of Pertussis disease			x		x		x	
Biological	Treatment of nephropathy	x				x	x	x	
Biological	Prevention of LRTD	x				x		x	
Biological	Treatment of adenocarcinoma.	x						x	
Biological	Treatment of ITP			x		x		x	
Biological	Treatment of glioma	x						x	
Biological	Treatment of narcolepsy		x					x	x
Biological	Treatment of non-small cell lung cancer	x						x	
Biological	Treatment of cancer			x				x	
Biological	Treatment of interstitial lung disease	x					x	x	
Biological	Treatment of retinitis pigmentosa				x			x	
Biological	Prevention of invasive ExPEC			x				x	
Chemical	Treatment of respiratory, thoracic and mediastinal disorders	x					x	x	
Chemical	Treatment of glioma		x					x	x
Chemical	Treatment of hypertension	x				x			
Chemical	Treatment of Ménière's syndrome	x					x		
Chemical	Treatment of hepatitis delta virus infection		x					x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of Duchenne muscular dystrophy		x			x	x	x	
Chemical	Treatment of alcohol use Disorder	x					x	x	
Chemical	Prevention of HIV-1			x		x			
Chemical	Treatment of hepatitis B virus	x					x	x	
Chemical	Treatment of hypoparathyroidism		x			x	x	x	
Chemical	Treatment of sickle cell disease				x			x	
Chemical	Treatment of HIV-1	x						x	
Chemical	Treatment of pulmonary arterial hypertension		x					x	
Chemical	Treatment of nephropathy	x				x	x	x	
Chemical	Treatment of cancer	x						x	
Chemical	Treatment of pulmonary arterial hypertension		x			x	x	x	
Chemical	Treatment of asthma			x		x			
Chemical	Treatment of cancer	x						x	
Chemical	Prevention of bronchopulmonary dysplasia		x					x	
Chemical	Treatment of NSCLC	x						x	
Chemical	Treatment of polycythemia vera	x					x	x	
Chemical	Treatment of cancer	x						x	
Chemical	Treatment of NSCLC	x				x			
Qualification	Medical Tool								

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 71 Scientific Advice letters – 45 Initial Scientific Advice, 10 Follow-up Scientific Advice, 10 Protocol Assistance letters, 5 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 24-27 June 2024.

### **New requests for scientific advice procedures**

The Committee accepted 73 new Requests for which the procedure started at the SAWP meeting held on 10-13 Jun 2024. The new requests are divided as follows: 44 Initial Scientific Advice, 11 Follow-up

Scientific Advice, 13 Protocol Assistance letters, 4 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.