



15 September 2022  
EMA/CHMP/SAWP/769857/2022  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 12 – 15 September 2022

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

	1995-2020	2022	Overall total
Scientific Advice	5226	337	5563
Follow-up to Scientific Advice	1623	113	1736
Protocol Assistance	1173	61	1234
Follow-up to Protocol Assistance	634	38	672
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	180	22	202
	<b>9001</b>	<b>571</b>	<b>9572</b>

### **Outcome of the September 2022 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 breast cancer	x						x	
Biological	Treatment of haemophilia A				x	x			
Chemical	Treatment of seizures			x			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 idiopathic pulmonary fibrosis			x			x	x	
Biological	Treatment of steatohepatitis			x			x		
Chemical	Treatment of intraocular pressure	x				x	x	x	
Biological	Treatment of fibrodysplasia ossificans progressiva		x					x	
Biological	Treatment of multiple myeloma				x			x	
Chemical	Prevention of ischaemic stroke			x				x	
Chemical	Treatment of pulmonary arterial hypertension			x			x		
Biological	Prevention of diphtheria	x				x		x	
Biological	Treatment of embolism	x						x	
Chemical	Treatment of prostate cancer			x				x	
Chemical	Treatment of adenocarcinoma	x				x			
Biological	Treatment of breast cancer	x					x	x	
Biological	Treatment of Netherton's syndrome	x						x	
Chemical	Treatment of psoriasis	x						x	
Chemical	Prevention of hereditary angioedema			x				x	
Chemical	Treatment of adenocarcinoma	x						x	
Chemical	Treatment of arousal disorder			x				x	
Biological	Treatment of malignant neoplasms	x					x	x	
Biological	Treatment of neuromyelitis optica				x			x	
Biological	Treatment of follicular lymphoma		x					x	
Biological	Treatment of osteoporosis			x				x	
Biological	Prevention of dengue disease			x		x			
Biological	Treatment of ulcerative colitis			x				x	
Chemical	Treatment of non-small cell lung cancer	x						x	
ATMP	Treatment of albuminuria	x				x		x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Prevention of respiratory tract infections			x				x	
Biological	Treatment of esophageal cell carcinoma	x						x	
Chemical	Treatment of breast cancer	x					x	x	
Biological	Treatment of sickle cell disease	x				x	x	x	
Chemical	Treatment of Friedreich's ataxia	x					x		
Chemical	Prevention of stroke			x				x	
Biological	Treatment of Alzheimer's disease			x				x	
Chemical	Treatment of type II diabetes mellitus	x						x	
Chemical	Treatment of acute myocardial infarction	x				x	x		
Chemical	Treatment of retinitis pigmentosa				x			x	
Biological	Treatment of colorectal cancer	x						x	
Chemical	Treatment of breast cancer	x						x	
Biological	Treatment of melanoma			x				x	
Biological	Treatment of rheumatoid arthritis			x		x			
Biological	Treatment of breast cancer	x						x	
Chemical	Treatment of intraocular pressure	x				x			
Chemical	Prevention of malaria	x				x		x	
Chemical	Treatment of asthma			x				x	
Biological	Treatment of cancer	x				x		x	
Chemical	Treatment of major depressive disorder	x				x	x	x	
Biological	Prevention of group B streptococcal diseases	x						x	
Chemical	Treatment of West syndrome	x				x	x	x	
Biological	Treatment of peripheral T-cell Lymphoma	x						x	
Biological	Treatment of heart block	x					x	x	
Biological	Treatment of rheumatoid arthritis	x				x	x	x	
Biological	Treatment of B-cell non-Hodgkin lymphoma	x					x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of myopathy	x						x	
Chemical	Treatment of congenital alpha-1 antitrypsin deficiency		x			x	x	x	x
Advanced Therapy	Treatment of spondyloepiphyseal dysplasia congenita	x				x	x	x	
Biological	Treatment of biliary tract cancer	x						x	
Chemical	Treatment of non-small cell lung cancer	x						x	
Chemical	Treatment of Parkinson's disease	x					x	x	
Biological	Treatment of multiple myeloma	x					x	x	
Chemical	Treatment of prostate cancer	x				x	x	x	
Chemical	Treatment of non-small cell lung cancer	x					x	x	
Chemical	Treatment of severe pain	x						x	
Qualification	Core dataset and global registries platform	x						x	
Qualification	Composite biomarker panel	x						x	
Qualification	Biomechanical computed tomography	x						x	
Qualification	Treatment of neurological diseases	x						x	

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 68 Scientific Advice letters - 40 Initial Scientific Advice, 17 Follow-up Scientific Advice, 3 Protocol Assistance letters, 4 Follow-up Protocol Assistance, 4 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 12-15 September 2022 CHMP meeting.

## New requests for scientific advice procedures

The Committee accepted 71 new Requests for which the procedure started at the SAWP meeting held on 29 August-1 September 2022. The new requests are divided as follows: 42 Initial Scientific Advice, 19 Follow-up Scientific Advice, 8 Initial Protocol Assistance, 2 Follow-up Protocol Assistance, 0 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.