



14 November 2024
EMA/CHMP/SAWP/7733/2025
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 11-14 November 2024.

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

	1995-2023	2024	Overall total
Scientific Advice	6072	385	6457
Follow-up to Scientific Advice	1928	143	2071
Protocol Assistance	1343	74	1417
Follow-up to Protocol Assistance	719	41	760
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	228	18	246
	10455	662	11116

Outcome of the November 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				
Advanced Therapy	Treatment of GvHD				X	X			
Advanced Therapy	Treatment of immunodeficiency		X			X			
Advanced Therapy	Treatment of AMD	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				
Advanced Therapy	Treatment of tumours	x						x	
Advanced Therapy	Treatment of cystic fibrosis	x				x			
Advanced Therapy	Treatment of tumours	x				x			
Biological	Prevention of pneumoniae	x				x	x	x	
Biological	Treatment of bronchiectasis	x					x	x	
Biological	Treatment of asthma	x					x	x	
Biological	Treatment of weight management	x						x	
Biological	Treatment of weight management			x		x		x	
Biological	Prevention of dengue			x		x		x	
Biological	Treatment of the same as refence product Dupixent	x				x	x	x	
Biological	Treatment of neuropathy	x				x	x	x	
Biological	Treatment of Antibody-mediated rejection	x					x	x	
Biological	Treatment of hemostasis in parenchymal bleeding	x				x	x	x	
Biological	Prevention of HPV			x				x	
Biological	Treatment of cancer	x						x	
Biological	Treatment of psoriasis	x				x	x	x	
Biological	Treatment of psoriasis	x				x	x	x	
Biological	Treatment of Non-Small Cell Lung cancer	x						x	
Biological	Prevention of cardiovascular disease	x						x	
Biological	Prevention of cardiovascular events	x						x	
Biological	Treatment of weight management	x						x	
Biological	Treatment of HeFH	x						x	
Biological	Treatment of cancer	x						x	
Biological	Treatment of neoplasm	x						x	
Biological	Treatment of neoplasm	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Biological	Treatment of cancer				x			x	
Biological	Treatment of thrombotic microangiopathy			x				x	
Biological	Prevention of respiratory syncytial virus			x				x	
Biological	Treatment of tumour	x				x			
Biological	Treatment of Duchenne Muscular Dystrophy	x						x	
Biological	Treatment of mucopolysaccharidosis			x			x	x	
Biological	Treatment of carcinoma	x						x	
Biological	Prevention of COVID-19	x					x	x	
Biological	Prevention of atherosclerosis			x				x	
Chemical	Diagnosis of tumour	x					x	x	
Chemical	Treatment of hepatitis			x			x	x	
Chemical	Treatment of in solid organ transplantation		x				x	x	
Chemical	Treatment of COPD	x					x	x	
Chemical	Prevention of heart failure			x				x	
Chemical	Treatment of kidney disease			x				x	
Chemical	Treatment of pancreatitis	x					x	x	
Chemical	Prevention of premature ovulation	x				x			
Chemical	Treatment of Amyotrophic lateral sclerosis	x					x	x	
Chemical	Treatment of Adenocarcinoma	x						x	
Chemical	Treatment of large B-cell lymphoma		x				x	x	
Chemical	Treatment of schizophrenia	x						x	
Chemical	Treatment of prostate cancer			x				x	
Chemical	Treatment of breast cancer	x				x			
Chemical	Treatment of Angelman syndrome		x				x	x	
Chemical	Treatment of uremic syndrome			x				x	
Chemical	Treatment of psoriasis			x		x			

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of osteoarthritis			x			x	x	
Chemical	Treatment of carcinoma	x						x	
Chemical	Treatment of neuropathic	x						x	
Chemical	Prevention of pregnancy	x				x		x	
Chemical	Treatment of ulcerative colitis	x						x	
Chemical	Treatment of Diabetic retinopathy	x						x	
Chemical	Treatment of ovarian cancer		x					x	
Chemical	Treatment of Sickle Cell Disease	x						x	
Chemical	Treatment of infections			x			x	x	
Chemical	Treatment of hidradenitis	x						x	
Chemical	Treatment of lymphocytic lymphoma			x				x	
Chemical	Treatment of lymphocytic leukaemia	x						x	
Chemical	Treatment of Stargardt's disease		x			x			
Chemical	Treatment of carcinoma	x				x			
Chemical	Treatment of Age-related macular degeneration	x					x	x	
Chemical	Treatment of coeliac disease	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 70 Scientific Advice letters – 46 Initial Scientific Advice, 16 Follow-up Scientific Advice, 6 Protocol Assistance letters, 2 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 11-14 November 2024.

New requests for scientific advice procedures

The Committee accepted 89 new Requests for which the procedure started at the SAWP meeting held on 28 - 31 October 2024. The new requests are divided as follows: 56 Initial Scientific Advice, 20 Follow-up Scientific Advice, 6 Protocol Assistance letters, 4 Follow-up Protocol Assistance, 3 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.