

19 May 2022 EMA/CHMP/SAWP/284919/2022 Press Office

### Scientific advice and protocol assistance

Adopted during the CHMP meeting 16- 19 May 2022

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

	1995-2020	2022	Overall total
Scientific Advice	5226	211	5437
Follow-up to Scientific Advice	1623	68	1691
Protocol Assistance	1173	35	1208
Follow-up to Protocol Assistance	634	28	662
EMA/EUnetHTA parallel consultation advice	165	0	165
Qualification of novel methodologies	180	7	187
	9001	349	9265

## *Outcome of the May 2022 CHMP meeting in relation to scientific advice procedures*

### Final scientific advice procedures

Substance	Intended indications	Type of request					Т	Торіс				
		New		Follow- up								
		SA	РА	SA	ΡΑ	Quality	Preclinical	Clinical	Significant benefit			
Biological	Treatment of neuromyelitis optica spectrum disorders				х			х				
Chemical	Treatment of pulmonary arterial hypertension				x	x						

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Substance	Intended indications	Type of request			Торіс				
		New		Foll up	ow-				
		SA	ΡΑ	SA	ΡΑ	Quality	Preclinical	Clinical	Significant benefit
Chemical	Treatment of myelodysplastic syndromes		x					x	x
Biological	Treatment of follicular lymphoma		х			x		х	х
Biological	Treatment of age-related macular degeneration			x		x		х	
Biological	Prevention of bleeding			х				х	
Biological	Treatment of haemophilia A				х			x	
Chemical	Treatment of primary mitochondrial myopathy	x					x	x	
Chemical	Treatment of glycosylation		х				х	х	
Chemical	Treatment of lymphocytic leukemia	х						x	
Chemical	Treatment of lymphocytic leukemia	х						х	
Chemical	Treatment of Fuchs endothelial corneal dystrophy			x				x	
Biological	Treatment of bleeding			x				x	
Biological	Treatment of bladder cancer	х						x	
Biological	Treatment of bladder cancer	х						x	
Chemical	Treatment of lupus erythematosus	х				x		x	
Chemical	Treatment of pneumonia	х					x	х	
Chemical	Treatment of haemophilia B				х			х	
Chemical	Treatment of Prion disease	х					х	х	
Biological	Treatment of colorectal cancer	х						x	
Biological	Treatment of type 2 diabetes mellitus	х					x	x	
Chemical	Treatment of breast cancer	х						x	
Chemical	Treatment of haemoglobinuria				х		х	x	
Chemical	Treatment of haemophilia A				x			x	
Chemical	Treatment of breast cancer	x						x	
Chemical	Treatment of colorectal cancer	х					x		
Advanced Therapy	Treatment of diffuse large B-cell lymphoma	x						x	

Substance	Intended indications	Type of request			Торіс				
		New		Foll up	ow-				
		SA	ΡΑ	SA	ΡΑ	Quality	Preclinical	Clinical	Significant benefit
Biological	Treatment of osteoporosis			x				x	
Advanced Therapy	Treatment of type 1 diabetes mellitus	х				х			
Biological	Treatment of diffuse large B-cell lymphoma			х				х	
Biological	Prevention of yellow fever			x				х	
Advanced Therapy	Treatment of large B cell lymphoma	х				x	х	x	
Biological	Treatment of growth hormone deficiency		x					х	
Chemical	Prevention of atherothrombotic and thromboembolic disorders	x						x	
Biological	Treatment of atopic dermatitis			x		x		x	
Biological	Treatment of masseter muscle prominence			x				x	
Biological	Treatment of X-linked hypo-hidrotic ectodermal dysplasia				х			x	
Biological	Treatment of rheumatoid arthritis			x		x			
Chemical	Treatment of insomnia in adults			x		x			
Chemical	Treatment of breast cancer	х						x	
Biological	Prevention of Neisseria meningitidis	х				x	x	x	
Biological	Treatment of psoriasis			x				x	
Chemical	Treatment of cholestatic pruritus		x					x	x
Chemical	Treatment of lung diseases			x				x	
Chemical	Treatment of nephropathy	х					х	x	
Biological	Treatment of non-alcoholic steatohepatitis	х				х	х		
Biological	Treatment of multiple myeloma	х						х	
Biological	Treatment of osteosarcoma	х					х	х	
Biological	Prevention of influenza infection	х						х	
Biological	Treatment of small cell lung cancer			x				х	
Biological	Treatment of non-small-cell lung carcinoma	х				х			
Advanced Therapy	Treatment of large B-cell lymphoma	х						x	

NewFollow: upBiologicalTreatment of solution: mailgnanciesTreatment of haematological and solid mailgnanciesXXX </th <th>benefit</th>	benefit
Image: Descent of the state	benefit
BiologicalTreatment of myasthenia gravisxxxxxxxBiologicalDiagnosis of low endotoxin recoveryxxxxxxxBiologicalTreatment of haematological and solid malignanciesxxxxxxxxBiologicalTreatment of squamous cell carcinomaxx	
BiologicalDiagnosis of low endotoxin recoveryxxxxxBiologicalTreatment of haematological and solid malignanciesxxxxxxBiologicalTreatment of squamous cell carcinomaxxxxxxxChemicalTreatment of prostate cancerxxxxxxxxAdvanced TherapyTreatment of haemophilia BxxxxxxxxxBiologicalPrevention of atrial fibrillationxx	
BiologicalTreatment of haematological and solid malignanciesxxxxxBiologicalTreatment of squamous cell carcinomaxxxxxxChemicalTreatment of prostate cancerxxxxxxxAdvanced TherapyTreatment of haemophilia BxxxxxxxBiologicalPrevention of atrial fibrillationxxxxxxChemicalTreatment of seizuresxxxxxxBiologicalTreatment of type 1 diabetesxxxxxxBiologicalPrevention of herpes zosterxxxxxx	
Biological       malignancies       x       x       x         Biological       Treatment of squamous cell carcinoma       x       x       x       x         Chemical       Treatment of prostate cancer       x       x       x       x       x         Advanced Therapy       Treatment of haemophilia B       x       x       x       x       x         Biological       Prevention of atrial fibrillation       x       x       x       x       x         Chemical       Treatment of type 1 diabetes       x       x       x       x       x         Biological       Treatment of large B-cell lymphoma       x       x       x       x       x         Biological       Prevention of herpes zoster       x       x       x       x       x	
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BiologicalTreatment of type 1 diabetesxxxxxBiologicalTreatment of large B-cell lymphomaxxxxxBiologicalPrevention of herpes zosterxxxxx	
Biological     Treatment of large B-cell lymphoma     x     x       Biological     Prevention of herpes zoster     x     x	
Biological     Prevention of herpes zoster     x     x	
Chemical Treatment of depressive disorder x x	
BiologicalPrevention of pertussis diseasexxx	
Advanced TherapyTreatment of progressive multifocal leukoencephalopathyxxxx	
BiologicalPrevention of hepatitis B virusxx	
BiologicalTreatment of multiple myelomaxx	<
BiologicalPrevention of renal allograft rejectionxxxx	
Chemical Treatment of thrombotic microangiopathy x x	
Chemical Treatment of interstitial lung diseases x x x x	
BiologicalTreatment of multiple sclerosisxxxx	
Chemical Treatment of HIV-1 x x	
Chemical Treatment of multiple myeloma x x	
Chemical Treatment of vanishing white matter disease x x x	
Chemical Treatment of urinary infections x x x x	

Substance	Intended indications	Type of request			Торіс				
		New		Foll up	ow-				
		SA	РА	SA	РА	Quality	Preclinical	Clinical	Significant benefit
Advanced Therapy	Treatment of NGLY1 deficiency		x			x	x	х	
Qualification	Artificial Intelligence for adjudication of clinical events	x							
Qualification	Novel endpoints for use in intermediate age- related macular degeneration	x							
Biological	Treatment of anti adeno-associated virus	x					x	х	
Chemical	Treatment of cardiomyopathy	x						х	
Biological	Diagnosis of cancer patient			x		x	x	х	
Qualification	Patient reported outcome for pulmonary arterial hypertension	x							
Chemical	Treatment of depressive disorder	x					x	х	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 85 Scientific Advice letters - 46 Initial Scientific Advice, 20 Follow-up Scientific Advice, 7 Protocol Assistance letters, 9 Follow-up Protocol Assistance, 3 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 16-19 May 2022 CHMP meeting.

### New requests for scientific advice procedures

The Committee accepted 77 new Requests for which the procedure started at the SAWP meeting held on 02-05 May 2022. The new requests are divided as follows: 46 Initial Scientific Advice, 12 Follow-up Scientific Advice, 12 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 2 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.