



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

30 January 2020  
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Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 27 – 30 January 2020

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

	1995 - 2019	2020	Overall total
Scientific Advice	4258	49	4307
Follow-up to Scientific Advice	1277	14	1291
Protocol Assistance	1003	1	1004
Follow-up to Protocol Assistance	525	4	529
EMA/EUnetHTA parallel consultation advice	159	2	161
Qualification of novel methodologies	142	2	144
	<b>7364</b>	<b>72</b>	<b>7436</b>

### ***Outcome of the January 2020 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				
Biological	Treatment of Gaucher's disease.			x				x	
Biological	Treatment of diabetes mellitus.	x				x	x	x	
Chemical	Treatment of Duchenne muscular dystrophy.	x						x	
Biological	Treatment of ulcerative colitis.	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 rhizomelic chondrodysplasia punctata.	x					x	x	
Biological	Prevention of major bleeding.	x				x	x	x	
Chemical	Treatment of menstrual cycle disturbances.	x					x	x	
Chemical	Contraceptive method.	x						x	
Chemical	Treatment of proteinuric glomerular disease.	x					x	x	
Chemical	Treatment of non small cell lung cancer.	x				x			
Chemical	Treatment of breast cancer.	x						x	
Biological	Treatment of renal cell carcinoma.	x						x	
Chemical	Treatment of plaque psoriasis.	x				x			
Chemical	Treatment of advanced renal cell carcinoma.		x					x	
Chemical	Treatment of prostate cancer.	x					x	x	
Chemical	Treatment of paroxysmal nocturnal haemoglobinuria.				x		x		
Chemical	Treatment of squamous cell carcinoma of the head and neck.	x				x	x	x	
Chemical	Treatment of breast cancer.	x					x	x	
Chemical	Treatment of adenoid cystic carcinoma.	x				x		x	
Chemical	Treatment of Duchenne muscular dystrophy.		x				x	x	
Biological	Treatment of squamous cell carcinoma of the anal canal.	x						x	
Biological	Treatment of IgG4-related disease.	x						x	
Biological	Desensitization in solid organ transplantation.	x						x	
Biological	Treatment of gastric or gastroesophageal junction cancer.	x						x	
Biological	Treatment of squamous cell carcinoma of the head and neck.	x					x	x	
Biological	Treatment of IV monotherapy indications.			x				x	
Biological	Treatment of bladder 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 non-small cell lung cancer.	x						x	
Biological	Treatment of renal cell carcinoma.			x				x	
Advanced therapy	Treatment of head and neck squamous cell carcinoma.	x				x	x	x	
Biological	Treatment of thrombotic microangiopathy .	x						x	
Biological	Treatment of advanced melanoma.	x						x	
Chemical	Treatment of breast cancer.	x					x	x	
Biological	Treatment of Graves' orbitopathy.	x						x	
Biological	Treatment of breast cancer.			x				x	
Biological	Treatment of juvenile psoriatic arthritis.	x						x	
Biological	Treatment of plaque psoriasis, psoriatic arthritis, Crohn's disease, ulcerative colitis.	x				x	x		
Advanced therapy	Treatment of haemophilia B.				x	x	x	x	
Biological	Treatment of anaemia.	x				x		x	
Biological	Treatment of thrombocytopenia.	x				x	x	x	
Advanced therapy	Treatment of haemophilia A.				x	x	x	x	x
Biological	Treatment of atopic dermatitis.	x				x			
Chemical	Treatment of endometriosis-associated pain and heavy uterine bleeding.	x				x			
Chemical	Prevention of bronchopulmonary dysplasia.			x				x	
Chemical	Treatment of HIV-1 infection.	x					x	x	
Chemical	Treatment of HIV-1 infection.	x						x	
Biological	Prevention of premalignant ano-genital lesions and cervical and anal cancers.	x				x			
Biological	Prevention of influenza disease.			x				x	
Biological	Prevention of acute gastroenteritis caused by			x				x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
	Norovirus.								
Biological	Treatment of dengue disease.	x				X	x	x	
Chemical	Treatment of influenza A or B virus infection.			X				x	
Biological	Broad clinical advice on vaccines.			X				x	
Biological	Treatment of osteoporosis.	x						x	
Chemical	Treatment of low back pain.	x						x	
Advanced therapy	Treatment of glycogen storage disorder type II.	x					X	x	
Chemical	Treatment of X-linked myotubular myopathy.	x				X	X	x	
Chemical	Treatment of Niemann-Pick disease, type C.				X	X			
Chemical	Treatment of Autism Spectrum Disorder.			X				x	
Biological	Treatment of B-cell lymphoma.	x					X	x	
Chemical	Treatment of multiple sclerosis.	x					X	x	
Chemical	Treatment of vasomotor symptoms.			X			X	x	
Chemical	Treatment of somatic pain.			X			X	x	
Advanced therapy	Treatment of transthyretin amyloidosis.	x				X	X	x	
Chemical	Treatment of major depressive disorder.	x						x	
Biological	Prevention of recurrence of nasal polyps in chronic rhinosinusitis.	x						x	
Chemical	Treatment of RSV infection.	x					x	x	
Chemical	Treatment of visual impairment.	x				x	x	x	
Biological	Treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema and diabetic retinopathy.			x		x		x	
Qualification opinion	Treatment of multiple sclerosis.	x						x	
Qualification Advice	Treatment of type 1 diabetes.	x						x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
EUnetHTA parallel	Treatment of non-small cell lung cancer.	x						x	
EUnetHTA parallel	Treatment of bladder cancer.	x						x	

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 49 Scientific Advice letters, 1 Protocol Assistance letters, 14 Follow-up Scientific Advice, 4 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 2 EMA/EUnetHTA parallel consultation advices, were adopted at the 27 - 30 January 2020 CHMP meeting.

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

The Committee accepted 58 new Requests for which the procedure started at the SAWP meeting held on 13 – 16 January 2020. The new requests are divided as follows: 36 Initial Scientific Advice, 12 Follow-up Scientific Advice, 4 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.