



26 March 2020
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Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 09 – 12 March 2020

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

	1995 - 2019	2020	Overall total
Scientific Advice	4258	123	4381
Follow-up to Scientific Advice	1277	31	1308
Protocol Assistance	1003	8	1011
Follow-up to Protocol Assistance	525	8	533
EMA/EUnetHTA parallel consultation advice	159	4	163
Qualification of novel methodologies	142	6	148
	7364	180	7544

Outcome of the March 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				
Chemical	Treatment of renal disease	x						x	
Chemical	Treatment of Gorlin syndrome		x				x	x	x
Chemical	Treatment of diabetic kidney disease	x						x	
Chemical	Treatment of cardiovascular disease	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				
Biological	Treatment of mucopolysaccharidosis type II			x			x	x	
Chemical	Treatment of iron deficiency	x				x	x	x	
Chemical	Treatment of sickle cell disease				x			x	
Biological	Treatment of bleeds in haemophilia A	x						x	
Biological	Treatment of bleeds in haemophilia B		x					x	
Biological	Treatment of bleeds in Factor VII deficiency	x					x	x	
Biological	Treatment of sepsis-associated acute kidney injury			x				x	
Chemical	Treatment of male erectile dysfunction	x					x	x	
Biological	Treatment of chronic spontaneous urticaria	x						x	
Chemical	Treatment of urinary tract infections	x					x	x	
Chemical	Treatment of hepatitis B and D virus co-infection	x						x	
Biological	Treatment of respiratory tract illness	x						x	
Biological	Treatment of lyme borreliosis			x		x		x	
Biological	Treatment of Chikungunya disease	x				x	x	x	
Chemical	Treatment of hepatitis D virus infection			x				x	
Biological	Treatment of chronic hepatitis D virus infection		x			x	x	x	
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis			x		x		x	
Chemical	Treatment of ovarian cancer, fallopian tube or primary peritoneal cancer	x						x	
Chemical	Treatment of sickle cell disease	x					x	x	
Chemical	Treatment of rheumatoid arthritis	x					x	x	
Chemical	Treatment of colorectal cancer	x				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 myasthenia gravis	x						x	
Chemical	Treatment of non-small cell lung cancer	x				x	x	x	
Biological	Treatment of metastatic breast cancer	x				x			
Chemical	Treatment of gastrointestinal stromal tumours		x			x	x	x	
Chemical	Treatment of multiple myeloma	x				x		x	
Biological	Treatment of oesophageal squamous cell carcinoma	x						x	
Biological	Treatment of plaque psoriasis and active psoriatic arthritis	x				x	x	x	
Chemical	Treatment of myelodysplastic syndromes	x						x	
Chemical	Treatment of myeloid leukaemia	x					x	x	
Advanced Therapy	Treatment of adrenoleukodystrophy				x			x	
Biological	Treatment of mild cognitive impairment	x					x	x	
Biological	Treatment of asthma	x				x	x	x	
Biological	Improvement in the appearance of glabellar lines, canthal lines and forehead lines	x				x	x	x	
Biological	Treatment of osteoporosis or increase of bone mass in osteoporosis at high risk of fracture	x				x	x	x	
Biological	Treatment of osteoporosis or increase of bone mass in osteoporosis at high risk of fracture	x				x		x	
Advanced Therapy	Treatment of haemophilia B				x	x			
Chemical	Treatment of Charcot-Marie-Tooth disease		x				x	x	
Chemical	Treatment of Parkinson's disease	x					x	x	
Biological	Prevention of ischemia/reperfusion injury in association with organ transplantation		x			x	x	x	

Substance	Intended indications	Type of request				Topic			
		New		Follow-up		Quality	Preclinical	Clinical	Significant benefit
		SA	PA	SA	PA				
Chemical	Treatment of schizophrenia	x					x	x	
EUnetHTA parallel	Treatment of transfusion dependent β -thalassaemia				x			x	
Qualification Advice	Treatment of non-alcoholic fatty liver disease and non-alcoholic steatohepatitis	x						x	
Qualification Advice	Treatment of non-alcoholic fatty liver disease and non-alcoholic steatohepatitis	x						x	
Qualification Advice	DCE as one method for performing patient preference studies to inform regulatory and HTA-body medical product decision-making	x						x	

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 31 Scientific Advice letters, 6 Protocol Assistance letters, 5 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance, 3 Qualifications of novel methodologies and 1 EMA/EUnetHTA parallel consultation advices, were adopted at the 23 - 26 March 2020 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 47 new Requests for which the procedure started at the SAWP meeting held on 09 – 12 March 2020. The new requests are divided as follows: 26 Initial Scientific Advice, 8 Follow-up Scientific Advice, 8 Initial Protocol Assistance, 4 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.