



28 February 2019  
EMA/CHMP/SAWP/147640/2019  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 25 - 28 February 2019

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

	1995 - 2018	2019	Overall total
Scientific Advice	3866	57	3923
Follow-up to Scientific Advice	1150	24	1174
Protocol Assistance	932	20	952
Follow-up to Protocol Assistance	477	5	482
EMA/EUnetHTA parallel consultation advice	139	5	144
Qualification of novel methodologies	126	2	128
	<b>6689</b>	<b>115</b>	<b>6804</b>

### ***Outcome of the February 2019 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 malaria				X	x	x	x	
Chemical/Biological	Treatment of cystic fibrosis				X	x			
Chemical	Treatment of leukaemia		X			x			
Biological	Treatment of ovarian cancer		X			x	x		
Advanced	Treatment of multiple myeloma		X			x			



Therapy									
Advanced Therapy	Treatment of lymphoma		X			x	x	x	
Chemical	Treatment of gastric tumours		X			x	x	x	x
Biological	Treatment of type 1 diabetes	X						x	
Chemical	Treatment of multiple myeloma		X					x	
Biological	Treatment of dry eye			X				x	
Chemical	Treatment of multiple sclerosis			X		x			
Chemical	Treatment of multiple sclerosis			X				x	
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis and ankylosing spondylitis			X		x			
Biological	Treatment of esophageal cancer	X						x	
Biological	Treatment of Type 2 diabetes			X				x	
Chemical	Treatment of myelofibrosis			X				x	
Chemical	Treatment of psoriatic arthritis	X						x	
Chemical	Treatment of renal acidosis		X			x		x	
Biological	Treatment of non-small cell lung cancer			X				x	
Chemical	Treatment of pulmonary arterial hypertension			X				x	
Chemical	Treatment of breast cancer			X				x	
Advanced Therapy	Treatment of choroideremia				X	x		x	
Advanced Therapy	Treatment of $\beta$ -thalassaemia				X			x	
Biological	Weight management	X						x	
Biological	Treatment of cutaneous squamous cell carcinoma	X						x	
Chemical	Treatment of Intra-Ocular Pressure			X		x		x	
Chemical	Treatment of hypercholesterolemia	X				X			
Biological	Treatment of breast cancer	X				x	x	x	
Chemical	Magnetic resonance imaging of Central Nervous System			X				x	
Chemical	Magnetic resonance imaging of pathologies	X						x	
Biological	Treatment of endometrial cancer	X						x	
Chemical	Treatment of septic shock	X						x	
Biological	Treatment of headache	X						x	
Biological	Treatment of non-small cell lung cancer			X				x	
Chemical	Treatment of candidiasis			X		x		x	
Chemical	Treatment of fungal disease			X				x	
Chemical	Treatment of constipation	X						x	
Chemical	Treatment of hepatitis D		X			x	x	x	

Chemical	Positron-emission tomography imaging of Central Nervous System			X				x	
Chemical	Treatment of melanoma	X					x	x	
Biological	Treatment of myeloma	X						x	
Chemical	Treatment of myopia	X				x	x	x	
Chemical	Treatment of hyperoxaluria		X				x	x	
Chemical	Treatment of hyperoxaluria		X				x	x	
Chemical	Cardiovascular risk reduction	X				x	x	x	
Chemical	Treatment of overactive bladder	X						x	
Advanced Therapy	Treatment of myotubular myopathy		X			x	x	x	
Biological	Treatment of progressive palsy	X				x	x	x	
Chemical	Treatment of tissue damages induced by radiation	X				x	x	x	
Chemical	Treatment of glioblastoma		X			x	x	x	
Advanced Therapy	Treatment of Gaucher disease	X					x		
Advanced Therapy	Treatment of haemophilia A	X					x		
Chemical	Treatment of multiple sclerosis	X						x	
Chemical	Treatment of multiple sclerosis	X					x	x	
Chemical	Treatment of gonorrhoea	X						x	
Biological	Treatment of rheumatoid and idiopathic arthritis	X				x	x	x	
Biological	Treatment of non-small cell lung cancer	X						x	
Biological	Immunisation against malaria			X		x	x	x	
Biological	Prevention of Plasmodium falciparum infection	X				x	x	x	

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 25 Scientific Advice letters, 12 Protocol Assistance letters, 16 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 25 – 28 February 2019 CHMP meeting.

## New requests for scientific advice procedures

The Committee accepted 62 new Requests for which the procedure started at the SAWP meeting held on 11 – 14 February 2019. The new requests are divided as follows: 29 Initial Scientific Advice, 19 Follow-up Scientific Advice, 6 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 3 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.