



15 September 2016  
EMA/CHMP/SAWP/604222/2016  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 12 – 15 September 2016

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

	1995 - 2015	2016	Overall total
Scientific Advice	2899	223	3122
Follow-up to Scientific Advice	846	58	904
Protocol Assistance	662	47	709
Follow-up to Protocol Assistance	310	29	339
HTA parallel advice	63	9	72
Qualification of novel methodologies	83	9	92
	<b>4863</b>	<b>375</b>	<b>5238</b>

### ***Outcome of the September 2016 CHMP meeting in relation to scientific advice procedures***

#### **Final scientific advice procedures**

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of atypical haemolytic uremic syndrome	x						x	
Biological	Treatment of active idiopathic inflammatory myositis	x						x	
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ulcerative colitis,			x		x			



Intended indications(s)		Type of request					Topic		
	Crohn's disease, psoriasis, ankylosing spondylitis								
Biological	Treatment of pleural mesothelioma				x		x	x	
Chemical	Treatment of advanced gastric cancer	x						x	
Chemical	Treatment of psoriasis	x						x	
Biological	Treatment of angiosarcoma		x				x	x	x
Chemical	Treatment of unresectable hepatocellular carcinoma			x		x			
Biological	Treatment of chronic rhinosinusitis with nasal polyposis	x						x	
Chemical	Treatment of IDO1 (Indoleamine 2,3-Dioxygenase 1) inhibitor for melanoma	x				x			
Chemical	Treatment of relapsing, remitting multiple sclerosis	x				x		x	
Chemical	Treatment of acute myeloid leukaemia				x	x			
Biological	Treatment of rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis			x				x	
Chemical	Treatment of metastatic castration-resistant prostate cancer	x					x	x	
Chemical	Treatment of small cell lung cancer	x						x	
Chemical	Treatment of systemic lupus erythematosus	x						x	
Biological	Treatment of solid malignant tumors.	x				x		x	
Biological	Treatment and prevention of bleeding episodes			x				X	
Advanced Therapy	Treatment of transfusion dependent $\beta$ -thalassaemia				x	x			
Chemical	Treatment (secondary prevention) of venous thromboembolism	x				x		x	
Chemical	Treatment of pulmonary arterial hypertension	x						x	
Biological	Treatment of haemophilia A	x				x	x	x	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Advanced therapy	Treatment of ischaemic cardiomyopathy			x				x	
Chemical	Treatment of atopic dermatitis	x						x	
Biological	Treatment of atopic dermatitis	x						x	
Chemical	Treatment of Gram-negative pneumonia			x				x	
Chemical	Treatment of uncomplicated gonorrhoea			x				x	
Chemical	Treatment of uncomplicated urinary tract infections (acute cystitis)	x					x	x	
Advanced therapy	Treatment of osteogenesis imperfecta type III and severe type IV	x				x	x	x	
Biological	Treatment of moderate to severe glabellar lines	x					x	x	
Advanced therapy	Recovery following surgery for hip fracture	x				x		x	
Biological	Treatment of early Alzheimer's disease	x					x	x	
Biological	Treatment of progressive supranuclear palsy		x				x	x	
Biological	Treatment of mucopolysaccharidosis type IIIB		x				x	x	
Chemical	Treatment of peripheral neuropathic pain	x					x	x	
Advanced therapy	Allogeneic hematopoietic stem cell transplantation			x		x			
Chemical	Treatment of schizophrenia	x					x	x	
Chemical	Treatment of symptomatic of Transthyretin cardiomyopathy			x				x	
Chemical	Treatment of airflow obstruction in chronic obstructive pulmonary disease	x					x	x	
Biological	Treatment of nasal polyposis	x				x		x	
Biological	Treatment of diabetic macular edema	x					x	x	
Biological	Treatment of geographic atrophy secondary to age-related macular degeneration			x				x	
Chemical	Solution for reduction	x				x	x	x	

Intended indications(s)		Type of request					Topic		
	of elevated intra-ocular pressure								
Chemical	Treatment of autosomal dominant retinitis pigmentosa		x					x	
Chemical	Treatment of elevated intraocular pressure in ocular hypertension or open-angle glaucoma	x				x		x	
Biological	For replacement therapy in children with growth hormone insufficiency	x				x	x	x	
Chemical	Treatment of osteoporosis	x				x	x	x	
Advanced therapy	Treatment of hand manifestations of scleroderma and Raynaud's phenomena due to scleroderma		x			x		x	
Chemical	Detection of adenomas and colon cancer during colonoscopy			x				x	

**SA: Scientific Advice**  
**PA: Protocol Assistance**

The above-mentioned 30 Scientific Advice letters, 5 Protocol Assistance letters, 11 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance, 0 Qualifications of novel methodologies and 0 HTA Parallel advice, were adopted at the 12 - 15 September 2016 CHMP meeting.

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

The Committee accepted 75 new Requests for which the procedure started at the SAWP meeting held on 30 August – 2 September 2016. The new requests are divided as follows: 45 Initial Scientific Advice, 7 Follow-up Scientific Advice, 10 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 4 Qualifications of novel methodologies and 4 HTA Parallel advice.