

28 January 2016  
EMA/CHMP/SAWP/57185/2016  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 25 – 28 January 2016

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

	1995 - 2015	2016	Overall total
Scientific Advice	2899	26	2925
Follow-up to Scientific Advice	846	7	853
Protocol Assistance	662	4	666
Follow-up to Protocol Assistance	310	5	315
HTA parallel advice	63	2	65
Qualification of novel methodologies	83	2	85
	<b>4863</b>	<b>46</b>	<b>4909</b>

### ***Outcome of the January 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				
Chemical	Treatment of Niemann-Pick type C disease.				x	x	x	x	x
Chemical	Treatment of Niemann-Pick type C disease.				x			x	
Chemical	Treatment of peptic ulcer and gastro-oesophageal reflux.	x				x		x	
Chemical	Treatment of prostate cancer.	x						x	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis.			x				x	
Biological/ Other innovative	Treatment of bladder cancer.	x						x	
Other innovative	Treatment of soft tissue sarcoma.	x				x	x	x	
Chemical	Treatment of liposarcoma.	x					x	x	
Biological	Treatment of colorectal cancer.	x						x	
Biological	Treatment of ulcerative colitis.	x						x	
Advanced therapy	Treatment of renal cell carcinoma.	x				x	x	x	
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis.	x					x	x	
Chemical/ Other innovative	Treatment of gastric cancer.	x						x	
Chemical	Treatment of multiple myeloma.				x		x		
Chemical/ Biological	Treatment of large B-cell lymphoma.	x						x	
Chemical/ Biological	Treatment of hepatocellular carcinoma.	x						x	
Chemical/ Biological	Treatment of Hodgkin's lymphoma.	x						x	
Chemical	Treatment of acute myeloid leukaemia.		x			x			
Chemical	Treatment of cutaneous T-cell lymphoma.	x						x	
Chemical	Treatment of ovarian cancer.				x			x	x
Biological	Treatment of polymyalgia rheumatica.	x						x	
Chemical	Treatment of multiple myeloma.	x						x	
Chemical	Treatment of anaemia.			x		x			
Chemical	Treatment of anaemia.	x						x	
Chemical	Treatment of pulmonary arterial hypertension.			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 thromboangiitis obliterans.		x			x	x	x	
Chemical	Treatment of chronic heart failure.	x				x	x	x	
Biological	Vaccination against pertussis or poliomyelitis.	x				x			
Chemical	Prevention of HIV-1.			x			x	x	
Chemical/ Other innovative	Treatment of urinary tract infections, intra-abdominal infections, febrile neutropenia and HABP/VABP and CABP.	x					x	x	
Biological	Prevention of gastro-enteritis.			x		x		x	
Chemical	Treatment of cytomegalovirus infection or disease.				x			x	x
Not applicable	Broad advice on clinical development.			x				x	
Other innovative	Broad advice on Alzheimer's dementia.	x						x	
Chemical	Treatment of spinal muscular atrophy.			x				x	
Chemical	Treatment of Alzheimer's disease.	x					x		
Chemical	Treatment of jet lag disorder.	x						x	
Chemical	Treatment of unproductive cough.	x						x	
Chemical	Treatment of ocular hypertension or glaucoma.	x						x	
Biological	Prevention of retinopathy.		x			x	x		
Biological	Broad advice on control system life cycle management.	x				x			
Chemical	Treatment of pulmonary arterial hypertension.	x					x	x	
Qualification advice	Treatment of follicular lymphoma.	x						x	
Qualification advice	Treatment of ulcerative colitis.	x						x	
HTA Parallel advice	Treatment of Duchenne muscular dystrophy.		x			x	x	x	
HTA Parallel advice	Prophylaxis of headaches.	x				x	x	x	

**SA: Scientific Advice**

**PA: Protocol Assistance**

The above-mentioned 26 Scientific Advice letters, 4 Protocol Assistance letters, 7 Follow-up Scientific Advice, 5 Follow-up Protocol Assistance letters, 2 HTA parallel advice letters and 2 Qualifications of novel methodologies letters were adopted at the 25 – 28 January 2016 CHMP meeting.

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

The Committee accepted 43 new Requests for which the procedure started at the SAWP meeting held on 11 – 14 January 2016. The new requests are divided as follows: 26 Initial Scientific Advice, 6 Follow-up Scientific Advice, 3 Initial Protocol Assistance, 6 Follow-up Protocol Assistance, 1 HTA parallel advices and 1 Qualifications of novel methodologies.