



23 January 2014  
EMA/CHMP/SAWP/44167/2014  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 20 – 23 January 2014

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

	1995 - 2013	2014	Overall total
Scientific Advice	2091	27	2118
Follow-up to Scientific Advice	594	4	598
Protocol Assistance	460	3	463
Follow-up to Protocol Assistance	236	1	237
HTA parallel advice	23	0	23
Qualification of novel methodologies	43	0	43
	<b>3447</b>	<b>35</b>	<b>3482</b>

FDA Parallel Scientific Advice	2006 - 2013	2014	Overall total
Completed	22	0	22

### ***Outcome of the January 2014 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	Lipid lowering agent.	x				x			
Biological	Treatment of type I diabetes.	x					x	x	
Chemical	Treatment of Crohn's Disease.	x					x	x	



Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Chemical	Treatment of Crohn's Disease.	x					x	x	
Chemical/Biological	Treatment of metastatic pancreatic cancer.		x					x	
Chemical	Treatment of chronic lymphocytic leukaemia.				x			x	x
Chemical	Treatment of chronic lymphocytic leukaemia.		x			x			
Biological	Treatment of relapsed diffuse large B cell lymphoma.	x						x	
Biological	Treatment of colorectal cancer with associated cachexia.	x						x	
Chemical	Treatment of metastatic urothelial carcinoma.	x						x	
Chemical	Treatment of primary biliary cirrhosis.	x					x		
Chemical	Treatment of metastatic breast cancer.			x				x	
Chemical	Prevention of recurrent stroke and systemic embolism.	x						x	
Biological	Prevention of invasive disease in infants caused by Group B streptococci.			x		x	x	x	
Chemical	Treatment of anaemia associated with chronic kidney disease.	x						x	
Biological	Treatment and prophylaxis of bleeding in haemophilia B.			x		x	x	x	
Chemical	Delay of renal disease progression in type 2 diabetes mellitus and nephropathy.	x					x	x	
Biological	Treatment of moderate to severe atopic dermatitis.	x					x	x	
Chemical	Treatment of recalcitrant/persistent non-tuberculous mycobacterial lung disease.	x						x	
Biological	Prevention of gastroenteritis caused by norovirus.	x				x	x	x	
Biological	Prevention of postoperative invasive disease caused by Staphylococcus aureus.	x						x	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Active immunisation against diphtheria, tetanus, pertussis, poliomyelitis and against invasive disease caused by Haemophilus influenzae type b and infection caused by all known subtypes of hepatitis B virus.	x				x	x	x	
Chemical	Treatment of bacterial vaginosis.			x		x	x	x	
Biological	Treatment of anovulation (including polycystic ovarian disease).	x				x	x	x	
Chemical	Treatment of female sexual dysfunction.	x					x	x	
Biological	Treatment of anovulation.	x				x	x	x	
Chemical	Treatment of hyposexual desire disorder and maladaptive activation of sexual inhibitory mechanisms.	x				x	x	x	
Chemical	Treatment of hyposexual desire disorder and low attention for sexual cues.	x				x	x	x	
Chemical	Treatment of neurological symptoms of ataxia telangiectasia.		x			x	x	x	
Chemical	Treatment of epilepsies with absence and/or myoclonic seizures.	x				x	x	x	
Biological	Treatment of chronic obstructive pulmonary disease.	x						x	
Biological/ Other innovative	Treatment of asthma.	x					x	x	
Chemical/ Other innovative	Measurement of glomerular filtration rate.	x					x	x	
Chemical	Diagnostic of primary and metastatic neuroendocrine tumours bearing somatostatin receptors.	x				x	x	x	
Biological	Change in primary container.	x				x			

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

The above-mentioned 27 Scientific Advice letters, 3 Protocol Assistance letters, 4 Follow-up Scientific Advice, 1 Follow-up Protocol Assistance letters, 0 HTA parallel advice letters and 0 Qualification of novel methodologies letters were adopted at the 20 – 23 January 2014 CHMP meeting.

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

The Committee accepted 36 new Requests for which the procedure started at the SAWP meeting held on 7 – 9 January 2014. The new requests are divided as follows: 17 Initial Scientific Advice, 9 Follow-up Scientific Advice, 2 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 1 HTA parallel advice and 2 Qualification of novel methodologies.