



25 April 2013  
EMA/CHMP/SAWP/239007/2013  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 22 – 25 April 2013

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

	1995 - 2012	2013	Overall total
Scientific Advice	1848	80	1928
Follow-up to Scientific Advice	496	29	525
Protocol Assistance	396	19	415
Follow-up to Protocol Assistance	189	12	201
HTA parallel advice	16	2	18
Qualification of novel methodologies	28	5	33
	<b>2973</b>	<b>147</b>	<b>3120</b>

FDA Parallel Scientific Advice	2006 - 2012	2013	Overall total
Completed	19	1	20

### ***Outcome of the April 2013 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 Clostridium difficile associated diarrhea (CDAD).			x			x	x	
Biological	Treatment of diabetes mellitus.			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 opioid induced constipation.			x				x	
Advanced therapy	Treatment of inflammatory bowel disease.	x					x		
Biological	Treatment of glioblastoma.		x					x	
Chemical	Treatment of ovarian and breast cancer.	x				x	x	x	
Chemical	Treatment of peripheral T-cell lymphoma (PTCL).		x					x	x
Biological	Treatment of steroid resistant acute Graft-versus-Host disease.				x	x	x	x	
Biological	Treatment of relapsed/refractory B-precursor acute lymphoblastic leukaemia.		x			x		x	
Chemical	Treatment of ovarian cancer, Kaposi's sarcoma and metastatic cancer.	x					x	x	
Biological	Treatment of non-small cell lung cancer (NSCLC).	x					x	x	
Chemical/Biological	Treatment of neoadjuvant HER2-positive breast cancer.	x						x	
Chemical/Biological	Treatment of HER2 positive early breast cancer.	x						x	
Chemical	Treatment of thyroid cancer.	x						x	
Biological	Treatment of dyskeratosis congenita.		x			x	x	x	
Chemical	Treatment of renal disease.	x						x	
Biological	Treatment of hyperlipidemia and prevention of cardiovascular events.	x					x	x	
Chemical	Treatment of stable plaque psoriasis vulgaris.	x						x	
Chemical	Treatment of complicated urinary tract infection (cUTI).	x						x	
Chemical	Treatment of hospital and ventilatory acquired pneumonia (HAP/VAP).	x						x	
Chemical	Treatment of HIV infection.			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 HIV-1 infection.	x					x	x	
Chemical	Prophylaxis of acute kidney injury.			x			x	x	
Biological	Treatment of Human Papillomavirus (HPV).	x					x	x	
Biological	Treatment of sepsis-associated acute kidney injury.			x			x	x	
Chemical	Treatment of overactive bladder.	x					x	x	
Advanced therapy	Treatment of cartilage wound damages.	x				x	x	x	
Chemical	Treatment of dementia of the Alzheimer's type.	x						x	
Chemical	Treatment of mild-to-moderate dementia of the Alzheimer's type.	x					x	x	
Chemical	Treatment of Lennox Gastaut Syndrome.	x						x	
Chemical	Treatment of Lennox Gastaut Syndrome.	x						x	
Chemical	Treatment of intellectual disability associated with Down syndrome.			x				x	
Biological	Treatment of Alzheimer's disease.			x				x	
Chemical/Biological	Treatment of cystic fibrosis.				x		x		
Chemical	Treatment of neovascular glaucoma.		x				x	x	x
Biomarker	Treatment of CLL.	x							
Biomarker	Treatment of intellectual disability associated with Down syndrome.	x							
Biomarker	Treatment of mild Alzheimer's disease.	x							
HTA	Treatment of osteoporosis.	x					x	x	

**SA: scientific advice**  
**PA: protocol assistance**

The above-mentioned 20 Scientific Advice letters, 5 Protocol Assistance letters, 8 Follow-up Scientific Advice, 2 Follow-up Protocol Assistance letters, 1 HTA parallel advice letters and 3 Qualification of novel methodologies letters were adopted at the 22 – 25 April 2013 CHMP meeting.

## New requests for scientific advice procedures

The Committee accepted 27 new Requests for which the procedure started at the SAWP meeting held on 02 – 04 April 2013. The new requests are divided as follows: 14 Initial Scientific Advice, 8 Follow-up Scientific Advice, 3 Initial Protocol Assistance, 0 Follow-up Protocol Assistance, 0 HTA parallel advice and 2 Qualification of novel methodologies.