



21 March 2013  
EMA/174552/2013  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 18 – 21 March 2013

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

	1995 - 2012	2013	Overall total
Scientific Advice	1848	59	1907
Follow-up to Scientific Advice	496	21	517
Protocol Assistance	396	14	410
Follow-up to Protocol Assistance	189	10	199
HTA parallel advice	16	1	17
Qualification of novel methodologies	28	2	30
	<b>2973</b>	<b>107</b>	<b>3080</b>

FDA Parallel Scientific Advice	2006 - 2012	2013	Overall total
Completed	19	0	19

### ***Outcome of the March 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				
Biological	Improvement of growth in preterm infants.	x						x	
Advanced therapy	Treatment of Crigler Najjar Syndrome.				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 chylomicronemia.		x			x			
Biological	Treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, psoriasis and Crohn's disease.	x				x	x	x	
Biological	Treatment of castrate resistant prostate cancer.	x					x	x	
Chemical	Treatment of neuroblastoma, Wilms tumors, rhabdomyosarcoma, Ewing's sarcoma, Acute Lymphocytic Leukaemia and other paediatric solid tumors.			x				x	
Biological	Treatment of multiple myeloma.		x			x			
Chemical	Treatment of lung cancer.			x				x	
Biological	Treatment of low-grade serous carcinoma of the ovary, fallopian tube or primary peritoneum.	x						x	
Biological	Treatment of squamous cell and non-small cell lung cancer.	x						x	
Chemical / Other innovative	Treatment of squamous cell cancer of the head and neck.		x					x	x
Chemical	Treatment of ovarian cancer.				x			x	x
Chemical	Treatment of colorectal cancer.	x					x	x	
Biological	Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia and rheumatoid arthritis.			x				x	
Chemical	Treatment of Acute Myeloid Leukaemia.				x	x	x	x	x
Chemical / Biological	Treatment of B-cell Non-Hodgkin Lymphoma.	x				x			
Biological	Treatment of HER2-overexpressing breast cancer.	x				x	x	x	
Chemical	Treatment of breast cancer.	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 melanoma and thyroid cancer.			x			x		
Chemical	Treatment of thromboembolic events and secondary venous thromboembolic prevention.	x				x		x	
Biological	Treatment of hyperlipidemia.	x				x	x	x	
Biological	Active immunisation against invasive disease and acute otitis media caused by Streptococcus pneumoniae.	x				x	x	x	
Biological	Prevention of rotavirus gastroenteritis.	x				x	x	x	
Chemical	Treatment of nosocomial pneumonia including ventilator associated pneumonia.	x						x	
Chemical	Treatment of local symptomatic pain and inflammation.	x					x	x	
Biological	Treatment of chronic inflammatory demyelinating polyneuropathy.	x				x	x	x	
Chemical	Treatment of idiopathic Parkinson's disease.			x				x	
Chemical	Treatment of prodromal and mild AD.	x						x	
Chemical	Treatment of Parkinson's disease.	x				x	x	x	
Biological	Treatment of chronic low back pain, chronic lower back pain and osteoarthritis.			x				x	
Chemical	Treatment of Chronic Obstructive Pulmonary Disease.	x						x	
Biological/Advanced therapy	Treatment of macular telangiectasia type 2.		x					x	
Biological	Treatment of methotrexate toxicity.				x			x	

**SA: scientific advice**

**PA: protocol assistance**

The above-mentioned 18 Scientific Advice letters, 4 Protocol Assistance letters, 7 Follow-up Scientific Advice, 4 Follow-up Protocol Assistance letters, 0 HTA parallel advice letters and 0 Qualification of novel methodologies letters were adopted at the 18 – 21 March 2013 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 04 – 06 March 2013. The new requests are divided as follows: 17 Initial Scientific Advice, 10 Follow-up Scientific Advice, 6 Initial Protocol Assistance, 1 Follow-up Protocol Assistance, 0 HTA parallel advice and 2 Qualification of novel methodologies.