



25 July 2013  
EMA/CHMP/SAWP/445836/2013  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 22 – 25 July 2013

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

	1995 - 2012	2013	Overall total
Scientific Advice	1848	146	1994
Follow-up to Scientific Advice	496	61	557
Protocol Assistance	396	34	430
Follow-up to Protocol Assistance	189	19	208
HTA parallel advice	16	2	18
Qualification of novel methodologies	28	9	37
	<b>2973</b>	<b>271</b>	<b>3244</b>

FDA Parallel Scientific Advice	2006 - 2012	2013	Overall total
Completed	19	2	21

### ***Outcome of the July 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 active distal colitis, proctitis and sigmoiditis.	x						x	
Biological	Treatment of diabetes mellitus.			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				
Biological	Treatment of functional constipation.	x					x	x	
Chemical	Treatment of primary biliary cirrhosis.				x	x			
Biological	Maintenance of glycemic control in hyperglycemia.	x						x	
Chemical	Treatment of small cell lung cancer.	x					x	x	
Chemical	Treatment of pancreatic adenocarcinoma.	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 rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, psoriasis and Crohn's disease.	x				x	x	x	
Biological	Treatment of metastatic carcinoma of the colon or rectum, metastatic breast cancer, non-small cell lung cancer and metastatic renal cell cancer.	x				x	x	x	
Biological	Treatment of CD30-positive mature T-cell lymphomas.			x				x	
Biological	Treatment of active and progressive psoriatic arthritis.	x						x	
Biological	Treatment of hereditary periodic fever syndromes.	x				x		x	
Advanced therapy	Treatment of glioblastoma.	x				x	x	x	
Chemical	Prevention of recurrent hepatitis C virus induced liver disease.	x					x	x	
Chemical	Treatment of anaplastic thyroid cancer.		x			x	x	x	x
Biological	Treatment of non-small cell lung 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/ Advanced therapy	Treatment of hepatocellular carcinoma.				x	x			
Chemical	Treatment of metastatic breast cancer.			x				x	
Chemical	Treatment of breast cancer.	x						x	
Chemical	Treatment of primary myelofibrosis.				x			x	x
Chemical	Treatment of primary myelofibrosis.		x			x	x		
Chemical	Treatment of ER+ HER2- advanced breast cancer.			x				x	
Chemical	Treatment of castration-resistant prostate cancer.	x					x	x	
Chemical	Treatment of systemic sclerosis.		x				x	x	x
Chemical	Treatment of soft tissue sarcoma.	x				x	x		
Biological	Treatment of hereditary factor X deficiency.				x			x	
Chemical	Prevention of atherothrombotic events.			x				x	
Chemical	Prevention of atherothrombotic events.	x				x			
Biological	Adjunct to hemostasis for use in surgery for control of bleeding.	x				x	x	x	
Chemical/ Other innovative	Treatment of moderate to severe internal haemorrhoids.	x					x	x	
Chemical	Treatment of hepatitis C virus infection.			x				x	
Chemical	Treatment of complicated skin and soft tissue infections and diabetic foot infection.			x				x	
Biological	Prevention of dengue illness.	x						x	
Biological	Treatment of hepatitis C.			x		x		x	
Chemical	Treatment of bloodstream infections and pneumonia.	x					x	x	
Chemical	Prophylaxis of acute kidney injury.	x				x	x	x	
Chemical	Treatment of symptomatic endometriosis.	x					x	x	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Prevention of relapses of vaginosis.	x				x		x	
Chemical	Treatment of severe traumatic brain injury.		x			x	x	x	
Biological	Improvement of mobility.	x					x	x	
Chemical	Treatment of TTR-mediated amyloidosis.		x			x	x	x	
Chemical	Treatment of multiple sclerosis.	x					x	x	
Biological	Treatment of Niemann-Pick disease type C.		x				x	x	
Chemical	Treatment of dementia with Lewy bodies.	x						x	
Chemical	Treatment of perinatal asphyxia.		x			x	x	x	
Advanced therapy	Treatment of Leber's congenital amaurosis.		x			x	x	x	
Chemical	Treatment of Leber's congenital amaurosis.				x			x	
Chemical	Reduction of risk of post-operative endophthalmitis.	x					x	x	
Chemical	Treatment of acromegaly.				x			x	x
Qualification advice	Treatment of chronic obstructive pulmonary disease.	x							
Qualification advice	Treatment of rheumatoid arthritis.	x							

**SA: scientific advice**

**PA: protocol assistance**

The above-mentioned 27 Scientific Advice letters, 8 Protocol Assistance letters, 9 Follow-up Scientific Advice, 6 Follow-up Protocol Assistance letters, 0 HTA parallel advice letters and 2 Qualification of novel methodologies letters were adopted at the 22 – 25 July 2013 CHMP meeting.

## New requests for scientific advice procedures

The Committee accepted 50 new Requests for which the procedure started at the SAWP meeting held on 08 – 11 July 2013. The new requests are divided as follows: 29 Initial Scientific Advice, 4 Follow-up Scientific Advice, 7 Initial Protocol Assistance, 4 Follow-up Protocol Assistance, 5 Protocol Assistance with significant benefit only, 0 HTA parallel advices and 1 Qualification of novel methodologies.