



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 12-15 March 2012

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

	1995 - 2011	2012	Overall total
Scientific Advice	1627	38	1665
Follow-up to Scientific Advice	400	15	415
Protocol Assistance	342	10	352
Follow-up to Protocol Assistance	162	7	169
HTA parallel advice	8	2	10
Qualification of novel methodologies	14	4	18
	<b>2553</b>	<b>76</b>	<b>2629</b>

FDA Parallel Scientific Advice	2006 - 2011	2012	Overall total
Completed	17	0	17

### ***Outcome of the March 2012 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 Graft-versus-Host disease.				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 chronic, severe sialorrhoea.	x				x	x	x	
Biological	Treatment of rheumatoid arthritis.			x		x		x	
Biological/Advanced therapy	Treatment of prostate cancer.	x				x	x	x	
Biological	Treatment of Polycythaemia Vera.		x			x	x	x	
Biological	Treatment of acute lung injury/acute respiratory distress syndrome.				x			x	
Biological	Treatment of haemophagocytic lymphohistiocytosis.		x				x	x	
Chemical	Treatment of advanced triple-negative breast cancer.	x						x	
Chemical	Treatment of hepatocellular carcinoma.		x			x	x	x	x
Chemical	Treatment of pancreatic cancer.		x				x	x	x
Biological/Other innovative	Treatment of HER2-overexpressing breast cancer and metastatic gastric cancer.	x				x	x	x	
Biological	Treatment of HER2-positive NSCLC.	x				x	x	x	
Biological/Chemical	Treatment of advanced HER2-positive gastric cancer.			x				x	
Chemical	Treatment of acute lymphoblastic leukaemia.		x				x	x	x
Biological	Treatment of Hemophilia B, factor VII deficiency, hemophilia A, thrombasthenia.	x				x	x	x	
Biological	Secondary prevention of major cardiovascular events in patients with ACS.	x					x	x	
Biological	Treatment of extensive or profound non-complicated diabetic mellitus foot ulcers.	x				x	x	x	
Chemical	Treatment of HIV-1 infection.			x				x	
Biological	Prophylaxis of influenza caused by A (H1N1)v 2009 virus.	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 invasive disease in infants caused by Group B streptococci.	x				x	x	x	
Chemical	Oral contraception in women who elect to use folate supplementation.	x						x	
Chemical	Treatment of pre-term labour in pregnant women.	x					x	x	
Biological	Treatment of osteoporosis in postmenopausal women at increased risk of fracture.			x			x	x	
Chemical	Adjunctive treatment of partial onset seizures in epilepsy.	x				x			
Other innovative	Prophylaxis of rhinoconjunctivitis in cat-allergic individuals.			x				x	
Biological	Reversal of the anticoagulation effect of dabigatran.	x						x	
Chemical	Treatment of pantothenate kinase-associated neurodegeneration.	x				x	x	x	
Advanced therapy	Treatment of Crohn's Disease, multiple sclerosis, rheumatoid arthritis, ischemic stroke and sarcoidosis.	x				x	x	x	
Chemical	Treatment of active psoriatic arthritis.			x				x	
Biomarker	Detection of potential bias following local evaluation of PFS in oncology phase III trials in patients with solid tumours.	x						x	
Biomarker	Caregiver Reported Outcome Measure that assesses dementia-related independence from/dependence on caregivers.	x						x	

**SA: scientific advice**

**PA: protocol assistance**

The above-mentioned 16 Scientific Advice letters, 5 Protocol Assistance letter, 7 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance letters, 0 HTA parallel advice letters and 2 Qualification of novel methodologies letters were adopted at the 12 – 15 March 2012 CHMP meeting.

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

The Committee accepted 31 new Requests for which the procedure started at the SAWP meeting held on 27 – 29 February 2012. The new requests are divided as follows: 19 Initial Scientific Advice, 8 Follow-up Scientific Advice, 2 Initial Protocol Assistance, 1 Follow-up Protocol Assistance, 0 HTA parallel advice and 1 Qualification of novel methodologies.