



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 14-17 November 2011

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

	1995 - 2010	2011	Overall total
Scientific Advice	1368	242	1610
Follow-up to Scientific Advice	320	76	396
Protocol Assistance	297	42	339
Follow-up to Protocol Assistance	133	24	157
	<b>2118</b>	<b>384</b>	<b>2502</b>

FDA Parallel Scientific Advice	2006 - 2010	2011	Overall total
Completed	9	8	17
<b>Ongoing</b>	0	4	4
Foreseen	0	2	2
	<b>9</b>	<b>14</b>	<b>23</b>

### ***Outcome of the November 2011 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	Treatment of diabetes mellitus.	x				x	x	x	
Chemical	Treatment of moderate to severe Crohn's 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 type-2 diabetes mellitus.			x				x	
Chemical	Treatment of type 2 diabetes mellitus.			x				x	
Chemical	Treatment of symptoms associated with gastro-oesophageal reflux disease (GORD).	x						x	
Biological	Treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, psoriasis and Crohn's disease.	x				x	x	x	
Chemical	Treatment of juvenile myelomonocytic leukaemia (JMML) and relapsed/refractory acute myeloid leukaemia (R/R AML).				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 colorectal, breast, renal and non-small cell lung cancers.	x				x	x	x	
Biological	Treatment of neuroblastoma.		x			x	x	x	
Chemical	Treatment of advanced or metastatic breast cancer.			x				x	
Advanced therapy	Adjunctive treatment in of haplo-identical hematopoietic cell transplant in high risk acute leukaemia.				x			x	x
Advanced therapy	Adjunctive treatment in of haplo-identical hematopoietic cell transplant in high risk acute leukaemia.			x			x		
Biological	Treatment of nasopharyngeal carcinoma.	x						x	
Biological	Treatment of multiple myeloma.	x						x	
Chemical	Treatment of moderate to severe active rheumatoid arthritis.	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 gastrointestinal stromal tumours.		x					x	
Biological	Prevention of the ischaemia reperfusion (I/R) injury associated with solid organ transplantation.		x				x		
Chemical	Prevention of graft loss in pancreatic islet transplantation.	x						x	
Biological	Treatment of HER2-overexpressing breast cancer and metastatic gastric cancer.	x				x	x	x	
Biological/Chemical	Treatment of HER2-positive breast cancer.	x						x	
Chemical	Prevention of symptomatic or fatal VTE in non-small cell lung cancer patients.	x						x	
Biological	Treatment of anemia.			x		x	x	x	
Chemical	Reduction of risk of cardiovascular (CV) death, myocardial infarction (MI) and stroke.	x						x	
Chemical	Reduction of risk of death and myocardial re-infarction.			x				x	
Chemical	Reduction of risk of death and myocardial re-infarction.	x				x			
Chemical	Prevention of late-onset sepsis.		x			x	x	x	
Other innovative	Treatment of epidermolysis bullosa.		x			x	x	x	
Chemical	Treatment of HIV infection.			x			x	x	
Biological	Immunization against Lyme Borreliosis.	x				x	x	x	
Biological	Active immunization of pregnant women to reduce severe RSV disease in neonates and infants.	x					x		
Biological	Prevention of cervical cancer and cervical, vulvar and vaginal dysplasia and genital warts.			x				x	
Biological	Treatment of HIV-1.	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				
Chemical	Treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH).	x				x	x	x	
Chemical	Treatment of bacterial vaginosis.	x				x	x	x	
Biological	Treatment of osteoporosis.	x					x	x	
Chemical	Treatment of Duchenne muscular dystrophy.				x	x			
Chemical	Treatment of gout.			x				x	
Chemical	Treatment of Parkinson's disease.	x						x	
Chemical	Treatment of mild to moderate dementia of the Alzheimer's type.	x					x	x	
Biological	Treatment of asthma.	x				x			
Chemical	Treatment of asthma.			x				x	
Chemical	Treatment of Leber Congenital Amaurosis (LCA).		x					x	
Biological	Treatment of neovascular (wet) age-related macular degeneration (AMD).			x				x	
Chemical	Treatment of osteoporosis.	x				x	x	x	
Biological	Prevention of ischemia/reperfusion injury associated with solid organ transplantation.				x		x	x	

**SA: scientific advice**

**PA: protocol assistance**

The above-mentioned 25 Scientific Advice letters, 7 Protocol Assistance letter, 10 Follow-up Scientific Advice and 4 Follow-up Protocol Assistance letters were adopted at the 14 – 17 November 2011 CHMP meeting.

## New requests for scientific advice procedures

The Committee accepted 26 new Requests for which the procedure started at the SAWP meeting held on 26 – 29 September 2011. The new requests are divided as follows: 18 Initial Scientific Advice, 3 Follow-up Scientific Advice, 2 Initial Protocol Assistance and 3 Follow-up Protocol Assistance.