



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 17 – 20 November 2014

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

	1995 - 2013	2014	Overall total
Scientific Advice	2091	257	2348
Follow-up to Scientific Advice	594	101	695
Protocol Assistance	460	52	512
Follow-up to Protocol Assistance	236	36	272
HTA parallel advice	23	7	30
Qualification of novel methodologies	43	15	58
	<b>3447</b>	<b>468</b>	<b>3915</b>

FDA Parallel Scientific Advice	2006 - 2013	2014	Overall total
Completed	22	3	25

### ***Outcome of the November 2014 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 type 2 diabetes mellitus.	x					x	x	
Biological	Treatment of Pompe disease.	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 X-linked adrenoleukodystrophy.	x					x	x	
Biological	Treatment of type 2 diabetes mellitus.			x		x	x		
Chemical	Treatment of X-linked adrenoleukodystrophy.		x				x	x	
Biological	Prevention of systemic inflammation induced organ dysfunction.	x						x	
Biological	Treatment of moderate to severe rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, severe ankylosing spondylitis, plaque psoriasis and non-radiographic axial spondyloarthritis.	x				x	x	x	
Chemical	Treatment of hepatocellular carcinoma.		x			x			
Advanced therapy	Treatment of glioblastoma.		x					x	
Biological	Treatment of cutaneous T-cell lymphoma.		x					x	
Chemical	Treatment of breast cancer.	x						x	
Chemical	Treatment of breast cancer.	x						x	
Biological	Treatment of NSCLC.			x		x		x	
Biological	Treatment of neutropenia.	x				x	x	x	
Biological	Treatment of HNSCC.	x						x	
Biological	Treatment of stage III melanoma.	x						x	
Chemical	Treatment of hepatitis C in hepatocellular carcinoma.		x					x	x
Biological	Treatment of urothelial cancer.	x						x	
Biological	Treatment of gastric cancer.		x					x	
Biological	Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, severe rheumatoid arthritis, severe vasculitis and microscopic polyangiitis.			x				x	
Biological	Treatment of giant cell arteritis.	x					x	x	
Biological	Treatment of systemic sclerosis.	x						x	
Chemical	Treatment of AML.				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 primary sclerosing cholangitis.	x					x	x	
Biological	Prevention of perinatal and early infant invasive infection via maternal immunisation.			x		x			
Chemical	Treatment of hypovolaemia.	x						x	
Chemical	Treatment of vasopressor-dependent septic shock.			x				x	
Chemical	Treatment of pulmonary arterial hypertension.	x						x	
Biological	Treatment of chronic spontaneous urticaria.			x				x	
Chemical	Treatment of influenza.	x					x		
Biological	Active immunisation against disease caused by V. cholera.	x						x	
Chemical	Treatment of Enterobacteriaceae infections.			x				x	
Biological	Treatment of inhalation anthrax infection.			x		x	x		
Biological	Treatment of glabellar lines.			x				x	
Chemical	Treatment of Duchenne muscular dystrophy.	x					x	x	
Advanced therapy	Treatment of childhood cerebral adrenoleukodystrophy.	x				x	x	x	
Chemical	Delay of disability and progression in Alzheimer's disease.			x				x	
Chemical	Treatment of intellectual disability associated with Down syndrome.			x			x		
Biological	Treatment of asthma.	x					x	x	
Biological	Treatment of asthma.	x					x	x	
Advanced therapy	Treatment of non-infectious uveitis.	x				x	x	x	
Advanced therapy	Treatment of total unilateral limbal stem cell deficiency.		x			x	x	x	
Biological	Treatment of neurotrophic keratitis.			x				x	
Chemical	Treatment of ocular hypertension or open-angle glaucoma.	x						x	
Biological/Other innovative	Treatment of growth hormone deficiency.			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 partial lipodystrophy.		x					x	
Chemical	Treatment of neuroendocrine tumours.				x			x	x
Chemical	Prophylaxis of acute kidney injury.		x					x	
Biological	Treatment of Ebola.			x		x		x	

**SA: Scientific Advice**

**PA: Protocol Assistance**

The above-mentioned 23 Scientific Advice letters, 9 Protocol Assistance letters, 14 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance letters, 0 HTA parallel advice letters and 0 Qualification of novel methodologies letters were adopted at the 17 – 20 November 2014 CHMP meeting.

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

The Committee accepted 55 new Requests for which the procedure started at the SAWP meeting held on 3 – 6 November 2014. The new requests are divided as follows: 35 Initial Scientific Advice, 7 Follow-up Scientific Advice, 6 Initial Protocol Assistance, 4 Follow-up Protocol Assistance, 0 HTA parallel advice and 3 Qualification of novel methodologies.