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Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 22 – 25 September 2014

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

	1995 - 2013	2014	Overall total
Scientific Advice	2091	206	2297
Follow-up to Scientific Advice	594	72	666
Protocol Assistance	460	39	499
Follow-up to Protocol Assistance	236	29	265
HTA parallel advice	23	6	29
Qualification of novel methodologies	43	15	58
	<b>3447</b>	<b>367</b>	<b>3814</b>

FDA Parallel Scientific Advice	2006 - 2013	2014	Overall total
Completed	22	1	23

### ***Outcome of the September 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				
Other innovative	Treatment of recurrent Clostridium difficile infection.	x				x		x	
Biological	Treatment of pancreatic exocrine insufficiency.	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				
Advanced therapy	Treatment of mucopolysaccharidosis type IIIA (Sanfilippo type A syndrome).		x				x	x	
Biological	Treatment of type 1 and type 2 diabetes mellitus.	x				x		x	
Biological	Treatment of short bowel syndrome.				x			x	
Biological	Treatment of recurrent glioblastoma multiforme.	x				x	x	x	
Chemical	Treatment of prostate cancer.	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	
Chemical	Treatment of NSCLC.			x		x		x	
Biological	Treatment of IgA nephropathy.	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	
Chemical	Treatment of breast cancer.	x				x			
Biological	Treatment of rheumatoid arthritis.			x				x	
Chemical	Treatment of B-cell non-Hodgkin's lymphoma.			x				x	
Chemical	Treatment of hormone receptor-positive advanced breast cancer, neuroendocrine tumours, renal cell carcinoma, renal angiomyolipoma, subependymal giant cell astrocytoma.	x				x		x	
Chemical	Treatment of pancreatic neuroendocrine tumours.		x					x	x
Chemical	Treatment of mastocytosis.				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 head and neck squamous cell carcinoma.	x						x	
Chemical/Biological	Treatment of metastatic breast cancer.	x						x	
Biological	Treatment of hypereosinophilic syndrome.				x			x	
Biological	Treatment of moderately to severely active rheumatoid arthritis.	x					x	x	
Biological	Treatment of bladder cancer.	x						x	
Biological	Treatment of diffuse-type giant cell tumour and tenosynovial giant cell tumour.	x				x	x	x	
Biological	Treatment of non-Hodgkin's lymphoma, and rheumatoid arthritis.	x				x	x	x	
Biological	Treatment of non-Hodgkin's lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis and granulomatosis with polyangiitis and microscopic polyangiitis.				x	x	x	x	
Chemical	Treatment of systemic sclerosis.		x				x	x	
Biological	Treatment of treatment of rheumatoid arthritis.				x			x	
Biological/Advanced therapy	Treatment of non-small cell lung cancer.				x			x	
Biological	Treatment of post-haemostatic short term episodic prophylaxis to reduce the frequency of joint bleeds.	x						x	
Biological	Treatment and prophylaxis of bleeding in haemophilia B.	x				x	x	x	
Biological	Treatment of myocardial infarction.	x				x			
Chemical	Reduction of risk of thrombotic cardiovascular events.	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 transthyretin mediated familial amyloidotic cardiomyopathy.		x			x	x	x	
Chemical	Treatment of pulmonary arterial hypertension.	x						x	
Chemical	Treatment of essential hypertension.	x					x	x	
Chemical	Control of hyperphosphataemia.	x						x	
Chemical	Treatment of lamellar ichthyosis.	x				x	x	x	
Chemical	Treatment of respiratory syncytial virus.	x					x	x	
Biological	Prophylactic vaccines.	x				x			
Chemical	Treatment of HIV-1 infection.	x					x	x	
Chemical	Treatment of complicated urinary tract infection.	x					x	x	
Chemical	Treatment of nosocomial pneumonia.	x						x	
Chemical	Treatment of HIV-1 infection.	x					x	x	
Chemical	Prophylaxis for HIV-1 infection.	x					x	x	
Biological	Immunisation against poliomyelitis.	x					x	x	
Chemical	Treatment of hepatitis C virus infection.			x				x	
Chemical	Treatment of postmenopausal osteoporosis.	x						x	
Advanced therapy	Treatment of metachromatic leukodystrophy.			x			x	x	
Chemical	Treatment of schizophrenia.	x				x		x	
Chemical	General anaesthesia.	x				x	x	x	
Chemical	Treatment of schizophrenia.			x		x			
Chemical	Treatment of asthma and COPD.	x				x		x	
Chemical	Treatment of allergic rhinoconjunctivitis.			x				x	
Chemical	Treatment of respiratory syncytial virus.	x				x	x	x	
Biological	Treatment of asthma.	x				x	x	x	
Biological	Treatment of osteoporosis.	x				x	x	x	
Biological	Treatment of follicular lymphoma.		x				x	x	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Qualification advice	Prognostic marker for diabetic macular edema.	x						x	
Qualification advice	Biomarker for kidney injury.	x						x	
HTA Parallel advice	Treatment of prostate cancer.	x						x	

**SA: Scientific Advice**

**PA: Protocol Assistance**

The above-mentioned 38 Scientific Advice letters, 5 Protocol Assistance letters, 11 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance letters, 1 HTA parallel advice letters and 2 Qualification of novel methodologies letters were adopted at the 22 – 25 September 2014 CHMP meeting.

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

The Committee accepted 58 new Requests for which the procedure started at the SAWP meeting held on 1 – 4 September 2014. The new requests are divided as follows: 34 Initial Scientific Advice, 13 Follow-up Scientific Advice, 6 Initial Protocol Assistance, 3 Follow-up Protocol Assistance, 0 HTA parallel advice and 2 Qualification of novel methodologies.