



23 July 2015  
EMA/CHMP/SAWP/502864/2015  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 20 – 23 July 2015

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

	1995 - 2014	2015	Overall total
Scientific Advice	2653	158	2811
Follow-up to Scientific Advice	758	55	813
Protocol Assistance	566	71	637
Follow-up to Protocol Assistance	267	26	293
HTA parallel advice	34	20	54
Qualification of novel methodologies	60	10	70
	<b>4338</b>	<b>340</b>	<b>4678</b>

FDA Parallel Scientific Advice	2006 - 2014	2015	Overall total
Completed	26	2	28

### ***Outcome of the July 2015 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 type 2 diabetes mellitus.			x		x		x	
Biological	Treatment of type 2 diabetes mellitus.			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 Merkel cell carcinoma.			x		x	x	x	
Biological	Prophylaxis of graft rejection.	x				x			
Biological	Treatment of breast cancer, non-small cell lung cancer, renal cell carcinoma and ovarian cancer.			x				x	
Chemical/Biological	Treatment of rheumatoid arthritis.	x						x	
Chemical	Treatment of castrate resistant prostate cancer.	x						x	
Chemical	Treatment of follicular lymphoma.				x			x	x
Chemical	Treatment of rheumatoid arthritis.			x		x		x	
Chemical	Treatment of AML.	x						x	
Chemical	Treatment of AML.				x			x	
Advanced therapy	Treatment of mantle cell lymphoma.	x						x	
Advanced therapy	Treatment of B-cell non-Hodgkin lymphoma.	x					x	x	
Chemical	Treatment of non-metastatic castrate resistant prostate cancer.			x			x	x	
Chemical	Treatment of metastatic breast cancer.	x				x	x	x	
Chemical	Treatment of malignant pleural mesothelioma and non-small cell lung cancer.	x				x	x	x	
Chemical	Treatment of mycosis fungoides-type cutaneous T-Cell lymphoma.	x				x	x	x	
Chemical	Treatment of activated PI3Kd syndrome.	x					x	x	
Biological	Treatment of steroid-resistance acute Graft-vs-Host Disease.		x			x	x	x	x
Biological	Treatment of breast cancer and gastric cancer.	x				x	x	x	
Biological	Treatment of breast cancer and gastric cancer.	x				x		x	
Advanced therapy	Treatment of beta thalassemia.		x			x	x		
Advanced therapy	Treatment of haematological malignancies.	x						x	

Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
Biological	Replacement therapy in severe protein C deficiency.	x						x	
Chemical	Treatment of resistant hypertension.	x					x	x	
Chemical	Treatment of diabetic foot ulcers.	x					x	x	
Biological	Diagnosis of tuberculosis.	x						x	
Chemical	Prevention of HIV-1 acquisition.			x				x	
Biological	Prevention of nosocomial pneumonia caused by <i>Pseudomonas aeruginosa</i> .	x					x	x	
Biological	Prevention of invasive meningococcal disease.	x				x		x	
Chemical	Treatment of primary dysmenorrhea.			x				x	
Chemical	Treatment of interstitial cystitis.		x			x	x	x	
Chemical	Prophylaxis of delayed graft function.		x			x	x	x	
Biological	Treatment of glabellar lines.			x				x	
Chemical	Treatment of Duchenne muscular dystrophy.		x				x	x	
Chemical	Treatment of Duchenne muscular dystrophy.	x					x	x	
Biological	Treatment of osteoarthritis.			x				x	
Chemical	Treatment of opioid drug dependence.	x					x	x	
Chemical	Treatment of pyridoxamine 5'-phosphate oxidase deficiency.		x			x	x	x	
Chemical	Treatment of Rett syndrome.	x				x	x	x	
Chemical	Treatment of acute pain.	x				x	x	x	
Chemical/Other innovative	Treatment of asthma.			x				x	
Chemical	Treatment of chronic cystic fibrosis.		x					x	
Advanced therapy	Treatment of Leber's congenital amaurosis.		x			x	x	x	
Biological	Treatment of end stage renal disease.	x				x	x	x	
Advanced therapy	Treatment of Crohn's disease.	x					x		
Chemical	Treatment of systemic sclerosis.				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	Treatment of Duchenne muscular dystrophy.	x						x	
Qualification advice	Treatment of Duchenne muscular dystrophy.	x						x	
HTA parallel advice	Prophylaxis for hemophilia A.	x						x	
HTA parallel advice	Treatment of non-small cell lung cancer.	x					x	x	
HTA parallel advice	Prevention of cytomegalovirus infection	x						x	
HTA parallel advice	Treatment of adenovirus infection	x						x	
HTA parallel advice	Management of symptomatic uterine fibroids	x					x	x	
HTA parallel advice	Treatment of triple-negative breast cancer.	x						x	

**SA: Scientific Advice**

**PA: Protocol Assistance**

The above-mentioned 25 Scientific Advice letters, 8 Protocol Assistance letters, 11 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance letters, 6 HTA parallel advice letters and 2 Qualifications of novel methodologies letters were adopted at the 20 – 23 July 2015 CHMP meeting.

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

The Committee accepted 48 new Requests for which the procedure started at the SAWP meeting held on 6 – 9 July 2015. The new requests are divided as follows: 21 Initial Scientific Advice, 9 Follow-up Scientific Advice, 9 Initial Protocol Assistance, 3 Follow-up Protocol Assistance, 4 HTA parallel advices and 2 Qualifications of novel methodologies.