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Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 23 – 26 March 2015

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

	1995 - 2014	2015	Overall total
Scientific Advice	2653	69	2722
Follow-up to Scientific Advice	758	20	778
Protocol Assistance	566	30	596
Follow-up to Protocol Assistance	267	12	279
HTA parallel advice	34	3	37
Qualification of novel methodologies	60	2	62
	<b>4338</b>	<b>136</b>	<b>4474</b>

FDA Parallel Scientific Advice	2006 - 2014	2015	Overall total
Completed	26	0	26

### ***Outcome of the March 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 celiac disease.	x						x	
Chemical	Treatment of ulcerative colitis.		x			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 IIIC.	x				x	x	x	
Advanced therapy	Treatment of mucopolysaccharidosis type VI.		x					x	
Biological	Treatment of glioblastoma.				x			x	x
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis			x				x	
Chemical	Treatment of acute myeloid leukaemia.	x						x	
Biological	Treatment of Breast cancer, NSCLC, RCC, ovarian cancer.	x				x	x	x	
Chemical	Treatment of solid tumours.	x						x	
Chemical	Treatment of familial cerebral cavernous malformations.		x					x	
Biological	Treatment of pancreatic cancer.		x			x	x	x	x
Chemical	Treatment of systemic sclerosis.		x				x	x	
Biological	Treatment of amyloid light-chain amyloidosis.		x				x	x	x
Chemical	Treatment of Aicardi-Goutières syndrome.		x				x	x	
Biological/Advanced therapy	Treatment of oncology indications.	x					x		
Chemical	Treatment of melanoma.			x				x	
Chemical	Treatment of systemic sclerosis.	x					x	x	
Biological/Other innovative	Treatment of mNSCLC.			x				x	
Chemical	Treatment of mBrC.			x				x	
Chemical	Treatment of mBrC.	x				x			
Chemical	Treatment of Aicardi-Goutières syndrome.		x				x	x	
Biological	Treatment of hyperlipidaemia.			x			x	x	
Chemical	Treatment of necrotising soft tissue infections.	x					x	x	
Chemical	Treatment of HIV-1 infection.	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 RSV disease.	x					x	x	
Chemical	Treatment of HIV infection and hepatitis B virus.	x					x		
Chemical	Treatment of complex regional pain syndrome.		x					x	
Chemical	Treatment of Charcot-Marie-Tooth disease Type 1A.				x			x	
Chemical	Treatment of acute sensorineural hearing loss.				x	x	x	x	
Chemical	Treatment of cystic fibrosis.		x					x	
Chemical	Treatment of elevated intraocular pressure.	x				x		x	
Chemical	Treatment of evaporative dry eye.	x					x	x	
Biological	Treatment of type 2 diabetes.	x					x	x	
Chemical	Treatment of endometriosis.	x					x	x	
Chemical	Treatment of uterine fibroids without surgery.	x					x	x	
Chemical	Treatment of Pb toxicity.		x				x	x	
Qualification	Medication adherence.	x						x	
HTA parallel	Treatment of degenerative disk disease (DDD)-caused back pain.	x						x	
HTA parallel	Treatment of soft tissue sarcoma.	x						x	

**SA: Scientific Advice**

**PA: Protocol Assistance**

The above-mentioned 17 Scientific Advice letters, 11 Protocol Assistance letters, 5 Follow-up Scientific Advice, 3 Follow-up Protocol Assistance letters, 2 HTA parallel advice letters and 1 Qualification of novel methodologies letters were adopted at the 23 – 26 March 2015 CHMP meeting.

## New requests for scientific advice procedures

The Committee accepted 42 new Requests for which the procedure started at the SAWP meeting held on 9 – 12 March 2015. The new requests are divided as follows: 19 Initial Scientific Advice, 7 Follow-up Scientific Advice, 10 Initial Protocol Assistance, 5 Follow-up Protocol Assistance, 1 HTA parallel advices and 0 Qualification of novel methodologies.