



25 February 2016
EMA/CHMP/SAWP/158000/2016
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 22 – 25 February 2016

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

	1995 - 2015	2016	Overall total
Scientific Advice	2899	49	2948
Follow-up to Scientific Advice	846	10	856
Protocol Assistance	662	6	668
Follow-up to Protocol Assistance	310	12	322
HTA parallel advice	63	2	65
Qualification of novel methodologies	83	2	85
	4863	81	4944

Outcome of the February 2016 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 Fabry disease.	x				x	x	x	
Chemical	Treatment of multiple myeloma.	x					x	x	
Biological	Treatment of rheumatoid arthritis and juvenile idiopathic arthritis.	x				x	x	x	
Chemical	Treatment of NSCLC.	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 metastatic colorectal cancer.	x						x	
Biological	Treatment of smouldering multiple myeloma.		x					x	
Chemical	Treatment of breast cancer, ovarian cancer, multiple myeloma and AIDS-related Kaposi's sarcoma.	x				x	x	x	
Biological	Treatment of relapsing neuromyelitis optica spectrum disorders.		x					x	
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile idiopathic arthritis, plaque psoriasis, ankylosing spondylitis			x		x		x	
Chemical	Treatment of chronic inflammatory demyelinating polyneuropathy.				x			x	
Biological	Treatment of psoriatic arthritis, rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis.	x					x	x	
Biological	Treatment of hypereosinophilic syndrome.				x			x	
Chemical	Treatment of breast cancer.	x						x	
Biological	Reduction in the duration of neutropenia and the incidence of febrile neutropenia.	x				x	x	x	
Chemical/Biological	Treatment of melanoma.	x					x	x	
Biological	Treatment of cutaneous squamous cell carcinoma.	x					x	x	
Chemical	Treatment of myelodysplastic syndrome.				x			x	
Biological	Treatment of polycythemia vera.				x			x	
Chemical	Treatment of breast cancer.	x				x			
Biological	Treatment of hyperlipidaemia.		x					x	
Chemical	Treatment of pulmonary arterial	x					x	x	

Intended indications(s)		Type of request				Topic			
Substance	Intended indications(s)	Type of request				Topic			
		New		Follow-up		Pharmaceutical	Pre-clinical	Clinical	Significant Benefit
		SA	PA	SA	PA				
	hypertension.								
Advanced therapy	Treatment of incomplete revascularisation.	x					x	x	
Biological	Replacement therapy in primary immunodeficiency syndromes.	x						x	
Biological	Vaccination against poliomyelitis.			x				x	
Chemical	treatment of acute influenza A.	x					x	x	
Chemical	Purge of HIV reservoir.	x					x	x	
Chemical	Imaging of GEP-NETs.				x	x	x	x	x
Advanced therapy	Treatment of ischaemic stroke.	x				x	x	x	
Advanced therapy	Treatment of childhood cerebral adrenoleukodystrophy.		x				x	x	
Chemical	Treatment of pain.	x					x		
Chemical	Treatment of severe persistent eosinophilic asthma.	x					x	x	
Chemical	Treatment of severe persistent eosinophilic asthma.	x					x	x	
Biological	Maintenance treatment of uncontrolled asthma.	x				x	x	x	
Biological	Treatment of diabetic macular oedema.	x					x	x	
Biological	Treatment of neurotrophic keratitis.				x		x		
Biological	Treatment of neurotrophic keratitis.				x	x		x	
Biological	Treatment of focal spasticity, blepharospasm, hemifacial spasm and idiopathic cervical dystonia, chronic migraine, bladder dysfunctions, hyperhidrosis of the axillae, temporary improvement in the appearance of glabellar lines and lateral canthal lines.	x				x	x	x	
Qualification advice	Safety biomarker of kidney tubular injury response.	x						x	

SA: Scientific Advice

PA: Protocol Assistance

The above-mentioned 24 Scientific Advice letters, 6 Protocol Assistance letters, 3 Follow-up Scientific Advice, 7 Follow-up Protocol Assistance letters, 0 HTA parallel advice letters and 1 Qualifications of novel methodologies letters were adopted at the 22 – 25 February 2016 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 46 new Requests for which the procedure started at the SAWP meeting held on 8 – 11 February 2016. The new requests are divided as follows: 19 Initial Scientific Advice, 10 Follow-up Scientific Advice, 11 Initial Protocol Assistance, 0 Follow-up Protocol Assistance, 3 HTA parallel advices and 3 Qualifications of novel methodologies.