



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 July 2021
EMA/CHMP/SAWP/412101/2021
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 19 – 22 July 2021

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

| | 1995-2020 | 2021 | Overall total |
|---|-------------|------------|---------------|
| Scientific Advice | 4766 | 323 | 5089 |
| Follow-up to Scientific Advice | 1413 | 161 | 1574 |
| Protocol Assistance | 1076 | 65 | 1141 |
| Follow-up to Protocol Assistance | 576 | 32 | 608 |
| EMA/EUnetHTA parallel consultation advice | 165 | 0 | 165 |
| Qualification of novel methodologies | 161 | 12 | 173 |
| | 8157 | 593 | 8750 |

Outcome of the July 2021 CHMP meeting in relation to scientific advice procedures

Final scientific advice procedures

| Substance | Intended indications | Type of request | | | | Topic | | | |
|------------|-----------------------------------|-----------------|----|-----------|----|---------|-------------|----------|---------------------|
| | | New | | Follow-up | | Quality | Preclinical | Clinical | Significant benefit |
| | | SA | PA | SA | PA | | | | |
| Chemical | Treatment of Stargardt's disease | | | | x | | | x | |
| Biological | Treatment of Rheumatoid arthritis | x | | | | x | | x | |
| Biological | Treatment of Fabry disease | x | | | | | | x | |

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| Substance | Intended indications | Type of request | | | | Topic | | | |
|------------------|--|-----------------|----|-----------|----|---------|-------------|----------|---------------------|
| | | New | | Follow-up | | | | | |
| | | SA | PA | SA | PA | Quality | Preclinical | Clinical | Significant benefit |
| Biological | Treatment of non-small cell lung cancer | x | | | | x | x | x | |
| Chemical | Treatment of presbyopia | x | | | | | | x | |
| Chemical | Treatment of breast cancer | x | | | | | x | x | |
| Chemical | Treatment of anorexia/cachexia | | | x | | | | x | |
| Biological | Treatment of cutaneous lupus erythematosus | x | | | | | | x | |
| Chemical | Treatment of schizophrenia | | | x | | | | x | |
| Biological | Treatment of small cell lung cancer | x | | | | | | x | |
| Chemical | Treatment of type 2 diabetes | x | | | | | | x | |
| Chemical | Treatment of COVID-19 disease | | | x | | x | | x | |
| Chemical | Treatment of von Hippel-Lindau disease | | x | | | | x | x | |
| Biological | Treatment of Asthma | x | | | | | | x | |
| Biological | Treatment of antiplatelet effect of ticagrelor | | | x | | | | x | |
| Biological | Prevention of lower respiratory tract infections | x | | | | x | | x | |
| Advanced Therapy | Treatment of retinitis pigmentosa | | | | x | | x | | |
| Biological | Prevention of Covid-19 infection | x | | | | x | | | |
| Advanced Therapy | Treatment of sickle cell disease | x | | | | x | | | |
| Chemical | Treatment of hepatitis B | | | x | | x | | | |
| Biological | Treatment of plasma cell myeloma | | x | | | | | x | |
| Biological | Treatment of non-small cell lung cancer | | | x | | | | x | |
| Biological | Treatment of breast cancer | x | | | | | | x | |
| Biological | Treatment of osteoporosis | | | x | | | | x | |
| Biological | Treatment of hypereosinophilic syndrome | x | | | | | x | x | |
| Biological | Treatment of eosinophilic granulomatosis with polyangiitis | x | | | | | x | x | |
| Chemical | Treatment of musculoskeletal pain | x | | | | | | x | |

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|------------------|---|-----------------|----|-----------|----|---------|-------------|----------|---------------------|
| | | New | | Follow-up | | | | | |
| | | SA | PA | SA | PA | Quality | Preclinical | Clinical | Significant benefit |
| Chemical | Treatment of HIV-1 | | | x | | x | | | |
| Chemical | Treatment of breast cancer | x | | | | x | x | | |
| Chemical | Treatment of Iron deficiency anaemia | x | | | | x | x | x | |
| Chemical | Treatment of vasomotor symptoms | | | x | | x | | | |
| Biological | Treatment of nonalcoholic steatohepatitis | x | | | | x | | | |
| Biological | Treatment of B-cell malignancies | x | | | | | x | | |
| Chemical | Treatment of uncomplicated gonorrhoea | | | x | | | | x | |
| Biological | Treatment of type 1 diabetes | | | x | | | | x | |
| Biological | Prevention of respiratory syncytial virus | | | x | | x | | | |
| Biological | Treatment of anaemia | x | | | | | | x | |
| Chemical | Treatment of calciphylaxis | | | | x | | x | x | |
| Biological | Treatment of primary immunodeficiency syndromes | x | | | | x | | x | |
| Biological | Treatment of diabetes mellitus | | | x | | x | | | |
| Biological | Treatment of intestinal malabsorption | x | | | | | | x | |
| Biological | Treatment of diabetes mellitus | x | | | | x | x | x | |
| Biological | Treatment of melanoma | x | | | | x | | x | |
| Advanced Therapy | Treatment of follicular lymphoma | | x | | | | | x | |
| Biological | Treatment of acute myeloid leukaemia | | x | | | | | x | |
| Chemical | Treatment of soft tissue sarcoma | | x | | | x | | x | |
| Chemical | Treatment of neurogenic detrusor overactivity | x | | | | | x | | |
| Biological | Treatment of pulmonary alveolar proteinosis | | | | x | | | x | |
| Chemical | Treatment of breast cancer | x | | | | x | | | |
| Biological | Prevention of haemolytic disease | | x | | | | | x | |
| Biological | Treatment of melanoma | x | | | | x | x | x | |

| Substance | Intended indications | Type of request | | | | Topic | | | |
|----------------------|---|-----------------|----|-----------|----|---------|-------------|----------|---------------------|
| | | New | | Follow-up | | | | | |
| | | SA | PA | SA | PA | Quality | Preclinical | Clinical | Significant benefit |
| Chemical | Treatment of primary sclerosing cholangitis | | x | | | | x | | |
| Chemical | Treatment of cognitive disorders | x | | | | x | x | x | |
| Biological | Prevention of diphtheria | x | | | | x | | | |
| Chemical | Treatment of autoimmune haemolytic anaemia | x | | | | | | x | |
| Biological | Treatment of pancreatic cancer | | x | | | x | x | x | |
| Chemical | Treatment of thrombotic microangiopathy | x | | | | | x | x | |
| Biological | Treatment of tumors | x | | | | x | x | x | |
| Chemical | Treatment of acute myeloid leukaemia | | x | | | | | x | |
| Chemical | Treatment of COVID-19 disease | x | | | | x | | | |
| Advanced Therapy | Treatment of haematopoietic stem cell transplantation | | x | | | | | x | x |
| Biological | Prevention of COVID-19 disease | x | | | | x | x | x | |
| Chemical | Treatment of endometrial carcinoma | x | | | | | | x | |
| Chemical | Treatment of osteoarthritis pain | x | | | | | x | x | |
| Biological | Treatment of spinal muscular atrophy | x | | | | | x | x | |
| Biological | Treatment of NSCLC | x | | | | | | x | |
| Advanced Therapy | Treatment of otoferlin deficiency | x | | | | x | x | x | |
| Chemical | Treatment of Leber's congenital amaurosis | | x | | | x | | | |
| Biological | Treatment of thrombocythaemia myelofibrosis | | x | | | | x | x | |
| Qualification Advice | Progressive multiple sclerosis trial | x | | | | | | x | |
| Advanced Therapy | Treatment of immunodeficiency | | | | x | | | x | x |
| Advanced Therapy | Treatment of limb-girdle muscular dystrophy | | x | | | x | x | x | |
| Chemical | Prevention of hereditary angioedema | x | | | | | x | x | |
| Chemical | Treatment of erectile dysfunction | x | | | | | | x | |
| Biological | Treatment of non-small cell lung | | | x | | | x | x | |

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|----------------------|--|-----------------|----|-----------|----|---------|-------------|----------|---------------------|
| | | New | | Follow-up | | | | | |
| | | SA | PA | SA | PA | Quality | Preclinical | Clinical | Significant benefit |
| | cancer | | | | | | | | |
| Chemical | Treatment of myasthenia gravis | x | | | | | x | x | |
| Qualification Advice | Treatment of Huntington's disease | x | | | | | | x | |
| Biological | Treatment of breast cancer | x | | | | x | x | x | |
| Chemical | Treatment of pulmonary arterial hypertension | x | | | | x | x | x | |
| Advanced Therapy | Treatment of b-cell lymphoblastic leukaemia | x | | | | x | | | |
| Biological | Treatment of plaque psoriasis | | | x | | | | x | |
| Biological | Treatment of ulcerative colitis | x | | | | x | x | x | |
| Biological | Prevention of Covid-19 disease | x | | | | x | x | x | |
| Advanced Therapy | Treatment of bladder cancer | x | | | | x | x | x | |
| Biological | Prevention of COVID-19 disease | | | x | | | | x | |

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 85 Scientific Advice letters - 49 Initial Scientific Advice, 16 Follow-up Scientific Advice, 13 Protocol Assistance letters, 5 Follow-up Protocol Assistance, 2 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 19-22 July 2021 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 73 new Requests for which the procedure started at the SAWP meeting held on 05-08 July 2021. The new requests are divided as follows: 47 Initial Scientific Advice, 12 Follow-up Scientific Advice, 10 Initial Protocol Assistance, 3 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.