



23 June 2022
EMA/CHMP/SAWP/603443/2022
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 20 – 23 June 2022

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

| | 1995-2020 | 2022 | Overall total |
|---|-------------|------------|---------------|
| Scientific Advice | 5226 | 258 | 5484 |
| Follow-up to Scientific Advice | 1623 | 82 | 1705 |
| Protocol Assistance | 1173 | 46 | 1219 |
| Follow-up to Protocol Assistance | 634 | 32 | 666 |
| EMA/EUnetHTA parallel consultation advice | 165 | 0 | 165 |
| Qualification of novel methodologies | 180 | 11 | 191 |
| | 9001 | 429 | 9430 |

Outcome of the June 2022 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 | | | | |
| Qualification | Simulation Platform for Parkinson's Disease | x | | | | | | x | |
| Biological | Treatment of inclusion body myositis | x | | | | x | x | x | |
| Biological | Treatment of retinal vein occlusion | x | | | | | | x | |

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

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|------------------|---|-----------------|----|-----------|----|---------|-------------|----------|---------------------|
| | | New | | Follow-up | | Quality | Preclinical | Clinical | Significant benefit |
| | | SA | PA | SA | PA | | | | |
| Chemical | Treatment of ovarian cancer | | | x | | | | x | |
| Advanced Therapy | Treatment of hemophilia B | x | | | | x | x | | |
| Biological | Treatment of atopic dermatitis | | | x | | | | x | |
| Chemical | Treatment of prostate cancer | x | | | | x | | | |
| Chemical | Treatment of acute myeloid leukaemia | | x | | | | x | x | |
| Biological | Treatment of chronic wounds | x | | | | x | x | x | |
| Chemical | Treatment of Gram-negative bacteria | x | | | | | | x | |
| Chemical | Treatment of myelodysplastic syndromes | | | x | | | | x | |
| Chemical | Treatment of heart failure | x | | | | | x | x | |
| Biological | Treatment of demyelinating polyneuropathy | x | | | | | x | x | |
| Biological | Treatment of thyroid eye disease | x | | | | | x | x | |
| Chemical | Treatment of pantothenate neurodegeneration | | x | | | x | x | x | |
| Chemical | Treatment of hyperoxaluria | | x | | | x | x | x | |
| Advanced Therapy | Treatment of Waldenstrom's macroglobulinemia | x | | | | | | x | |
| Chemical | Treatment of chronic obstructive pulmonary disease | | | x | | | x | x | |
| Chemical | Treatment of breast cancer | x | | | | | x | x | |
| Biological | Prevention of Chikungunya disease | | | x | | | | x | |
| Biological | Treatment of nonsquamous non-small cell lung cancer | x | | | | | | x | |
| Biological | Treatment of osteoporosis | x | | | | x | | x | |
| Chemical | Treatment of systemic lupus erythematosus | x | | | | | | x | |
| Qualification | Dimensional anhedonia rating scale | x | | | | | | x | |
| Biological | Treatment of urothelial carcinoma | x | | | | | x | x | |
| Chemical | Treatment of thymidine kinase 2 deficiency | | x | | | x | | | |
| Chemical | Treatment of cystic fibrosis | | x | | | x | | | |
| Chemical | Treatment of glioblastoma | x | | | | | | x | |

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| | | SA | PA | SA | PA | | | | |
| Biological | Treatment of large B-cell lymphoma | | x | | | | | x | |
| Chemical | Treatment of schizophrenia | x | | | | | x | x | |
| Chemical | Treatment of relapsed multiple sclerosis | | | x | | x | | | |
| Biological | Treatment of multiple cancers | x | | | | x | | | |
| Chemical | Treatment of spondyloarthritis | x | | | | | | x | |
| Chemical | Treatment of myeloid leukaemia | | | | x | | | x | x |
| Chemical | Treatment of celiac disease | x | | | | | x | x | |
| Biological | Prevention of cytomegalovirus infection | x | | | | x | x | x | |
| Biological | Treatment of immunodeficiency syndromes | x | | | | x | x | x | |
| Biological | Treatment of systemic lupus erythematosus | x | | | | | | x | |
| Chemical | Treatment of respiratory distress syndrome | | x | | | x | x | x | |
| Chemical | Treatment of breast cancer | | | x | | | | x | |
| Chemical | Treatment of chronic kidney disease | x | | | | | x | x | |
| Biological | Treatment of sickle cell disease | x | | | | x | | | |
| Chemical | Treatment of IgA nephropathy | x | | | | x | x | x | |
| Advanced Therapy | Treatment of age-related macular degeneration | x | | | | | x | x | |
| Biological | Treatment of Alzheimer's disease | | | x | | | | x | |
| Chemical | Prevention of pregnancy | x | | | | | | x | |
| Chemical | Treatment of epidermolysis bullosa | | x | | | x | x | x | |
| Advanced Therapy | Treatment of GM1 gangliosidosis | | x | | | | x | | |
| Biological | Treatment of prostate cancer | x | | | | | x | x | |
| Chemical | Prevention of thrombotic events | x | | | | | | x | |
| Biological | Treatment of solid tumors | x | | | | x | | | |
| Biological | Treatment of pancreas adenocarcinoma | | x | | | | x | x | x |
| Chemical | Treatment of myelofibrosis | | | | x | | | x | |

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|---------------|---|-----------------|----|-----------|----|---------|-------------|----------|---------------------|
| | | New | | Follow-up | | Quality | Preclinical | Clinical | Significant benefit |
| | | SA | PA | SA | PA | | | | |
| Chemical | Treatment of lymphocytic leukemia | x | | | | x | | | |
| Biological | Treatment of melanoma | x | | | | x | x | x | |
| Biological | Treatment of multiple sclerosis | x | | | | | | x | |
| Biological | Treatment of multiple sclerosis | x | | | | x | | x | |
| Chemical | Prevention of pregnancy | x | | | | | x | x | |
| Biological | Treatment of mucopolysaccharidosis II | | | | x | | | x | x |
| Biological | Treatment of breast cancer | | | x | | | | x | |
| Biological | Treatment of Parkinson's disease | x | | | | | | x | |
| Chemical | Treatment of immune thrombocytopenia | | | | x | | | x | |
| Biological | Treatment of atopic dermatitis | x | | | | | | x | |
| Biological | Treatment of polymyalgia rheumatica | x | | | | | | x | |
| Biological | Treatment of tendinopathy | | | x | | | | x | |
| Biological | Treatment of osteogenesis imperfecta | | | x | | | | x | |
| Biological | Treatment of small cell lung cancer | x | | | | | x | | |
| Chemical | Prevention of cardiovascular events | x | | | | | | x | |
| Biological | Treatment of rheumatoid arthritis | | | x | | x | | x | |
| Biological | Treatment of breast cancer | x | | | | x | x | x | |
| Chemical | Treatment of intraocular pressure | | | x | | x | | x | |
| Chemical | Treatment of spinocerebellar ataxia | | x | | | x | | | |
| Qualification | Patient-reported outcome for ulcerative colitis | | | x | | | | x | |
| Chemical | Treatment of squamous cell carcinoma of the head and neck | | | x | | | | x | |
| Qualification | Pragmatic test of functional vision | x | | | | | | x | |
| Chemical | Treatment of neuromyelitis optica spectrum disorder | x | | | | | x | x | |
| Chemical | Treatment of hypertension | x | | | | | | x | |
| Biological | Treatment of heart failure | x | | | | | | x | |

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|------------|---|-----------------|----|-----------|----|---------|-------------|----------|---------------------|
| | | New | | Follow-up | | Quality | Preclinical | Clinical | Significant benefit |
| | | SA | PA | SA | PA | | | | |
| Biological | Prevention of major adverse cardiovascular events | x | | | | | | x | |
| Chemical | Treatment of AL amyloidosis | x | | | | x | x | x | |

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 80 Scientific Advice letters - 47 Initial Scientific Advice, 14 Follow-up Scientific Advice, 11 Protocol Assistance letters, 4 Follow-up Protocol Assistance, 4 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices - were adopted at the 20-23 June 2022 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 65 new Requests for which the procedure started at the SAWP meeting held on 07-10 June 2022. The new requests are divided as follows: 40 Initial Scientific Advice, 12 Follow-up Scientific Advice, 11 Initial Protocol Assistance, 1 Follow-up Protocol Assistance, 1 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.