



17 September 2020
EMA/CHMP/SAWP/483496/2020
Press Office

Scientific advice and protocol assistance

Adopted during the CHMP meeting 14 – 17 September 2020

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

| | 1995 - 2019 | 2020 | Overall total |
|---|-------------|------------|---------------|
| Scientific Advice | 4258 | 348 | 4606 |
| Follow-up to Scientific Advice | 1277 | 97 | 1374 |
| Protocol Assistance | 1003 | 42 | 1045 |
| Follow-up to Protocol Assistance | 525 | 37 | 562 |
| EMA/EUnetHTA parallel consultation advice | 159 | 5 | 164 |
| Qualification of novel methodologies | 142 | 13 | 155 |
| | 7364 | 542 | 7906 |

Outcome of the September 2020 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 solid tumors | x | | | | x | x | x | |
| Advanced Therapy | Treatment of multiple myeloma | | x | | | | | x | |
| Chemical | Treatment of prostate cancer | x | | | | | | x | |
| Chemical | Treatment of gastric adenocarcinoma | x | | | | | | x | |



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|------------------|--|-----------------|----|-----------|----|---------|-------------|----------|---------------------|
| | | New | | Follow-up | | Quality | Preclinical | Clinical | Significant benefit |
| | | SA | PA | SA | PA | | | | |
| Chemical | Treatment of leukaemia C | x | | | | | | x | |
| Advanced Therapy | Treatment of transfusion-dependent β -thalassaemia | | x | | | | x | x | |
| Advanced Therapy | Treatment of sickle cell disease | | x | | | | | x | |
| Chemical | Treatment of osteoarthritis of the knee | x | | | | x | x | x | |
| Chemical | Treatment of asthma | x | | | | | | x | |
| Advanced Therapy | Treatment of chronic kidney disease | x | | | | x | | x | |
| Chemical | Treatment of cancer-related cachexia | x | | | | x | x | x | |
| Biological | Prevention of clostridioides difficile infection | x | | | | x | | x | |
| Biological | Treatment of diabetes mellitus | x | | | | x | | x | |
| Biological | Prevention of type I diabetes | x | | | | | x | | |
| Biological | Treatment of obesity | x | | | | x | x | x | |
| Biological | Treatment of squamous cell carcinoma | x | | | | | | x | |
| Biological | Treatment of renal cell carcinoma | | | x | | | | x | |
| Chemical | Treatment of neuroblastoma | | x | | | x | | | |
| Chemical | Treatment of breast cancer | x | | | | | x | x | |
| Chemical | Treatment of diffuse cutaneous systemic sclerosis | x | | | | | | x | |
| Biological | Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile idiopathic arthritis, plaque psoriasis, ankylosing spondylitis. | x | | | | x | | x | |
| Advanced Therapy | Treatment of multiple myeloma | | | | x | | | x | |
| Chemical | Treatment of mantle cell lymphoma | x | | | | | | x | |
| Chemical | Treatment of leukaemia | x | | | | | | x | |
| Biological | Treatment of food allergy | x | | | | | x | x | |
| Biological | Treatment of non-small cell lung cancer | x | | | | x | | | |
| Biological | Treatment of hepatocellular carcinoma | | | x | | | | x | |
| Biological | Treatment of bullous pemphigoid | | x | | | | x | x | x |
| Biological | Treatment of axial spondyloarthritis | x | | | | | | x | |

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| | | New | | Follow-up | | Quality | Preclinical | Clinical | Significant benefit |
| | | SA | PA | SA | PA | | | | |
| Chemical | Treatment of autoimmune haemolytic anaemia | x | | | | | x | | |
| Chemical | Treatment of Gorlin syndrome | | | | x | x | | | |
| Chemical/Biological | Treatment of renal cell carcinoma | x | | | | | | x | |
| Biological | Treatment of large B-cell lymphoma | | x | | | | | x | |
| Biological | Treatment of acute myeloid leukaemia | x | | | | x | | | |
| Biological | Treatment of giant cell arteritis | x | | | | | | x | |
| Advanced Therapy | Treatment of Epstein Barr virus | | | | x | x | | | |
| Chemical | Treatment of schistosomiasis | | | x | | x | | x | |
| Chemical | Treatment of thalassemia | x | | | | | | x | |
| Advanced Therapy | Treatment of sickle cell disease | | x | | | x | | x | |
| Chemical | Treatment and prevention of chemotherapy-induced neutropenia | x | | | | x | | x | |
| Biological | Treatment of elevated LDL-cholesterol | x | | | | | x | x | |
| Chemical | Treatment of hypercholesterolaemia and dyslipidaemia | | | x | | | | x | |
| Chemical | Treatment of chronic kidney disease | x | | | | | x | x | |
| Chemical | Treatment of atopic dermatitis | x | | | | x | x | | |
| Chemical | Treatment of HIV-1 infection | x | | | | | x | x | |
| Biological | Treatment of rare viruses | x | | | | x | x | | |
| Chemical | Treatment of neurogenic detrusor overactivity | x | | | | x | x | x | |
| Biological | Treatment of osteoporosis | | | x | | | | x | |
| Biological | Treatment of knee osteoarthritis | x | | | | | x | x | |
| Biological | Treatment of Duchenne muscular dystrophy | | | | x | | | x | |
| Chemical | Treatment of breast cancer | | | x | | | | x | |
| Chemical | Treatment of acute pain | x | | | | x | | | |
| Chemical | Treatment of schizophrenia | x | | | | | | x | |
| Biological | Treatment of cluster headache | x | | | | | | x | |
| Chemical | Treatment of Angelman syndrome | x | | | | | x | | |

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| | | SA | PA | SA | PA | | | | |
| Advanced Therapy | Treatment of Parkinson's Disease | x | | | | | | x | |
| Chemical | Treatment of Leber's congenital amaurosis | | | | x | | | x | |
| Chemical | Treatment of COPD | x | | | | | x | x | |
| Chemical | Treatment of COPD | x | | | | | | x | |
| Biological | Treatment of asthma and chronic idiopathic urticaria | | | x | | x | | | |
| Biological | Treatment of diabetic macular edema | | | x | | | | x | |
| Biological | Treatment of neovascular macular degeneration | | | x | | | | x | |
| Chemical | Treatment of non-infectious uveitis | | x | | | x | x | x | |
| Chemical | Treatment of COVID-19 disease | x | | | | | x | x | |
| Biological | Broad advice | x | | | | x | | | |
| Chemical | Treatment of hepatic injury | | | x | | | | x | |
| Chemical | Treatment of oral mucositis | | | x | | x | x | x | |
| Advanced Therapy | Treatment of Wilson disease | x | | | | | | x | |
| Chemical | Treatment of pulmonary arterial hypertension | x | | | | | x | | |

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| | | SA | PA | SA | PA | | | | |
| Biological | Prevention of COVID-19 disease | x | | | | | x | | |
| Biological | Prevention of COVID-19 disease | x | | | | x | | | |
| Biological | Prevention of COVID-19 disease | x | | | x | | | | |
| Biological | Treatment of COVID-19 disease | | | x | | | x | | |
| Biological | Prevention of COVID-19 disease | x | | | | x | x | | |
| Biological | Prevention of COVID-19 disease | x | | | x | x | x | | |
| Biological | Treatment of COVID-19 disease | x | | | x | | x | | |
| Biological | Treatment of COVID-19 disease | x | | | | | x | | |
| Biological | Prevention of COVID-19 disease | x | | | x | x | x | | |
| Biological | Treatment of COVID-19 disease | x | | | x | x | x | | |
| Biological | Treatment of COVID-19 disease | x | | | x | x | x | | |
| Chemical | Treatment and prevention of COVID-19 disease | x | | | x | x | x | | |
| Biological | Prevention of COVID-19 disease | x | | | x | x | x | | |
| Chemical | Treatment of COVID-19 disease | x | | | | | x | | |
| Chemical | Treatment of COVID-19 disease | x | | | | x | | | |
| Chemical | Prevention of COVID-19 disease | x | | | | | x | | |
| Biological | Treatment of COVID-19 disease | x | | | x | x | x | | |
| Chemical | Treatment of COVID-19 disease | x | | | x | x | x | | |
| Chemical | Treatment of COVID-19 disease | x | | | | x | x | | |
| Biological | Prevention of COVID-19 disease | x | | | x | x | x | | |
| Qualification Advice. | Treatment of X-linked retinitis pigmentosa | x | | | | | | | |
| Qualification Advice. | Treatment of drug-induced kidney injury | x | | | | | | | |

SA: Scientific Advice
PA: Protocol Assistance

The above-mentioned 65 Scientific Advice letters, 10 Follow-up Scientific Advice, 8 Protocol Assistance letters, 6 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices, were adopted at the 14-17 September 2020 CHMP meeting.

New requests for scientific advice procedures

The Committee accepted 103 new Requests for which the procedure started at the SAWP meeting held on 31 Aug-3 Sept 2020. The new requests are divided as follows: 65 Initial Scientific Advice, 22 Follow-up Scientific Advice, 11 Initial Protocol Assistance, 3 Follow-up Protocol Assistance, 2 Qualification of novel methodologies and 0 EMA/EUnetHTA parallel consultation advices.