



25 January 2023  
EMA/CHMP/SAWP/35437/2024  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 22-25 January 2023

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

|   | 1995-2023    | 2024      | Overall total |
|---|--------------|-----------|---------------|
| Scientific Advice                         | 6072         | 42        | 6114          |
| Follow-up to Scientific Advice            | 1928         | 15        | 1943          |
| Protocol Assistance                       | 1343         | 4         | 1347          |
| Follow-up to Protocol Assistance          | 719          | 4         | 723           |
| EMA/EUnetHTA parallel consultation advice | 165          | 0         | 165           |
| Qualification of novel methodologies      | 228          | 1         | 229           |
|   | <b>10455</b> | <b>67</b> | <b>10521</b>  |

### **Outcome of the January 2023 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 |         |             |          |                     |
| Biological | Treatment of head and neck cancer     | x               |    |           |    | x       |             | x        |                     |
| Chemical   | Treatment of epilepsy                 | x               |    |           |    |         |             | x        |                     |
| Biological | Treatment of non-melanoma skin cancer | x               |    |           |    |         |             | x        |                     |

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|------------------|--|-----------------|----|-----------|----|---------|-------------|----------|---------------------|
|                  |  | New             |    | Follow-up |    | Quality | Preclinical | Clinical | Significant benefit |
|                  |  | SA              | PA | SA        | PA |         |             |          |                     |
| Chemical         | Treatment of neurofibromatosis                     |                 |    |           | x  |         |             | x        |                     |
| Biological       | Treatment of autoimmune disease                    |                 | x  |           |    |         |             | x        |                     |
| Biological       | Treatment of multiple myeloma                      |                 | x  |           |    |         |             | x        |                     |
| Biological       | Treatment of multiple myeloma                      |                 |    | x         |    |         |             | x        |                     |
| Chemical         | Prevention of fungal infections                    |                 | x  |           |    |         |             | x        |                     |
| Biological       | Treatment of chronic obstructive pulmonary disease |                 | x  |           |    | x       |             | x        |                     |
| Chemical         | Treatment of urinary tract infections              | x               |    |           |    | x       |             |          |                     |
| Advanced Therapy | Treatment of melanoma                              |                 | x  |           |    | x       |             |          |                     |
| Biological       | Treatment of rheumatoid arthritis                  |                 | x  |           |    | x       |             |          |                     |
| Biological       | Prevention of influenza                            | x               |    |           |    |         |             | x        |                     |
| Biological       | Treatment of non-melanoma skin cancer              | x               |    |           |    |         |             | x        |                     |
| Chemical         | Treatment of MELAS                                 | x               |    |           |    |         | x           | x        |                     |
| Biological       | Treatment of metastatic colorectal cancer          | x               |    |           |    |         |             | x        |                     |
| Chemical         | Treatment of non-segmental vitiligo                | x               |    |           |    |         |             | x        |                     |
| Biological       | Treatment of cancer                                |                 | x  |           |    |         |             | x        |                     |
| Chemical         | Treatment of chronic kidney disease                | x               |    |           |    | x       | x           | x        |                     |
| Biological       | Treatment of hidradenitis suppurativa              | x               |    |           |    |         | x           | x        |                     |
| Biological       | Treatment of myasthenia gravis                     | x               |    |           |    |         |             | x        |                     |
| Chemical         | Prevention of pregnancy                            | x               |    |           |    |         |             | x        |                     |
| Biological       | Prevention of COVID-19                             | x               |    |           |    |         | x           | x        |                     |
| Biological       | Prevention of diphtheria and tetanus               |                 | x  |           |    |         |             | x        |                     |
| Chemical         | Treatment of depressive disorder                   | x               |    |           |    |         | x           | x        |                     |
| Biological       | Treatment of breast cancer                         |                 | x  |           |    |         |             | x        |                     |
| Chemical         | Treatment of Psoriasis                             |                 | x  |           |    | x       |             |          |                     |
| Advanced Therapy | Treatment of cystic fibrosis lung disease          | x               |    |           |    | x       | x           | x        |                     |

| Substance  | Intended indications                       | Type of request |    |           |    | Topic   |             |          |                     |
|------------|--|-----------------|----|-----------|----|---------|-------------|----------|---------------------|
|            |  | New             |    | Follow-up |    | Quality | Preclinical | Clinical | Significant benefit |
|            |  | SA              | PA | SA        | PA |         |             |          |                     |
| Chemical   | Treatment of amyotrophic lateral sclerosis | x               |    |           |    |         | x           | x        |                     |
| Chemical   | Prevention of HIV                          | x               |    |           |    |         | x           |          |                     |
| Chemical   | Treatment of plaque psoriasis              | x               |    |           |    |         | x           | x        |                     |
| Biological | Treatment of Haemophilia A                 | x               |    |           |    |         |             | x        |                     |
| Biological | Treatment of Hodgkin lymphoma              | x               |    |           |    |         | x           | x        |                     |
| Chemical   | Treatment of Friedreich's ataxia           |                 |    | x         |    |         |             | x        |                     |
| Biological | Prevention of influenza type A and type B  | x               |    |           |    | x       | x           |          |                     |
| Biological | Treatment of Crohn's Disease               | x               |    |           |    |         |             | x        |                     |
| Chemical   | Treatment of epilepsy                      | x               |    |           |    |         |             | x        |                     |
| Chemical   | Treatment of cell lymphoma                 | x               |    |           |    |         | x           | x        |                     |
| Biological | Treatment of hidradenitis suppurativa      | x               |    |           |    |         |             | x        |                     |
| Chemical   | Treatment of Alzheimer's disease           |                 | x  |           |    |         |             | x        |                     |
| Chemical   | Treatment of peripheral T-cell lymphomas   | x               |    |           |    |         |             | x        |                     |
| Chemical   | Treatment of refractory chronic cough      |                 | x  |           |    |         |             | x        |                     |
| Chemical   | Diagnosis of artery disease                | x               |    |           |    | x       |             | x        |                     |
| Biological | Treatment of gastric cancer                |                 |    |           | x  |         |             | x        |                     |
| Chemical   | Treatment of cervical neoplasia            | x               |    |           |    |         | x           | x        |                     |
| Chemical   | Treatment of sclerosing cholangitis        |                 |    |           | x  |         |             | x        |                     |
| Chemical   | Treatment of adjustment disorders          | x               |    |           |    |         |             | x        |                     |
| Chemical   | Treatment of mesothelioma                  |                 |    | x         |    | x       | x           | x        | x                   |
| Chemical   | Treatment of hepatitis D                   | x               |    |           |    |         |             | x        |                     |
| Chemical   | Treatment of Down syndrome                 | x               |    |           |    | x       | x           | x        |                     |
| Biological | Prevention of rabies                       |                 | x  |           |    | x       | x           | x        |                     |
| Biological | Treatment of Crohn's disease               | x               |    |           |    |         |             | x        |                     |
| Chemical   | Treatment of macrocytosis                  | x               |    |           |    |         |             | x        |                     |
| Biological | Treatment of severe asthma                 | x               |    |           |    |         |             | x        |                     |

| Substance        | Intended indications  | Type of request |    |           |    | Topic   |             |          |                     |
|------------------|---|-----------------|----|-----------|----|---------|-------------|----------|---------------------|
|                  |   | New             |    | Follow-up |    | Quality | Preclinical | Clinical | Significant benefit |
|                  |   | SA              | PA | SA        | PA |         |             |          |                     |
| Chemical         | Treatment of the chronic weight disease                         |                 | x  |           |    |         | x           | x        |                     |
| Biological       | Treatment of small cell lung cancer                             | x               |    |           |    |         |             | x        |                     |
| Advanced Therapy | Treatment of ovarian cancer                                     | x               |    |           |    |         | x           | x        |                     |
| Chemical         | Prevention of hypertrophic scar formation                       | x               |    |           |    |         | x           | x        |                     |
| Biological       | Treatment of adenomatous polyposis                              |                 |    |           | x  |         |             | x        |                     |
| Chemical         | Treatment of carcinoma  | x               |    |           |    |         |             | x        |                     |
| Chemical         | Treatment of breast cancer                                      | x               |    |           |    |         | x           | x        |                     |
| Chemical         | Treatment of Demodex blepharitis                                |                 | x  |           |    | x       | x           | x        |                     |
| Biological       | Prevention of alloimmune thrombocytopenia                       |                 |    | x         |    |         |             | x        |                     |
| Advanced Therapy | Treatment of lymphocytic leukaemia                              | x               |    |           |    | x       | x           | x        |                     |
| Chemical         | Diagnosis of contrast enhancement in magnetic resonance imaging | x               |    |           |    | x       |             |          |                     |
| Qualification    | Medical devices innovation                                      |                 |    |           |    |         |             | x        |                     |

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 66 Scientific Advice letters – 42 Initial Scientific Advice, 15 Follow-up Scientific Advice, 4 Protocol Assistance letters, 4 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 22-25 January 2024 CHMP meeting.

### **New requests for scientific advice procedures**

The Committee accepted 66 new Requests for which the procedure started at the SAWP meeting held on 8-11 January 2024. The new requests are divided as follows: 42 Initial Scientific Advice, 15 Follow-up Scientific Advice, 4 Protocol Assistance letters, 4 Follow-up Protocol Assistance, 1 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.