



24 September 2015  
EMA/CHMP/SAWP/635474/2015  
Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 21 – 24 September 2015

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

|                                      | 1995 - 2014 | 2015       | Overall total |
|--------------------------------------|-------------|------------|---------------|
| Scientific Advice                    | 2653        | 176        | 2829          |
| Follow-up to Scientific Advice       | 758         | 67         | 825           |
| Protocol Assistance                  | 566         | 80         | 646           |
| Follow-up to Protocol Assistance     | 267         | 30         | 297           |
| HTA parallel advice                  | 34          | 22         | 56            |
| Qualification of novel methodologies | 60          | 10         | 70            |
|                                      | <b>4338</b> | <b>385</b> | <b>4723</b>   |

| FDA Parallel Scientific Advice | 2006 - 2014 | 2015 | Overall total |
|--------------------------------|-------------|------|---------------|
| Completed                      | 26          | 2    | 28            |
|                                |             |      |               |

### ***Outcome of the September 2015 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 |                |              |          |                     |
| Chemical  | Treatment of acute exacerbations in cystic fibrosis. |                 |    |           | x  |                |              | x        |                     |
| Chemical  | Treatment of Huntington's disease.                   |                 | x  |           |    |                | x            | x        |                     |



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|---------------------------|--|-----------------|----|-----------|----|----------------|--------------|----------|---------------------|
|                           |  | New             |    | Follow-up |    | Pharmaceutical | Pre-clinical | Clinical | Significant Benefit |
|                           |  | SA              | PA | SA        | PA |                |              |          |                     |
| Chemical                  | Treatment of gastro oesophageal reflux disease.  | x               |    |           |    |                |              | x        |                     |
| Biological                | Treatment of type II refractory celiac disease.  | x               |    |           |    |                | x            | x        |                     |
| Chemical                  | Treatment of breast cancer.  | x               |    |           |    | x              | x            | x        |                     |
| Biological                | Treatment of psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriasis, ankylosing spondylitis. | x               |    |           |    | x              | x            | x        |                     |
| Biological                | Treatment of ovarian cancer.   | x               |    |           |    |                |              | x        |                     |
| Biological                | Treatment of glioblastoma.   | x               |    |           |    |                |              | x        |                     |
| Chemical                  | Treatment of castration-resistant prostate cancer.   |                 |    | x         |    |                |              | x        |                     |
| Advanced therapy          | Treatment of melanoma.   | x               |    |           |    | x              | x            | x        |                     |
| Chemical                  | Treatment of prostate cancer.  | x               |    |           |    | x              |              |          |                     |
| Chemical                  | Treatment of metastatic hormone-sensitive prostate cancer.   |                 |    | x         |    |                |              | x        |                     |
| Biological                | Treatment of non-small cell lung cancer.   |                 |    | x         |    |                |              | x        |                     |
| Biological                | Prevention of graft rejection.   |                 | x  |           |    |                | x            | x        |                     |
| Chemical                  | Treatment of metastatic hormone-sensitive prostate cancer.   | x               |    |           |    |                |              | x        |                     |
| Biological                | Treatment of diffuse large B-cell lymphoma.  | x               |    |           |    |                | x            | x        |                     |
| Chemical                  | Treatment of acute myeloid leukaemia.  |                 | x  |           |    |                |              | x        |                     |
| Biological                | Treatment of rheumatoid arthritis, chronic lymphocytic leukaemia, non-Hodgkin lymphoma.  |                 |    | x         |    | x              | x            | x        |                     |
| Biological                | Treatment of sickle cell disease.  |                 | x  |           |    | x              | x            | x        | x                   |
| Biological                | Treatment of haemophilia A.  |                 | x  |           |    | x              |              | x        |                     |
| Chemical/Other innovative | Treatment of diabetic foot ulcers.   | x               |    |           |    | x              | x            | x        |                     |

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|---------------------------|---|-----------------|----|-----------|----|----------------|--------------|----------|---------------------|
|                           |   | New             |    | Follow-up |    | Pharmaceutical | Pre-clinical | Clinical | Significant Benefit |
|                           |   | SA              | PA | SA        | PA |                |              |          |                     |
| Chemical                  | Treatment of hepatitis C.   |                 |    | x         |    |                | x            | x        |                     |
| Biological                | Prevention of dengue virus disease.   | x               |    |           |    | x              | x            | x        |                     |
| Biological                | Treatment of influenza type A.  | x               |    |           |    | x              | x            | x        |                     |
| Biological                | Broad advice on vaccines.   |                 |    | x         |    |                |              | x        |                     |
| Biological                | Treatment of severe influenza A.  | x               |    |           |    |                | x            | x        |                     |
| Other                     | Treatment of cystitis.  | x               |    |           |    | x              | x            | x        |                     |
| Chemical/Other innovative | Treatment of female sexual interest/arousal disorder.   |                 |    | x         |    |                |              | x        |                     |
| Chemical                  | Treatment of molybdenum cofactor deficiency type A.   |                 |    |           | x  |                |              | x        |                     |
| Chemical                  | Treatment of schizophrenia.   |                 |    | x         |    |                | x            | x        |                     |
| Chemical                  | Treatment of asthma.  |                 |    | x         |    | x              |              | x        |                     |
| Chemical                  | Treatment of eosinophilic asthma.   | x               |    |           |    | x              | x            | x        |                     |
| Chemical                  | Treatment of pulmonary tuberculosis.  |                 | x  |           |    | x              |              |          |                     |
| Chemical                  | Treatment of dry eye disease.   | x               |    |           |    |                |              | x        |                     |
| Chemical                  | Treatment of Stargardt's disease.   |                 | x  |           |    |                | x            | x        |                     |
| Biological                | Treatment of neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion and diabetic macular edema. |                 |    | x         |    |                |              | x        |                     |
| Chemical                  | Treatment of acromegaly.  |                 |    |           | x  |                |              | x        | x                   |
| Other innovative          | Treatment of grass-induced allergic rhinitis.   | x               |    |           |    |                | x            | x        |                     |
| Chemical                  | Treatment of mastocytosis.  |                 |    |           | x  |                |              | x        |                     |
| Advanced therapy          | Treatment of mucopolysaccharidosis IIIA.  |                 | x  |           |    | x              | x            | x        |                     |
| Advanced therapy          | Treatment of mitochondrial neurogastrointestinal encephalomyopathy.   |                 | x  |           |    | x              | x            | x        |                     |
| Biological                | Prophylaxis for Ebola virus disease.  |                 | x  |           |    | x              | x            | x        |                     |
| Biological                | Treatment of Ebola Zaire virus.   |                 | x  |           |    | x              | x            | x        |                     |

| Substance           | Intended indications(s)  | Type of request |    |           |    | Topic          |              |          |                     |
|---------------------|--|-----------------|----|-----------|----|----------------|--------------|----------|---------------------|
|                     |  | New             |    | Follow-up |    | Pharmaceutical | Pre-clinical | Clinical | Significant Benefit |
|                     |  | SA              | PA | SA        | PA |                |              |          |                     |
| HTA parallel advice | Treatment of invasive aspergillosis and invasive scedosporiosis. | x               |    |           |    |                |              | x        |                     |
| HTA parallel advice | Treatment of glioblastoma multiforme.                            |                 | x  |           |    |                |              | x        |                     |

**SA: Scientific Advice**

**PA: Protocol Assistance**

The above-mentioned 18 Scientific Advice letters, 9 Protocol Assistance letters, 12 Follow-up Scientific Advice, 4 Follow-up Protocol Assistance letters, 2 HTA parallel advice letters and 0 Qualifications of novel methodologies letters were adopted at the 21 – 24 September 2015 CHMP meeting.

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

The Committee accepted 38 new Requests for which the procedure started at the SAWP meeting held on 1 – 4 September 2015. The new requests are divided as follows: 25 Initial Scientific Advice, 4 Follow-up Scientific Advice, 5 Initial Protocol Assistance, 1 Follow-up Protocol Assistance, 2 HTA parallel advices and 1 Qualifications of novel methodologies.