



13 November 2025  
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Press Office

## Scientific advice and protocol assistance

Adopted during the CHMP meeting 10-13 November 2025.

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

|                                           | 1995-2024    | 2025       | Overall total |
|-------------------------------------------|--------------|------------|---------------|
| Scientific Advice                         | 6457         | 480        | 6937          |
| Follow-up to Scientific Advice            | 2071         | 14         | 2085          |
| Protocol Assistance                       | 1417         | 102        | 1519          |
| Follow-up to Protocol Assistance          | 760          | 6          | 766           |
| EMA/EUnetHTA parallel consultation advice | 165          | 0          | 165           |
| Qualification of novel methodologies      | 246          | 15         | 261           |
|                                           | <b>11116</b> | <b>617</b> | <b>11733</b>  |

### ***Outcome of the November 2025 CHMP meeting in relation to scientific advice procedures***

#### **Final scientific advice procedures**

| Substance        | Intended indications                     | Type of request |    |           |    | Topic   |             |          |                     |
|------------------|------------------------------------------|-----------------|----|-----------|----|---------|-------------|----------|---------------------|
|                  |                                          | New             |    | Follow-up |    |         |             |          |                     |
|                  |                                          | SA              | PA | SA        | PA | Quality | Preclinical | Clinical | Significant benefit |
| Advanced Therapy | Treatment of Duchenne muscular dystrophy |                 |    | x         |    | x       |             | x        |                     |
| Advanced Therapy | Treatment of multiple myeloma            | x               |    |           |    |         | x           | x        |                     |
| Advanced Therapy | Treatment of multiple myeloma            | x               |    |           |    |         |             | x        |                     |

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|------------------|-----------------------------------------------------------------------|-----------------|----|-----------|----|---------|-------------|----------|---------------------|
|                  |                                                                       | New             |    | Follow-up |    |         |             |          |                     |
|                  |                                                                       | SA              | PA | SA        | PA | Quality | Preclinical | Clinical | Significant benefit |
| Advanced Therapy | Treatment of myasthenia gravis                                        |                 |    | x         |    | x       | x           | x        |                     |
| Advanced Therapy | Treatment of melanoma                                                 | x               |    |           |    | x       |             |          |                     |
| Biological       | Prevention of stroke                                                  | x               |    |           |    |         |             | x        |                     |
| Biological       | Prevention of peripheral arterial disease                             | x               |    |           |    |         |             | x        |                     |
| Biological       | Treatment of asthma                                                   | x               |    |           |    | x       |             | x        |                     |
| Biological       | Treatment of aesthetic surgery complication                           | x               |    |           |    |         | x           | x        |                     |
| Biological       | Treatment of allergic asthma                                          | x               |    |           |    | x       |             |          |                     |
| Biological       | Treatment of asthma                                                   | x               |    |           |    |         |             | x        |                     |
| Biological       | Treatment of Crohn's disease                                          | x               |    |           |    |         | x           | x        |                     |
| Biological       | Treatment of thyroid eye disease                                      | x               |    |           |    | x       | x           | x        |                     |
| Biological       | Prevention of stroke                                                  | x               |    |           |    |         |             | x        |                     |
| Biological       | Treatment of atopic dermatitis                                        | x               |    |           |    |         |             | x        |                     |
| Biological       | Treatment of multiple myeloma                                         |                 |    | x         |    |         |             | x        | x                   |
| Biological       | Treatment of patients aged 1 to 7 years diagnosed with peanut allergy | x               |    |           |    |         |             | x        |                     |
| Biological       | Treatment of cancer                                                   | x               |    |           |    | x       | x           | x        |                     |
| Biological       | Treatment of atopic dermatitis                                        | x               |    |           |    | x       |             | x        |                     |
| Biological       | Treatment of lupus erythematosus                                      | x               |    |           |    |         | x           | x        |                     |
| Biological       | Prevention of Dengue disease                                          | x               |    |           |    | x       |             |          |                     |
| Biological       | Treatment of kidney disease                                           | x               |    |           |    |         |             | x        |                     |
| Biological       | Treatment of burns                                                    | x               |    |           |    |         |             | x        |                     |
| Biological       | Treatment of lupus erythematosus                                      | x               |    |           |    |         |             | x        |                     |
| Biological       | Treatment of advanced or metastatic non-squamous                      | x               |    |           |    |         |             | x        |                     |
| Biological       | Treatment of cancer                                                   | x               |    |           |    |         | x           | x        |                     |
| Biological       | Treatment of Graves' disease                                          | x               |    |           |    |         |             | x        |                     |

| Substance  | Intended indications                       | Type of request |    |           |    | Topic   |             |          |                     |
|------------|--------------------------------------------|-----------------|----|-----------|----|---------|-------------|----------|---------------------|
|            |                                            | New             |    | Follow-up |    |         |             |          |                     |
|            |                                            | SA              | PA | SA        | PA | Quality | Preclinical | Clinical | Significant benefit |
| Biological | Treatment of Diabetic macular edema        | x               |    |           |    |         | x           | x        |                     |
| Biological | Treatment of atopic dermatitis             | x               |    |           |    | x       |             | x        |                     |
| Biological | Treatment of amyotrophic lateral sclerosis |                 |    | x         |    | x       | x           | x        | x                   |
| Biological | Prevention of diarrhoea                    | x               |    |           |    | x       | x           | x        |                     |
| Biological | Treatment of cancer                        | x               |    |           |    |         |             | x        |                     |
| Biological | Treatment of carcinoma                     |                 |    | x         |    |         |             | x        | x                   |
| Biological | Packaging replacement                      | x               |    |           |    | x       |             |          |                     |
| Biological | Prevention of Nipah virus infection        | x               |    |           |    | x       | x           |          |                     |
| Biological | Prevention of peripheral arterial disease  | x               |    |           |    |         |             | x        |                     |
| Chemical   | Treatment of leukaemia                     |                 |    | x         |    |         |             | x        |                     |
| Chemical   | Treatment of allergic reactions            | x               |    |           |    |         |             | x        |                     |
| Chemical   | Treatment of retinal dystrophies           |                 |    | x         |    |         |             | x        |                     |
| Chemical   | Treatment of fibrosis                      | x               |    |           |    | x       |             | x        |                     |
| Chemical   | Prevention of oesophageal stricture        | x               |    |           |    |         |             | x        |                     |
| Chemical   | Prevention of obesity                      | x               |    |           |    |         |             | x        |                     |
| Chemical   | Preparation of material for radiolabelling | x               |    |           |    | x       |             |          |                     |
| Chemical   | Treatment of adenocarcinoma                | x               |    |           |    | x       |             | x        |                     |
| Chemical   | Treatment of thrombocythemia               |                 |    | x         |    | x       | x           |          |                     |
| Chemical   | Treatment of breast cancer                 | x               |    |           |    |         |             | x        |                     |
| Chemical   | Treatment of neurofibromatosis             |                 |    | x         |    |         |             | x        |                     |
| Chemical   | Treatment of narcolepsy                    | x               |    |           |    | x       | x           | x        |                     |
| Chemical   | Treatment of biliary atresia               |                 |    | x         |    |         |             | x        |                     |
| Chemical   | Treatment of prostate cancer               | x               |    |           |    |         |             | x        |                     |
| Chemical   | Treatment of diabetic macular oedema       | x               |    |           |    |         |             | x        |                     |
| Chemical   | Packaging modification                     | x               |    |           |    |         | x           | x        |                     |
| Chemical   | Treatment of diabetes mellitus             | x               |    |           |    | x       |             |          |                     |

| Substance     | Intended indications                                 | Type of request |    |           |    | Topic   |             |          |                     |
|---------------|------------------------------------------------------|-----------------|----|-----------|----|---------|-------------|----------|---------------------|
|               |                                                      | New             |    | Follow-up |    |         |             |          |                     |
|               |                                                      | SA              | PA | SA        | PA | Quality | Preclinical | Clinical | Significant benefit |
| Chemical      | Treatment of spinal muscular atrophy (SMA)           | x               |    |           |    |         |             | x        |                     |
| Chemical      | Treatment of urticaria                               | x               |    |           |    |         |             | x        |                     |
| Chemical      | Treatment of primary biliary cholangitis             | x               |    |           |    |         |             | x        |                     |
| Chemical      | Treatment of Alzheimer's disease                     | x               |    |           |    |         |             | x        |                     |
| Chemical      | Treatment of Progressive Keratoconus                 | x               |    |           |    |         |             | x        |                     |
| Chemical      | Treatment of steatosis liver disease                 | x               |    |           |    |         |             | x        |                     |
| Chemical      | Treatment of neurofibromatosis                       |                 |    | x         |    |         | x           | x        |                     |
| Chemical      | Treatment of Acute Radiation Syndrome                | x               |    |           |    |         | x           | x        |                     |
| Chemical      | Treatment of Pancreatic ductal adenocarcinoma (PDAC) | x               |    |           |    |         |             | x        |                     |
| Chemical      | Treatment of invasive aspergillosis                  |                 |    | x         |    |         |             | x        |                     |
| Chemical      | Treatment of cancer                                  | x               |    |           |    | x       | x           | x        |                     |
| Chemical      | Treatment of diabetes mellitus                       | x               |    |           |    | x       |             | x        |                     |
| Qualification | Medical Tool                                         |                 |    |           |    |         |             |          |                     |
| Qualification | Medical Tool                                         |                 |    |           |    |         |             |          |                     |
| Qualification | Medical Tool                                         |                 |    |           |    |         |             |          |                     |
| Qualification | Medical Tool                                         |                 |    |           |    |         |             |          |                     |

SA: Scientific Advice  
PA: Protocol Assistance

The above-mentioned 69 Scientific Advice letters – 53 Initial Scientific Advice, 12 Protocol Assistance letters, 4 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice were adopted at the 10 - 13 November 2025.

## New requests for scientific advice procedures

The Committee accepted 83 new Requests for which the procedure started at the SAWP meeting held on 27-30 October 2025. The new requests are divided into as follows: 64 Initial Scientific Advice, 17 Protocol Assistance letters, 2 Qualifications of novel methodologies and 0 EMA/EUnetHTA parallel consultation advice.