Recommendations on eligibility to PRIME scheme
Adopted at the CHMP meeting of 19-22 June

During its June 2017 meeting, the CHMP reviewed 10 recommendations for eligibility to PRIME: 2 were granted and 8 were denied.

The individual outcomes adopted this month are listed below.
# Eligibility granted

<table>
<thead>
<tr>
<th>Name*</th>
<th>Substance type</th>
<th>Therapeutic area</th>
<th>Therapeutic indication</th>
<th>Type of data supporting request</th>
<th>Type of applicant</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-hydroxy-6-((2-(1-isopropyl-1H-pyrazol-5-yl)pyridin-3-yl)methoxy)benzaldehyde (GBT440)</td>
<td>Chemical</td>
<td>Haematology - Hemostaseology</td>
<td>Treatment of Sickle Cell Disease</td>
<td>Nonclinical + Clinical exploratory</td>
<td>Other</td>
</tr>
<tr>
<td>Polatuzumab vedotin</td>
<td>Biological</td>
<td>Oncology</td>
<td>Treatment of relapsed and refractory patients with diffuse large B cell lymphoma</td>
<td>Clinical exploratory</td>
<td>Other</td>
</tr>
</tbody>
</table>

* Name of the active substance, INN, common name, chemical name or company code.

SME applicants are micro-, small- and medium-sized-enterprises registered with the Agency’s SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.
## Eligibility denied

<table>
<thead>
<tr>
<th>Substance type</th>
<th>Therapeutic area</th>
<th>Therapeutic indication</th>
<th>Type of data supporting request</th>
<th>Type of applicant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical</td>
<td>Gastroenterology-Hepatology</td>
<td>Treatment of Diabetic Gastroparesis</td>
<td>Nonclinical+ Clinical exploratory</td>
<td>Other</td>
</tr>
<tr>
<td>Biological</td>
<td>Oncology</td>
<td>Treatment of acute myeloid leukaemia (AML)</td>
<td>Non-clinical + Clinical exploratory</td>
<td>Other</td>
</tr>
<tr>
<td>Chemical</td>
<td>Neurology</td>
<td>Treatment of autism spectrum disorder</td>
<td>Clinical exploratory</td>
<td>Other</td>
</tr>
<tr>
<td>Immunological</td>
<td>Neurology</td>
<td>Treatment of myasthenia gravis</td>
<td>Non-clinical + Clinical exploratory</td>
<td>SME</td>
</tr>
<tr>
<td>Biological</td>
<td>Oncology</td>
<td>Treatment of soft tissue sarcoma</td>
<td>Nonclinical + Clinical exploratory</td>
<td>Other</td>
</tr>
<tr>
<td>Biological</td>
<td>Oncology</td>
<td>Treatment of mesothelioma</td>
<td>Nonclinical + Clinical exploratory</td>
<td>SME</td>
</tr>
<tr>
<td>Biological</td>
<td>Infectious Diseases</td>
<td>Treatment of HIV infection</td>
<td>Nonclinical + Clinical exploratory</td>
<td>SME</td>
</tr>
<tr>
<td>Advanced Therapy</td>
<td>Dermatology</td>
<td>Treatment of partial deep dermal and full thickness burns</td>
<td>Nonclinical + Clinical exploratory</td>
<td>SME</td>
</tr>
</tbody>
</table>

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Cumulative overview of recommendations on PRIME eligibility requests adopted by 22 June 2017

By therapeutic area

- Oncology: 8
- Haematology-haemostaseology: 7
- Infectious diseases: 9
- Neurology: 8
- Cardiovascular diseases: 6
- Immunology-rheumatology-transplantation: 4
- Gastroenterology-Hepatology: 4
- Pneumology-allergology: 4
- Vaccines: 3
- Endocrinology-Gynaecology-Fertility-Metabolism: 2
- Ophthalmology: 3
- Dermatology: 3
- Psychiatry: 2
- Diagnostic: 1
- Musculo-skeletal system: 1
- Neonatology-paediatric intensive care: 1
- Uro-nephrology: 1

By type of applicant

- SME: 11
- Academic: 2
- Other: 16

*One eligible product has subsequently been withdrawn from the scheme at the applicant’s request.
Out of scope indicates eligibility requests received but not started by EMA as they were deemed outside the scope of the scheme or with a format and content inadequate to support their review. These are not included in the breakdown by type of applicant or by therapeutic area.