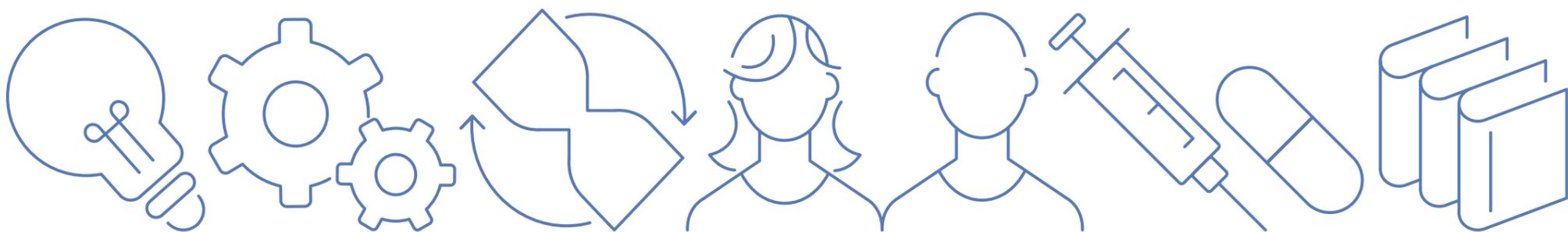


PRIME

The first 12 months

The European Medicines Agency (EMA) developed its PRiority MEDicines (PRIME) scheme in line with the European Commission's priorities and the European medicines regulatory network's strategy to 2020.



Addressing patients' needs

- ▶ PRIME aims to bring promising medicines that meet regulatory requirements to patients earlier by optimising and supporting their development.
- ▶ The scheme focuses on medicines that address an unmet medical need and that have the potential to bring a major therapeutic advantage to patients.
- ▶ With PRIME, EMA translates scientific advances into the development of medicines that can make a real difference to patients' lives.

20 requests granted

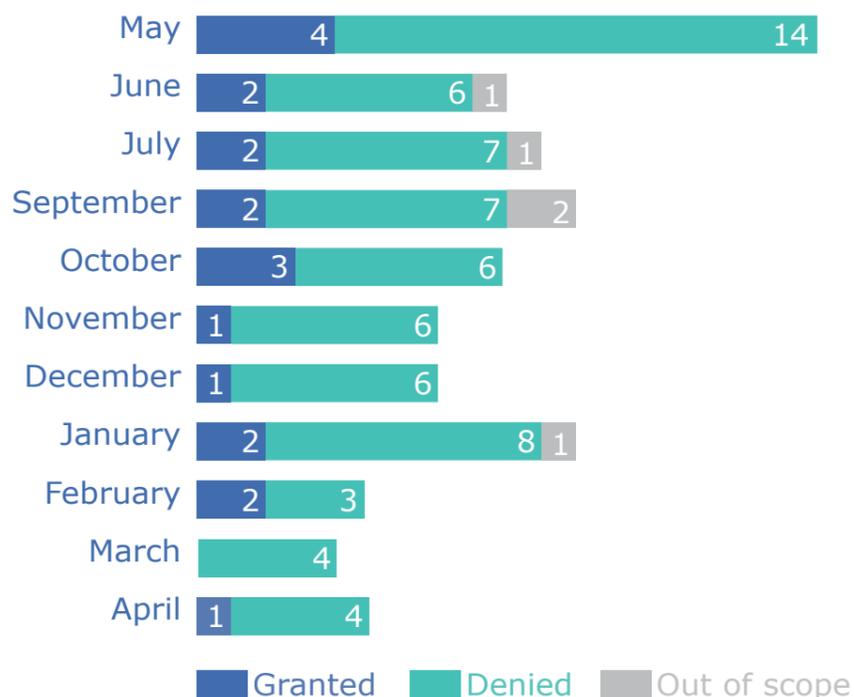
(by type of medicine)

- 12 advanced therapies (of which 8 orphan medicines)
- 2 biological medicines (of which 1 orphan medicine)
- 5 chemical medicines (of which 3 orphan medicines)
- 1 vaccine

1 in 3 medicines targets a disease for which no treatment exists

96 requests processed

(between April 2016 and April 2017)



22% success rate

71 requests denied

(multiple reasons in some cases)

- ~70% Data not sufficiently robust
- ~40% Justification of therapeutic advantage insufficient
- ~20% Development too advanced

PRIME medicines

(by therapeutic area)

