**What it is**

- An EU early access route for medicines
- For medicines that fulfil an unmet medical need
- Only granted if the benefit of immediate availability for patients is greater than the risk of less comprehensive data than normally required
- Valid for a year; can be renewed annually
- Comprehensive data is generated post-authorisation, to agreed timelines

**Scope includes**

- Medicines to target seriously debilitating or life-threatening diseases
- Medicines to fight public health threats in emergency situations (e.g., a pandemic)
- Medicines to treat rare diseases

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**30 CMAs**

- **24** Target debilitating or life-threatening conditions
- **14** Are orphan medicines
- **3** Address emergency situations linked to a public health threat

**By therapeutic area**

- **17** Oncology
- **9** Infectious diseases
- **3** Neurology
- **1** Ophthalmology

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**107 post-authorisation obligations**

(of these, 57 obligations were fulfilled before June 2016)

**Categories of specific obligations imposed to companies**

- 78 Final results from clinical studies or pool of studies
- 9 Interim results of a clinical trial
- 8 Additional analysis
- 3 Quality data
- 9 Other measures

**How timely was the submission of specific obligation results?**

- **33** Due date +/- 1 month
- **15** Early (1-6 months)
- **4** Early (6-12 months)
- **1** >1 year early
- **2** Late (1-6 months)
- **2** Late (6-12 months)

**>90%** of completed specific obligations did not have major changes to their scope

**≈70%** of specific obligations were completed within specified timelines

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**By year**

- **2006**: 1
- **2007**: 4
- **2008**: 2
- **2009**: 2
- **2010**: 1
- **2011**: 1
- **2012**: 1
- **2013**: 1
- **2014**: 1
- **2015**: 3
- **2016**: 3

**Conversion pending**

- **2009**: 1
- **2010**: 1
- **2011**: 1
- **2012**: 1
- **2013**: 1
- **2014**: 1

**MA withdrawn for commercial reasons**

- **2015**: 1

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**MA withdrawn for commercial reasons**

- **2016**: 1

**The cut-off date for data collection is June 2016**

**EMA’s Committee for Medicinal Products for Human Use (CHMP) reviews all data collected annually to decide about a further renewal of the CMA or its conversion into a standard marketing authorisation.**

On average, a CMA is converted into a standard marketing authorisation **within 4 years.**