CMA

Conditional Marketing Authorisation

How early access to medicines has helped patients from 2006 to 2016

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

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

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)

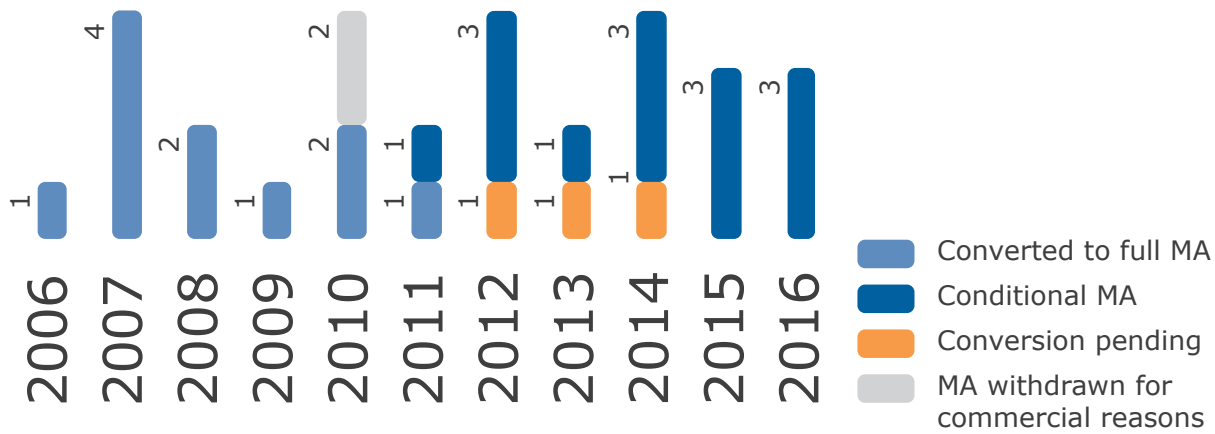
>90% of completed specific obligations did not have major changes to their scope

≈70% of specific obligations were completed within specified timelines

By year

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.**



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

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