# Analysis of approval times of anticancer drugs between 2010-2017

**F. Scarpisi, A. Zwiers**

Over the last decade there has been a significant increase in marketing authorisation approvals of anticancer drugs in the EU. We performed an analysis over the period 2010-2017 to investigate which factors impact the approval time of anticancer products and compared this to data from a similar analysis by Hartmann et al covering 2006-2011.

**Aims**

- To define the duration of approvals of marketing authorisation applications for anticancer drugs in the EU
- To highlight the differences among them based on biological properties, therapeutic indication, the restrictions of the authorisation and the regulatory review type.

**Methods**

European Public Assessment Reports of drugs approved within the timeframe of 2010 and 2017 were analysed for:

- time of approval (i.e. 1st day of assessment up until positive CHMP opinion);
- restrictions of the authorisation (conditional marketing authorisation);
- review type (accelerated vs normal);
- type of indication;
- biological properties class;
- designation (orphan)

**Results and Conclusions**

A total of 65 anticancer drugs were included in the database. Around 50% of the drugs were for the indications blood cancer (12%), skin cancer (18%) and leukaemia (22%).

No special status

Approximately 50% of anticancer drugs (23 small molecules and 11 biologicals) which obtained a positive CHMP opinion did not have a special status. For these drugs, the median time to CHMP approval is 365 days which is slightly more than the default time of 330 days (Figure 1, black line).

Special status

Compared with the anticancer drugs (small molecules (blue) and biologicals (orange)) without a special status (see Figure 2, black line is 330 days):

- a statistically significant shorter time to positive CHMP opinion was seen for the accelerated review;
- the time to positive CHMP opinion was significantly longer for small molecules with a conditional approval status;
- small molecules which lost their accelerated assessment status during review had the same time to positive opinion as products with no special status.

Orphan drug status had no significant impact on time to positive CHMP opinion.

Figure 1: Approval time (median days) for products without special status

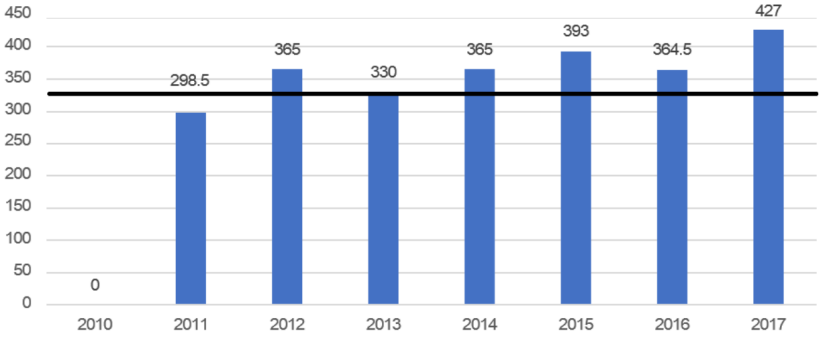
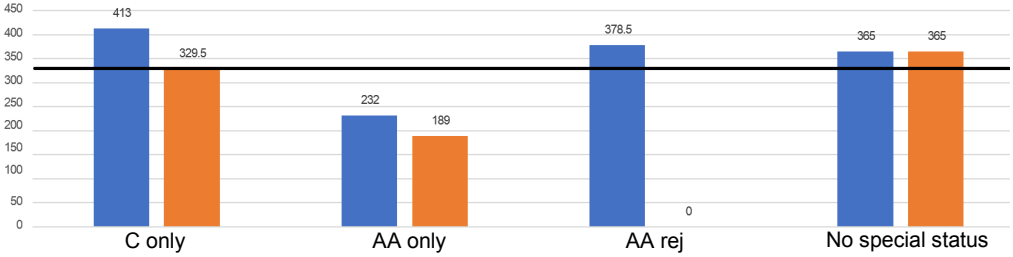



Figure 2: Small molecule and biologicals anticancer drugs approval time (median days) for products without special status




C only: Conditional approval status AA only: Accelerated assessment AA rej: Accelerated assessment rejected

The comparison of the information in our database with Hartmann et al revealed that the time to a positive CHMP opinion for:

- accelerated assessment decreased from 9 to 7 months; and
- orphan drugs decreased from 13,1 to 11,2 months

Comparison Median Value Approval time

| | 2006-2011 Median Value all drugs (days) | 2006-2011 Median Value all drugs (months) | 2010-2017 Median Value all drugs (days) | 2010-2017 Median Value all drugs (months) | δ |
|---|---|---|---|---|---|
| Anticancer drugs | ≈398 | 13,3 | 358 | 11,9 | 1,4 |
| Orphan drugs | ≈394 | 13,1 | 337 | 11,2 | 1,9 |
| AA drugs | ≈270 | 9 | 210,5 | 7 | 2 |

**References**

Hartmann M, Mayer-Nicolai C, Pfaff O: Approval probabilities and regulatory review patterns for anticancer drugs in the European Union. Critical Reviews in Oncology/ Hematology 87 (2013) 112-121.