

Background

Since 1995, for each anticancer drug registered in Europe following the so called Centralised Procedure, a “European Public Assessment Report” (EPAR) is made available by the European Medicines Agency (EMA). Especially for anticancer drugs, the impact of the drug on health-related quality of life (HRQoL) is of major importance. To date, there is no overview of the current European regulatory practice regarding HRQoL assessment for anticancer drugs.

Methods

For all anticancer drugs approved since 1995, the EPARs are collected and screened on different characteristics including “assessment of HRQoL” and, when applicable, “name of the health status instrument used”.

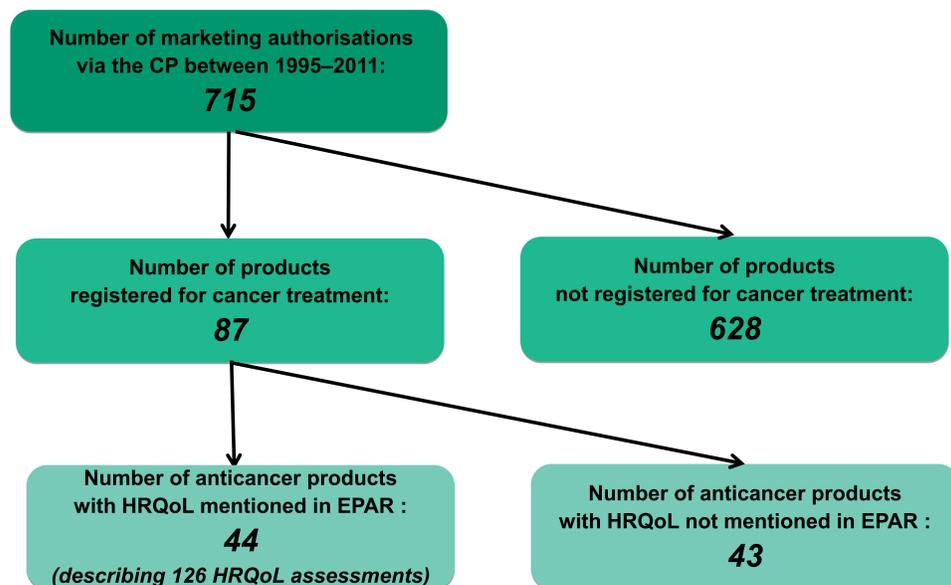


Figure 1: Anticancer products and HRQoL assessment in the Centralised Procedure (CP).

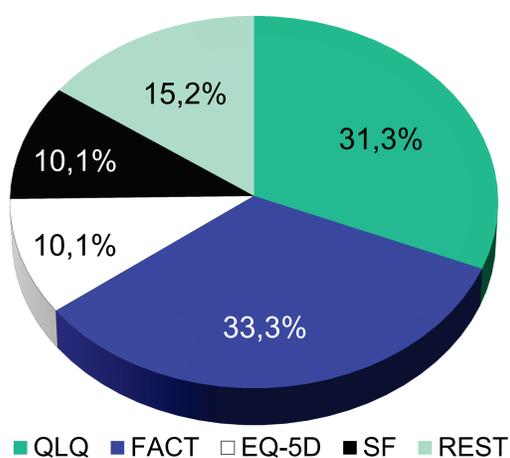


Figure 2: Distribution of different types of HRQoL instruments (only specified instruments are included).

QLQ	= Quality of Life Questionnaire from the EORTC. Exists of a core version QLQ-C30 and various disease specific modules like QLQ-BR23, QLQ-LC13 etc.
FACT	= Functional Assessment of Cancer Therapy. Exists of a general version FACT-G and various disease specific modules like FACT-B, FACT-L etc.
EQ-5D	= Generic HRQoL Instrument developed by the EuroQol group.
SF	= Short Form. Exists of a basic Questionnaire SF-36 and the more compact versions SF-12 and SF-8.

Results

Until 28/11/2011, EPARs for 87 anticancer drugs are available. The EPARs of 44 (51%) of these drugs mention HRQoL assessment in a total of 103 clinical trials in which 126 different HRQoL assessments are described. In 27 of the 126 cases (21%), the applied HRQoL instrument is not specified. In 64 of the 99 specified cases (65%), the applied instrument belongs to one of the two most commonly used health status instruments in cancer patients, the FACT- or QLQ-C30 questionnaire. The average percentage of new anticancer drugs with HRQoL is as follows: 70% (1995–1999), 73% (2000–2004), 47% (2005–2009) and 78% (2010–2011).

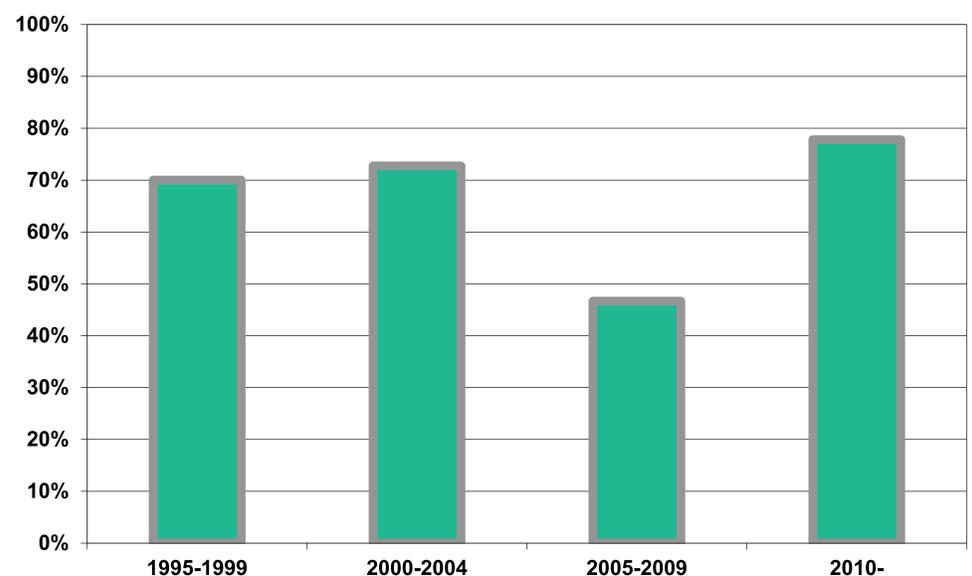


Figure 3: Percentage of anticancer products with HRQoL in EPAR in different time intervals (excluding generics).

Conclusion

In only about half of all anticancer drugs approved by EMA, the EPAR mentions the assessment of HRQoL, for which the applied instrument is not specified in 21% of the cases. Under the specified instruments, the most established ones (FACT- or QLQ-C30-questionnaires) are the two most frequently applied types. Over the period 1995–2011 the average percentage of new anticancer drugs with HRQoL is constant at around 75% with a decline seen in the period 2005–2009. To fully evaluate the harms and benefits of new anticancer drugs, it is important to improve the inclusion of HRQoL assessment in clinical trials. In addition, reporting on HRQoL should be more detailed.