The Next Steps Matter? New Cancer Medicines and Their Extensions of Indication in Europe, 2010-2020

HPR211

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Introduction and aim

Extensions of therapeutic indications are one of the most common methods to extend the lifecycle of a medical product in the post-authorisation phase. Another major trend is the shift towards outpatient cancer care. The aim of the study was to explore the role and the level of evidence of extension of indication for outpatient cancer medicines in the Europe. The study examines and compares three groups: first indications for multi-indication medicines, extensions and medicines without extensions.

Methods

We conducted a document analysis of all new outpatient cancer medicines approved in Europe 2010-2020 and the extensions to their indications. We collected the general research characteristics from European public assessment reports, compared them using the Joanna Briggs Institute's critical appraisal tools, and we compiled the clinical added value (CAV) assessments by Haute Autorité de Santé.

Results

We identified altogether 55 new cancer medicines. 31 medicines had one or more extension(s) of indication while 24 had none. Altogether, 57 extensions were observed. The most common indications of medicines were the treatment of hematological cancers (24%, n=13). The most frequent type of extension involved a shift in the line of treatment (35%). Compared to the initial indications, the studies supporting the extensions generally demonstrated higher quality in terms of study design. Furthermore, the proportion of medicines offering CAV was greater among extensions than among first indications and medicines without extensions.

Conclusions

Drawing on various evaluations and viewpoints, our analysis indicates that indication extensions represent a prevalent and significant part for prolonging the lifecycle of outpatient cancer medicines in Europe. Moreover, the results suggest that the clinical value of these medicines tends to increase with the addition of new indications.

Key findings

- 55 new outpatient cancer medicines. 56% of them had at least one extension of indication by 2022
- Study design quality was higher for extensions than for first indications
- The proportion of medicines offering clinical added value was greatest among extensions

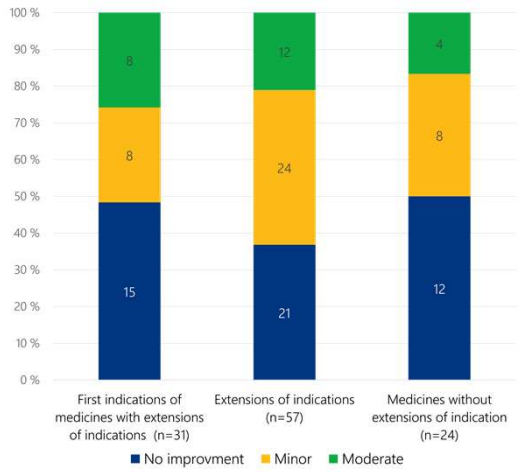

Figure 1. Assesment of clinical added value by Haute Autorité de Santé

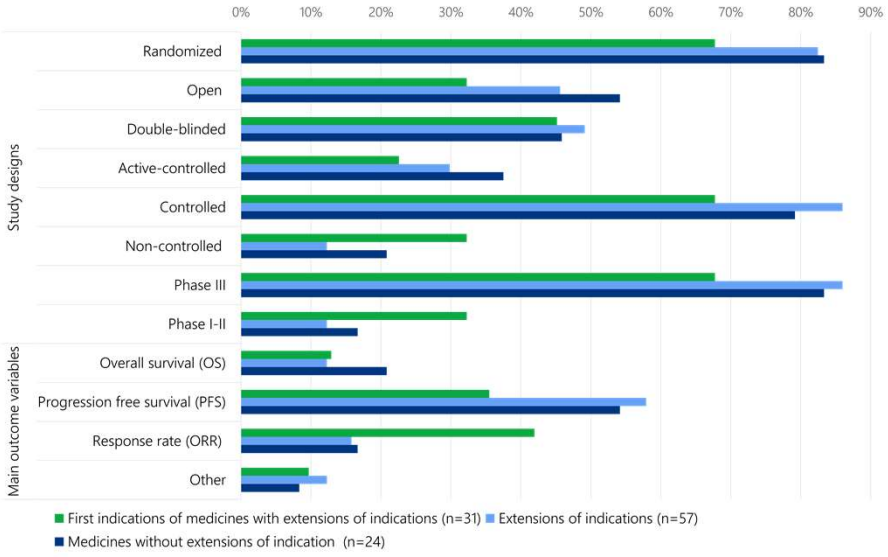

Figure 2. Key characteristics of new cancer medicines with and without extensions of indication

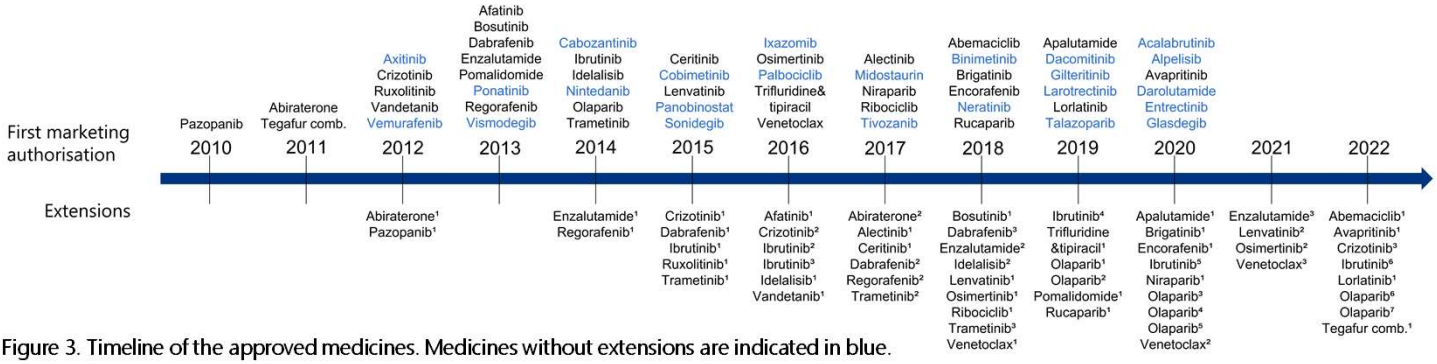

Figure 3. Timeline of the approved medicines. Medicines without extensions are indicated in blue.

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