Impact of dynamic changes of the definition of the appropriate comparative therapy (ACT) on market access performance of new active substances in Germany

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Introduction

Since 2011, the Federal Joint Committee (G-BA) has assessed the added benefit of new drugs launched in Germany. The outcome of this assessment is the basis for reimbursement and price negotiations with the statutory health insurance. For orphan medicines, an added benefit is granted by law. For non-orphan drugs, the G-BA determines an appropriate comparative therapy (ACT) according to criteria defined in the G-BA Code of Procedure. New active substances regularly appear on the market, especially for indications with a somewhat' crowded' market. Hence, the ACT may change dynamically, even during already ongoing benefit assessment procedures.

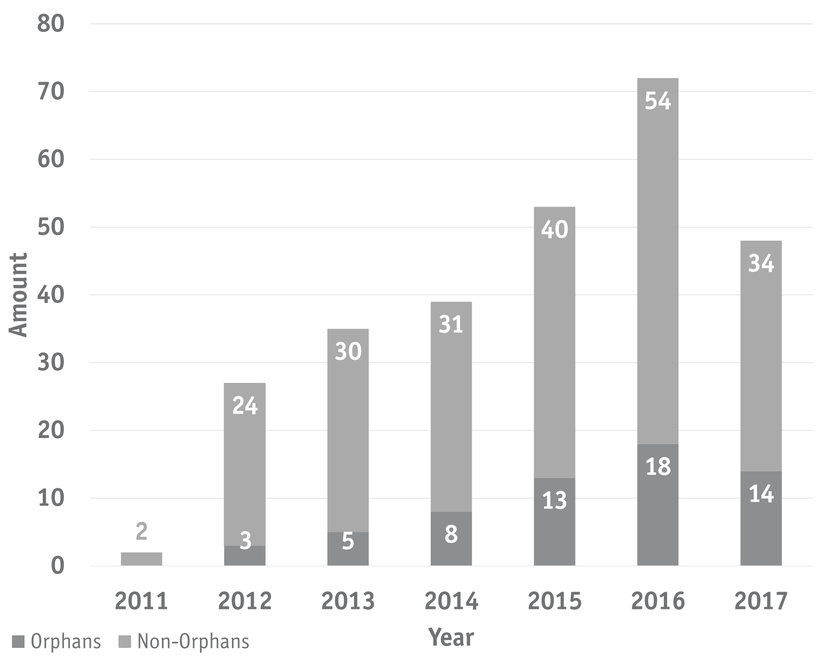
Methods

- All final resolutions released by the G-BA between 2011 and 2017 were screened and assigned to their respective fields of indication and orphan drug status.
- The number of proceedings and the outcomes, including the extent of the granted added benefit of all subpopulations made by the G-BA, were analyzed per field of indication.
- Changes of the ACT over time and their impact on price negotiations (rebates) were analyzed *pars pro toto* for the indication non-small cell lung cancer (NSCLC).

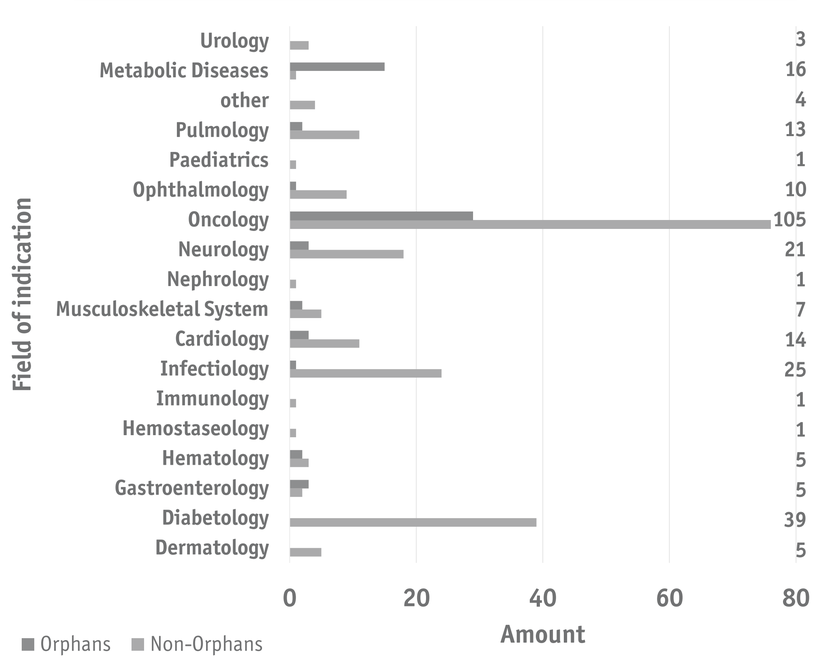
Results

1

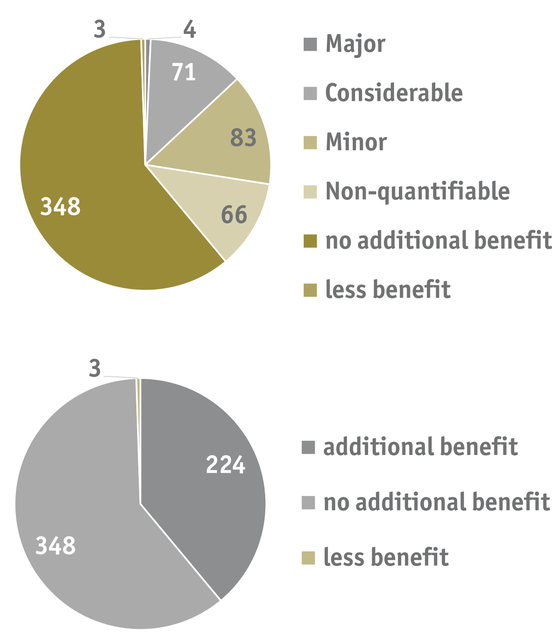
Overview of concluded proceedings from 2011-2017



Overview of concluded proceedings from 2011-2017 assigned to their field of indication

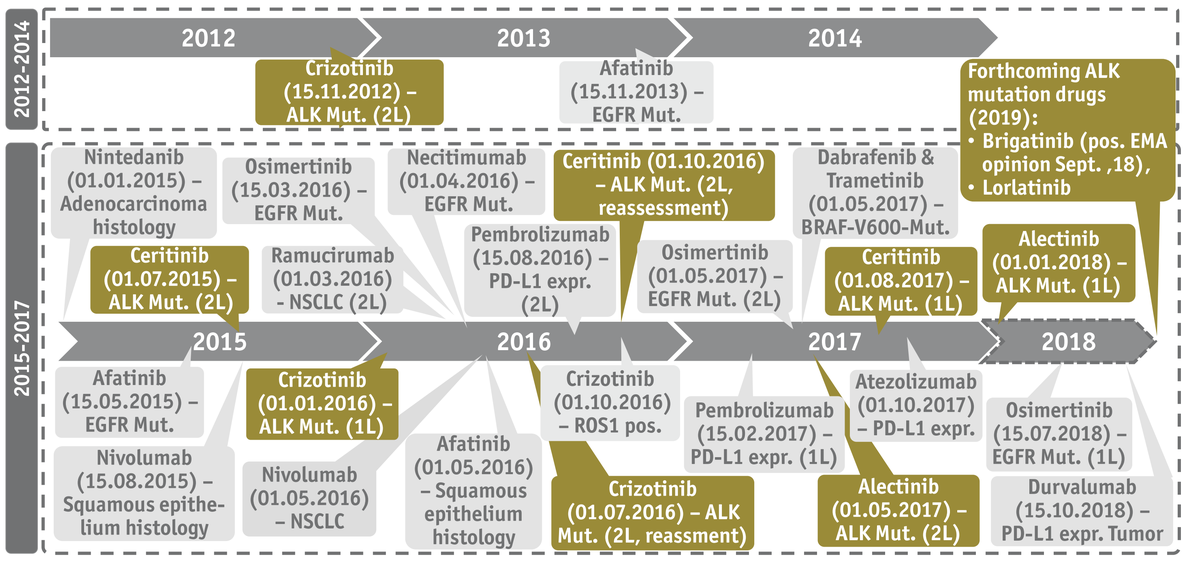


Granted added benefit of all 575 subgroups (G-BA)

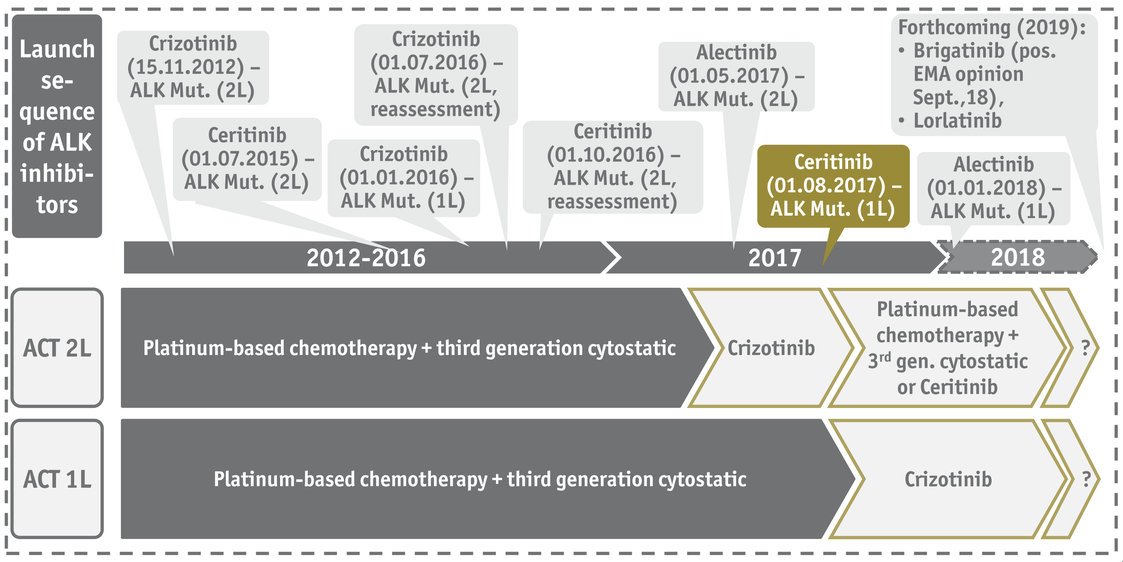


2

NSCLC as a field of indication with a crowded market



Dynamic changes of the ACT in ALK+ NSCLC



3

Drug	Benefit assessment	Added benefit	Outcome price negotiations/ rebate	Annual therapy costs/ patient
Ceritinib* (01.07.2015) – ALK Mut. 2L	- Lack of data; limited resolution (ongoing phase III study); historical comparison of data not suitable allowing an assessment of the added benefit of Ceritinib to the ACT (platinum based chemotherapy + third generation cytostatic)	No benefit/ no benefit	-43,82%	50.000,00 €
Ceritinib* (01.10.2016) – ALK Mut. 2L, reassessment	+ Relevant reduction of symptoms (in particular characteristic symptoms), benefit in several dimensions of QoL and specific adverse Events	Minor (Hint)/ no benefit	-35,96% (+7,86%)	57.000,00 €
Ceritinib* (01.08.2017) – ALK Mut., 1L	- **No relevant data that allows an assessment of the added benefit of Ceritinib to the ACT** (change of the ACT during the AMNOG process: platinum-based chemotherapy + third generation cytostatic → Crizotinib)	**No benefit/ no benefit**	**-39,25%** (-3,29%, +4,57%)	**54.067,45 €**

* Launch: 01.07.2015; annual therapy costs/ patient: 89.000 €

Conclusion

A successful market access strategy for Germany is especially dependent on the extent of the additional benefit described in the final G-BA resolution. It is important to show a high level of evidence, particularly comparing the new active substance to the ACT determined by the G-BA. However, ACTs can dynamically change even during already ongoing benefit assessment procedures (e.g. Ceritinib, 1L). Continuous monitoring of previous and ongoing HTA proceedings may help to predict the dynamics in specific indications for HTA in Germany and could support the development of a concept for a clinical trial design that anticipates the required ACT (e.g. as a control arm in a RCT) and shows convincing study data. Furthermore, an agile project team and project approach during the whole dossier preparation process could overcome such unfavorable scenarios by adequately reacting to the situation (change of the ACT).

References:
1 https://www.g-ba.de | 2 https://www.cgm.com/lauer-fischer/index.de.jsp | 3 http://clinicaltrials.gov/

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