Cancer drugs in Germany: HTA decisions of new and innovative oncology drugs in Germany – an analysis using the Prismaccess® database

OBJECTIVE:
- The German Pharmaceutical Market Restructuring Act (AMNOG) enters its eighth effective year.
- The aim of the law is to disclose the added benefit of a new patented drug over existing therapies by an early assessment, which also serves as the basis for the price negotiation.
- This study is a descriptive analysis of the early benefit assessments for new oncologies in Germany.

METHODS:
- The international HTA database Prismaccess® includes all decisions by market access authorities, among others also from Germany.
- All decisions on therapeutic areas labeled for “oncology” and “cancer” launched in Germany were considered for a systematic analysis.
- Decisions of the German Federal Joint Committee (G-BA) have been extracted and analyzed regarding the extent of the added benefit, subgroups and results of the benefit assessment between January 2011 and May 2018.

RESULTS:
- Out of a total of 335 process, 84 decisions on new oncologies were identified for 43 different drugs.
- 23 of them had been assessed multiple times due to time restrictions and/or new indications. 21 (48.8%) decisions included only one single subgroup.

- The mostly assessed indication between 2011 and 2018 was non-small cell lung cancer (24 assessments; 29%) followed by melanoma (13 assessments; 15%).

- It is striking that the G-BA did not accept PFS at all as the endpoint for the benefit assessment. As a reason for the non-acceptance of the PFS data, the G-BA stated that PFS is regarded as a minor indication with medium or a “hint” with little certainty of stating an additional benefit.

- The analysis showed that 43% (64/150) of the defined subgroups reached a positive added benefit in at least one subgroup. In all 150 subgroups evaluated, the following were obtained only 43% (64/150) of the added benefit. 4 of the 43 procedures with several subgroups received added benefit in more than one subgroup. Only one subgroup of 41 proceedings and several (2-6) subgroups of 43 proceedings were evaluated.

- In addition, the added benefit was specified more precisely with the statement as to whether it was a “proof”, an “indication” with medium or a “hint” with little certainty of stating an additional benefit.

- The analysis showed that 71% (60/84) of the assessments received an added benefit in at least one subgroup. In all 150 subgroups evaluated, the following were obtained only 43% (64/150) of the added benefit. 4 of the 43 procedures with several subgroups received added benefit in more than one subgroup. Only one subgroup of 41 proceedings and several (2-6) subgroups of 43 proceedings were evaluated.

- The specification of the procedures indicates whether it is a new product that is gaining market access in Germany for the first time or whether, for example, it is a new indication or combination. Table 4 shows the number of individual specifications.

CONCLUSIONS:
- The analysis showed that 43% (64/150) of the defined subgroups reached a positive added benefit in Germany. In most cases 71% (60/84), a drug received an added benefit for at least one subgroup.
- Furthermore, it was shown in a systematic analysis of all oncology assessment in Germany, that PFS is not accepted as a patient-relevant endpoint in Germany.