

## BACKGROUND

The importance of new immuno-oncology medicinal products such as pembrolizumab and nivolumab is increasing drastically from both the therapeutic and the economic point of view. Due to their numerous indication extensions, more patient groups may benefit from them while payers are facing increasing prescription quantities.

Moreover, this phenomenon of new indications ( $\hat{=}$  indication extensions) and the corresponding negotiations for the reimbursement price in Germany is not restricted to immuno-oncology medicinal products, but is observed in other therapeutic fields as well. It is to be expected that the National Association of Statutory Health Insurance Funds (SHI/"GKV-Spitzenverband") lowers reimbursement prices to offset the increased number of prescriptions.

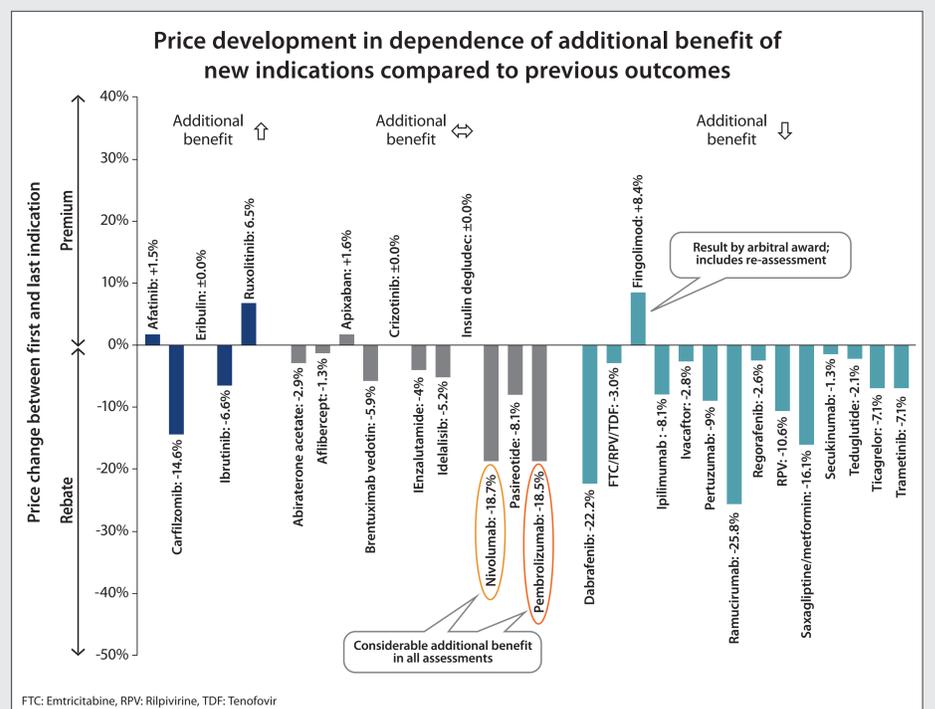
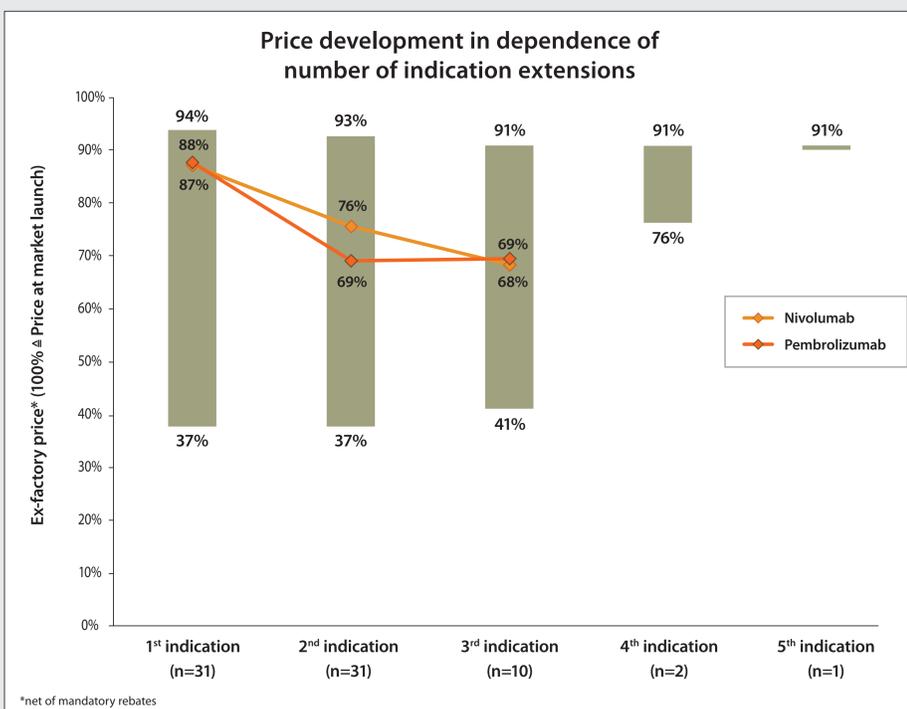
## OBJECTIVES

This analysis investigates the effect of indication extensions over time on the level of reimbursement prices of drugs that are subject to early benefit assessment ("AMNOG") in Germany.

## METHODS

- A selection was made of all completed AMNOG procedures with at least one assessed indication extension for which also a relevant reimbursement price had been negotiated until June 1<sup>st</sup>, 2018.
- For these procedures, the development of reimbursement prices over time was extracted from the German pharmacy price schedule.
- The subsequent evaluation of the price development was made by means of a before and after comparison in the context of the additional benefit that had been determined for the first indication and for the new indications.

## RESULTS



- 31 medicinal products that had undergone AMNOG assessment with at least one indication extension were identified (75 procedures in total).
- For 24 medicinal products, indication extensions resulted in a further price decline independent from their category of additional benefit compared to previous assessment outcomes.
- Indication extensions for 4 drugs resulted in an increase of the negotiated reimbursement price for the first assessed indication. An exceptional case is the price increase of fingolimod, since the reimbursement price was determined by the German arbitration board in consideration of re-assessment of previous indication extensions.
- In 3 cases (eribulin, crizotinib, insulin degludec), prices remain stable with 1 indication extension each (category of additional benefit is constant or higher).
- It is striking that immuno-oncology drugs show an additional rebate of up to 18.7% on the reimbursement price of the first indication, leading to a total price decline of up to 32% on the launch price, although they have constantly been assigned to high-level categories of additional benefit ("considerable").

## CONCLUSIONS

The analysis demonstrates that new indications generally lead to a further price decline, irrespective of the result of the new assessment. Therefore, other factors (comparator costs, costs of comparable drugs, epidemiology, quantity development) may presumably be of higher importance.

## REFERENCES

- National Association of Statutory Health Insurance Funds (SHI/"GKV-Spitzenverband") [Internet]: Overview of all price negotiations on the online presence of the "GKV-Spitzenverband" [only available in German, last modified on Sep 14<sup>th</sup>, 2018, last accessed: Oct 10<sup>th</sup>, 2018]: [https://gkv-spitzenverband.de/krankenversicherung/arzneimittel/verhandlungen\\_nach\\_amnog/ebv\\_130b/ebv\\_nach\\_130b.jsp](https://gkv-spitzenverband.de/krankenversicherung/arzneimittel/verhandlungen_nach_amnog/ebv_130b/ebv_nach_130b.jsp)
- The Federal Joint Committee ("Gemeinsamer Bundesausschuss/G-BA") [Internet]: Overview of resolutions to benefit assessments [only German version up-to-date, last modified on Oct 1<sup>st</sup>, 2018, last accessed: Oct 10<sup>th</sup>, 2018]: <https://www.g-ba.de/informationen/nutzenbewertung/>
- Initial prices and reimbursement prices were taken from: "ABDATA Pharma-Daten-Service der Werbe- & Vertriebsgesellschaft Deutscher Apotheker (WuV), ABDA-Artikelstamm": <https://go.pharmazie.com/en/portfolio-item/drug-pricing-germany-tool/>

