

## Healthcare & Life Sciences - Germany

### Pricing for new innovative drugs – public payers attempt new approach

Contributed by **McDermott Will & Emery**

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In 2011 an additional benefit assessment for innovative drugs and consecutive price negotiations – known as the AMNOG procedure – entered into force. The law terminated free prices for new innovative drugs without imposing a 'fourth hurdle'. A new drug which is licensed to the European or German market by the European Medicines Agency or a national licensing authority is still available on the German market and public payers must pay the price that the producer charges for the product (minus a compulsory 7% discount provided for by law).

Contrary to pre-2011, the pharmaceutical producer's determined price is applicable for one year only. Thereafter, the applicable price (to both public and private payers) is based on the results of an early compulsory evaluation by the Federal Joint Committee of the additional benefits of the new drug compared with appropriate comparable therapies for the relevant indications and patient populations. When a new innovative product enters the market, its producer must submit a complete dossier containing all relevant clinical trial data to the Federal Joint Committee. Within six months of market entry, the committee must determine the appropriate comparable therapies for the medical indications of the new product, and whether and to what extent the new product is better than the appropriate comparable therapies. The law describes this as "having an additional benefit". These rules apply to any new innovative drug understood to contain a new active ingredient or a new composition of existing active ingredients.

If after the early benefit assessment the Federal Joint Committee decides that the new drug has no additional benefit when compared with existing appropriate comparable therapies, the new price must be no higher than the price of the adequate comparable therapy. In most cases, the Federal Joint Committee regulates the price at the price of the comparable therapy (or a weighted average of different adequate comparable therapies, if there are several).

If the committee decides that the new product has no additional benefit, the price of the new drug must be negotiated between the pharmaceutical producer and the umbrella association of public payers GKV Spitzenverband. The negotiations must lead to a mutual price determination within a year of market entry.

If the parties reach no agreement, a pricing arbitration panel will determine the price. Until now, this has been the case in only a few instances, probably because pricing arbitration panel decisions and their reasoning are published, whereas the reasoning for negotiated prices is unpublished. This appears occasionally to incentivise GKV after long and tiring negotiation talks. The pharmaceutical producer, on the contrary, is often incentivised to avoid a price decision by the pricing arbitration panel. Even though the panel is supposed to decide in an unbiased manner, it consists predominantly of representatives of public payers and other governmental entities.

In its decision, the arbitration panel – and likewise, GKV and the pharmaceutical producer in their negotiations – must consider:

- the degree of additional benefit;
- the price of the new product in other European countries (the weighted average in accordance with product sales and parity of purchase power between various relevant countries); and
- the price of comparable drugs.

GKV seems increasingly to take the view that the meaning of 'comparable drug' is much wider understood than 'comparable adequate therapy'. Thus, the association seems to aim at considering older drugs with less benefit than the therapy considered to be an adequate comparable therapy in the early benefit assessments. Such understanding, if upheld, will render the concept of early compulsory benefit

assessments absurd. The entire price concept aimed at by law is based on the evaluation of the existence and degree of additional benefit of a new drug compared with the adequate comparable therapy. Such therapy can only be the best therapy available. Thereby, the law explicitly wishes to allow high prices for successful new products, but to restrict prices for products which render little or no additional benefit.

Since this new price determination system has entered into effect, more than 60 new innovative drugs have entered the German market and have undergone early compulsory benefit assessments by the Federal Joint Committee. The committee has determined that approximately two-thirds of these new drugs render some additional benefit to at least a certain sub-population of patients.

Overall, the new price determination concept, which constitutes a change of paradigm in the pharmaceutical pricing structure, can be considered a success, as it aims to reward successful innovations and limit expense for unsuccessful new products. However, the risk exists that this system is being jeopardised by public payers. It remains to be seen whether GKV will uphold its view and whether the pricing arbitration panel will support it. In view of the law's clear intent, it is difficult to imagine that the pricing arbitration panel will do so.

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