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Germany's new early benefit assessment for innovative pharmaceuticals

Jörg Schickert and ***Andreas Schmitz*** bring clarity to some of the pressing questions surrounding the new system of assessment that replaced free drug pricing. There is confusion over the scope of the assessment, dossier obligations and the determination of the comparable therapy.

There is considerable confusion among pharmaceutical companies in Germany about the new law that subjects innovative drugs to an "early benefit assessment". The legislation on the realignment of the pharmaceutical market (referred to as AMNOG), which came into effect on 1 January 2011, replaced free pricing for new drugs with an assessment of the value they bring compared to existing products.

Under the law, the price of an innovative pharmaceutical is based on the extra benefit that it demonstrates over comparable therapies. This extra benefit is assessed by the joint federal healthcare committee, the G-BA. Questions that have been raised by the industry about the law relate to the scope of the assessment; the dossier that has to be submitted by the company in order to demonstrate the extra benefit; and the determination of which therapies are considered comparable.

Early benefit assessment

There are two scenarios in which a medicinal product is subject to an assessment under AMNOG. For pharmaceuticals that are placed on the market for the first time or that receive a line extension, the G-BA has to conduct an assessment (this is known as "mandatory assessment"); for other pharmaceuticals, the G-BA may choose to conduct an assessment at its own discretion ("discretionary assessment").

While the final assessment decision rests with the G-BA, the committee may assign the evaluation of extra benefit to the Institute for Quality and Cost-effectiveness in the Healthcare Sector (IQWiG) or to other third parties.

The actual evaluation must be completed and the results published within three months. Subsequently, there is an advisory procedure under which the G-BA has to hear comments from the companies concerned and other specialists from the healthcare sector. The G-BA takes a final decision within three months of the results being published. With this decision, the G-BA determines whether an innovative pharmaceutical has an extra benefit or not.

If the company is not able to demonstrate that its product has an extra benefit, it will be allocated into a group of comparable substances within Germany's reference price scheme. Where there is no reference price group, the company has to enter into negotiations on the reimbursement price with the Federal Association of Statutory Health Insurance funds (SpiBu). The reimbursement price – where there is no extra benefit – may not be set higher than the price of the comparable therapy.

If the pharmaceutical is able to demonstrate an extra benefit, it has to enter into negotiations with the SpiBu as well. The reimbursement price will be negotiated on the basis of the assessment and it will be higher than that of the comparable therapy. The reimbursement price will become effective at the latest six months after the G-BA's decision on the assessment.

Scope

The G-BA is required to assess pharmaceuticals launched in Germany for the first time after 1 January 2011 whose active substance is new to the German market. In addition, it has to assess line extensions if an early benefit assessment of the pharmaceutical in question has been initiated before. Thus, pharmaceuticals that are already on the market and whose field of application will be extended are not automatically subject to the mandatory assessment.

Other pharmaceuticals that have been placed on the market before 1 January may only be assessed if they contain a new active substance. In more detail this means that the G-BA may not assess pharmaceuticals that are no longer subject to data exclusivity or whose active substance was already placed on the market in another pharmaceutical and that pharmaceutical is no longer subject to data exclusivity. The G-BA may not even assess these pharmaceuticals under a discretionary assessment.

Thus, an assessment may generally only be made as long as the first pharmaceutical containing the active substance in question has data exclusivity. Generic pharmaceuticals, therefore, may not be assessed by the G-BA.

Requirement to submit a dossier

For the mandatory assessment, the company has to submit a dossier without being requested to do so by the G-BA if:

- the pharmaceutical is launched for the first time after 1 January and its active substance is on the German market for the first time; or
- the pharmaceutical receives a line extension and an assessment for that pharmaceutical has been initiated before.

The Ordinance on the Early Benefit Assessment sets out the corresponding deadlines for the submission of the dossier.

If the G-BA wants to assess a pharmaceutical at its discretion, it has to request the dossier from the company. Furthermore, the G-BA has to grant the company at least three months to submit the dossier. If the company misses the deadline, the extra benefit will be deemed not proven. However, in the case of a mandatory assessment, this only happens if the G-BA has additionally explicitly requested submission of the dossier.

Comparable therapy

The company may obtain advice from the G-BA before an assessment takes place. Within the scope of this advice, the company has a right to present its views on the determination of the comparable therapy. The company and the G-BA can also negotiate on the comparable therapy decision. The G-BA, however, will usually unilaterally determine which product is to be the comparable therapy.

All companies concerned have a right to present their case. This right to be heard, however, is not explicitly regulated by law. As the comparable therapy will be fixed for an entire class of active substances, this can include companies not directly involved in the assessment. Apparently, there will only be one comparable therapy determined for every indication.

The G-BA will tend to choose as the comparable therapy the one that has the lowest price. However, it must give preference to those comparable therapies which are able to prove a higher benefit with higher evidence.

A different comparable therapy has to be determined for every indication (as the case may be); accordingly, a pharmaceutical may have an extra benefit for one indication and have no extra benefit in others. However, there will only be one reimbursement price for the pharmaceutical, which will be valid for all indications even if the extra benefit differs according to indication.

References

1. *New German healthcare reform law to significantly change pricing system, Regulatory Affairs Pharma, 19 November 2010*

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