The medicine of the future needs a modern AMNOG



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>> The coalition agreement states: "We will make Germany the world's most innovative chemical, pharmaceutical and biotechnology location." That is a smart decision. The healthcare industry is a sector that stands for innovation, economic growth, high-quality jobs and health. It is rightly seen as a leading and key industry. At the same time, medical progress is booming. We have never been better at treating serious illnesses such as cancer, cardiovascular diseases such as high blood pressure and respiratory or rare diseases. The pipelines of research-based pharmaceutical companies are well filled. We are working with great commitment on the medicine of the future - for the benefit of patients and society.

However, innovations do not always have an easy time in the healthcare system. The AMNOG procedure is increasingly becoming a barrier to access for innovations because it dates back to a different era. Gene and immunotherapies and personalised medicine were still in their infancy, and research into rare diseases was only just gaining momentum. However, this has fundamentally changed the way we organise our clinical trials. Because medicine can intervene much more precisely, study populations are now much smaller. This is electrifying news because it increasingly allows us to develop a therapy that is as personalised as possible, taking into account genetic, molecular, biological and personal factors. This is the promise of personalised precision medicine: it can provide the right therapy for the right patient at the right time. Shouldn't we be doing everything we can to realise this?

However, small patient groups present us with major but solvable challenges when it comes to obtaining evidence. Unfortunately, the current situation is that today's innovation meets yesterday's methodology. In the worst case, this leads to a new therapeutic approach being denied benefit - simply because the system is not able to quantify the degree of innovation and does

not take into account globally recognised scientific advances, as is the case in the USA. However, this means that sick people cannot benefit from certain new drugs. The implication is that the current AMNOG system does not fulfil its purpose of ensuring access to innovation.

Next-generation AMNOG: key for Germany as a premium location

In order to promote innovation and ensure access for patients, the AMNOG must be radically modernised in order to be equipped for the innovations of today and tomorrow. Above all, medical progress needs to be consistently incentivised - so that Germany remains an attractive location for pharmaceuticals. We need a next-generation AMNOG.

Above all, it must become more flexible. Rigid adherence to traditional study structures, some of which are scientifically outdated, often leads to methodological dead ends and places narrow limits on modern benefit assessment. Alternative and adaptive study designs are also necessary. We need greater acceptance of indirect comparisons, especially for rare diseases. Single-arm, non-comparative authorisation studies should be considered in the early benefit assessment in combination with indirect comparisons or real world data (RWD).

The use of the latest internationally recognised clinical standards and the best available evidence is central to the contemporary assessment of innovative therapies. Particularly in the case of smaller subgroups or rare diseases, traditional evidence generation via large, randomised studies is often not possible. For this reason, centralised indication registers must be set up and high-quality register studies established in order to systematically record care data. We owe it to people with such diseases that synthetic data and new data sources can be utilised. This is because they are the key to a broader evidence base - and therefore to better medicines and better care.

Developing innovative medicines: Planning certainty is a must

The development of innovative drugs is complex and takes years, sometimes decades; planning reliability is therefore crucial for the pharmaceutical industry. Short-term changes to the comparator therapy in ongoing procedures jeopardise this. One flaw in the AMNOG is that innovation leaps are often compared with a generic drug as a comparator therapy - for example in an indication such as high blood pressure, where the last innovations were around 20 years ago. This can lead to therapies with breakthrough potential not being available. This is already a reality today: 19 drugs that are considered "breakthrough" therapies in the USA are currently not available in the European Union.

Planning security - this also applies in particular to unforeseeable price fixing, additional discounts or combination discounts born out of necessity. The SHI Financial Stabilisation Act has shown that such measures do more harm than good. The "AMNOG guard rails" implemented there have brought a fraction of the intended savings, but have caused a great deal of damage. Medicinal products with little additional benefit are treated in the same way as those without additional benefit. As a result, the added value is not honoured; solid refinancing of research efforts is made impossible. The original logic of the AMNOG, that what is better is rewarded better, is thus undermined. The guard rails must be abolished.

New thinking: spending on healthcare is an investment for tomorrow

In general, there is a danger that the holistic relevance of healthcare will be lost sight of when looking purely at costs. New medicines not only create individual benefits for sick people, but can also lead to financial and resource savings for society as a whole. A healthy population is a crucial prerequisite for a country's prosperity. Spending on health is an investment in the future. This must be the guiding principle when we think about the urgently needed reforms in the healthcare system.

For an innovative, healthy and economically prosperous Germany, we now need a comprehensive AMNOG reform: more flexibility in the process, the use of internationally recognised clinical standards and the best available evidence, openness towards new reimbursement models such as "pay for performance".

The AMNOG is unfortunately outdated. We now urgently need a reform and modernisation - for more medical progress, more security of supply and as a decisive impetus for a premium pharmaceutical location. <<

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