Roche Pharma on the HSK: 'Innovations under pressure: Do cutting-edge research & medicine have a future?'

AMNOG 2.0 for 'special therapeutic situations'

'Innovations under pressure: Do cutting-edge research & medicine have a future?' This was the title of this year's press dinner organised by the research-based pharmaceutical company Roche on the occasion of the Capital City Congress 2024 - once again at the Austrian restaurant Ottersbach zu Berlin with probably the best veal cutlets west of Vienna. This time, the speakers were Prof Wolfgang Schütte, Medical Director, Clinic for Internal Medicine II - Pneumology at the Martha-Maria Halle-Dölau Hospital, who addressed the topic of 'Clinical research: Is Germany losing touch?', and Friedrich Fichtner, Access Lead Strategic Pricing & Reimbursement at Roche Pharma AG, who explained in his presentation why an AMNOG 2.0 is needed. Fichtner's presentation is the focus of this report.

>> ‚Why do we need an AMNOG 2.0?' Market Access specialist Friedrich Fichtner began his remarks with this rhetorical question. As he said, his aim is not to shed light on what is good today, but above all on what needs to change so that progress and innovation can continue to be reflected in the German system in the future. Fichtner went on to say that the 'desired balance between innovation and affordability in the system' must ultimately be achieved.

According to Fichter, the first question that needs to be asked is what progress in medicine actually is. Using the example of oncology, he emphasised that today we no longer have to talk about survival rates, but rather about the probability of a cure. Since the 1970s, this has increased on average across all indications from around 25 per cent to a good 60 per cent. According to Fichtner, this is due to the transition from the 'age of chemotherapy' to the era of 'drug therapy' and 'cancer immunotherapies' with completely new mechanisms of action at the beginning of the 2000s, through to targeted therapies such as antibody therapy. And according to Fichtner, the next leap in innovation is just around the corner: in mRNA-based treatment options and vaccinations against cancer.

All of these innovations, supported by corresponding step innovations, would make an important contribution to patients, which would translate into a longer life. However, according to Fichtner, there is one caveat: 'Provided these innovations reach the patients.' According to him, this requires 'a system that recognises progress and innovation and ideally also rewards them'.

With these words, the market access specialist from Roche came to the AMNOG benefit assessment procedure, which, introduced in 2011, is a system that is not only 'getting on in years', but has also been watered down or actually damaged by reforms. However, his main point of criticism is that the AMNOG is primarily optimised for classic therapeutic situations and aims to assess the benefit for large populations using controlled trials (RCTs) that are relatively easy to carry out. However, this ignores the fact that there are now 'special therapeutic situations', particularly for novel therapies, for which RCTs are not readily possible on the one hand, and for which there is only justifiably limited evidence at the time of authorisation on the other. Fichtner: 'This unbalances the system.' On the one hand, the current AMNOG would no longer be able to include innovations in the system, let alone provide them with an appropriate price in the sense of fair pricing. In principle, this applies to all special therapy situations that - according to Fichtner - 'simply no longer fit into this system', such as ATMPs and gene and cell therapies, some of which now even promise a cure, but which cannot yet prove at the time of authorisation whether this 'promise of a cure really works in the long term'.



To make matters worse, RCTs with very small populations - often only 50 patients are affected in Germany - are not technically possible without further ado. And if they are, such RCTs cannot be statistically validated, which all in all means that such innovations are not recognised as having an additional benefit for purely formal reasons. This, in turn, means that no price premium can be negotiated compared to the comparator therapies despite a patient-relevant additional benefit and therefore innovative treatment alternatives are not available on the German market.

According to Fichtner, the framework agreement would therefore have to be amended at G-BA level so that it is possible to deviate from the dogma of overall survival in favour of other endpoints for these treatment situations. Fichtner: 'To do this, you have to take a close look at each individual indication and define the appropriate endpoints.'" <<

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Citation

Stegmaier, P.: AMNOG 2.0 for 'special therapeutic situations' (04/24), S. 24. http://doi.org/10.24945/MVF.04.24.1866-0533.2636