SVR Report 2025 'Prices of innovative medicines in a learning healthcare system'

Pharma funding exclusively from tax revenue

'Prices of innovative drugs in a learning healthcare system' is the title of the current report 2025 (1) by the German Council of Economic Experts for the Assessment of Developments in Healthcare and Long-Term Care (SVR) - a topic, incidentally, that the Council chose independently in its own interests. In this report, the Expert Council, which is responsible for health and care (but not for economic or location promotion) and was appointed for this purpose by the Federal Ministry of Health, endeavours to develop a new approach to the German healthcare system based on the 1997 special report entitled 'Healthcare in Germany. Cost Factor and Future Industry' (2): In its 170-page work, it outlines measures within the framework of the role assigned to it, the implementation of which is intended to maintain a needs-based and economical, solidarity-financed supply of innovative drugs, but also those that can simultaneously promote Germany as a pharmaceutical location with suitable means beyond the SHI/ICP cost level.

>> The SVR justifies its excursion into the remit of the German Council of Economic Experts (3) with the Federal Government's strategy paper published in 2023 on 'Improving the framework conditions for the pharmaceutical sector in Germany' (4). In this paper, the pharmaceutical industry was described as a 'key sector' and 'leading industry of the German economy'. According to the SVR report, the rationale behind the promotion of Germany as a pharmaceutical location was the 'importance of the pharmaceutical industry for the national economy on the one hand and for ensuring the best possible care for the population on the other'. The latter is based on the assumption of a causal relationship between a strong, local pharmaceutical industry and fast, reliable access to effective medicines.

The SVR thus implicitly assumed a connection between location policy and the pricing of innovative medicines. According to the report, such a link between price regulation and location decisions is also used by the pharmaceutical industry as an argument in favour of certain price and sales expectations. Here, the SVR refers, among others, to Han Steutel, President of the German Association of Research-based Pharmaceutical Companies, who wrote in July 2023 in the foreword to the joint study 'Pharma- Innovationsstandort Deutschland' (5) by vfa and Kearney: 'The SHI Financial Stabilisation Act has recently significantly worsened the framework conditions for the reimbursement of innovative drugs in Germany, which is likely to further accelerate the negative trends in research.'

For a long time, this link had only been an argument in the political discussion about drug prices. However, as part of the Act to Combat Supply Bottlenecks for Off-Patent Medicinal Products and to Improve the Supply of Paediatric Medicinal Products in 2023 in Section 130a (8a) SGB V, 'an explicit link between location promotion and pricing has been implemented by law for the first time'. Similarly, with the entry into force of the Medical Research Act (MFG) in October 2024, such a direct link between price regulation and location policy was also enshrined in law in the area of patent-protected medicinal products. Specifically, this concerns exemptions from the guard rails introduced in 2022: if at least 5% of the trial subjects in the authorisation studies for an innovative medicinal product were recruited in Germany, the pharmaceutical company is granted an exemption from these guard rails for a period of 30 months (Section 35a para. 3, Section 130b para. 3 SGB V).

This brief excursion makes it clear why the German Advisory Council on Health also addresses issues of economic and location promotion in its report. After all, there are many overlaps between health-related and macroeconomic issues, which can encourage or lead to a focus on neighbouring topics. As explained in the report, the state not only has direct ways of supporting the pharmaceutical industry, such as through support measures (e.g. subsidies, tax benefits or infrastructure investments). There are also indirect ways in which the state can regulate pricing through its legislation and thus promote the industry by securing revenue. Because in the latter case the costs are borne by the SHI and private health insurance funds, the 'social benefit of economic promotion' must be weighed against both the costs of direct promotional measures and the 'indirect costs resulting from higher drug prices'. In this context, the possible effects of linking location policy and price regulation must be critically reflected upon and their congruence with the objectives of the AMNOG procedure must be reviewed: A central principle of the AMNOG procedure is that the negotiated price should reflect the additional benefit of the medicinal product. However, exemptions from the guard rails for economic policy reasons lead to price mark-ups that are decoupled from the additional benefit and influence the price level in the long term. According to the report: 'As soon as pharmaceuticals are subject to location-based price mark-ups, they can also increase the prices of subsequent innovations in future - if they are used as a comparative therapy - even if these were not researched and developed in Germany.' According to the SVR, this leads to a distortion of prices: 'This is a cause for concern, as the promotion and financing of private-sector R&D activities motivated by economic policy is not one of the tasks of the SHI system enshrined in the German Social Code Book V.' In addition, financing the promotion of the location through health insurance contributions would lead to rising contributions for SHI members, employers, private health insurance policyholders and the allowance and thus to an increase in non-wage labour costs.

The SVR report does not stop at these

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statements, but goes on to point out that there are various important factors for location decisions, including the costs associated with conducting clinical trials for the location decision, proximity to key opinion leaders (KOLs), the reputation of a location with regard to good clinical practice and reliably high trial quality and, above all, parameters that favour the rapid implementation of clinical trials. Secondary, on the other hand, is the effect of price premiums on Germany as a location - this is 'economically dubious'. There are studies that show a negative correlation between exposure to price regulations (and therefore lower price levels), but R&D investments tend to be recorded across locations at a global level and therefore do not allow any clear conclusions to be drawn about location-related investment decisions. An analysis of more recent data from 2000 to 2017 also showed that price regulation and R&D investment volumes do not correlate significantly, but that R&D investments are primarily dependent on company-specific factors. In addition, the studies analysed by the SVR were based on a temporal relationship between price regulation and R&D investments of one to two years, which, according to the report, is unlikely to correspond to the actual timeline of pharmaceutical R&D decisions. The SVR's conclusion: 'Overall, the attractiveness of the national sales market is unlikely to play an overriding role in the choice of R&D locations, as the pharmaceutical market is global and generally characterised by low transport costs. If several potential locations equally fulfil the most important decision criteria, differences in national price regulation could also come into play. However, in view of the large number of factors that decision-makers in pharmaceutical companies consider to be significantly more important for the choice of location, the Council believes that the effect of indirectly subsidising the pharmaceutical industry through generous price regulation is low.'

Nevertheless, in its report, the Council makes recommendations for the sustainable promotion of Germany as a pharmaceutical location. This is because the pharmaceutical industry is an important sector for the German economy and society and contributes to the preservation and generation of prosperity through secure jobs and investments. The Council therefore considers the promotion of Germany as a centre for the pharmaceutical industry to be an economic and socio-political objective. According to all the findings available to the Council, the most important criterion for location-related investment decisions in pharmaceutical research and development (the decisive value creation step in the industry) is the quality of the research location and the combination of a sufficiently large pool of highly qualified specialists and excellent, publicly funded basic research. According to the report, efficiency and speed are also of great importance, particularly when conducting clinical trials, for which the organisation of administrative processes and the options for using national digital healthcare infrastructure are important. However, excessive bureaucratisation and a still incompletely digitalised, poorly networked healthcare system have led to significant delays and competitive disadvantages in Germany compared to other countries.

Based on the above analysis, the Council recommends that the expansion of a networked, digital research (data) infrastructure should also be emphatically prioritised as part of location promotion. Special attention should be paid to this project, which is already part of the German government's pharmaceutical strategy, as part of the establishment of coordinated health registries. A networked registry structure could also significantly accelerate the implementation of clinical trials (e.g. through faster recruitment) and provide a basis for innovative study designs such as transcriptome-based expression studies (TTEs) and platform studies in the future. In addition, such a structure would enable long-term evidence generation independent of pharmaceutical companies and would therefore be of great benefit to the solidarity community. Particularly in view of the increasing importance of machine learning in basic pharmaceutical research, pharmaceutical companies' access to health data should be discussed.

However, as there is no empirical evidence to suggest a direct or indirect link between price regulation and location factors as an effective measure to promote the German pharmaceutical industry and a distortion of the price signal could lead to an increase in the price level in the long term, the Council is therefore in favour of withdrawing the location-related exceptions to the guard rails adopted in the MFG. Instead, it recommends that pharmaceutical site promotion measures be financed exclusively from tax revenues and not be subject to the complex redistribution mechanisms of the SHI and PHI systems. Instead, the Council recommends identifying existing competitive advantages and consistently building on these. Consideration should be given to bundling funding for expansion measures geographically in order to achieve agglomeration effects. The Council also considers the establishment of a central contact point for the smooth initiation of clinical trials to be particularly promising. In view of the rapidly advancing initiatives in Denmark and the UK, Germany is at risk of becoming less attractive as a location for clinical trials, which could further reduce the already declining number of clinical trials (although still in the European midfield). In addition, innovation monitoring in combination with improved framework conditions for venture capitalists would be a promising starting point for further expanding the translation of basic research. <<

by: MVF Editor-in-Chief Peter Stegmaier

Literature:

1: https://t1p.de/j99il
2: https://t1p.de/i79zi
3: https://t1p.de/6ide5
4: https://t1p.de/duin7
5: https://t1p.de/4olex