Symposium 40 years of the German Council of Economic Experts and the SVR Report 2025

Focus on the value-based pricing system

At the end of June, a symposium was held at the 'Hotel Aquino' conference centre in Berlin to mark the 40th anniversary of the German Advisory Council on the Assessment of Developments in Health Care and Nursing (SVR) and the publication of the SVR report 'Prices of innovative drugs in a learning healthcare system'. Following a keynote speech by former Bundestag President Prof Norbert Lammert, two discussion rounds on the role of scientific policy advice and the Council's recommendations as well as a welcome address by Federal Minister of Health Nina Warken, the two Council members Prof Dr Leonie Sundmacher and Prof Dr Jochen Schmitt presented important key findings of the current SVR report in the second part of the event.

>> 'At a time when trust in political institutions and processes has declined, an independent scientific foundation is an important source of inspiration. Its well-founded findings broaden the social basis for an objective dialogue, which in turn can regain lost trust in our political system.' With these words, Federal Health Minister Nina Warken emphasised the importance of the German Advisory Council on the Assessment of Developments in Health Care and Long-Term Care (SVR). According to Warken, the population rightly expects health policy decisions to be made on the basis of facts, research and responsibility and not on the basis of vested interests or short-term moods. The Expert Council makes an essential contribution to this against the backdrop of the increasing spread of disinformation - which makes institutions that are committed to independent scientific principles all the more important. The current SVR recommendations and analyses could provide important impetus. For example, the aspects of 'evidence assessment' and 'pricing' of new drugs - keyword 'guard rails' - would be discussed in the pharmaceutical dialogue with all stakeholders. It is also particularly important to further promote and facilitate research and development, for example by reducing bureaucratic hurdles in the planning and implementation of clinical trials. However, this also includes 'enabling data protection' and an expanded and established electronic patient file.

Schmitt: a lack of evidence

Two important 'pillars' of the image of a foundation used by Nina Warken are the two SVR members Prof Dr Leonie Sundmacher and Prof Dr Jochen Schmitt, who presented selected individual results of the current report to the participants of the symposium '40 Years of the German Council of Experts'. 'We are faced with the major challenge of reviewing the evaluation and pricing mechanisms if we want to guarantee insured persons access to cost-effective and needs-based pharmaceutical care in the future,' explained Schmitt, Director of the Centre for Evidence-based Healthcare (ZEGV) at the University Hospital and the Carl Gustav Carus Faculty of Medicine at TU Dresden and a member of the SVR since 2023.

As the German Social Code requires the price to be closely linked to the actual patient benefit in standard care, he took a chart from the 2025 report, which shows the 'Results of the benefit assessments since 2011 at procedure level, subgroup level and patient level' (Fig. 1).

While an additional benefit relevant to patients could still be demonstrated for just under half (46.9%) of the innovative medicines at the decision level (left chart), the results at the patient level (right chart) were

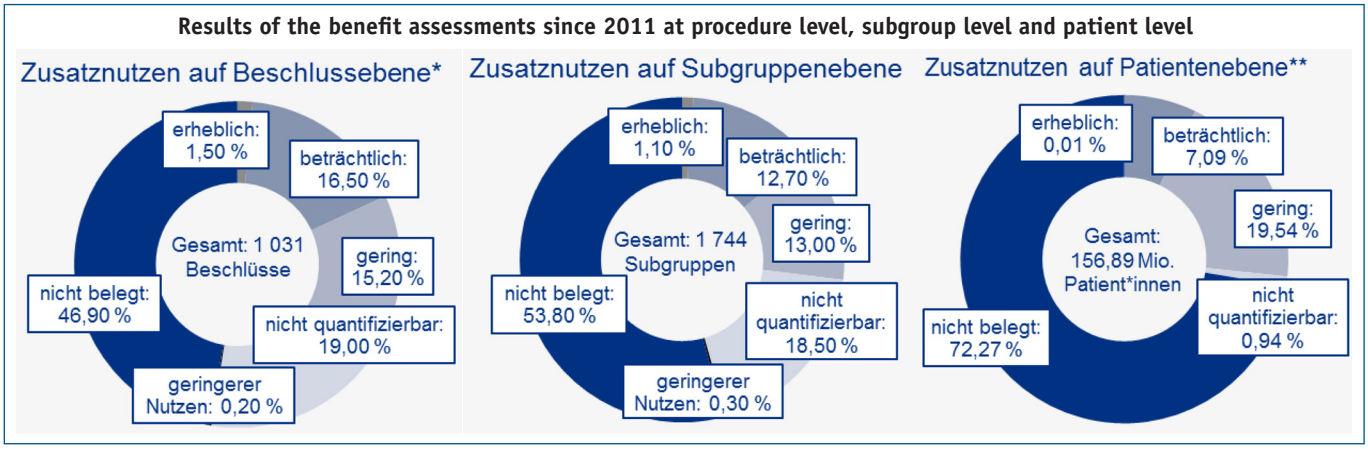


Fig. 1: Results of the benefit assessments since 2011 at procedure level, subgroup level and patient level. Legend: * The highest additional benefit awarded was assumed for each decision. ** Number of patients with the respective added benefit; a lesser benefit was attested at patient level for ~0.01% of patients. The figures do not add up to 100% as they were rounded to two decimal places. Source: own presentation based on the AMNOG Monitor of the Institute of Pharmacology and Preventive Medicine, as at the end of 2024, from: SVR Report 2025, page 31.

'somewhat more sobering': no additional benefit could be demonstrated for almost three quarters (72.27%) of the target population. According to Schmitt, the extrapolation made here is also subject to the assumption that the evidence from the clinical trial can be directly transferred to standard care, which is not necessarily the case: Schmitt: 'We really have a lack of evidence here, which is also a reason for this result.'

In addition, there is the particularity that more and more customised, individualised therapies are coming onto the market. This is a major methodological challenge, as large double-blind placebo-controlled studies - the gold standard of benefit assessment and EBM - cannot always be implemented here. To better measure effectiveness, the Council recommends the use of innovative study designs, such as platform studies, register-based randomised studies or target trial emulation (TTE).

According to Schmitt, it is necessary to overcome the efficacy-efficiency gap, as the benefit in standard care is decisive for patients, but the benefit in everyday care can differ significantly from the benefit determined in clinical trials - this is not always the case, but it is possible, and this is mainly due to two factors. One is due to a difference in the populations: According to Schmitt, strict inclusion and exclusion criteria in clinical trials result in a selection of particularly healthy people and those with high adherence, which can differ significantly from the population in standard care. The second, more important argument, however, is that the care processes differ greatly between the setting in randomised controlled trials and standard care.

For this reason, more healthcare-related data should be used. This would be data that is generated in the context of standard care - for example from indication registers - and then used in addition to randomised controlled trials. Schmitt's demand: 'To make this possible, we must finally implement a coordinated research data infrastructure in Germany.' The first important steps towards this have been taken with the Health Data Utilisation Act. But now we need to 'step on the gas as quickly as possible and catch up internationally' in order to remain competitive. This is not only important for the supply of medicines, but also for Germany as a business location.

Bureaucratic and data protection hurdles should also be removed. Here, the Minister spoke of 'enabling data protection', which the Council could only endorse. However, data linkage, i.e. the connection and linking of data from different sources, should also be made more possible. So far, many things have failed due to bureaucratic and official procedures. His final plea: 'We need key procedures that review the benefits of medicines in standard care and, in the case of new important evidence, also a new assessment of patient benefit with subsequent renegotiation of the price.'

Although this is already possible, it is almost never done - simply because the necessary data and new evidence from healthcare are usually not available. 'Our vision is that

Key note by Prof Norbert Lammert: 'Politics and scientific advice'



According to Lammert, former President of the German Bundestag and Chairman of the Konrad Adenauer Foundation since January 2018, the relationship between politics and science is 'certainly a special, occasionally tense one' and is also 'by no means only characterised by devout mutual admiration'. For the seasoned politician with well over 30 years of experience, it is plausible to observe a 'mutual mistrust' that is characterised not least by the assumption that he 'does not have the qualifications for the respective tasks that are particularly important for their careful completion'.

This assumption, which he believes is not entirely unfounded, has less to do with a problem of understanding or communication than with the fundamentally different tasks: 'Science wants to know what is and why it is the way it is. Politics wants to change what is or prevent what is from changing.'

At this point, Lammert quoted Albert Einstein with the words: 'How is it that nobody understands me and everyone likes me?' This witty remark goes to the heart of the issue and is also the dream of every politician, especially during election campaigns: 'Nobody understands me, but everyone likes me'.

Scientists, on the other hand, are in a 'doubly luxurious position' according to Lammert, because it is almost irrelevant for science and its findings whether they are understood and, quite literally, whether they are liked. Nevertheless, the scope of science and its practical possibilities are just as limited - albeit differently - as those of politics. Lammert: 'On sober reflection, both are in a relationship of mutual dependence: neither can politics isolate itself completely and certainly not permanently from scientific findings, nor is science completely independent of the rights and resources that the respective political system makes available to it or occasionally denies it.' Nevertheless, 'politics, not science, must decide what is right and what is wrong', said Lammert, quoting former German President Johannes Rau, who was 'almost right'. Because: 'Of course politics must decide responsibly. But it cannot decide what is right and what is wrong. For the simple reason that they don't know.'

And because it does not know or cannot know many things, it needs 'procedures to reach decisions', according to Lammert. In principle, two variants are available here: the authoritarian and the liberal variant. One is decision-making by command and the other is decision-making through discourse. The latter is one of the great achievements of our civilisation, namely to establish what should apply through majorities. Moreover, it is part of the brilliant logic of a democratic system that decisions reached in this way hold until other majorities decide something else, which - Lammert realises - does not necessarily make them more correct, but does have a claim to validity. Incidentally, Frederick the Great, who always considered the democratic theories that were gradually developing in his time to be quite absurd, used precisely this reasoning to dismiss them with the rude remark: 'Majority decisions mean the rule of nonsense'. Only a system with clear responsibilities and the ability to decide independently of such silly considerations could actually enforce what was necessary and right for a society. For Lammert, this would be a relatively strong argument if 'authoritarian regimes had not repeatedly and demonstrably made even more nonsensical decisions than can be observed under the conditions of democratic decision-making and decision-making'.

In social reality, we are dealing with two facts and perspectives that cannot be mutually compensated: Facts and judgements, because the assessment of facts is always associated with judgements which, for their part, elude conclusive, let alone scientific, proof.

we, as a community of solidarity for innovative medicines, can create an evolutionary strategy in which we can regularly re-evaluate with the help of healthcare data.' At this point, Schmitt referred to a social court ruling (1) from December 2024, which no longer allows the Federal Joint Committee to initiate a new benefit assessment based on new evidence. Schmitt: 'We are calling on politicians to urgently remedy this and correct the law. Otherwise, social insurance and the social insurance system will not actually be able to fulfil their mandate to provide medicines in line with demand and then economically.'

Sundmacher: Value-based pricing system

Prof Dr Leonie Sundmacher, Professor of Health Economics at the TUM School of Medicine and Health at the Technical University of Munich (CHEC-TUM), Scientific Director of the Munich Center for Health Economics and Policy (M-CHEP) and SVR Council member, focused in her presentation on the dualism of pricing and location promotion. According to Sundmacher, the Council has found 'no reliable evidence' for the thesis that a high price level not only ensures rapid access to innovations, but also leads to more industry settling here. This also makes sense because pharmaceutical companies are, after all, internationally active groups and are generally not dependent on immediate proximity to the sales market.

For the report, the Council analysed how other European countries deal with the issue. 'There is a coexistence of strict pricing policies on the one hand and a successful pharmaceutical sector on the other,' explained Sundmacher. To prove this, she cited a few examples: Denmark has a strict pricing policy and a cost-benefit assessment, but conducts more clinical trials in relation to the population than Germany. Spain, which ranks third in the world in terms of conducting clinical trials, also has a cost-benefit assessment. The same applies to Ireland, which is gradually becoming stricter in its pricing policy, carries out a cost-benefit assessment and, despite an explicit threshold value of 45,000 euros per QALY (quality-adjusted life years), also has a very flourishing pharmaceutical industry. According to the economist, this is of course also due to the low corporate tax rate of 15 per cent. The UK and France, on the other hand, have pharmaceutical budgets, but also a flourishing pharmaceutical sector.

Knowing this, the recommendation, according to Sundmacher, is that the Council should expressly advocate the promotion of the pharmaceutical industry in Germany, but favour economic policy instruments for this purpose. 'We do not consider a combination of pricing on the one hand and location promotion on the other to be expedient for promoting the pharmaceutical industry,' explained Sundmacher. The same applies to exemptions such as the AMNOG guidelines - particularly in relation to medicines with unproven additional benefits.

For this reason, a conceptual separation of location promotion on the one hand and pricing policy on the other was made in the report. The aim of this report is to show instruments and ways in which the additional benefit can be closely linked to the reimbursement amount - with the aim that the available money can be spent on real innovation.

With regard to pricing policy, Sundmacher explained that the Council recommends in its 2025 report that pharmaceutical companies should continue to be free to choose a price and display it as a list price after market launch. However, as an innovation in pricing, a confidential discount on the list price should be introduced. This is to be based on the level of the annual therapy costs of the zVT, with justified exceptions permitted. As soon as a new reimbursement amount has been found, the difference between the reimbursement amount and the new interim price is to be reimbursed from day 1.

However, according to Sundmacher, Germany finds itself in a situation in which the finances of the statutory health insurance system have come under pressure and the cost block of pharmaceuticals has moved into second place with an upward trend, so the Council is proposing a further means of control. Similar to France, Spain, Italy and the UK, a global pharmaceutical budget is to be introduced. In other words, a prospective budget for annual expenditure on innovative medicines is to be introduced, with pro rata repayments based on the respective market share being due retrospectively if the budget is exceeded.

According to Sundmacher, exceptions should also be possible here, and an extra-budgetary part is also planned. Furthermore, the budget would not have to be adjusted annually. In an international comparison, a global budget is linked to gross domestic product, but it could also be linked to the development of SHI revenue. Sundmacher: 'In this sense, we recommend the budget as a protective shield for controlling expenditure in order to keep SHI costs within a limited framework.' However, such a budget only makes sense if both the therapy costs and the additional benefit are closely linked to the reimbursement amount. Because: 'Budgeting only makes sense in a value-based pricing system.' <<

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Literature:
1: https://t1p.de/rnnip

Citation

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