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A plea in favour of the possibility of confidential prices

>> Based on the Federal Government's pharmaceutical strategy presented in December 2023, there is currently a renewed - and more passionate - debate than in 2016 about replacing the publicly listed reimbursement amount for new medicinal products with a confidential reimbursement amount. The option of confidentiality was recently introduced into the legislative process for the Medical Research Act (MFG). According to the interpretation, the non-listing of the reimbursement amount in public registers is to be interpreted as an 'optional' regulation, which indicates that further room for manoeuvre is to be created for confidential price discounts, particularly in complicated negotiation situations. Confidentiality itself would thus also become a negotiation criterion and replace the EU prices used to date, which, according to the wording of the MFG, would no longer provide any meaningful price orientation if German prices were confidential. A departure from the previous practice is that the pharmaceutical company will have the sole right to apply for confidentiality, meaning that it can enforce confidentiality even against the will of the payers. At the same time, however, they will have to compensate for any overpayments by the statutory health insurance funds for the surcharges for pharmacies and wholesalers (as these are calculated according to the public list price and not the 'true', now confidential reimbursement amount).

Before, during and after publication of the MFG draft, the idea of confidentiality met with great resistance from payers. Fears were expressed that confidential prices would apply to the entire patent market in future and that this lack of transparency could lead to additional annual expenditure in the double-digit billion range in the medium term. But is it at all realistic that the option of confidentiality (at the given costs) could be considered for all medicinal products? The rather mixed feedback from the industry so far suggests the opposite. As part of the DAK-AMNOG Short Report 2024, we conducted a systematic process evaluation and asked various stakeholders for a statement.1 The following comparison is intended to show whether the arguments presented against confidentiality really hold water.

Advantages of confidentiality (or non-listing)

The potential advantages of non-listing are obvious: ideally, payers can negotiate higher discounts. At the same time, the industry can plan better, particularly in the case of cross-border price discrimination, as negative effects from a quasi-publicly visible negotiation result in Germany can be avoided. Or to put it another way: higher discounts are conceivable if the whole world does not benefit from them, but only Germany for the time being. In individual cases, this could also prevent an effective product from leaving the market altogether.

Arguments against confidentiality and their validity

1st argument: Confidentiality increases the lack of transparency in pricing and thus raises the price level.

Counter-argument: Transparency of prices does not currently lower prices, but on the contrary increases them, because a discount in Germany also lowers prices in other countries via the system of international price referencing. Companies are therefore less inclined to grant higher discounts than in the scenario of confidential prices, which have no influence on prices in other countries. All comparable industrialised countries in the world behave similarly for this reason and agree on confidential prices.

2nd argument: Confidentiality of prices is a gift from the federal government to the pharmaceutical industry.

Counter-argument: The aim of confidentiality is to increase the possible discount in negotiations (which have always been confidential). In this respect, both contracting parties should benefit, especially the health insurance funds. This argument could be strengthened if confidentiality were not to be determined unilaterally by the industry. Rather, it could be organised as part of the negotiation process between providers and health insurance funds 'at eye level'.

3rd argument: Confidential prices lead to more bureaucracy.

Counter-argument: Processing is made easier by the fact that the manufacturer would have to bear the overpayment at the retail stages. In addition, the system is familiar with backbilling due to the discount agreements for generics, the backbilling of the discount for new launches (i.e. between the 7th and 12th month after market entry) and occasional confidential price agreements within the framework of the existing negotiation system. Enormous additional auditing costs would only arise if confidential prices were agreed for all new medicinal products in future. This cannot be assumed at present.

4th argument: The financial benefits of confidential prices accrue primarily to pharmacies because their fees are based on the higher list prices.

Counter-argument: The higher costs for distribution are likely to ensure that confidential prices are not used very frequently, but only in special cases where the product might otherwise disappear from the market altogether. In this respect, the financial impact will be manageable and will be borne by the manufacturers. It is not yet possible to estimate whether additional cash register-specific discounts are possible and, if further discounts were no longer compatible, would have to be compared with the level of confidential discounts.

5th argument: Confidential prices are not confidential at all, because many people in Germany would know them.

Counter-argument: It still makes a difference whether it is a confidential price or an official selling price. Moreover, the institutions that would have to be informed of

the confidential prices would be obliged to maintain confidentiality, so it cannot become an official business model to pass on confidential price information.

6th argument: If prices are confidential, they can no longer be used as the price of the appropriate comparative therapy.

Counterargument: Of course, the competitor's confidential price would be disclosed (confidentially) in the event of price negotiations. For this reason, the amendments to the MFG in the draft bill also included the G-BA as an information reporter.

7th argument: The reversal of pharmaceutical expenditure significantly impairs the liquidity of the health insurance funds.

Counter-argument: The segment of confidential prices is unlikely to become a mass phenomenon, but will only be used in individual cases. The liquidity effect thus clearly takes a back seat to the effect of lower expenditure (price effect).

8th argument: Confidential price discounts send the wrong signals regarding the economic efficiency of prescriptions by doctors' practices and hospitals.

Counter-argument: Exact prices are not necessary to assess the cost-effectiveness of a prescription. It is sufficient to know how the prices are ranked. It is obvious that generics have lower prices than innovative products whose price is confidential. Corresponding categorisations (e.g. in price classes) could continue to be published. In addition, the list price itself could also be a corresponding price signal if it is higher than the confidential actual price, but still accurately indicates the price ranking in relation to the competition.

9th argument: Confidential prices hinder antitrust control measures.

Counterargument: Confidential prices would have to be disclosed to the cartel office in the event of proceedings.

10th argument: Confidential prices abroad only make sense if there is a fourth hurdle.

Counter-argument: Confidential prices do not fundamentally change the current system of negotiating pharmaceutical prices. In this respect, such an option would have nothing to do with a system in which market access is only possible after negotiations have been concluded ('fourth hurdle'). In addition, the regulation could be further developed so that the manufacturer could no longer determine confidentiality unilaterally, but this would be the result of the negotiation process between companies and health insurance funds.

11th argument: Whether confidentiality has ever resulted in lower prices in other countries than without confidentiality has never been scientifically proven.

Counter-argument: Such proof is virtually impossible because there is no control group. However, one indication of the usefulness of confidentiality for payers is that almost all other countries worldwide use this instrument and have apparently had good experiences with it. In addition, the theoretical incentive structure is obvious.

12th argument: Health services research in the pharmaceutical sector will lose important information if prices are confidential.

Counter-argument: This is correct, but should not be a decisive argument for foregoing possible savings through confidentiality. Moreover, the analysis of quantitative effects on the supply of medicines is still not affected by confidentiality.

13th argument: Countries that reference their prices to Germany must pay higher prices themselves if prices in Germany are confidential.

Counter-argument: As Germany has a reputation for still agreeing comparatively high prices internationally despite the negotiations, this argument is not very strong. Countries such as the Netherlands have already removed Germany from their reference basket because they feared that it would have too strong a price-increasing effect on their own prices. Moreover, it is hard to see why only Germany should ensure international transparency when hardly any other healthcare system behaves in this way.

What happens next?

Three scenarios are now conceivable:

Firstly, non-listing survives the further legislative process in its current form (unilateral right of application of the pharmaceutical company).

Secondly, non-listing is implemented as a bilateral negotiation option for the industry and the SHI-SV. However, this would require the health insurance funds and other parties involved in the process to open up to this new (for Germany) instrument in price negotiations. This would address the concern that confidentiality would become the new normal in the AMNOG. If no agreements are reached by mutual consent after a reasonable period of time, the legislator could make further adjustments.

Thirdly , it is conceivable that the option of confidentiality could be 'swapped' for another AMNOG mechanism in the political discourse. However, abandoning the confidentiality option altogether could represent a missed opportunity. <<

Literature:
1: Greiner, W., Witte, J., Gensorowsky, D. (2024): AMNOG-Kurzreport 2024. Vertrauliche Erstattungsbeträge. Fluch oder Segen? Medhochzwei Verlag, Heidelberg.

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