

Are German health insurers obliged to purchase drugs by public tender?



Maren Bedau

Just three months ago, reforms to the German healthcare system came into effect bringing profound changes to the market for pharmaceuticals. Cost-benefit analyses and compulsory second opinions have been introduced into the prescribing process, and payers and care providers now have more power to negotiate. Bettina Tugendreich and Maren Bedau examine companies' legal rights in the face of the reforms.



Bettina Tugendreich

Since the right to negotiate discounts was granted to the statutory health insurance funds (Krankenkassen) last year, the insurers have signed rebate contracts with individual companies regarding the delivery of particular medications without a Europe-wide tender, in some instances with the requirement of specified maximum prices. As the signing of such rebate contracts – particularly those that are nation-wide – leads to a virtual market exclusion for other companies, vehement

discussion has broken out as to whether such rebate contracts without Europe-wide tenders should be allowed at all.

...rebate contracts as a reaction to the increase in expenditure

The expenditure on pharmaceuticals by the Krankenkassen rose to E23.7bn – an increase of 1.3% in 2006. In Germany, approximately 90% of the population currently falls under the Statutory Health Insurance System. In order to reduce expenditure by introducing elements of competition, the recent healthcare reforms granted the Krankenkassen the right to negotiate discounts with individual manufacturers of medicinal products. Rebates can only be granted to Krankenkassen, resulting in the exclusion as contracting parties of other institutions of the social insurance system, private insurers, wholesalers and pharmacies.

Germany's most recent Act to Increase Competition in the Statutory Healthcare Insurance Scheme (Gesetz zur Stärkung des Wettbewerbs in der gesetzlichen Krankenversicherung) includes various incentives for such agreements. Drugs subject to rebate contracts are exempt from certain prescribing restrictions such as bonus-penalty regulations (Bonus-Malus Regelung) and efficiency assessments. Under the bonus-penalty regulation, doctors are personally fined if they prescribe certain drugs above an agreed financial threshold, i.e. they are ordered to pay a "penalty". Since rebated drugs are exempted from penalty payments, physicians can prescribe these drugs without fear of being held liable for "unnecessary costs". Furthermore the pharmacies are now obliged to substitute prescriptions and to dispense pharmaceuticals which are subject to discounts as long as the physician does not explicitly specify in the prescription which product must be offered.

In July 2006, the Federal Joint Committee (Gemeinsamer Bundesausschuss) banned reimbursement for short-acting insulin. Barmer and Techniker, two of Germany's largest Krankenkassen, seized the opportunity to negotiate rebates with drug companies. This

gave them a competitive advantage in securing a share of the market. Barmer and Techniker have entered into to discount agreements with Lilly, Sanofi-Aventis and Novo Nordisk, which will allow the uninterrupted reimbursement of short-acting insulin products, as long as their prices do not exceed those of normal insulin.

Another attempt to make use of the new instrument caused widespread consternation within the pharmaceutical industry. Last year, the German general local health insurance fund (Allgemeine Ortskrankenkasse/AOK) tried to centralise negotiations concerning medicines discounts for 89 separate products with the industry so that drug prices would be uniform across the AOK's federalised, heterogeneous structure. The sixteen local health insurance funds of the AOK - operating separately in each state – wrote to all pharmaceutical producers on 31 October 2006 requesting offers for discount contracts. The plan is that for each agent rebate contracts will be signed with a maximum of three manufacturers who are able to offer this agent at the lowest price.

The industry feared that the AOK's large presence in the German medicines market – it accounts for more than 40% of all prescription medicines purchased – would ultimately affect its revenues if the health insurance fund used its position to force down prices. The German Cartel Office (Bundeskartellamt/FCO) became involved after Germany's four main industry associations lodged an official complaint about the AOK's centrally organised operative methods. The FCO confirmed that the proposals by the AOK to negotiate discounts on medicines centrally might have infringed German commercial law. However, the FCO stated that it could not commence proceedings against AOK due to legal restrictions but encouraged the associations to challenge the centrally organised procurement mechanism before the courts.

Two health insurance fund associations (Verband der Angestellten-Krankenkassen/VdAK and Arbeiterersatzkassen-Verband/AEV) have called upon pharmaceutical companies to make price offers, whilst the funds simultaneously advertise their own maximum price. VdAK and AEV only want to enter into rebate contracts with those pharmaceutical companies that accept the maximum prices offered. However, these maximum prices are often less than the current market prices.

Another Krankenkasse, the Barmer Ersatzkasse, has signed rebate contracts with the pharmaceutical companies Hexal and Stada, without any public notification nor any public tender process. Recently, the German association of generic drugs companies (Deutscher Generikaverband) filed a complaint with the European Commission and the German federal insurance authority against several

.....
 continued...

Krankenkassen. The association argued that the Krankenkassen had concluded rebate contracts in violation of European and German public procurement law¹.

... the public procurement law

Thus far in Germany, it has not yet been determined by the courts whether rebate contracts are governed by general German public procurement law – which is based on the adopted European Directive 2004/18/EG. Furthermore, it is also uncertain in which form – if at all – legal protection is available against contracts that have been signed without the issuing of a Europe-wide tender or that violate German public procurement law in some other way. The jurisprudence thus far in existence on this issue from the various competent courts – including the public procurement appeals board – is inconsistent. It can only be stated that the relevant judicial bodies, when requested in such cases, refuse to accept the legal responsibility to make a decision on such issues – with the exception of one decision from the Düsseldorf Higher Regional Court.

... Krankenkassen as “public contracting entities”

For some years it has been discussed whether Krankenkassen are required to publicly tender contracts. The jurisprudence is inconsistent². It is arguable in this situation whether Krankenkassen are considered to be public contracting entities. According to German public procurement law – which is in line with European requirements – Krankenkassen are only public contracting entities – see Sec. 98.2 of Act Against Restraints of Competition – when:

- their founding purposes are those of general public interest rather than commercial aims;
- they have legal personality; and
- they are predominantly financed, supervised or otherwise controlled by the state or by any other public body (state-proximity).

The first two requirements are not problematic. Krankenkassen are public bodies and have the appropriate founding interest – i.e. public interest – with regard to the maintenance, rehabilitation or improvement of public health. Krankenkassen are also – at least in the majority of cases – not commercially active. The discussion is therefore focused on the third requirement, that of required proximity to the state. Some experts argue that a predominantly state funding source is in place. The Krankenkassen are predominantly financed via mandatory payments required by law. Such indirect state financing would qualify the Krankenkasse as having the necessary state proximity. It is therefore argued that it makes no difference whether the state collects the contributions itself and then pays it to the Krankenkassen or whether the state merely makes the contributions mandatory by law. However, the leading opinion of the relevant literature on the subject – as well as the relevant jurisprudence – states that the Krankenkassen are at least subject to state control, due to the various opportunities that the public authorities have, to exercise influence and discretionary powers.

The Düsseldorf Higher Regional Court has, with its Decision of 23 May 2007, requested the European Court of Justice to rule on whether Krankenkassen are to be considered statutory contracting entities under European law³.

... exclusion of the use of public procurement law

Currently in Germany, discussion is continuing – independent of the issue regarding the term “statutory contracting entity” – as to whether rebate contracts are excluded from public tender requirements on the

basis of social security legislation. The jurisprudence in this area is thus far inconsistent.

The Higher Social Court of Baden-Württemberg holds that Sec. 69 of the Act of Social Law Volume V specifically provides that the regulations of the Act against Restraints of Competition – and thereby also public procurement law – is not applicable to the Statutory Health Insurance System at all⁴. The subject of this Decision was medical aids. For contracts involving medical aids the legislator meanwhile included a specific tender requirement in the recent health care reforms (Sec. 127.1 of Act of Social Law Volume V). A correlating regulation for rebate contracts was provided for in the draft legislation but was not included in the final reforms. Reasons for this omission have not been provided. For that reason the Decision issued remains still applicable to rebate contracts.

The Baden-Württemberg public procurement appeals board has, with its Decision of 26 January 2007, refused to acknowledge jurisdiction in the field of rebate contracts⁵. Pursuant to this Decision, such legal disputes are, due to the specific regulation in the Act of Social Law Volume V (Sec. 130(a)(9)), exclusively the responsibility of the social law courts. Nevertheless, the Baden-Württemberg board did not exclude the role of public procurement law. The appeals board suggested in its Decision that parties that have been overlooked – where contracts have been awarded without a public tendering process – would be able to obtain legal redress in the social courts as a result of breaches of public procurement law. It remains undecided, however, as to whether the social courts should and could use the public procurement law based on the Act against Restraints of Competition.

In contrast, the Düsseldorf Higher Regional Court has, in its aforementioned Decision of 23 May 2007, stated that, in its view, public procurement law is not ruled out by Sec. 69 of the Act of Social Law Volume V, at least according to interpretation methods that conform to European law. According to the Decision, public procurement law should be considered as superseding social law. There is no reason why this argument of superiority should not apply for rebate contracts as well.

In a nutshell: legal jurisprudence regarding the use of public procurement law principles for rebate contracts does not yet exist. Taking into account the aforementioned conflicting decisions it can only be stated that the legal situation in Germany on this issue is completely unclear. Against this background, two questions require answering. Firstly, whether rebate contracts need to be publicly tendered at all. Secondly, whether and according to which regulations will legal protection exist for companies affected, should a breach of the public tender requirement occur. *

Bettina Tugendreich and Maren Bedau are Associates at international law firm Hogan & Hartson's Berlin offices.

¹ See Comment from Complaint of German Association of Generic Drugs Companies, PharmaR 2007, Book 5, p. 192 and following.

² Opposed to the requirement for public tender: Bavarian Higher Regional Court, Decision of 25.5.2004, Az: Verg 6/04. In favour of a requirement for public tender: Federal Public Procurement Appeals Board, Decision of 9.5.2007, Az: VK 1 26/07; Public Procurement Appeals Board Lüneburg, Decision of 21.9.2004, Az: 203-VgK-42/04; Public Procurement Appeals Board Hamburg, Decision of 21.4.2004, VgKFB 1/4.

³ Düsseldorf Higher Regional Court, Decision of 23 May 2007, Az.: VII-Verg 50/06.

⁴ Social Court Baden-Württemberg, Decision of 4.4.2007, Az.: L5 KR 518/07 ER-B.

⁵ Baden-Württemberg Public Procurement Appeals Board, Decision of 26.1.2007, Az.: 1 VK 82/06.