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SCHWERPUNKT

Decision making in Germany: Is health economic evaluation as a supporting tool a sleeping beauty?

Kosten-Nutzen-Bewertung zur Unterstützung der Entscheidungsfindung in Deutschland: im Dornröschenschlaf?

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Summary For many years, the legal situation within the statutory health insurance (SHI) system in Germany has allowed for health economic evaluations. There are various reasons why health economic evaluations have played virtually no role in decision making until now: to begin with, a method for the evaluation of the relation between benefits and costs which needed to be in accordance with the legal requirements had to be developed, the outcome of which was the efficiency frontier approach. Subsequent health care reforms have led to changing objectives and strategies. Currently, price negotiations of newly launched drugs are based on an early benefit assessment of dossiers submitted by pharmaceutical manufacturers. Other reasons might be the presently very comfortable financial situation of the statutory health insurance system as well as a historically grown societal fear and discomfort towards what is perceived to be a rationing of medicinal products. For the time being, it remains open how long the German health care system can afford to continue neglecting the benefits of health economic evaluations for drug and non-drug interventions, and when it will be time to wake this sleeping beauty.

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SCHLÜSSELWÖRTER
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Zusammenfassung Nach vorherrschendem Recht sind Kosten-Nutzen-Bewertungen im System der gesetzlichen Krankenversicherung in Deutschland explizit bereits seit Jahren vorgesehen. Die Ursachen dafür, dass sie bisher in der Entscheidungsfindung nicht genutzt wurden, sind vielfältig: Zunächst musste eine Methode für die Bewertung von Verhältnissen zwischen Nutzen und Kosten entwickelt werden, die im Einklang mit der deutschen Gesetzgebung steht (das Effizienzgrenzen-Konzept). Danach brachten Gesundheitsreformen veränderte Zielsetzungen und Herangehensweisen mit sich. So ist gegenwärtig eine frühe Nutzenbewertung von neuen Arzneimitteln basierend auf den von pharmazeutischen Unternehmen eingereichten Dossiers Grundlage für Preisverhandlungen. Weitere Gründe sind unter anderem in der aktuell guten finanziellen Lage des deutschen Gesundheitssystems sowie historisch gewachsenen gesellschaftlichen Überzeugungen wie beispielsweise der Angst vor Rationierung zu suchen. Gegenwärtig ist offen, wie lange die Entscheidungsträger im deutschen Gesundheitssystem auf Kosten-Nutzen-Bewertungen verzichten wollen, die transparent Informationen zur Preisgestaltung von Arzneimitteln und nicht-medikamentösen Verfahren liefern können, und wann es an der Zeit sein wird, Dornröschen aus ihrem Schlaf zu erwecken.

Introduction

As of early 2014, the health economic evaluation has been a tool of last resort and practically plays no role in decision-making in the German statutory health insurance (SHI) system, which serves about 90% of the German population [1]. While the Institute for Quality and Efficiency in Health Care (*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen* = IQWiG), which was founded in 2004, in its very name contains a reference to efficiency (= *Wirtschaftlichkeit*), it was not commissioned with any health economic evaluation until 2009. Even though drugs were explicitly exempted from health economic evaluation until 2007, the law previously allowed commissioning the IQWiG with a combination of a health economic evaluation and a full benefit assessment of other kinds of interventions.

So why does the health economic evaluation not have a more prominent role in the decision-making process and has remained a sleeping beauty in the German SHI system? Before we attempt to answer this important question we would like to present an overview of how health economic evaluation is utilized in the decision-making process in the German health care system. This is done against the background of the historic development of health economic evaluation and the current legal and procedural situation, especially for new drugs entering the market.

History of health economic evaluation since 2004

The German SHI system is based on one basic legal document: The German Social Code Book V (*Sozialgesetzbuch*, SGB V). A history of the relevant paragraphs sheds light on the intricacies of health economic evaluation in Germany. When IQWiG, an independent scientific HTA body providing the SHI system and its decision-makers with scientifically sound information on interventions in the health care system, was founded in 2004 by the SHI Modernization Act (*GKV-Modernisierungsgesetz*) [2], the institute was assigned to assess the benefit and harm of drugs and then deliver this information to the Federal Joint Committee (FJC = *Gemeinsamer Bundesausschuss*), the decision-making body in the German SHI system of self-governance. With this information, the FJC was then able to tailor reference price groups for chemical entities with a similar benefit and harm, e.g. statins. After a market access of new drugs, a fourth hurdle, however, was meant to be avoided. This point was mirrored in the legal text of the Social Code Book V: Drugs were explicitly exempted from health economic evaluation (see §139a sec. 3 in the 2003 version) [2,p.2223]. This legal stipulation was the result of a compromise with the pharmaceutical industry.

Under the pressure of fast rising prices of pharmaceuticals and patented drugs in particular [3], the coalition government of Christian and Social Democrats decided to come to some kind of price cap regulation. In §35b of the health care reform of 2007 (SHI Act to Promote Competition, *GKV-Wettbewerbsstärkungsgesetz*) [4], health economic evaluation was therefore explicitly introduced with the goal of setting maximum reimbursement prices for drugs. This was to be attained by performing a full benefit assessment and under the condition that an added benefit was proven and attested by IQWiG. In addition, §139a sec. 3 specified that drug costs could also become the subject of an assessment by IQWiG.

With a new coalition government of Christian Democrats and Liberal Democrats coming into power in late 2009, the Act on the Reform of the Market for Medicinal Products (*Gesetz zur Neuordnung des Arzneimittelmarktes*, AMNOG) was passed and came into effect on January, 1st 2011 [5—7]. At this time, §35b in the Social Code Book V was altered: 1) IQWiG was no longer to be responsible for delivering a maximum reimbursement price. The legal text, though unclear about what exactly the outcome of a health economic evaluation should encompass, alludes in a more general way to a health economic evaluation providing information to assist the FJC in the decision about the appropriateness (*Angemessenheit*) and affordability (*Zumutbarkeit*) of the price of a drug. 2) Procedural changes now required—in case a health economic evaluation is requested—the submission of a dossier (containing a health economic evaluation) by the manufacturer and a subsequent health economic evaluation by IQWiG (please also see the section labelled "Current legal