

# Pharmaceutical reform 2010 in Germany:

## Striking a balance between innovation and affordability

Diana Ognyanova, Annette Zentner and Reinhard Busse

*Summary: The German Parliament passed a reform aiming to reorganise the regulatory framework for pharmaceuticals in order to curb growing expenditure. For the first time, all newly-licensed pharmaceuticals will be subject to benefit assessment. While pharmaceuticals without added benefit compared to treatment alternatives should be included in the reference pricing system, innovative pharmaceuticals with clear added value should be subject to price negotiations. Earlier cost-containment measures reinforce rebate contracts and introduce a three-year freeze on pharmaceutical prices.*

*Key words: Pharmaceutical reform, cost-effectiveness assessment, pricing, reimbursement, Germany*

### The pharmaceutical market in Germany

Germany is the third largest pharmaceutical market in the world and the largest in Europe. It is one of the few EU countries where until now pharmaceutical companies have been largely free to set prices. Pharmaceutical coverage is comprehensive, with a high level of public funding. In principle all licensed pharmaceuticals (apart from a few exceptions) can be prescribed by a physician and are eligible for reimbursement through Statutory Health Insurance (SHI). Exceptions include, among others, licensed pharmaceuticals appearing on a so-called negative list (until 2010), lifestyle and over-the-counter pharmaceuticals.<sup>1</sup>

The SHI spends 19% of its budget on pharmaceuticals. In 2009, SHI spending on pharmaceuticals (excluding vaccines) reached €32.4 billion, a 4.8% increase compared to 2008. The reasons for this are a 3% increase in the number of prescriptions, as well as an increase of 3.7% in the cost of the average prescription.<sup>2</sup>

German pharmaceutical prices have been found to be amongst the highest in the Organisation for Economic Co-operation and Development (OECD), both for patented and generic pharmaceuticals, at either manufacturer or retail level.<sup>3</sup> According to a recent publication, the 50 top-selling patented pharmaceuticals are on average 48% more expensive than in Sweden. For generic pharmaceuticals the corresponding figure is 98%.<sup>2</sup>

As Germany is a reference country for most EU Member States, higher price levels are reflected in the pharmaceutical prices of other countries. Furthermore, the system of free pricing makes Germany a preferred destination for market launches of new products. With patented pharmaceuticals being identified as the main driver of expenditure growth, the recent reform, not surprisingly, primarily targets producers of patented pharmaceuticals.

While most off-patent pharmaceuticals, especially those subject to generic competition, are reimbursed up to a set maximum

reference price level, the vast majority of patented pharmaceuticals are usually not subject to price restrictions.

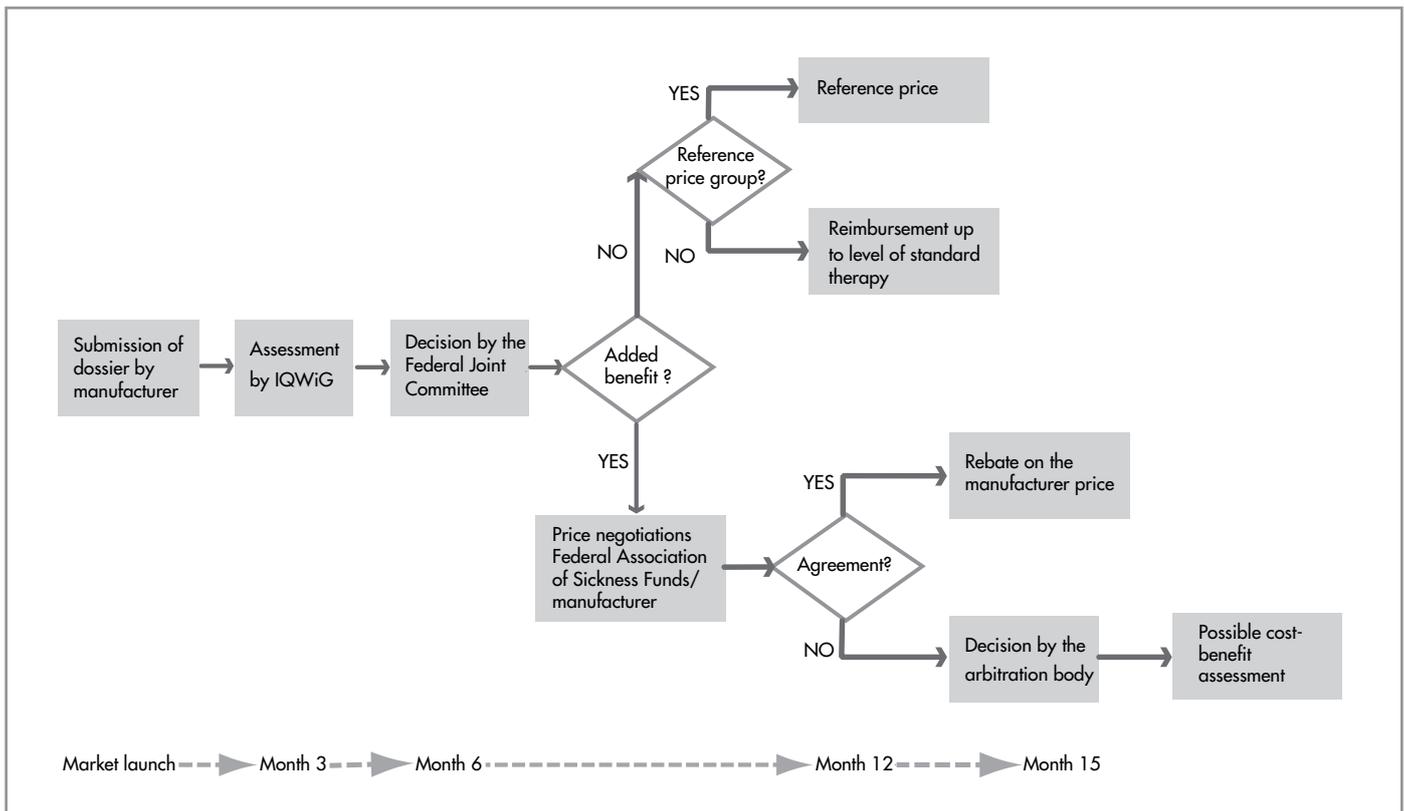
Since 2000, the sales of patented pharmaceuticals have almost doubled, reaching €13.2 billion in 2009. 85% of the sales of patented pharmaceuticals are not subject to reference pricing or any kind of price regulation. Sickness funds in Germany are hence price takers for patented pharmaceuticals, which represents a major obstacle to reducing pharmaceutical expenditure.

A particular problem is posed by pharmaceuticals which enjoy patent protection, but contain only very minor variations of already established active pharmaceutical ingredients and have the same or similar pharmacological effects as the original patented pharmaceutical (known as 'me-too' pharmaceuticals). In 2009, €2.3 billion was spent on 'me-too' pharmaceuticals.<sup>2</sup>

In 1989, Germany, as the first country to do so, introduced a reference pricing system which sets a maximum reimbursement ceiling for groups of pharmaceuticals: those with the same active ingredients, i.e. an off-patent branded original plus generics (Level 1); those with comparable active ingredients and effects (Level 2) or those with different

*Diana Ognyanova is Research Fellow, Annette Zentner is Senior Research Fellow, and Reinhard Busse is Professor and Department Head, Department of Health Care Management, Berlin University of Technology, Germany.  
Email: diana.ognyanova@tu-berlin.de*

Figure 1: Pharmaceutical reform 2010

Source: <sup>6</sup>

substances with comparable effect (Level 3).<sup>4</sup> In 2009 the reference pricing system covered approximately 44% of pharmaceutical sales reimbursed under the SHI and 74% of all prescriptions. While SHI expenditure on pharmaceuticals excluded from the reference pricing system rose by 8.9% in 2009, expenditure on pharmaceuticals within the reference pricing system dropped by 2% compared to the previous year.<sup>2</sup>

In 2004 the reference pricing system was extended to include patented pharmaceuticals in the Level 2 category. Explicitly excluded from the reference pricing system, however, were pharmaceuticals which represent a therapeutic improvement compared to treatment alternatives. In order to assess the therapeutic added benefit of pharmaceuticals, post-licensing evaluation was introduced in Germany in 2004 when the Institute for Quality and Efficiency in Health Care (IQWiG) was established. It generally does not act independently; assessments are commissioned by the Federal Joint Committee.

Cost-effectiveness assessment was made legally possible in Social Code Book V through the 2007 Act to Strengthen

Competition in Statutory Health Insurance in order to set a maximum level of reimbursement for pharmaceuticals with existing standard therapy and an added benefit.<sup>5</sup>

However, because assessments were only performed if the Federal Joint Committee commissioned them, i.e., for a selected number of prioritised pharmaceuticals, a considerable number of patented pharmaceuticals without demonstrable added therapeutic benefit have not been assessed with regard to their added benefit and are therefore not subject to reference pricing. According to Schwabe and Paffrath, potential savings could amount to €4.1 billion if patent-free pharmaceuticals are prescribed rather than equivalent expensive patented 'me-too' products, coupled with consistent use of the cheapest generics and prohibition of the use of controversial pharmaceuticals.<sup>2</sup>

#### Pharmaceutical reform 2010

In November 2010, in order to curb prices, Parliament passed a reform act (Act to Reorganise the Pharmaceutical Market in the SHI), which aims to strengthen the assessment of the benefit of pharmaceu-

ticals. The reform came into effect on 1 January 2011. Whenever a new pharmaceutical enters the market, pharmaceutical companies will now be obliged to produce a scientific dossier demonstrating its added therapeutic benefit compared to treatment alternatives.

Taking into consideration the dossier submitted by the pharmaceutical company, the Federal Joint Committee will then evaluate the added benefits of the new pharmaceutical. In this context, the Federal Joint Committee may – and in practice will – authorise IQWiG to review the dossier and claims made. The assessors shall also be legally entitled to receive and review the licensing documents. Within three months the Federal Joint Committee must publish its assessment report on the internet.

Following hearings with experts and the pharmaceutical manufacturer, the Federal Joint Committee will come to a decision on the added benefit within three months of publication of the assessment report. Based on that decision, one of two courses of action will follow (Figure 1):

1. *Pharmaceuticals that do not offer additional therapeutic benefits* compared to

treatment alternatives (supposedly the majority) will be directly included in Germany's reference pricing system.

The reform stipulates that all classes of branded pharmaceuticals which do not demonstrate added value will be eligible for reference pricing. In case a pharmaceutical cannot be classified in an existing reference price group, the level of reimbursement should not exceed the costs of the standard treatment.

If a pharmaceutical company receives a negative assessment with regard to the additional benefit of a pharmaceutical, it can ask for a renewed assessment no sooner than after one year.

2. *Pharmaceuticals that demonstrate a clinical added value* will be subject to price negotiations between the Federal Association of Sickness Funds and the respective pharmaceutical company, in consultation with the Association of Private Health Insurance Companies.

Negotiations will address the level of rebate on the manufacturer price according to the level of added benefit and the agreement will apply to both statutory and private health insurance. Within the first year after marketing authorisation, the pharmaceutical manufacturer is free to set the price, while negotiations are being undertaken.

If no agreement is reached during this first year, an arbitration body – consisting of representatives of the sickness funds, the pharmaceutical industry and neutral members – has three months to set a price that takes into consideration international prices. The price set by the arbitration body applies to all health insurers with retrospective effect starting one year after marketing authorisation. Both parties can appeal the decision by asking the Federal Joint Committee for a cost-effectiveness assessment, which in turn might lead to a different price.

Each sickness fund, in order to ensure access to innovative pharmaceuticals, is allowed to conclude contracts with selected pharmaceutical manufacturers, complementing or modifying the collective price negotiation scheme.

Further reform measures, which were passed by the German Parliament in June 2010 as part of the Act to Amend SHI Relevant and Other Regulations, comprise a freeze on pharmaceutical prices (technically only for SHI, i.e. not affecting private

health insurance) and an increase from 6% to 16% in the mandatory rebate SHI imposes on manufacturers of pharmaceuticals outside of the reference pricing system. These price control measures apply for the period from 1 August 2010 to 31 December 2013.

The government expects that the reform measures will lead to savings for the SHI of up to €2.2 billion. However, it is debatable whether price negotiations will reduce costs so considerably, as pharmaceutical firms might simply start negotiations with a price already in mind, for example, prices that already have a discount factored in. Such concerns are supported by the experience that some pharmaceutical companies raised prices by exactly the amount of the increased mandatory rebate two weeks before the latter came into effect on 1 August, thereby effectively circumventing any price reduction.

Another major criticism refers to the fact that orphan drugs are basically excluded from the obligation of benefit assessment after licensing. Benefit assessment is foreseen only if sales exceed €50 million in twelve months. Hence patients with rare diseases are at a disadvantage, because licensing does not guarantee the added benefits of orphan drugs.<sup>7</sup>

International reference pricing is expected to play an important role in future. The reform stipulates that from 2011 onwards prices in other European countries should be taken into consideration by the arbitration body when determining the price levels of pharmaceuticals. Germany, in turn, is a reference for many European countries. The reform will therefore not only have a significant impact in the country but also in Europe where Germany, along with France and the United Kingdom, is considered one of the most influential reference countries in terms of pricing.

### Conclusion

The German pharmaceutical reform of 2010 follows an international trend of linking pricing and reimbursement decisions to systematic, evidence-based benefit and increasingly also the cost-effectiveness assessment of pharmaceuticals compared to treatment alternatives. While Germany has been rather reticent, some countries have gained considerable experience in this approach. Nevertheless, post-licensing evaluation procedures and methods still vary among countries and international

collaboration in health technology assessment is expected to play a trend-setting role.<sup>8</sup> The challenge in all countries will be to strike a balance between innovation, affordability and cost-effectiveness

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