

Pharmaceutical Policies in Germany and European Competition Law

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The statutory health insurance system (SHI) is one of the five pillars of social security in Germany. It is the so-called Bismarck-System introduced more than 120 years ago and based on the principles of solidarity, subsidiarity, self-government and benefits in kind. It covers 90 per cent of the population and guarantees free access to a comprehensive catalogue of services and benefits determined by legislation regardless of age, sex, health status and income. In 2000, the revenue of the health insurance system amounted to some 260,000m DM and employers and employees contribute roughly equal shares. The average monthly contribution rate of the some 400 legally independent health insurance organizations is 13.6 per cent of gross salary (July 2001). For macro-economic reasons, contribution rates are not meant to increase.

The health insurance system is organized according to benefit areas, each with their own contract law and financial responsibility. Some 130,000 GPs and specialists, 21,500 pharmacies and 15,000 suppliers of medical devices and remedies share in the care of the sick. In comparison to all other benefit areas, expenditure on pharmaceuticals is increasing above average and - both in Germany and almost all other European Union (EU) member states - usually exceeds growth in gross domestic product. Since the early 1980s, governments have been reacting to this development by legislation exclusively aimed at curbing expenditure while it would be more reasonable to deal with the weak spots of the system, i.e. to reduce overcapacities and to achieve economies of scale by striving to closer integrate the individual benefit areas. To enumerate but a few measures taken in Germany:

- in 1984, a first "negative list", i.e. a list banning certain medicinal products, was introduced;
- in 1989, a reference price system (RPS) was established and the negative list was extended;
- in 1993, regional budgets to limit the expenditure on pharmaceuticals were introduced, with only the years 1998 and 1999 being excepted and
- since 2000 work on a "positive list", i.e. a list of reimbursable medicinal products, which failed in 1995, has been continued.

Like all health insurance benefits, the supply with medicinal products must be "sufficient, adequate and economical and must not exceed what is necessary" (§12 Social Welfare Code, [SGB V]). Under the law, self-administrative bodies and in particular the Federal Standing Committee of Physicians and Sickfunds (BÄK) are responsible for implementing this principle of cost effectiveness in detail. To the tasks of BÄK belong:

- the drawing up of a list of trade marks which are included in the "negative list";
- the establishment of groups for which reference prices are to be set;
- the implementation of guidelines concerning the conditions for the prescription of drugs
- and the evaluation and registration of new examination and therapy methods.

The allocation of such extensive rights and duties to self-administrative bodies enabling them to pass regulations binding third parties which have no part in the decision-making process has come under scrutiny by German constitutional aspects since 1995 and by European competition aspects since 1999. Thus, it is particularly the pharmaceuticals industry which has filed suits before different courts and in all instances. As a consequence of the near deadlock of self-administrative bodies, which are no longer in a position to fulfil their statutory task of shaping benefits and services, expenditure and contributions have been rising.

REFERENCE PRICES FOR MEDICINAL PRODUCTS

Also the European Commission is of the opinion that a RPS as practised in Germany is close to market mechanisms and to be preferred to any form of state price controls. Reference prices make it possible for:

- manufacturers to set their prices independently;
- physicians to choose their own therapies;
- patients to be prescribed all medicines which are necessary
- and statutory health insurance organizations to introduce an upper price limit for the reimbursement of pharmaceuticals.

Physicians who prescribe medicines above the reference price must inform their patient and patients who want the more expensive drugs must pay the difference.

Without any damage to the quality of the supply with medicinal products, reference prices can help achieve additional economies – in Germany currently 3,200 m DM annually. From the point of view of drug pricing, reference prices are also a considerable incentive for the research and development of innovative medicines. However, this only applies as long as reference prices are only introduced for such medicines whose patents have expired or for such medicines which are still protected by patents, whose therapeutic principle however is well known and does not lead to a therapeutic improvement, i.e. so called me-too drugs.

According to the Federal Social Welfare Court, the authorization granted the federal associations of the statutory sickfunds to set reference prices might be in breach of the German constitution. As doing so the sickfunds practically pass legislative norms, the court says, and it is debatable whether the setting of reference prices is not the responsibility of authorities which are entitled to pass laws and legal rules and which are subject to democratic legitimation and control. The decision of the Federal Constitutional Court is expected still in 2001. According to rulings of civil courts, the German practice is in breach of European competition law. In Germany, the federal associations of the statutory sickfunds by setting reference prices together and in unity are classified as associations of enterprises. By focusing the collective demand of their some 400 individual and independent sickness funds they exercise a monopoly and thus interfere with competition. On 3 July 2001, the German Federal Supreme Court decided to refer the question of whether the German RPS is compatible with European competition law to the European Court of Justice for a preliminary ruling, which is not to be expected before 2003.

RPS has proved to be an appropriate instrument for influencing prices of drugs. However, it is not sufficient to control the development of expenditure on pharmaceuticals. In addition to the price component, expenditure is also influenced by the development of the number of prescriptions written and the sort of drugs being prescribed. That is why a balanced and coordinated concept is required which is aimed at the individual factors involved in this development.

PRESCRIPTION GUIDELINES

In Germany, all registered drugs with a market authorization under German and European law are in general prescribable at the expense of the statutory sickness funds. Registration is primarily made according to aspects of safety in the sense of a risk-benefit analysis and does not so much depend on a significant proof of the effectiveness of medicinal products. Yet the social welfare law stipulates that medicinal products are supplied in a both appropriate and economically sound way. In this context, the proof of therapeutic usefulness is of major importance, as is a cost-benefit evaluation if there are other therapeutic options.

Drugs law and social welfare law are, thus, two evaluation systems with different objectives of regulation.

It is the statutory core task of BÄK, in detailed guidelines to make concret the general requirement that statutory health insurance organizations supply their services economically. With the prescription guidelines, physicians dealing with out-patients are to be supplied with a systematically arranged, clear guideline summarising all the exceptions and restrictions placed on the prescription of pharmaceuticals which have been made either by law, by legal rules or by decisions of the Federal Standing Committee. An entirely new set of guidelines has not come into force in April 1999 due to an injunction applied for by several pharmaceuticals manufacturers. On the one hand, the civil court ruled, that the same anti-trust arguments are applicable to both the Federal Standing Committee and the federal associations of sickness funds in connection with reference prices. On the other hand it was against the constitution if the legislator and BÄK have the same right to exclude medicinal products either via "negative lists" or through guidelines.

"NEGATIVE LISTS" AND "POSITIVE LISTS"

According to the stipulations of the relevant act, there are in theory four different "negative lists":

- firstly, medicinal products which are used to treat certain minor diseases;
- secondly, medicinal products which by definition are usually prescribed in the case of minor health complaints;
- thirdly, medicinal products whose therapeutic usefulness is debatable
- and fourthly, medicinal products which contain ingredients which are either unnecessary or whose effectiveness cannot be evaluated as a result of the large number of ingredients.

In practice, only the latter exists. It has been in force since 1989 and contains a large number of preparations. Their market significance for the statutory sickness funds, however, is negligible. In connection with the November 2000-update, a list of preparations is currently being put together which accounts for approximately one per cent of the sickfunds' expenditure on pharmaceuticals. Resistance within the pharmaceuticals industry is therefore rather weak. Still, in individual cases there are applications to be granted provisional legal protection even before the list has been published.

All "negative lists" are on principle to be integrated into the planned "positive list". It is to include all medicinal products which outpatients can be prescribed. As early as in 1993 work began on a "positive list", which however never got beyond the draft stage and was not implemented in 1996 as legally foreseen. Again and as a result of the health care reform 2000, an institute was commissioned to draw up a positive list. The medicinal products in this list will have to be appropriate for the adequate, sufficient and necessary treatment, prevention and diagnosis of diseases or considerable impairments of health, and – in comparison to the possible therapeutic effects – their therapeutic usefulness will have to be more than minor. This evaluation will have to be based:

- on the quality and significance of the documents submitted;
- on the therapeutic relevance of the scientific findings
- and on the degree of probability that the measures intended are going to be successful.

After in mid-July a draft was submitted for a public hearing, the institute intends to submit the list to the Federal Ministry of Health by the end of the year. It remains however to be seen whether subsequently, as required by law, the ministry is going to implement this positive list

by a statutory order. It is in any case extremely doubtful whether the Second Chamber of German Parliament is going to give its statutory consent since at present the red-green coalition does not have a majority there.

The market participants' attitude towards the positive list varies with their interests:

- according to an opinion poll, the majority of patients believe that in future they will have to do without medicinal products they are used to;
- while "official" physicians associations explicitly advocate a positive list, especially general practitioners fear that the doctor-patient relationship will be disturbed;
- the sickness funds are of the opinion that their long years of fighting for a fourth licensing hurdle have been successful. The positive list will make the evidence of therapeutic usefulness the standard for deciding whether a medicinal product is to be prescribed at the expense of sickfunds. This usefulness must go beyond the statistically significant proof that a preparation is more useful than a placebo, which is the key test for granting market authorization;
- the pharmaceuticals industry regards registration under the drugs law as the decisive criterion. The research based companies would agree to such a positive list if all newly registered drugs were automatically admitted. However, the small and medium-sized companies, the majority of whose preparations are still in the re-registration phase, are of the opinion that a positive list is in breach of the 1988 European transparency directive (89/105/EEC). They support their view by referring to the European Commission's case against the Austrian medicinal products register and they threaten the Federal Ministry of Health with lodging a complaint with the EU and with resorting to litigation in a number of cases.

PARALLEL IMPORT, DISTANCE SELLING AND E-COMMERCE

Like in the case of the positive list, German legislation is not marked by continuity concerning parallel imports either but rather by dithering. In the market segment of patented drugs, conditions in Germany, i.e. unrestricted pricing by manufacturers and no reference prices, leave the import of medicinal products as the only corrective element promoting competition. Since the 2000 health care reform, pharmacists have again been obliged to sell inexpensive parallel imports. After several years, a lawsuit was at last decided in October 2000, which commits wholesalers to keeping in stock parallel imports. Given degressive yet percentage profit margins, it is obvious for economic and sound reasons that pharmacists cannot be interested in inexpensive parallel imports. Equally obvious are the various tricks of the pharmaceuticals industry to hinder imports by changing trade marks, the amount of active ingredients, excipients, etc. Medicinal products which gain access to all EU markets if they have been registered once with European Medicines Evaluation Agency (EMA) must also be for sale in all EU member states. This is to be achieved either by launching them in the markets of the respective countries or by importing them. Thus, it appears imperative that the European Commission's plan to make it illegal for manufacturers to introduce quota systems should be implemented.

If one takes into account both the differences in the national prices of drugs and the costs for distributing them, mail order trade opens a further field for increased competition. It was only in 1998 that the German drugs law made the mail order trade illegal. Pharmacists in some other EU member states, however, also send medicinal products to Germany and they justify this by referring to the fundamental right of the free trade in goods and services, the 1997 European Directive on the protection of consumers in respect to distance contracts (97/7/EC), the 2000 European directive on electronic commerce and respective national regulations. German courts which are concerned with lawsuits of pharmacists and the pharmaceuticals industry against DocMorris, the Dutch mail order pharmacy, hold that a ban

cannot be maintained in the long run. What is more, they say, this is a typical case of discrimination against Germany-based pharmacies. The Federal Minister of Health has meanwhile confirmed several times that Germany is going to introduce the mail order trade in medicinal products as well. However, Ms Schmidt has not made any statement concerning the time frame required for the necessary legislation. Ultimately, the European Court of Justice is also going to set the course in this case.

RESTRUCTURING SHI BY COMPETITION

In Germany, competitive elements have been being introduced into health insurance legislation since 1993. Thus, in a first step, a so-called risk-compensation scheme was introduced in order to harmonize the individual sickness funds' widely differing contribution rates. These are the result of the varying age- and gender-specific morbidity rates applying in the various sickfunds. Secondly, since 1996 the insured have been free to select their own sickfund. This has not only led to a substantial reduction in the number of independent sickfunds from over 1,000 in 1993 to some 400 in 2001 but also to a shift in the market shares of the various types of statutory sickness funds. Thus, company sickness funds – and on this occasion please permit me to make a point for my own employer – have been able to increase their market share from roughly 10 % to more than 16 % not at least due to a 1 % less contribution rate on average. Thirdly, since 1997, sickfunds have been allowed to conduct so-called model surveys for a certain time on how to further develop the ways in which services are rendered. These surveys are to take into account the areas of organization, financing and benefits. Last but not least, the centre piece of the 2000 health reform is integrated health care to overcome the barriers of segmented benefit areas. This means that now also contracts with individual service providers are permitted whereas before 2000 there were collective agreements on the level of regional associations.

However, there is hardly enough time to continue the process of moderately opening SHI to competition. The above-average increase in expenditure on pharmaceuticals will even this year lead to large-scale increases in contributions, thus also to increases in ancillary wage costs that will ultimately weaken Germany's position as an economic location. The attempt of the federal government of Social Democrats and Greens to drastically change its health policy – away from regulatory instruments like budgets and reference pricing towards a consensus policy and mutual confidence, has failed after only few months. This means that health policy is going to be a central issue in the 2002 election campaign.

On the basis of significant rulings of the European Court of Justice in other benefit areas, the control mechanisms in the pharmaceuticals supply of German statutory sickness funds are increasingly going to be scrutinized concerning their compatibility with European law. This will not only have consequences for the area of pharmaceuticals but also for our health care system as such. Anyhow, European jurisdiction is likely to harmonize markets and systems faster and more comprehensively than desired by the public and politicians. After all, there is still agreement that the EU member states are free to organize their own health care systems. However, if the federal government wishes to maintain a proven system, one will also have to stand up for it. In 2003, the outlines of the future organization of health care in Germany will become obvious. In this context, one will have to consider:

- splitting up the benefits catalogue into statutory and voluntary benefits;
- severing the link between social benefits and wages by widening the financing basis;
- or even abolishing financing by contributions in favour of financing through taxation.