

Coordination and Quality in the Health Care System

ADVISORY COUNCIL
on the Assessment of Developments
in the Health Care System

**Coordination and Quality
in the Health Care System**

Report for 2005
Abridged version

Contents

1.	Foreword	7
2.	Corporative coordination and competition in the health care system	9
3.	Socioeconomic status and distribution of mortality, morbidity and risk factors	17
4.	Primary prevention strategies	23
5.	Interfaces between health insurance and long-term care insurance	45
6.	Therapeutic appliances and remedies in SHI	59
7.	Factors influencing the prescription of drugs	65
	Appendix	89

Tables

<i>Table 1:</i>	Intervention level, reference to a context, and examples of behaviour-based preventive interventions	26
<i>Table 2:</i>	Comparison of the organisational differences between statutory health insurance and social long-term care insurance	47
<i>Table 3:</i>	Effects of index-linking and redistribution of funds in the in-patient sector if introduced in 2006	51
<i>Table 4:</i>	Frequency of the recommendation of rehabilitation measures in expert opinions on long-term care requirements (in percent)	52
<i>Table 5:</i>	Prevalence of moderate and severe dementia in Germany (in percent)	56
<i>Table 6:</i>	Drug prescriptions of general practitioners and doctors of internal medicine by indication groups (in DDDs per physician for 2003)	73

Figures

<i>Figure 1:</i>	Overview of empirical results concerning the statistical connection between SES and morbidity	19
<i>Figure 2:</i>	Primary prevention as risk reduction	28
<i>Figure 3:</i>	Hierarchy of planning levels in the setting approach	37
<i>Figure 4:</i>	Public Health Action Cycle	38
<i>Figure 5:</i>	Change in SHI expenditure on drugs per member compared to the previous year (in percent)	67
<i>Figure 6:</i>	Variation in expenditure on drugs by KV regions, illustrated by the example of a substitute fund in 2003	80

1. Foreword

This is the abridged version of the Council's report for 2005, entitled "Coordination and Quality in the Health Care System". In addition to addressing the subject of corporative coordination, the report focuses on the connection between socioeconomic status and health, the strategies of primary prevention, the interfaces between health and long-term care insurance, the supply of therapeutic appliances and remedies in statutory health insurance (SHI), and the factors influencing the prescription of drugs. The Council thus fulfils its mandate formulated in Section 142 Para. 2 of Book V of the German Social Security Code (SGB V), i.e. to identify priorities for the elimination of deficits in provision and existing overprovision, as well as ways and means of further developing the health care system, taking into account the financial framework conditions and the existing efficiency reserves.

In the course of preparing the report, the Council conducted numerous discussions and received many valuable suggestions. It could always rely on the expert counsel of the Federal Ministry of Health and Social Security. In particular, the Council would like to extends its thanks to: Prof. Dr. med. Dieter Borgers, University of Bremen; Prof. Dr. med. Erland Erdmann, University of Cologne; Mag. Andrea Ernst, arte Editorial Department, Cologne; Dr. rer. pol. Raimund Geene, Gesundheit Berlin e. V.; Prof. Dr. phil. Dr. rer. med. Thomas Gerlinger, University of Frankfurt; Prof. Dr. phil. Siegfried Geyer, Department of General Medicine, Hanover Medical School; Andreas Grossmann, BKK Bundesverband, Essen; Dr. rer. nat. Ulrich Hagemann, Federal Institute for Drugs and Medical Devices, Bonn; Dipl. Politikwiss. Marc-Stephan Hübner, M.A., Department of General Medicine, Hanover Medical School; Dipl.-Soz. Holger Kilian, Gesundheit Berlin e. V.; Prof. Dr. med. Johan P. Mackenbach, Erasmus University, Rotterdam; Dr. phil. Andreas Mielck, MPH, GSF-Institut für Gesundheitsökonomie und Management im Gesundheitswesen; Prof. Dr. phil. Martin Moers, Osnabrück Technical College; Dr. med. Michael de Ridder, Krankenhaus am Urban, Berlin; Prof. Dr. phil. Doris Schaeffer, University of Bielefeld; PD Dr. med. Christian A. Schneider, University of Cologne; Dr. rer. soc. Ingrid Schubert, University of Cologne; Prof. Dr. phil. Johannes Siegrist, University of Düsseldorf; Prof. Dr. med. Klaus Stegmüller, Fulda Technical College; Prof. Dr. med. Gerold Stucki, Institut für Gesundheits- und Rehabilitationswissenschaften of Ludwig Maximilian University, Munich; Dipl.-Psych. Susanne Wurm, Deutsches Zentrum für Altersfragen, Berlin.

The Council also extends its thanks to the staff of the faculties and institutions of the Council members, particularly Dipl.-Volksw. Holger Cischinsky, University of Mannheim; Dipl.-Pflegepäd. Dagmar Dräger, Free University of Berlin; PD Dr. med. Dr. rer. pol. Afschin Gandjour, MBA, University of Cologne; Dr. rer. pol. Markus Lüngen, University of Cologne; Apotheker Frank Meyer, University of Bremen; Dr. med. Elke Scharnetzky, University of Bremen; Dr. rer. cur. Maik Winter, Free University of Berlin; Dr. phil. Michael T. Wright, Wissenschaftszentrum Berlin für Sozialforschung.

As in the past, the Council was able to rely on the support of the scientific staff at its office for the preparation and review of important sections of the report and for the final editorial work. The members of staff include Dr. med. Sabine Maria List, MPH, Dipl.-Volksw. Claus Michel, Dr. med. Jan Paehler, M.Sc., Dr. med. Dipl.-Sozialw. Sonja Schlemm, Dr. oec. publ. Dipl.-Volksw. Astrid Selder and the director of the office, Dr. oec. Dipl.-Volksw. Lothar Seyfarth. These individuals deserve special thanks for their extraordinary dedication and their tireless, professional support.

The Council also thanks Ms. Anette Bender, who handled the technical preparation of the report with the utmost care and patience. Finally, the Council would like to thank Ms. Sabine VanDen Berghe and Ms. Annette Wessel for their support of the Council's work at its office.

The Council bears the responsibility for any errors in the report.

Bonn, May 2005

Gisela C. Fischer

Gerd Glaeske

Adelheid Kuhlmeij

Karl W. Lauterbach

Rolf Rosenbrock

Peter C. Scriba

Eberhard Wille

2. Corporative coordination and competition in the health care system

- 1.** Corporatism is based on agreements concluded by organisations as private associations or public corporations. Alongside the market and price mechanism, and public planning or governmental administrative control, corporative coordination constitutes a general economic allocative mechanism. It played a dominant role as a coordination instrument in the guild-based economy of the Middle Ages and has experienced a renaissance in several countries since World War I.
- 2.** As in other branches of the economy, numerous associations in the health care system likewise attempt to assert their particular interests in the political process and thus to influence specific allocation decisions. More than any other sector of the economy, the German health care system has a wealth of corporative elements. Joint Self-Administration in the context of the provision of services by SHI-accredited physicians and dentists is a prime example of corporative coordination. The misallocations identifiable in the German health care system, and the coordination processes in the framework of Joint Self-Administration - which have proven lengthy and yielded few results, particularly in recent years - have given rise to doubts as to the efficiency of corporative coordination and, in this context, also as to the *raison d'être* of the Regional Associations of SHI-Accredited Physicians (KVs).
- 3.** When giving an assessment of corporative coordination, it is first necessary, from both the legal and the economic point of view, to make a distinction as to whether the organisations involved are private associations or public corporations. While private associations represent their group-specific interests vis-à-vis political decision-making units, the public corporations are assigned sovereign rights for fulfilling public tasks. Although corporative coordination displays certain constitutional advantages and disadvantages, regulatory aspects also make it seem appropriate to differentiate between the weaknesses of a state dominated by pressure groups and the corporatively-induced misallocations in the German health care system.
- 4.** One special regulatory feature of the German health care system is that different allocation mechanisms predominate in its individual sub-markets. While corporative coordination serves as the central control instrument in the out-patient sector, and public planning or state administration in the in-patient sector, it is essentially the market and price mechanism that coordinates the scarce resources when it comes to drugs and the majority of therapeutic appliances. In this context, each of these three coordination instruments can also supplement one of the others in subsidiary fashion.

While competition processes represent a necessary condition for a functioning market and price mechanism, they also take place in the framework of state administrative control and corporative coordination. For example, SHI-accredited physicians compete for positions within the KVs - which permit (involvement in) the structuring of the remuneration systems, among other things - and for patients as service providers. Varieties of corporative coordination can in this respect also be open to discussion from the point of view of competition, thus suggesting corresponding reforms.

The general weaknesses of corporatism are that

- The agreements reached are often at the expense of uninvolved third parties,
- The organisations have only little interest in innovations, insofar as they see their market position as being threatened by technical progress,
- Defending the status quo leads to a loss of efficiency, as well as damaging growth and employment, and
- The organisations create the often false impression of being in a position to minimise or guard against possible risks.

5. The corporative organisations range from Medical Chambers and other public corporations, such as KVs and health insurance funds, which perform sovereign tasks with a state mandate, all the way to private associations, such as the Hartmann Bund, the Marburger Bund or associations of the pharmaceutical industry. A number of private-law organisations have an interesting, in-between position here: although they do not have compulsory membership, they are involved in the fulfilment of public-law functions. These organisations include the German Medical Association, the national associations of the health insurance funds, the associations of the substitute funds and the German Hospital Federation.

6. In the last 30 years or so, there was no clear trend in the development of corporative coordination. Rather, phases of strengthening and weakening alternated, and there was also occasionally simultaneous expansion and abolition of elements of corporative control. While corporative coordination is currently under scrutiny, the 2nd SHI Reorganisation Act of 1997 was still geared to the motto "priority for self-administration". The strongest growth of corporative control elements was recorded in the in-patient sector, including a marked upgrading of the competencies of the German Hospital Federation (DKG). Although it is not a public corporation, the Hospital Committee assumed tasks

comparable to those of the Federal Committee of Physicians and Health Insurance Funds in the context of out-patient treatment. In the Joint Federal Committee (GBA), the DKG also plays an allocative role similar to that of the National Association of SHI-Accredited Physicians (KBV), for example. The GBA is a kind of central, corporative "super-organisation" with expanded powers regarding medical services.

Compared to the tendencies towards centralised, corporative control, the reforms aiming at the substitution of corporative elements by decentralised competition processes were quite modest. They primarily include the intensification of competition between the health insurance funds, the pilot projects and structural contracts, and a number of measures in the 2004 Health Insurance Modernisation Act, particularly the modification of integrated health care. However, it will probably be quite some time yet before decentralised competition processes achieve a significant market share.

7. In the context of corporative coordination, it is primarily inflexibility in the following areas that prevents processes improving efficiency, effectiveness and quality:

- The options of the health insurance funds in the healthcare and contract sector are too limited.
- The office-based SHI-accredited physicians merely act as adjusters as regards the quantity or quality of services, this triggering a vicious circle in the direction of overprovision and misprovision in the event of rigid budgets.
- Allocation in the in-patient sector suffers due to dual financing and because of distortions of competition resulting from the different financing of the respective funding agencies.
- With the ban on third-party ownership of pharmacies and the very tight restrictions on ownership of more than one pharmacy, drugs are still distributed via guild-like distribution structures.
- Joint Self-Administration is achieving ever fewer stable compromises and offloads the decisions onto arbitrators or alternative government measures.
- The medically and economically segmented treatment types still provide too few incentives for cross-sectoral provision and target-oriented competition at the interfaces.

The integration of decentralised competition processes in the form of selective contract negotiations between health insurance funds and service providers would be an obvious option for eliminating the inflexibility to which corporative coordination is subject. In this context, competition is not a means in itself, even in the health care system, but an instrument that primarily serves allocative and distributive objectives. Under suitable framework conditions, competition among the health insurance funds for insureds, and among the service providers for patients, may be capable of enhancing efficiency and stimulating the search for more effective, i.e. also more insured and patient-oriented, offers. In this context, functionally oriented intensification of competition at the level of the service providers presupposes flexible contract law.

8. In the framework of decentralised competition processes, the activity of the service providers is no longer based on once-only accreditation acts, but on selective contracts with individual health insurance funds. German and European competition and public contract law imposes certain limits on these contracts with the aim of ensuring fair competition. While Art. 69 Para. 1 SGB V precludes the application of German competition law to relations between the health insurance funds and the service providers, the higher-ranking European law on competition does apply. Moreover, the sovereign status of the health insurance funds binds them to specific norms of Germany's Basic Law, e.g. the general principle of equality and freedom of occupation. Like cartel law, national and European public contract law aims at the transparent, market-oriented and non-discriminatory award of public contracts. Although selective contracting between health insurance funds and service providers usually does not involve public contracts, a public invitation for bids, containing transparent, objectifiable and justiciable criteria, would suggest itself here from both the legal and the economic point of view.

9. In selective contracting, two levels of competition emerge in the form of a staged process. At the first level, the health insurance funds look for service providers for their medical service network on the basis of certain selection criteria, while the patients then decide on certain service providers at the second or lower level. At the first level, which does not exist in the case of collective contracts, the health insurance funds and the service providers mutually compete for contracts or contract partners, while the service providers compete for patients at the lower level. To be able to estimate the effects of the individual processes, it is first necessary to delimit the respective competition-relevant healthcare market in terms of both the product in question and its spatial dimension. In this context, the delimitation of the product market is essentially dependent

on the substitutability of the goods, while user or patient flows often serve as a criterion when it comes to the geographical market.

10. The (partial) transition from collective contracts to selective contracting gives both the health insurance funds and the service providers incentives to enter into combinations or to intensify existing concentration processes. This predominantly involves horizontal concentration processes, which *a priori*, i.e. without reference to the respective market or competition constellation, deserve neither a positive, nor a negative assessment in terms of the overall economy. They can increase efficiency and effectiveness by, for example, reducing transaction costs, realising returns to scale, eliminating excess capacities, promoting specialisation and spreading the risk. On the other hand, horizontal combinations entail the danger of the merging providers exploiting their strong market position to the detriment of insureds and patients.

Vertical combinations encompass service providers operating on different, but interconnected product markets, e.g. health insurance funds, office-based physicians and hospitals. The possible forms range from mergers or acquisitions, to exclusive, tie-in and most-favoured-treatment clauses, all the way to joint projects. In principle, vertical combinations can, like horizontal ones, improve efficiency and effectiveness, but they can also generate effects that are hostile to competition, primarily in healthcare markets with access barriers. Regardless of these risks, the German health care system still offers substantial room for decentralised competition processes that harmonise with overall economic goals. Given that there are still some 250 health insurance funds and approximately 21,000 pharmacies, as well as regions displaying overprovision in the in-patient sector, at least horizontal combinations should probably tend to improve efficiency and, in some cases, also quality.

11. Since all coordination instruments in the overall economy have their specific advantages and disadvantages, deficits in corporative coordination do not automatically mean that it must be partially or even totally replaced by alternative control elements. In the interests of overall economic goals, the question of whether substitution of this kind is appropriate depends on whether and to what extent the alternative control systems are better capable of fulfilling the fiscal, allocative and distributional policy functions on balance. Thus, the KVs are also only disposable if other institutions can perform the corresponding tasks more efficiently and more effectively. It must also be borne in mind in this context that dissolution of the KVs would probably be accompanied by strengthening of existing private-law medical associations and the founding of new ones. Not

having the obligations of a public corporation and possibly being unionised, associations of this kind can be expected to negotiate far more aggressively than the current KVs. In contrast to the KVs, which also mediate among the physicians in the event of remuneration problems, individual groups of specialists, for example, represent much more homogeneous units and are thus far more capable of asserting themselves.

12. SHI expenditure for out-patient treatment by SHI-accredited physicians has risen at a disproportionately low rate compared to the total expenditure on benefits, and also to a much lesser extent than the corresponding expenditure for in-patient treatment and drugs. Independently of the question as to its allocative justification, the fiscal postulate of stable contribution rates was, in the framework of sectoral budgeting, realised comparatively better with the help of a public corporation than by alternative control systems in the fields of the in-patient sector and drugs. This fiscal finding is primarily attributable to the possibilities that a corporation of this kind has, unlike private associations, for enforcing measures vis-à-vis its members when it comes to remuneration. As regards the remuneration of SHI-accredited physicians, both theoretical considerations and empirical studies show that the KVs did not, and could not, assume monopoly or cartel-like positions.

13. Both internally and externally, the negotiation processes of the participating organisations in the context of corporative coordination have in recent years generated increasing conflict, become ever more arduous and produced ever fewer results. In this context, the dual function of the KVs, i.e. of lobbying and simultaneously exercising sovereign tasks in relation to the same group of persons, had a negative effect, particularly from the allocative point of view. In contrast, the assessment of the allocative efficiency of corporative coordination was still far more positive until roughly the mid-Nineties.

The finding that, within the space of about ten years, the mood has swung from "priority for self-administration" to a demand for its - partial or extensive - suspension, was also dependent on exogenic factors to which the system was increasingly or newly exposed. These factors include, for example, the weak growth of a budgeted global remuneration, the wave of physicians setting up in private practice in 1993, the division into a budget for family physicians and specialists, the integration of the rapidly growing services of psychological psychotherapists, and the task of controlling drugs and remedies. The effects resulting from these factors burden not only the consensus-finding processes within the KVs, but also the negotiations between the KVs and the health insurance funds.

- 14.** The greatest allocative deficits of corporative coordination currently lie in a weak capacity for innovation and the fact that quality assurance is still unsatisfactory. These tasks can be assumed on a subsidiary basis by decentralised competition processes, in that the health insurance funds provide appropriate financial incentives, e.g. in the framework of integrated health care. To promote the quality competition, those physicians and hospitals should also be allowed to participate who are currently not accredited, but meet the required quality standards or have corresponding certifications. Provided that, in the framework of an increasing proportion of integrated health care, a quality competition of this kind reaches a small share - e.g. 5% - of the out-patient and in-patient sector, it should not only have a positive effect for the respective insureds, but also make itself felt in the overall system.
- 15.** At the moment, neither theoretical considerations, nor empirical facts advocate total abolition of corporative coordination and the organisations on which it is based. In the event of a complete transition to individual contracts, the threat of differences in the level of quality of medical services, and also of higher transaction costs, is far greater than in the system of collective agreements. If small and medium-sized health insurance funds, which are unable to assume the service guarantee in the framework of the benefits-in-kind principle at reasonable expense, join up to form larger communities and negotiate with medical associations, collective units again face each other. In the course of processes of this kind, tight oligopolies can emerge, both on the side of the health insurance funds and on the side of the physicians, which then conduct negotiations not on the basis of collective contracts, but at the level of individual contracts. The total or partial transition to selective contracts can also lead to fragmentation of the contract landscape, this confusing patients and insureds, and confronting physicians with virtually insurmountable administrative problems. On the other hand, aspects relating to innovative capacity and quality enhancement speak in favour of supplementing corporative coordination with decentralised competition processes, or confronting it with them.

Consequently, general economic aspects do not speak in favour of abolishing corporative coordination, and thus the KVs, but rather of giving greater weight to decentralised competition processes in order to counteract the tendency of corporative coordination, or the organisations on which it is based, to prevent or impede innovative processes that enhance efficiency, effectiveness and quality. To this end, it would be a logical step to integrate decentralised competition processes in a collective-law framework. Within this framework, the health insurance funds can then conclude selective contracts with the service providers involving for, among other things, different forms of provision, higher

quality standards and also different forms of remuneration. While the service providers are still at liberty to remain in the "collective framework", this could entail substantial economic losses in the long term. The service networks emerging as a result of decentralised competition processes thus compete both with each other and with the remaining or collective-contract system. In the framework of this competition process, the service quality should decide whether and how rapidly the proportion of medical services increases that is covered by decentralised competition processes.

3. Socioeconomic status and distribution of mortality, morbidity and risk factors

16. It has been shown in epidemiological studies on the connection between social situation and state of health that persons with a low socioeconomic status (i.e. with a low level of education, a low occupational status and/or a low income) disproportionately often display an impaired state of health and a shorter life expectancy than persons with a higher socioeconomic status (SES). According to the available findings, the life expectancy of men from the bottom quarter of the income scale is ten years shorter than that of men from the top quarter (72 years vs. 82); the corresponding difference for women is five years (81 years vs. 86).

17. The term "social inequality" is used to denote differences as regards education, occupational status and income. These are attributes of "vertical" social inequality. The population can also be differentiated with the help of such attributes as age, sex and nationality (or migration background). "Horizontal social inequality" may exist between these groups. Furthermore, attributes such as marital status, number of children and characteristics of the place of residence can also be used to form groups.

18. The fact is often emphasised in the sociological debate that clearly distinguishable social strata can no longer be identified, and that the diverse "situations in life" can no longer be classified in a consistent, hierarchical system with the aid of such criteria as education, occupational status and income. Attributes of vertical social inequality are, however, of importance for health policy in that they are accompanied by empirically demonstrated incidences and probabilities of morbidity and mortality.

19. Empirical studies on status-specific differences in mortality are mainly based on an "ecological design". A regional comparison is performed in this context, i.e. data on the average mortality in a region are compared with data on the socioeconomic structure of the region. The results of regional comparisons are, however, often difficult to interpret. In contrast, studies that are based on a comparison of individual data and manage without a comparison between regions, are rare in Germany.

Studies for which individual data were analysed indicate a statistical connection between school education, occupational status and income, on the one hand, and mortality and morbidity, on the other.

20. Much more is known about socioeconomic differences in morbidity than about differences in mortality. The study results available for Germany refer to

- The general state of health of children and young people,
- The general state of health of adults,
- Cardiovascular diseases,
- Diabetes mellitus,
- Cancer,
- Dental health,
- Allergies,
- Respiratory tract diseases,
- Skin diseases,
- Accidents,
- Diseases of the skeletal and locomotor system,
- Psychological morbidity, and
- Multimorbidity.

Figure 1 contains an overview of empirical results concerning the connection between social stratum or socioeconomic status (SES) and morbidity.

Figure 1: Overview of empirical results concerning the statistical connection between SES and morbidity

<p>Connection between SES and morbidity I: Disproportionately high morbidity with a low SES</p> <ul style="list-style-type: none"> - General state of health of children and young people, - General state of health of adults, - Cardiovascular diseases, - Diabetes mellitus, - Stomach/intestinal cancer, lung cancer, kidney/bladder cancer, leukaemia and malignant lymphomas, - Gastric diseases, - Dental health, - Intervertebral disk lesions, rheumatic diseases, gout, - Accidents (in children), - Psychological morbidity, and - Multimorbidity. 	<p>Connection between SES and morbidity II: Disproportionately high morbidity with a high SES</p> <ul style="list-style-type: none"> - Allergies (in children and adults), - Pseudocroup (in children), - Some skin diseases, e.g. neurodermatitis (in children), and - Impaired eyesight (short-sightedness, long-sightedness).
<p>Connection between SES and morbidity III: Greater severity with a low SES</p> <ul style="list-style-type: none"> - Asthma (in children), - Accidents (in children). 	<p>No connection confirmed with the help of results from Germany:</p> <ul style="list-style-type: none"> - For other diseases, since statistical connections with the SES were not investigated or do not exist.

Source: Own representation

21. Empirical results on status-specific differences in connection with risk factors are available on the subjects of smoking, obesity, lack of sporting activity, and nutrition. These risk factors, which are not only of a cardiovascular nature, are regarded as being of great importance in Public Health research.

A relatively large number of studies on smoking have been published. The results are clear. Smoking is disproportionately widespread in the lower status groups, both among young people and among adults. Social inequality as regards smoking declines with increasing age, more so among women than among men.

The studies available from Germany regarding status-specific differences in alcohol consumption do not yield a clear picture. Some studies show that alcohol consumption

is higher in the upper social stratum than in the lower stratum, while other studies indicate the opposite situation.

The "obesity" risk factor displays a clear connection with social status, comparable to that found for the "smoking" risk factor. The empirical results match in that the prevalence of obesity is disproportionately high in the lower status group. There is also a connection between sporting activity and SES: the prevalence of lacking sporting activity rises with increasing age and declining social status. Social differences moreover exist in nutritional patterns.

22. With a view to working conditions, a distinction can be made between the following "job strains":

- Ambient strains (e.g. noise, vapours, heat) and accident hazards,
- Physical strains (heavy loads, one-sided muscle strain), and
- Psychological and psychosocial strains (monotony, pressure of time, behaviour of supervisors).

What is needed are empirical studies that investigate, for each status group, how great these strains are and what contribution they make to explaining inequalities in health. In the framework of Public Health research, only few empirical studies from Germany have been presented on the subject, even though the importance of status-specific differences in working conditions for explaining inequalities in health is repeatedly emphasised.

Efforts have been made to arrive at a better understanding of psychosocial job strains in recent years. The "job strain" approach focuses on the combination of high demands and little freedom of action, while the "effort-reward imbalance" approach centres on the discrepancy between great occupational exertion and low reward.

23. In the debate on the subject of "health and social inequality", attention has so far too rarely been paid to the fact that highly strained groups of the population are often concentrated in certain regions or city districts. It is important to pay attention to the regional distribution of health-related problems and opportunities, particularly when planning interventions aimed at reducing inequalities in health. Measures holding the promise of success are those that are implemented where groups of persons exposed to particularly great strains either live, work or spend their leisure time.

24. If insufficient consideration is given to the complex causes of social status-specific differences in resources and strains, morbidity and mortality, there is a risk of problem situations being reduced to oversimplified explanations, this leading to interventions that are too limited. The connection between SES and state of health must be taken into account when developing strategies in the field of prevention. As a matter of principle, target groups should be precisely defined and delimited in the sense of "social marketing", giving consideration to social differences, in order to guarantee the effectiveness of interventions. Vertical attributes (education, occupational status, income) and horizontal attributes (age, sex, marital status, nationality or migration background) can be combined in this context.

With a view to the data base of decisions in health and social policy, two demands can be derived from the connection between socioeconomic status and the distribution of mortality, morbidity and risk factors:

1. Consideration of inequalities as regards health-related opportunities in health reporting and in reporting on poverty and affluence, or combination of the two reporting systems.
2. Implementation of further studies, and of surveys regarding the study situation, with the aim of monitoring the development of the connections described over the course of time.

4. Primary prevention strategies

Goals and forms of intervention in primary prevention

25. A major portion of the improvement in the state of health and the increase in life expectancy since the 19th century is attributable less to medical, curative innovations than to economic and social developments, as well as progress made regarding the environment, nutrition, hygiene and education. The contribution made by medical, curative care towards improving the health situation amounts to between roughly 10 and 40%, depending on the model approach and the methodological procedure, and also depending on gender. The remaining portion can primarily be explained by improvements in living conditions and lifestyles. Therefore, in addition to explicit health policy, i.e. that referred to as such and for which ministries of health are responsible, various other policy fields are of fundamental importance for primary prevention:

- Economic and social policy, including labour market policy,
- Education policy, including school policy,
- Consumer protection, food and agriculture,
- Transport, construction and housing, and
- Environmental policy.

Under these conditions, effective and sustainable primary prevention presupposes a common target horizon, consensus regarding the suitability of strategies, and close, intersectoral and intrasectoral cooperation between the players in different spheres of life and policy fields.

26. On a general level, the objective of primary prevention can be defined more precisely as follows:

- Avoidance, reduction or deferment of mortality and morbidity and the resultant loss of quality of life and restrictions on participation in social life ("intangible" illness costs),
- Avoidance, reduction and/or deferment of the use of resources for curative care, rehabilitation and long-term care, or of expenditure in health, accident, pension and long-term care insurance ("direct" illness costs),

- Investment in health as an element of "human capital" that is becoming increasingly important due to demographic trends, and
- Avoidance, reduction and/or deferment of "indirect" illness costs (losses of production and welfare in society as a whole); preservation or augmentation of the "production potential", where "production" in a broad sense includes every form of social commitment and active social participation.

27. Situation-based prevention targets living, working and environmental conditions as the framework conditions for the preservation of health and the development of illness. In this context, the focuses of prevention also changed in the course of time, in line with the living conditions and developments in morbidity and mortality. In the late 19th century and into the 20th century, primary prevention interventions centred on the control of infectious diseases and, in this context, also on such aspects as housing and nutritional conditions, as well as public hygiene. Aspects of environmental policy acquired growing importance in the course of the 20th century following the perception of potentially harmful environmental burdens. Other relevant policy fields are consumer protection and agriculture. Situation-based prevention also include numerous "health protection" measures, e.g. in the following fields:

- Health-related consumer protection (protection of drinking water; safety of products, including foodstuffs and drugs),
- Protection against infections, e.g. mandatory reporting of infectious diseases,
- Environment-related health protection (air pollution control, radiation protection, plant safety),
- Occupational safety in companies,
- Road safety,
- Security policy (prevention of "bioterrorism").

Situation-based prevention accounts for the greatest share of the regulations in German administrative law having preventive content. Consequently, situation-based prevention is, in principle, an established form of intervention. Many regulations, interventions and initiatives of importance for primary prevention are, however, beyond the traditional range of tasks of (explicit) health policy or explicitly health-related prevention policy, at

least insofar as this falls within the sphere of responsibility of ministries of health and social security.

28. The development and course of various chronic illnesses, which largely dominate morbidity and mortality today, are decisively influenced by individual behavioural and consumption patterns. It is for this reason that preventive interventions often focus on behavioural patterns (behaviour-based prevention), in which context, however, some of these interventions get no further than informational and educational measures. Consequently, this kind of prevention frequently lacks any link to the conditions in which behavioural and consumption patterns emerge. The effectiveness of interventions that are independent of target groups and contexts, and reduced to risk information and "health education", is slight.

29. While "pure" situation-based prevention ideally presupposes no lifestyle-related decisions, "pure" behaviour-based prevention, being the opposite extreme, has no link to the contextual and framework conditions of behavioural patterns and lifestyles, or the conditions under which they emerge. Above all, intermediate forms between these two extremes appear to point the way. Intermediate forms of this kind can be referred to as "context-oriented behaviour-based prevention". They can be implemented in comprehensive, "multi-level" prevention campaigns on individual health problems (e.g. anti-smoking campaigns), but particularly in the framework of the "setting approach". Since prevention campaigns display widely differing degrees of complexity, and since the setting approach is likewise interpreted differently, primary prevention interventions can also be classified as follows as regards their reference to a context:

- "Pure" behaviour-based prevention with no explicit reference to a context (e.g. information on health problems, context-independent media campaigns, counselling, information and training offers in courses and groups in institutions of the health insurance funds).
- Context-oriented behaviour-based prevention
 - a) Behaviour-based prevention with an explicit reference to a context, e.g. interventions for precisely defined target groups using concepts and tools of social marketing, and utilising a setting as a way of gaining access to defined target groups ("health promotion in a setting").

- b) Integration of situation-based and behaviour-based prevention, e.g. in the framework of "multi-level" campaigns on individual health problems, such as smoking or lack of exercise, or in the structuring of behaviour and lifestyle-shaping settings ("health-promoting settings").
- "Pure" situation-based prevention without a need for individual decisions regarding behavioural and consumption patterns (e.g. by standardisation in consumer protection and air pollution control).

30. Interventions in behaviour-based prevention can be classified not only according to the criterion of the behavioural context, but also according to the intervention levels of individual, setting and population (Table 1).

Table 1: Intervention level, reference to a context, and examples of behaviour-based preventive interventions

Intervention level	Behaviour-based prevention focusing on information, motivation and counselling, without elements of situation-based prevention	Behaviour-based prevention with a reference to a context, or further development of framework conditions for the behaviour
Individual (micro level)	Medical health counselling for a patient in the physician's office	"Preventive house call" with a reference to / counselling on living conditions and lifestyle
Setting (micro or meso level)	Educational offers in schools ("health education"), information offers in companies	Health promotion in schools, companies and administrations, e.g. through organisational development, "health-promoting settings"
Population (macro level)	Motivation campaigns with no reference to a context ("Eat more fruit", "Smoking damages your health"), social marketing without influencing framework conditions	Anti-smoking campaign, including situation-based preventive measures (removal of cigarette machines, regulation of advertising, tobacco tax)

Source: Own representation

An explicit reference to a context ensures that the respective living environment, and thus the framework conditions for the behaviour, are incorporated into the planning and implementation of interventions. The aim is to make it easier to take health-promoting behaviour-related decisions and turn this behavioural pattern into a habit in this way, and also to guarantee the sustained effect of interventions.

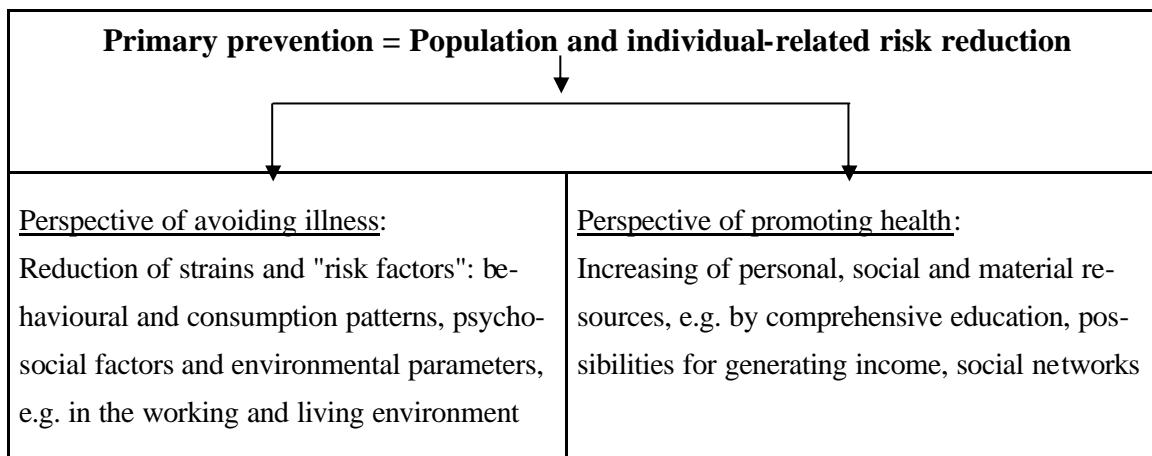
31. The Ottawa Charter of the WHO (1986) is still regarded as a fundamental document of modern health policy today. A policy geared to the Ottawa Charter develops activities in several fields of action:

- Development of a health-promoting overall policy that is not restricted to the classical health department (health insurance and health care, public health service), but also gives consideration to other spheres of life and policy fields,
- Development of health-promoting settings,
- Reorientation of the health services, e.g. hospitals, rehabilitation facilities, senior citizens' and nursing homes (target groups: staff and users), and
- Development and strengthening of health-related resources in the population and/or in certain target groups.

32. In the scientific literature, reference is made to numerous health-related resources that are of relevance for preserving or strengthening health, although they are not all equally accessible to quantitative determination. A distinction can be made in this context between personal, social and material resources. General "life skills" and education count among the personal resources. This includes formal schooling, vocational education and experience, as well as general character development and the entire repertoire of strategies for styling one's life and coping with adverse circumstances and crises. Social resources result from the structure and quality of social relationships and networks. They encompass psychosocial support in a relationship or a family, at the workplace and in the framework of other social networks, but also aspects of society-wide social cohesion. Material resources, such as income from employment, private assets and financial planning security, increase an individual's options for styling his or her life in a manner conducive to health.

33. Primary prevention encompasses both the reduction of strains and the strengthening of resources, in order to lower the risk of illness (or an accident) and the incidence rate in relation to the individual and the population (Figure 2).

Figure 2: Primary prevention as risk reduction



Source: Own representation

Differences in personal, social and material resources, and differences in the strains imposed by behavioural and consumption patterns, living and working conditions, lead to differences in health-related opportunities and the risk of illness. Conversely, interventions and developments in the various policy fields can be judged by whether and to what extent they influence the balance of strains and exposures, on the one hand, and health-related resources, on the other, both for the population as a whole and for definable groups of the population over different periods of time.

34. In Germany, different terminologies are used for prevention and health promotion. One reason for preserving the distinction between health promotion and prevention can be seen in the fact that the approach of strengthening resources could otherwise fall by the wayside.

Distribution of health-related opportunities

35. Connections between socioeconomic status - measured with the help of the indicators education, occupation and income - and health status can be demonstrated empirically and are of relevance for primary prevention. However, they have not yet been explained satisfactorily. Theories explaining the emergence of specific differences between social strata and their development over time, and indicating the relative signifi-

cance of individual influencing factors and supporting the planning of interventions, are either not available, or so far lack sufficient empirical confirmation.

36. The wide range of factors influencing the health status yields a host of possible combinations of strains and resources. In this context, not only the ratio of strains and resources at a specific time is of importance for the emergence and course of illnesses, but also, and in particular, its development in the course of time. However, the balance of resources and strains not only varies between individuals with their different prerequisites and lifestyles, but also displays distribution patterns associated with socioeconomic status differences. Members of social strata of lower status tend to be exposed to more strains (e.g. strains in the working world and from the living environment), disproportionately often demonstrate behavioural patterns that are detrimental to health, and simultaneously have fewer resources and coping strategies than members of social strata of higher status. Against this backdrop, it would appear inadequate to reduce the problem of "socially induced inequality in health-related opportunities" to individual causal origins. It is more realistic to assume the existence of a host of possible effects, only the interaction of which leads to the empirically demonstrable unequal distribution of health-related opportunities.

37. Key factors influencing differences in socioeconomic status lie beyond the sphere of influence of (explicit) health policy. For example, an expert report by the Institute of Medicine in the USA sees the greatest achievements in the past and the greatest potential for reducing differences in health status, as well as for improving the health of the population in general, as lying in the improvement of the socioeconomic status of the disadvantaged groups of the population. This analysis leads to the conclusion that economic growth and favourable development of the labour market, which permit improvement of the socioeconomic situation of these groups, are also of major importance from the point of view of primary prevention.

38. In terms of content, there are links between primary prevention and economic, social and education policy. The connection between health status and unemployment makes the current unemployment situation, and particularly long-term unemployment, appear to be not only one of the greatest, unsolved problems of economic and social policy, but also a priority Public Health problem.

39. Differences in the social situation must be considered when elaborating implementable primary prevention strategies and planning interventions. A realistic strategy for implementing Section 20 SGB V will have to focus on interventions for the benefit of

groups that are disadvantaged in terms of health. Among others, the following attributes are open to consideration as criteria for forming clusters for intervention planning:

- Persons on a low income and their families and, in this context, especially children and young people as the primary target group of national primary prevention strategies,
- Persons with a low level of school education and poor chances on the labour market,
- Other groups of persons exposed to above-average strains, e.g. single parents, families with numerous children, the long-term unemployed, people with disabilities, the homeless, etc.

A decision has to be taken in each instance as to whether the goal can best be achieved by sociopolitical interventions in the broader sense, or by directly health-related measures and offers of institutions of the health care system.

40. Above and beyond preventive interventions for the benefit of target groups with a relatively unfavourable balance of resources and strains, there will also be a fundamental need for public support of sectors of the population that are disadvantaged socially and in terms of health. A further political task is to also firmly establish the prevention concept outside the health system and "explicit health policy", i.e. in other fields of political action as well ("implicit health policy"). The main problems in this connection are the tightly limited, and occasionally decreasing, room for action in the public budgets, which makes health and social policy initiatives more difficult, and the absence of decisive successes in the economic policy fields of labour market, structural and growth policy.

41. Insofar as interventions take place solely in the field of "explicit" health or prevention policy, the following are primarily open to consideration:

- Appeals to change behaviour detrimental to health by means of target group-oriented public relations concepts and social marketing, but particularly comprehensive "multi-level" prevention campaigns on selected topics, such as tobacco consumption, alcohol abuse, exercise and nutrition, and

- Interventions based on the setting approach, particularly in schools or educational institutions in general, in private and public businesses and administrations, as well as in the municipalities, especially in "social hotspots" in cities and communities.

The setting approach is suitable for reducing socially induced differences in health-related opportunities. It combines the advantages of comparatively easily organised and largely non-discriminatory access to different target groups with the possibility of integrating situation and behaviour-based prevention elements and strengthening or increasing health-related resources. Settings can be specifically selected for interventions, e.g. in city districts with a high percentage of socially disadvantaged residents. Of particular relevance in this context are the settings of school, company or administration, city district or quarter, and leisure facilities.

Models of health psychology and factors determining health-related behaviour

42. Health and social psychology models of behaviour and behavioural modification (above all the model of health belief, the theory of rational action, salutogenesis, the model of stages of change) differ as regards their focus and the limits of their validity. They are made up of a limited selection of variables and do not reflect all the factors influencing health-related behaviour. For example, the influence of different situations in life on behaviour is occasionally not included in the examination. Although the models are, in principle, open to additional influencing factors, e.g. of a sociostructural or socioeconomic nature, they often do not include them explicitly, or in all their complexity, even though there is an empirically proven connection between risk-increasing behavioural patterns and socioeconomic influencing factors.

43. Among the theories and models of health psychology, the salutogenesis model holds a special position because of its comprehensive approach. It centres on the notion that individual convictions and values contribute to being able to classify and cope with stressful events in life, such as illness. This ability is seen as being a health-forming resource. The model has in the meantime been put on stronger empirical foundations, which justifies the recommendation to more accurately ascertain its health-promoting potency and suitability for interventions by means of further research. Moreover, the term "salutogenesis" should be used more precisely than is currently sometimes the case.

44. For prevention policy, the importance of contextual factors and resources leads to the conclusion that complex approaches, such as the setting approach - which permits

the combination of specific interventions on certain strains with non-specific interventions - are often superior to conceptually more limited approaches.

Health communication, social marketing and prevention campaigns

45. "Mass media" provide information on products and services, the consumption of which can potentially influence the state of health of consumers. In addition to product-related information, which partly serves advertising purposes, mass media communicate biographies and role models. Consequently, the search should be stepped up for possibilities of cooperating with communication experts and the film and entertainment industry to develop communication strategies which combine lifestyles, role and consumption models that are attractive to certain target groups with behavioural patterns that are sensible from the point of view of primary prevention.

46. Tools of public relations have in the past contributed to the success of prevention measures (e.g. vaccination campaigns, iodine prophylaxis). Primary prevention interventions should, however, use public relations tools as part of an overall concept, e.g. for a "multi-level" campaign, and not limit themselves solely to the communication of health-related information.

47. Since the 1950s, tools of commercial marketing have also been used for non-commercial purposes ("social marketing"). However, when used for the purposes of primary prevention, the fields of action *product, price, promotion* and *place* that belong to the set of tools of commercial marketing take on a meaning of their own that sometimes differs from that in commercial marketing.

48. One central element of social marketing is careful determination of the target group. It appears necessary simply because health-related strains and resources vary between social strata and groups of the population. In this context, it is also necessary to give consideration to influencing factors, such as cultural characteristics of immigrants from a different cultural sphere ("migration background"), gender aspects, different phases in life and other factors characterising the situation in life.

49. In the practice of prevention, "campaigns" are often taken merely to mean information, education and motivation activities that aim to communicate health-related information and develop intentions conducive to health. While comprehensive, "multi-level campaigns" utilise the possibilities of health-related communication and social market-

ing, they also avail themselves of other tools to establish a reference to a context. Consequently, they act at different knowledge and intervention levels:

- Individual behaviour-related strains and resources (behaviour-based prevention, e.g. by health-related communication, social marketing, educational offers),
- Interventions based on the setting approach (shaping of settings), e.g.:
 - a) City and community setting (interventions in the living and residential environment, development of districts and quarters, coordination of health and social policy at the municipal level),
 - b) Company and administration setting (occupational safety, workplace health promotion or workplace health management),
 - c) Kindergarten, day-care centre, school and possibly college/university setting (interventions in educational institutions),
 - d) Hospital, senior citizens' and nursing home setting (interventions in health and social institutions), and
- Socioeconomic framework conditions (particularly economic, labour market, social, education, consumer and environmental policy).

"Multi-level campaigns" aim at catering to the host of factors influencing health and sickness by combining measures at different levels, thereby enabling synergistic effects.

50. So far, only few prevention campaigns have been implemented in Germany, including a successful safety-belt campaign in the 1960s, the "Trimm Dich" fitness campaign since the 1970s and the HIV/AIDS campaign since the 1980s, success mainly being achieved in key target groups. Above and beyond these campaigns, other information and motivation campaigns were initiated without explicit reference to target groups and contexts. Although measures of this kind are relatively easy to organise, their effectiveness is doubtful.

Workplace health policy

51. In workplace health policy, a distinction can be made between two perspectives of prevention. The one focuses on individual health problems, such as occupational accidents and accidents *en route*, lack of exercise, alcohol or tobacco consumption. Preventive interventions in the working world can supplement campaigns on these problems aimed at the general population, or can be intensified in the framework of campaigns of this kind. The other perspective targets systemic interventions that are geared to the workplace context, the concrete requirements in individual companies and/or the model of a "healthy organisation". Regardless of the perspective chosen, the working world is important as a field of action for prevention policy simply because of the size of the target group (the working population).

52. A shift in the workforce age structure in businesses can be expected in the coming years and decades. This is due to the change in the age distribution of the population, and possibly also to shortages of qualified workers on the labour market, and an increase in the retirement age. Consequently, workplace health management faces the task of reducing the sickness burden or the number of employee working days lost as a result of incapacity for work, and generally preserving and increasing the availability and productivity of the workforce on a long-term basis. Increasing importance of primary prevention in businesses means that workplace health management should become an integral element of human resources policy.

53. One classical field of workplace-related health policy is occupational safety, for which mainly the statutory accident insurance system and its funding agencies (employers' liability insurance associations and occupational accident insurance funds of the public sector) are responsible within the social insurance system. In no other segment of social insurance has the task of primary prevention been rooted in the law for so long.

Occupational safety was shaped by legal and by scientific and technical perspectives. It led to a wealth of safety regulations. In an expansion of the prevention mandate, the statutory accident insurance system was, in 1996, assigned responsibility for the prevention of work-related health risks, in addition to the prevention of occupational accidents and illnesses.

54. The starting point for the development of workplace health promotion was completely different to that for occupational safety. The concerns, concepts and strategies of health promotion were essentially shaped by WHO initiatives and publications, primar-

ily by the Ottawa Charter. The WHO was also involved in the development of the setting approach. Like the "hospital", "school" and "city" settings, the "workplace" setting became the target for health promotion activities in many countries. Workplace health promotion is today also an established field of action for the health insurance funds. However, its potential is not yet being fully exploited, meaning that more extensive use of this prevention approach must be called for. Moreover, experience gained and successes achieved in the "workplace setting" should be utilised for interventions in non-workplace settings.

55. Section 20 Para. 2 SGB V enables the health insurance funds to implement workplace health promotion measures that supplement occupational safety. There are incentives for a health insurance fund to carry out workplace health promotion measures in that a lower level of morbidity reduces the expenditure on treatment and sickness benefits and because successful interventions enhance the image of the health insurance fund in companies. To give employers an additional incentive for workplace health promotion, health insurance funds can incorporate bonus models based on Section 65a Para. 3 SGB V in their statutes. In this case, both the employer and the insureds taking part in the respective measure receive a bonus. This kind of bonus model can be justified by the fact that work-related illnesses are also at the expense of SHI. Health-related costs originating in the working world and elsewhere are partly externalised by companies. Conversely, the burden on SHI is relieved by effective workplace primary prevention.

56. Interventions in workplace health management display a broad range of goals, concepts and instruments, and operate between the poles of classical, partly legally enforced, relatively clearly structured occupational safety and systemic interventions of organisational development. The latter integrate health-related goals alongside other goals (e.g. quality goals) in the company principles and in management systems.

57. Measures targeting specific health problems, such as smoking and alcohol abuse, are more easily organised than interventions of organisational development. Moreover, they can carry on from prevention campaigns aimed at the general population. However, interventions relating to individual problems do not yet do justice to the intention of the setting approach. Above all, they are no substitute for a convincing, global concept for health management in a business enterprise or a public administrative body.

Municipal health and social policy

58. The policy of cities and communities determines the residential and working environment of the entire population, and living conditions in general. Many spheres of life of fundamental importance for primary prevention are partly shaped by decision-making processes at the local government level. The sphere of influence of local government policy includes, among other things, the economic development of the city or region, and thus employment, income and career prospects, the environmental and traffic burden, the social infrastructure, educational institutions and health service facilities. Some starting points for preserving and improving Public Health were already established as a field of action for local government policy at the end of the 19th century.

59. Above and beyond its fundamental responsibility for an "implicit health policy", municipal health policy also has a variety of starting points for specifically strengthening primary prevention:

- Explicit consideration of health-related topics in all spheres of life and fields of local government policy, including sports and education policy (e.g. day-care centres, adult education centres)
- Cooperation in the "healthy cities" network,
- Primary prevention interventions in settings and shaping of "health-promoting settings" below the "city and community" level,
- Development of city districts, e.g. by "quarter management",
- Integration of health and social policy, as well as the associated reporting,
- Offers of the public health service, e.g. school medical service, diagnosis and counselling in connection with infectious diseases, vaccinations, and
- Disease-related concepts, e.g. on cardiovascular diseases.

60. One task of prevention policy consists in intersectoral cooperation across several levels of state action. For example, not only nutrition policy is of importance for the prevention of the health problems of overweight and obesity, but also the sports and transport policy of the Federal Government, the Länder and the municipalities. The prevention of possible health-related consequences of poverty, e.g. among children and

young people, likewise presupposes the networking of initiatives and players, e.g. in education, social and health policy.

61. Local government policy can be geared to the goal of a "healthy city" not only by giving consideration to "health" as a cross-sectional task in all spheres of local government policy, but above all also by means of concepts based on the shaping of settings below the level of action of the city as a whole. This results in a hierarchy of planning levels in the "city" setting:

Figure 3: Hierarchy of planning levels in the setting approach

"City" setting					
Area / City district / Quarter A		Area / City district / Quarter B			
Businesses and administrations		Educational institutions		Health care system facilities	
Private enterprises and businesses	Public enterprises and administration	Schools (of the various types)	Other educational institutions	Public health service/Local health department	Hospitals, senior citizens' and nursing homes

Source: Own representation

62. Activities in the setting should be coordinated with other preventive offers and programmes. For instance, schools can strengthen school sports by cooperating with sports clubs in order to also create an attractive offer in this way and thereby arouse the enthusiasm of children and young people for sporting activities and an active lifestyle. Corresponding offers for adults can, for example, be devised in the context of workplace health policy. Networking of municipal activities with campaigns aimed at the population as a whole offers greater prospects of success.

Evaluation and quality assurance

63. The efficiency rule (Section 12 SGB V) applies to primary prevention interventions financed from SHI contributions, as well as to curative and rehabilitative services. Proof

of the effectiveness and efficiency of such offers and initiatives must be demanded on principle. One quality criterion in this context is the sustained effect of interventions.

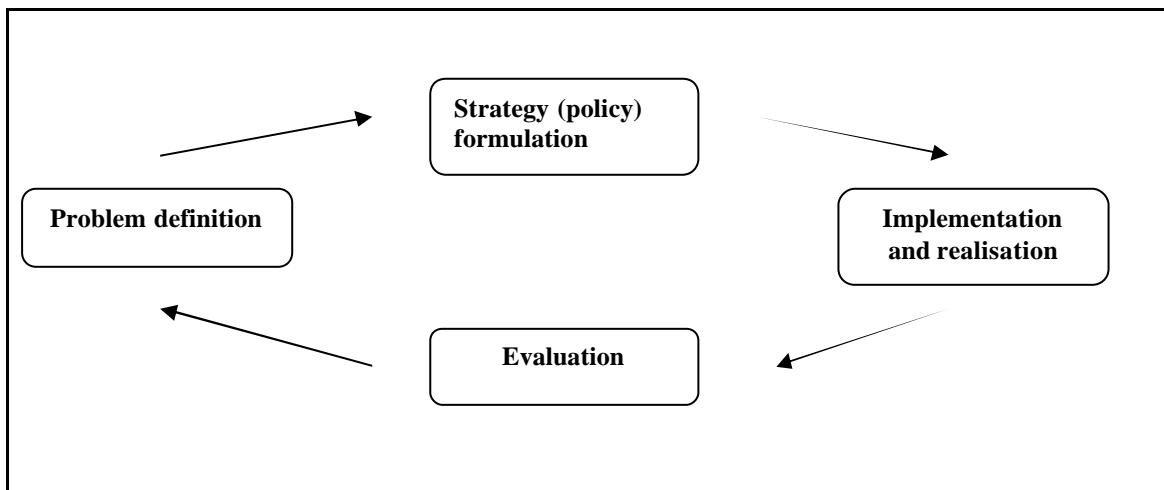
Where SHI implements primary prevention interventions on the basis of Section 20 SGB V, the available evidence must be incorporated in intervention planning. In addition, however, health insurance funds should promote complex interventions that are difficult to evaluate, even if proof of effectiveness is lacking, if

- proof of effectiveness is available for analogous interventions,
- the effectiveness of the intervention appears plausible, and
- professional quality assurance of the intervention is ensured,

but without fundamentally dispensing with proof of effectiveness. Careful documentation of interventions and results is necessary in order to accumulate experience and knowledge. To increase the transparency of activities funded from contributions, documentations should be uploaded onto the Internet promptly.

64. The *Public Health Action Cycle* can serve as a starting point for systematisation of the quality assurance of primary prevention interventions.

Figure 4: **Public Health Action Cycle**



Source: Own representation

The individual phases of this cycle cannot always be clearly distinguished from each other. Overlaps occur, for example, if the experts commissioned with evaluation already influence strategy formulation and/or implementation in a "development-oriented" evaluation.

65. There is no shortage of suitable concepts and instruments for quality assurance. Bottlenecks exist more in the willingness and motivation of the players to adapt these instruments to the conditions of the respective intervention, and possibly also in the availability of resources. However, sufficient motivation of the players to engage in quality assurance presupposes that requirements are not only imposed on the sponsors of the intervention from outside. Rather, the requirements should reflect their concerns and their perception of the problem and be formulated with their involvement. Otherwise, requirements profiles can provoke dysfunctional processes, such as the merely formal working-off of test criteria, and possibly even impair quality. The methods of participative quality assurance already in existence and yet to be developed can counteract this risk.

Economic incentives in primary prevention

66. Incentive structures can both support and counteract realisation of the prevention concept. Consequently, the effects and the use of economic incentive structures should be reviewed and further developed, particularly in a field that is widely considered to have been neglected for a long time. This line of thought is in keeping with the goal of a "healthy public policy", which embeds the concerns of primary prevention in all spheres of life and policy fields.

67. Investigations into the connection between cigarette prices and consumption led to the result that raising the price tends to reduce consumption. The available studies indicate that young people and people of lower social status, in particular, reduce their cigarette consumption following a price increase. An increase in tobacco tax, which is partly or wholly passed on to the consumer in the form of a price rise, serves as an instrument of primary prevention, among other things. Thus, the impending further increase in the tax on cigarettes in September 2005 is in keeping with preventive objectives. Use of the "tobacco tax" instrument should, however, be supplemented in the framework of an anti-smoking campaign by complementary measures primarily targeting the advertising and distribution of cigarettes and the black-market trade.

68. The level of alcohol prices influences per capita consumption of alcoholic beverages and the health-related consequences associated with alcohol consumption. It would thus appear possible to conclude that taxation of alcoholic beverages contributes to reducing alcohol consumption and that alcohol taxes have a positive impact on the state of health of the population.

As part of further considerations regarding the taxation of alcoholic products, the question should also be examined of whether the currently inconsistent taxation of alcohol consumption can be replaced by a uniform alcohol tax. Regardless of the type of product, it could be geared exclusively to the absolute alcohol quantity per unit sold (bottle, pack). In this way, products previously not taxed, such as wine, would be included in taxation and there would be fewer incentives for evasive reactions when creating mixed drinks. The abolition of several excise taxes on alcohol would at the same time contribute to simplifying the tax system. However, differentiated taxation can also offer advantages from the point of view of prevention policy, e.g. if relatively high tax rates lead to a decline in consumption in certain target groups, such as among young people.

69. Statutory health insurance funds have devised and implemented bonus models for "health-conscious behaviour" on the basis of Section 65a SGB V. A sound assessment of the ongoing programmes presupposes currently outstanding evaluations. At the moment, the legal situation is such that expenditure on bonuses must be funded from savings and efficiency increases in the medium term. Health insurance funds are required to render account of these savings to the responsible supervisory authority at regular intervals, but at least every three years. Future considerations regarding the use of bonuses, which the Council also advocated in previous reports, should be based on the empirical values and evaluation results available in a few years' time.

70. In many cases, joint activities of health insurance funds, also of different types of fund, can facilitate the implementation of "setting" projects. The health insurance funds still have relatively few competition parameters at their disposal. In this respect, there is an incentive first and foremost to assess primary prevention interventions from the point of view of the publicity effect, to implement them under the management of individual health insurance funds, and to focus primarily on the target group of "good risks" in the sense of a ratio of income to expenditure that is favourable for the health insurance fund. This can result in preference being given to settings that are not suited to achieving the goal of reducing socially induced differences in health-related opportunities.

Incentives for providers in the health system

71. Hospitals are centres of regional medical service systems and perform important functions for the health care system, for instance in the basic and specialist training and continuing education of physicians and other healthcare professionals. For this reason, and in order to further improve health management in these relatively complex operations, primary prevention based on the setting approach should also be strengthened in hospitals, in particular.

Incentives for health promotion in hospitals could, for example, be provided by taking health-promoting activities into account in agreements on hospital charges between the hospital owners and health insurance fund associations. However, one possible problem exists in the assignment of competencies and responsibility to different decision-makers at the health insurance funds - for workplace health promotion, on the one hand, and for hospital care and hospital charges negotiations, on the other.

72. Deficits in primary prevention also exist as regards vaccination practice. In addition to information and motivation deficits, inadequate remuneration of vaccination services has also been mentioned as a possible reason, although vaccinations are partly remunerated from non-budget funds. Consequently, on top of providing information, consideration should also be given to additional or different financial incentives in order to arrive at better vaccination rates.

Predictive genetic diagnosis

73. The availability of tests in modern predictive genetic diagnosis will probably increase as a result of DNA chip technology, which makes it possible to perform numerous tests in automated work steps. Under these circumstances and given a sufficient number of examinations, genetic tests can be offered even in return for low remuneration by the statutory health insurance funds and private insurance companies. A development of this kind could possibly lead to further intensification of as yet unsatisfactorily resolved ethical and legal problems as regards quality assurance in genetic diagnosis and human genetic counselling.

74. Multifactorial disease processes, which cannot yet be clarified by genetic tests, are of most importance for industrial medicine and occupational safety. Reservations regarding preventive genetic tests in industrial medicine and occupational safety are based

on the fundamental risk of discrimination, and particularly the possibility of occupational safety measures being replaced by selection of specific employees with a "suitable" genetic disposition. A need for regulation could arise with respect to the right of an employer to ask questions, the duty of an employee to report certain facts, the use of genetic tests in medical examinations prior to hiring, and the handling of personal data.

75. Although improved knowledge of the genetic conditions for health and sickness can, in principle, open up new opportunities for prevention and curative care, the practical use of predictive genetic diagnosis for primary prevention is limited in several ways:

- Numerous illnesses are of multifactorial origin. Living and working conditions, the respective strains and resources are of great importance as regards the development and course of illnesses. In this respect, it would appear appropriate to see the genetic constitution as being an element of the balance of strains and resources that determines health-related opportunities. The combination of resources and strains can be influenced by different primary prevention interventions and by initiatives and developments in social and economic policy.
- Even if genetic tests permit probability statements in conjunction with other influencing variables, it is often the case that no suitable interventions are available, or only the already familiar ones.
- The use of genetic diagnosis cannot be assessed solely from the point of view of prevention policy. It also touches on other aspects of health and social policy, e.g. regulatory prerequisites of health insurance (obligation to contract, premium structure) and other spheres of life and policy fields.

Primary prevention as an opportunity and task for society

76. "Health" is a leading topic in society, with increasing political and economic importance. The development of modern and sustainable primary prevention to strengthen and preserve "health", without secondary or tertiary preventive or curative interventions becoming necessary, is a central development task for the whole of society.

77. Research and practice in the health sciences have made significant progress in recent years and decades. This applies not only to the explanation of interactions between the social environment, lifestyles, health-related behaviour and illness, but also to the

development of interventions for reducing strains and strengthening resources. However, there is still a need for research into the emergence and reduction of health risks.

Insofar as prevention relates to reducing the probability of occurrence of specific illnesses, prevention research is primarily based on medical and epidemiological knowledge. However, the conception, testing and quality assurance of interventions requires social science competencies, and mostly also interdisciplinary collaboration. Since the subject of Health Sciences/Public Health has only been established at German universities again since the 1990s, there is still a substantial need for a transfer of knowledge and experience from other countries.

78. Despite the gaps in knowledge and research, it can be noted that the practice of prevention still lags behind the available knowledge. This can be seen in the use of methods and instruments of risk-related information and education whose low level of effectiveness is known, and in the still too infrequent use of context-related approaches that - in the framework of a setting, for example - are geared to the correlation between living (and working) conditions and health-related attitudes and behavioural patterns and secure the support of the target groups by actively incorporating them.

79. Sustainable primary prevention presupposes that the players in politics, in the responsible ministries, in social insurance and, above all, in the intervention areas (e.g. public administrations, private enterprises, educational institutions, such as schools, and other spheres of life) recognise that health-related opportunities and the probabilities of sickness depend on countless decisions, by which they influence the prerequisites for, and the possibility of, health for themselves and others. One task of health policy is to promote cooperation and communication in order to improve the prerequisites for health-related decisions being taken responsibly in the various spheres of life and at all levels.

5. Interfaces between health insurance and long-term care insurance

80. Noticeable progress has been made in the development of the German nursing sector in recent years. This includes the quantitative expansion of out-patient nursing offers and equally success in nursing quality assurance, e.g. by means of new statutory targets (Long-Term Care Quality Assurance Act) or the elaboration of national expert standards for central nursing services (including a standard for prevention of decubitus and falls). The initiated training reforms and the establishment of the nursing discipline in the higher education sector led to the reduction of qualification deficits and improved the attractiveness of the occupation. Changed training forms, contents and quality standards, and also the growing scientific potential, are unmistakeable indications of progressive professionalisation in certain segments of nursing.

On the other hand, nursing reality is still and repeatedly characterised by pronounced deficits. These include unacceptable deficiencies in elementary areas, such as basic care, nutrition and mobility, as well as gaps in services, e.g. in connection with the care of dementia patients, the mentally ill, dying or dangerously ill patients requiring medical equipment. In addition, there are problems in the areas where medical and nursing care overlap. Today, there can be just as little talk of the implementation of truly innovative concepts in nursing practice ("primary nursing", "home care", participation in integrated health care models) as there can of nationwide, flexible nursing services geared to the needs of the users.

81. Nursing will be one of the central fields of action for society in the future. Its development requires that the sustainability of the initiated modernisation process be ensured and structural deficits eliminated at the same time. One challenge lies in encouraging young people to take up a career in nursing and optimising their training and employment with a view to the specific requirements of persons in need of care. Any reform of the Long-Term Care Insurance Act that fails to consider these relationships will fall short of the mark.

82. In Germany's ageing society, guarding against the risk of a need for long-term care by means of social insurance was an important step in health and social policy. It led to numerous development stimuli for nursing and improved the services for the old and the chronically sick, in particular. Regardless of this assessment, the need for reform in long-term care insurance is evident today. Apart from the funding basis of the insurance and the development of demand-oriented and needs-based long-term care, the focus is mainly on questions relating to quality and the elimination of underprovision, e.g. in the

case of dementia patients, persons with disabilities, seriously ill patients following premature discharge from hospital, or the dying.

Demographic developments lead to two consequences in this context: on the one hand, the existing service landscape will not be able to cope with the forecast increase in the need for long-term care in the coming decades and, on the other, the increasing demand for nursing care will entail rising expenditure, which will be accompanied either by increasing contribution rates for insurance and/or by a decline in the service level. This trend will not even be substantially alleviated if a further improvement can be achieved in the health of the younger generations. A reform of long-term care insurance must lead to the provision of user-oriented and differentiated care services nursing that are no longer geared to an understanding of nursing based solely on somatic aspects. It should be part of a global concept of measures for an ageing society.

83. In future, both the risk of becoming in need of long-term care and the prevention of the need for long-term care will require greater attention in society and health policy. In this context, self-organised and self-funded preventive measures will probably have to supplement safeguarding by the community of insureds more than has so far been the case. It is not solely a matter of guarding financially against the risk of being dependent on long-term care, but equally of developing an awareness of the fact that requiring long-term care is not an inevitable condition, but can be prevented, or at least alleviated or delayed, e.g. by an appropriate lifestyle or adaptation of the residential environment. In the political field, the debate on redistribution processes must be incorporated in the long-term care and support of the chronically ill, and must set new points of emphasis regarding health care services in a society whose age structure has changed (cf. on this subject also 2000/2001 Report, Vol. III, Para. 7.4.1).

84. All reform proposals should be examined as regards their fairness to the generations. The postulates of fairness and sustainability demand that future generations paying comparable taxes and contributions receive benefits from the community of insureds comparable to those received by today's generation. With an eye to fairness to the sexes, the future statutory framework conditions should also make an effort to divide the tasks of nursing care more fairly between the sexes. Today, it is mainly women (wives, daughters and daughters-in-law) who bear the - frequently very great - strain of caring for members of the family at home.

Reorganisation of the insurance class

85. Comparable risks in life are insured in health and long-term care insurance. The organisational separation of partially competition-oriented statutory health insurance from non-competitive social long-term care insurance entails substantial disadvantages for the users. It permits shifting of the costs between the two insurance classes and in many cases leads to unclear responsibilities that can make it considerably more difficult to provide the person requiring long-term care with medical services.

Table 2: **Comparison of the organisational differences between statutory health insurance and social long-term care insurance**

Statutory health insurance	Social long-term care insurance
Comprehensive insurance	Partial insurance
Risk structure compensation	Expenditure-oriented fiscal equalisation
Competitive system	Non-competitive system
Fixing of the contribution rate by the respective health insurance fund (with an identical assessable income limit)	Fixing of the contribution rate by the legislature (with an identical assessable income limit)
Benefits based on the demand principle	Benefits based on the budget principle
Heterogeneity in the formulation of contractual responsibilities (different contract formulation at the Länder level, pilot projects, etc.)	Joint and uniform procedure in the formulation of contractual responsibilities (the individual long-term care insurance fund has no decision-making latitude of its own)
Benefits generally granted upon utilisation (implicit granting of benefits)	Benefits granted after application and expert assessment (explicit granting of benefits)
Sectoral budgeting	Global budget
Few options regarding benefits	Wider options regarding benefits (non-cash or cash benefits in-patient care; out-patient or in-patient care)

Source: Own representation

86. Because of inter-fund fiscal equalisation, the long-term care insurance funds do not have to pay attention to the efficiency of the services rendered. Efficiency-promoting competition via the contribution rates is ruled out by the fixing of a uniform nationwide contribution rate. Long-term care insurance funds not only have no incentive to act economically, they also have no decision-making possibilities in the contract sector. Ap-

ropriate use should be made of the potential of competition in the further development of social long-term care insurance. The efficiency principles prescribed by law are not enough to achieve the necessary improvement in efficiency and quality. From the point of view of the insurance funds, there is an interest in shifting expenditure to long-term care insurance. The following aspects advocate closer meshing of statutory health insurance and social long-term care insurance in the medium term:

- The coexistence of statutory health insurance and social long-term care insurance is not effective, since they guard against similarly structured risks,
- In the case of older insureds, there is often overlapping of claims from the two classes of insurance,
- Prevention and rehabilitation measures for avoiding a need for long-term care are not taken to a sufficient extent owing to different economic incentive structures,
- Opportunities for establishing models of integrated health care are hardly used, and
- Eligible persons in need of long-term care suffer major disadvantages if benefits are shifted from statutory health insurance to budgeted social long-term care insurance.

87. In the long term, these weighty interface problems suggest a need to integrate statutory health insurance and social long-term care insurance. However, the integration of social long-term care insurance in a competitive insurance system presupposes functioning, morbidity-oriented risk structure compensation. Experience with risk structure compensation in statutory health insurance can provide some useful information as a basis for devising it. Integration of these two classes of social insurance will not solve all the interface problems in that the conflict of interests between the insureds and the health insurance funds will often remain owing to the partial nature of social long-term care insurance. In a competitive system, however, the insureds have the possibility of exerting an influence on the decisions of the health insurance funds, i.e. by threatening or reacting with a switch to a different fund. If statutory health insurance is expanded into "citizens insurance" by abolishing the compulsory insurance income threshold - a move advocated by some members of the Council - corresponding organisation of social long-term care insurance would also be logical in the event of integration of these two classes of insurance. Similarly, a transition to fund-specific, flat-rate per capita contributions in statutory health insurance would also - as advocated by other members of the Council - suggest corresponding funding of social long-term care insurance.

Even independently of integration of these two classes of insurance, i.e. if social long-term care insurance were to continue to exist independently in the current regulatory framework, efficiency aspects speak in favour of competitive social long-term care insurance with risk structure compensation instead of fiscal equalisation. In this event, too, some members of the Council advocate the introduction of citizens insurance, while others are in favour of flat-rate per capita contributions.

88. As already recommended by the Council in connection with the funding of SHI, the contributions paid by the insureds should be extended to cover all types of income, although the premium based on earned income should continue to be shared between employee and employer. The co-insurance of dependents is - also against the backdrop of the decision of the Federal Constitutional Court - considered to be sensible. It is recommended that the joint employment remuneration or income be split, and half the contribution rate then applied to each income element. Below the assessable income limit, this method leads to no additional financial burden in the event of one income of the working partner, or of two incomes after splitting. Compared to the existing system, the splitting method only imposes a greater burden on those families where the earned income of the working partner exceeds the assessable income limit, and those where the earned income of one partner is above the assessable income limit and that of the other below it (cf. 2003 Report, Vol. I, Section 2).

89. At €1,023, the monthly long-term care insurance payments in Care Level I for in-patient care are more than twice as high as the non-cash out-patient benefits of €384 and five times as much as the constant attendance allowance of €205. These substantial differences in financing are a great incentive for in-patient care, which is in keeping neither with fiscal, nor with nursing objectives. To strengthen the incentives for out-patient care, two extreme solutions offer themselves at first glance, although both of them conflict with certain (different) goals. Radical reduction of the payments for in-patient care to the current level for out-patient care would again make more people in need of long-term care dependent on income support. A development of this kind would be contradictory to one of the central goals of introducing long-term care insurance. Conversely, an increase in the benefits for out-patient care to the current level for in-patient care falls down due to fiscal restrictions. A sensible (middle-of-the-road) way to solve the problem of incentives, which primarily arises in connection with Care Level I, would be to slightly increase the rates in the out-patient sector and slightly reduce them in the in-patient sector.

90. In the in-patient sector, persons in need of long-term care are left to finance a personal share, calculated as the difference between the prices of the nursing home and the respective benefits from long-term care insurance. In the western Länder, this personal share of persons in need of long-term care increases noticeably from approx. €1,100 in Care Level I to approx. €1,280 in Care Level II and approx. €1,580 in Care Level III. This increase in the personal share to be paid by persons in need of long-term care is dependent on the level of the Care Level and cannot be justified in terms of distribution policy because, regardless of their classification in a particular Care Level, the persons involved have an unchanging personal income in each case. Both this distribution policy effect of a personal share of the persons in need of long-term care that is roughly equal in the Care Levels, and also the allocative incentive problems between the in-patient and out-patient sectors, speak in favour of redistribution of the funds in the in-patient sector without affecting revenue, i.e. of substantially increasing the benefits in Care Level III and moderately reducing them in Care Level I. Without affecting revenue, the proposed increase of the benefits by €200 in Care Level III would necessitate a reduction of only €50.43 in Care Level I, since there are far more people in this Care Level.

91. The nominal amounts, which have remained constant since the introduction of long-term care insurance, are subject to a permanent decline in real value. This is all the more true in the long-term care sector in that the specific price index there exceeds the general inflation rate, primarily because of the limited possibilities for enlarging the amount of capital. Consequently, safeguarding a constant real value of the nominal amounts requires their periodic adjustment using a special price index for nursing services that is roughly one percentage point above the general inflation rate. This index-linking should enter into effect for in-patient rates when the corresponding reform comes into force, and with retroactive effect from the year of introduction of long-term care insurance for the out-patient rates in Care Level I. The greater increase in the rates in Care Level I in the out-patient sector gives further incentives for looking after people in need of long-term care in the private environment and weakens the current incentives acting in the opposite direction. Together with the slight decrease in the in-patient benefits in Care Level I, the more extensive index-linking of out-patient benefits reduces the previous disproportion of €1,023 vs. €384 or €205 to €972 vs. €439 or €234 (see Table 3). The more extensive index-linking of out-patient benefits that cannot be financed without affecting revenue causes additional funding requirements of approx. €708 million, this corresponding to approx. 0.1 (exactly: 0.074) contribution rate points. This marginal increase in the contribution rate appears justifiable when it comes to preserving the functional capacity of the social long-term care insurance system.

Table 3: Effects of index-linking and redistribution of funds in the in-patient sector if introduced in 2006

	Care Level I		Care Level II		Care Level III	
	Now	From 2006	Now	From 2006	Now	From 2006
Benefits for home care (constant attendance allowance)	€205	€234	€410	€469	€665	€760
Benefits for home care (non-cash care benefits)	€384	€439	€921	€1,053	€1,432	€1,638
Benefits for in-patient care	€1,023	€972	€1,279	€1,279	€1,432	€1,632

Source: Own calculations

92. In the hitherto non-competitive system of long-term care insurance, elements of competition could benefit people in need of long-term care. If long-term care insurance funds negotiate special rates for their insureds with individual nursing homes or nursing home chains, they reduce the personal share of the insureds. However, every insured has the option of deciding on a different provider, but must then accept the risk of having to pay a higher personal share.

93. For their part, the nursing homes could develop more flexible nursing offers in future, making it possible to integrate care services provided by relatives in the nursing services of the home, or to network external care packages with the services of the home. This could give rise to a differentiated service and price structure, while at the same time eliminating the strict separation of out-patient, in-patient and home care by the family.

94. The generative contribution made by parents must be honoured when implementing the decision of the Federal Constitutional Court on relieving the burden on people raising children in the contribution system of long-term care insurance. The relief granted to child-raisers should not be global and uniform, but based on the number of children. Compensation solely in the long-term care insurance system brings up a number of questions and causes administrative costs. The tax system is a suitable means for partial compensation of the financial burdens involved. In addition, the Federal Constitutional Court instructed the legislature to examine all branches of social insurance for distortions resulting from the burden of raising children.

Rehabilitation before long-term care

95. The higher-ranking goal of enabling people in need of long-term care to live in their familiar surroundings with opportunities for self-determination and the most extensive possible participation in social life, has so far been implemented to only a limited extent in the framework of long-term care insurance. This goal should above all be reached by giving rehabilitation measures priority over long-term care services, and out-patient care priority over in-patient care. However, it is precisely in relation to older people that the potential of prevention and rehabilitation has so far been given inadequate consideration (cf. 2000/2001 Report, Section 2; 2003 Report, Section 5) (see Table 4).

Table 4: **Frequency of the recommendation of rehabilitation measures in expert opinions on long-term care requirements (in percent)**

	Persons of all age groups	Persons over 60
Physiotherapy	11.5 to 15.3	6.6
Ergotherapy	2.1 to 3.2	0.7
Logotherapy	1.2 to 2.3	0.8
Other rehabilitation measures	4.7 to 5.4	No data

Source: Own representation

96. The chance of avoiding, reducing or delaying a need for long-term care by means of prevention and rehabilitation is so far not exploited sufficiently. The current structure of the insurance system unintentionally restricts the existing preventive and rehabilitative options for counteracting the need for long-term care. For health insurance funds, there is an incentive to shift benefits to long-term care insurance. They themselves are only interested in preventive and rehabilitative measures if their success is reflected in SHI and not as an external effect in social long-term care insurance. They act rationally when, at the interface, they decide in favour of inefficient solutions that are also contrary to the interests of the insureds. Rehabilitation should be funded by the agency that also benefits from the success of the measure. Only in this way is the burden of funding accompanied by an interest in a potential success of prevention or rehabilitation. This results in the demand for the long-term care insurance funds to be recognised as rehabilitation funding agencies. A decision of this kind would eliminate the separation of

funding burden and interest in success in geriatric rehabilitation, transferring the responsibility for geriatric rehabilitation to the long-term care insurance funds.

97. This interface problem between health and long-term care insurance funds in relation to rehabilitation can also be solved by creating a cross-fund budget for people in need of long-term care. This budget should be established at the long-term care insurance funds, and its funds granted in accordance with the expert recommendations of the Medical Advisory Service of SHI (MDK). The rehabilitative potential of the persons in need of long-term care should be taken into account in every classification report in future. The written decision on long-term care should communicate the rehabilitation recommendations to the person in need of long-term care, his or her relatives and the family physician. Together with the eligible insured, the family physician can then submit an application for rehabilitation.

98. The incentives for prevention and rehabilitation are also wrong on the side of the people in need of long-term care. While exhausting rehabilitation potentials may be accompanied by improvements in health and function for the affected persons, and thus by an enhanced quality of life, it also automatically leads to benefit cuts if the result is a different (improved) classification of the need for long-term care. This circumstance may restrict the motivation of people in need of long-term care to avail themselves of prevention and rehabilitation measures. Therefore, one target-oriented possibility would seem to be for willingness to undergo rehabilitation to be materially promoted if it proves successful, e.g. by correcting the Care Level after six months at the earliest in the event of an improvement in condition, or by paying out the difference between the Care Levels to the person in need of long-term care in one sum.

99. Long-term care itself has not been able to adequately implement the "rehabilitation before long-term care" reform approach, e.g. because of existing training deficits. Moreover, the one-sided priority of rehabilitation over long-term care reflects a sequential view of the course of illness, which does not do justice to the conditions of the chronically ill and persons in need of long-term care (cf. 2003 Report, Section 5). Rehabilitation and prevention must in future be implemented as integral elements of long-term care work. This will make it possible to promote and preserve the resources of people in need of long-term care with the help of rehabilitation, and to utilise the professionally available rehabilitative potential of long-term care.

100. Pilot projects on cross-agency personal budgets, as now made possible by the law, offer an opportunity to test even more flexible personal handling of the benefits of long-

term care insurance. The people in need of long-term care should not - as current envisaged - have to finance case management themselves.

101. The municipalities and Länder also bear part of the responsibility for the prevention of dependence on long-term care. It is their duty to create and maintain the necessary infrastructure. This includes the facilities in residential buildings, the provision of community-based services for forms of assistance that cannot be part of long-term care or long-term care insurance, and also the strengthening and support of voluntary commitment.

Quality assurance in long-term care

102. Like all other healthcare professions, nursing has in recent years expanded its efforts in the field of quality assurance and achieved some success. Nevertheless, there are major differences between institutions and regions. The decisive yardsticks for the quality of long-term care are the preservation of the self-determination of people dependent on nursing and their participation in social life. For this reason, quality development serves the improvement of services for persons in need of long-term care. So far, however, there has been a lack of user-defined quality criteria. Only the establishment of corresponding, empirical basic knowledge would make it possible to develop quality criteria from the point of view of the users. The "Round Table on Long-Term Care", in particular, should devote itself to this task, because the establishment of this initiative by the Federal Ministries for Family, Senior Citizens, Women and Youth, and for Health and Social Security is associated with the task of an offensive for improving the quality of nursing in Germany.

103. However, quality development also aims at increasing the professionalism of the service providers. In this respect, there is a substantial need to create more attractive framework conditions for work in the nursing sector. This includes not only financial incentives for taking up work in the nursing sector, but also the integration of prevention and rehabilitation in the basic and specialist training and continuing education of all nursing staff, the promotion of physiotherapy and ergotherapy, comprehensible systems for determining nursing times or nursing staff requirements, and the development of evidence-based expert standards for nursing. Upgrading the nursing professions in society and the creation of improved options for professional advancement would make these occupations attractive for a larger group of persons.

104. The purpose of the statutorily prescribed care counselling meetings in the home-care sector is to check the standard of quality of family care. One problem in this context is the repeatedly occurring conflict between counselling and control, and the reduction of the counselling task to administrative questions and financial benefits. Yet, targeted assistance and counselling could both counteract overtaxing of the relatives and help avoid the potential risk of the person in need of long-term care receiving insufficient care.

The quality of in-patient long-term care is examined not only by means of in-house quality management, but also by external procedures (supervision of homes and MDK). In addition to further intensification of external audits (increase in the number of unannounced visits to the institutions), quality development in the in-patient long-term care of persons dependent on long-term care should also be achieved by the affected parties having a greater influence and by committing the institutions and funding agencies to implement an offensive and user-friendly information policy.

105. There is a lack of dependable research results concerning the long-term care requirement, on which the planning of future long-term care could be based. The long-term care market will grow rapidly in the coming decades. Sound investigations regarding the anticipated development of expenditure, contribution rates and the workforce requirement are an essential prerequisite in order to do justice to the demands and permit longer-term planning in this sector.

Improvement of services for special problem situations

106. Following the introduction of long-term care insurance, a relatively uniform service landscape initially emerged in which, for example, chronically ill patients in advanced stages of their illness, or terminally ill patients, cannot be given the services they need. This estimation particularly also applies to the provision of nursing services for dementia patients.

Given increasing life expectancy, dementia illnesses will acquire increasing significance for society as a whole in the coming years (see Table 5). New support and counselling structures must be created in order to be able to meet these challenges.

Table 5: Prevalence of moderate and severe dementia in Germany (in percent)

Age in years	65-69	70-74	75-79	80-84	85-89	90+
Share in percent	1.2	2.8	6.0	13.3	23.9	34.6

Source: Bickel, H. (1999)

107. The growing number of dementia patients, the existing underprovision and the differences in the treatment of affected persons advocate the management of this illness in the framework of integrated structures. Medical and nursing services for dementia patients should initially be provided on a cross-sectoral and cross-insurance basis with the aim of arriving at better treatment through integrated concepts. In the framework of programmes of this kind, success could be achieved in eliminating knowledge deficits concerning this illness among attending physicians and in further educating nursing staff regarding the special demands created by a growing number of dementia patients.

Case management offers are suitable for providing needs-based services in the case of illnesses like dementia, which occur in old age and are accompanied by other illnesses. The affected persons and their relatives often find it difficult to organise treatment and support as soon as they have claims on different areas. A central organisation could improve treatment and guard the relatives against being overtaxed.

108. Particularly relatives who nurse dementia patients are greatly stressed by providing this care and often suffer from health problems themselves. Despite the progress made, long-term care insurance does not give adequate consideration to this special need for assistance. This applies not only to financial allowances, but also to measures for strengthening home care that relieve the burden on informal care systems and transfer part of the work to the professional sector. Care-giving relatives need more opportunities for relieving their burden than is currently the case, and the nursing sector must be given incentives to establish supportive assistance structures of different kinds.

109. Experience gained to date can be utilised in the search for new forms of accommodation, especially for people suffering from dementia. Further support and expansion of the pilot projects in Germany could yield new stimuli for diversified services. In the framework of offers and pilot projects of this kind, success could be achieved in integrating voluntary commitment in the support of sick - and mainly old - people even more than up to now.

110. There is a substantial need for research into dementia, its management-related problems and care. In addition to the purely physiopathological knowledge regarding the genesis of the illness and slowing-down its progression, the effects of the available drug therapy and their sustainability are also up for discussion. The benefit of the current drug therapy is not undisputed. Cost-benefit analyses in everyday management that compare the cost of drug and non-drug therapies with the savings, e.g. resulting from a reduced support effort, hold the promise of improving the decision-making basis in this respect. The judgements of the patients themselves, and of their relatives, would also have to be incorporated in analyses of this kind.

There is a need for more detailed analyses and research to identify the proportion of the total volume of long-term care insurance that is attributable to the care of dementia patients, and to determine the distribution of the costs between health insurance, long-term care insurance and the patients themselves.

6. Therapeutic appliances and remedies in SHI

111. Health policy and reporting should devote greater attention to the "therapeutic appliances" and "remedies" service segments with the aim of improving the transparency, efficiency and effectiveness of provision. One of the points indicating this necessity is the fact that therapeutic appliances and remedies are integral elements of the rehabilitation of disabled, chronically ill, elderly and aged people, whose numbers are increasing on account of demographic trends.

112. The range of therapeutic appliances, as a section of the market for medical products, and remedies, as services to be rendered personally, constitute different medical service segments, each with its own structural problems. The "therapeutic appliances" segment, in particular, comprises various sub-markets and is characterised by extensive heterogeneity. The content-related links to rehabilitation should be taken into consideration when defining spheres of duty, competence and responsibility, e.g. at the social insurance funding agencies.

113. More than other medical service areas, the provision of therapeutic appliances and remedies is characterised by a large number of contracts with service providers at the association level and at the level of the individual health insurance funds, and by a complex contract landscape. By introducing the new regulations of the Health Insurance Modernisation Act (GMG) in the therapeutic appliances sector, the legislature aimed to strengthen the contract principle at the health insurance fund level and make it possible for insureds to be provided with medical services of the same quality at lower prices. The handling of this leeway should be evaluated with the objective of securing the quality and efficiency of the provision of therapeutic appliances. To be able to assess the conceivable impact of granting further latitude for the individual health insurance funds to formulate their own contracts with service providers, there is a need to monitor the utilisation of existing options. Among others, the self-help and disabled persons' associations, as well as the Federal Government Commissioners for Patients' Affairs and for Matters Relating to Disabled Persons, should also be involved in corresponding projects in the fields of therapeutic appliances and remedies.

114. Even more than the supply of drugs, the supply of therapeutic appliances lacks an infrastructure permitting assessment of the benefit of products and the associated conclusions regarding the reasonableness of prices and price relationships. Under these conditions, support is given to the establishment of a Task Force, comprising experts from the head associations of SHI, individual health insurance funds and the Medical

Advisory Service of the head associations of SHI, and involving additional specialists and representatives of manufacturers and patients on a case-to-case basis. The priority tasks of this body would be issues relating to quality assurance, updating and maintenance of the catalogue of therapeutic appliances and, in this context, primarily the creation of product groups and the formulation of quality standards, the improvement of the calculation basis for fixed reimbursement rates and diagnosis-related flat rates, and the re-use of therapeutic appliances. Results of the Task Force, particularly on the methodology of health technology assessment (HTA) for therapeutic appliances, the inclusion of products in the catalogue of therapeutic appliances and the calculation of fixed reimbursement rates, should be documented on the Internet.

While the power of the Joint Federal Committee to determine policy guidelines encompasses the prescribability of therapeutic appliances by SHI-accredited physicians, it does not include the compilation and updating of the catalogue of therapeutic appliances. However, since the Joint Federal Committee is responsible for specifying the details of the SHI benefits catalogue, which is only outlined generally in SGB V, it should be included in the Task Force.

115. The importance of the catalogue of therapeutic appliances, as the key instrument for structuring the market and increasing the transparency of the range of therapeutic appliances, is to be strengthened. The health insurance funds, their associations and the service providers, including the retail trade and pharmacies, should generally use the catalogue of therapeutic appliances for market observation, in contract negotiations, for rendering accounts of benefits and services, and for statistical purposes. In this context, the question should be examined of whether, in order to arrive to unequivocal product designations, it would make sense to expand the catalogue to include additional levels, also in order to prevent the incorrect use of therapeutic appliance item numbers. Ongoing expansion, updating and revision of the catalogue must be ensured. A time limit on the use of therapeutic appliance item numbers could also be helpful in this respect.

In addition to supplementary product information, the catalogue of therapeutic appliances should gradually be expanded to include the price information already envisaged in Section 128 SGB V, as well as the nationally valid fixed reimbursement rates. Price ranges and average values can be indicated in the event of substantial price variations.

116. Further offers of information regarding the provision of therapeutic appliances are to be developed for insureds and their physicians, above and beyond the catalogue of therapeutic appliances and existing search options, such as the therapeutic appliances

database of the REHADAT information system. Ideally, a quality-assured information base accessible via the Internet would emerge for all groups with an interest in the provision of therapeutic appliances (primarily manufacturers, specialist retailers, insureds and relatives, self-help, patient, disabled persons' and consumer associations and institutions, office-based physicians, hospitals, rehabilitation and nursing institutions, nursing services and "home care" enterprises). This information base would be usable for information enquiries in varying degrees of detail and provide both an initial, general overview and also specific information. The information offered could extend to product and quality attributes, study results, case and test reports, prices, fixed reimbursement rates, the part-payment of insureds and special offers of health insurance funds in the field of therapeutic appliances management. Foreign manufacturers from the EU region are to be taken into consideration on principle in this context, in order to exploit advantages of the Common Market both for patients or people with disabilities and for the insurers. An information offer of this kind would also improve the conditions for objective decision-making by physicians, insureds and health insurance funds, and for efficient prescription and supply practice. Above all, people with disabilities, prescribing physicians and experts from the social insurance sector should be involved in elaborating the concept for an offer of this kind.

117. The health insurance funds are recommended to take the following criteria into account in their contract policy in the therapeutic appliances sector:

- Gearing to product groups and quality standards in the catalogue of therapeutic appliances, fundamental consideration of the cost-benefit ratio of the provision of therapeutic appliances instead of the pure costs of acquisition and, in this context, consideration of the maintenance and replacement costs,
- Safeguarding of qualified counselling, individual adaptation of therapeutic appliances and support of insureds in the calculation of fixed reimbursement rates, in contracts with providers of therapeutic appliances and in the framework of integrated health care,
- Stipulation of diagnosis-related flat rates for defined periods of time instead of (or based on) fixed reimbursement rates, especially when therapeutic appliances require individual counselling and adaptation or maintenance, when used therapeutic appliances are suitable for further use, or when innovative methods of therapeutic appliances management are to be tested, and

- Creation, e.g. on the Internet, of information offers for insureds concerning product characteristics, complementary services, such as counselling and adaptation, distribution channels, prices and fixed reimbursement rates, as well as service and therapeutic appliances management contracts of the respective health insurance fund.

118. Health reporting must give increasing consideration to the therapeutic appliances and remedies service segments. In contrast to the fields of out-patient medical care, hospital care and the supply of drugs, only relatively few analyses and data are available that permit a sound assessment of the supply situation and market developments. The "2004 Remedies and Therapeutic Appliances Report" of the Gmünder Ersatzkasse substitute health insurance fund is a first step, but also illustrates the extent of the existing information deficits.

119. Health reporting should also be expanded to include structural data and benefit statistics relating to the remedies sector, with the aim of presenting regional differences in the service provider density and the benefits structure. This would create points of reference for medical service research and the organisation of regional service structures. A contribution to achieving this aim could mainly be made by publishing data from the planned SHI Remedies Information System.

Health insurance funds and their associations should seek and exploit possibilities for influencing regional provider structures in the supply of remedies by means of their contract policy, and for balancing out any existing capacity surpluses or shortages. Instruments open to consideration are the regional remedies agreements according to Section 84 Para. 8 SGB V and, above all in this context, the adjustment parameters for drug agreements, which are to be applied similarly to remedies (cf. Section 84 Paras. 2 and 8 SGB V), as well as data on the benefits structure from the new Remedies Information System and results of medical service research.

120. Medical service research and health technology assessment (HTA) should be further expanded in the German healthcare system. The effectiveness, adequacy and efficiency of the use of therapeutic appliances and remedies offers itself as a subject for medical service research and HTA projects. Since both segments contribute to the rehabilitation of chronically ill and disabled persons, rehabilitation research should also devote greater attention to these medical service fields. Owing to their importance for the analysis and organisation of the range of benefits of social insurance, research projects of this kind are, in principle, also a task of SHI, statutory pension insurance, statutory accident insurance and, where appropriate, other social insurance funding agencies. Re-

search projects should be based on impairments of functioning and, in this context, on the International Classification of Functioning, Disability and Health (ICF). Use of the ICF will improve the international comparability and exploitability of study results.

121. As is generally the case in connection with rehabilitation, the prescription of therapeutic appliances and remedies should be decided less by the medical diagnosis and more on the basis of the classification of functioning as defined in the ICF. In this context, it is important to ascertain not only the deficits, but also the patient's resources and living conditions. Physicians must have a knowledge of functional diagnostics on the basis of the ICF, and also of the effectiveness of therapeutic appliances and remedies. At least in the case of expensive therapeutic appliances and remedies, prescribability should be subject to proof of qualification and continuing education, and the justification of prescriptions for therapeutic appliances should require a utilisation forecast in the case of high-value products. A trial phase may also be helpful in selecting a suitable therapeutic appliance.

Physicians should acquire more in-depth knowledge relating to the provision of therapeutic appliances and remedies in their basic training, specialist training and continuing education. To also increase the scientific qualification of members of non-medical healthcare professions, e.g. graduates of full-time vocational schools, and to enable them to engage in research and utilise study results, universities and/or specialised technical colleges should set up more in-service courses of study. Among others, Institutes of Rehabilitation Sciences, Physical Medicine and Rehabilitation, Epidemiology and Health Sciences would be open to consideration in this context.

7. Factors influencing the prescription of drugs

122. Modern, scientifically based pharmacotherapy is not even 100 years old. Since antiquity, however, drugs have counted among the most effective instruments for controlling disease, psychophysical illnesses and pain. They are an indispensable prerequisite for maintaining the working capacity and performance of large segments of the population in Western societies. However, there are still many pathological conditions that cannot be treated, or only unsatisfactorily. In Germany, the supply of drugs generally reaches everyone who needs them and has reached a high standard in terms of the degree of innovation and its scientific foundations.

123. Regardless of the existing deficits, which continue to manifest themselves in the form of underprovision, overprovision and misprovision, there has been a demonstrable improvement in the supply of drugs in some sectors in recent years (e.g. reduction in the prescription of controversial drugs or of potentially addictive drugs). The participation of office-based physicians in "pharmacotherapy circles", e.g. in the framework of integrated health care, indicates growing quality-consciousness. This is also reflected in the trend towards formulating and implementing more scientifically based recommendations, such as evidence-based guidelines.

124. The range of drugs prescribed and the financial resources expended on them are in the region of the average for other European nations. Various attempts at cutting expenditure on drugs only resulted in temporary cost reductions and proved incapable of preventing a steady rise in expenditure on medicines (see Figure 5). Success in realising savings can still be achieved in certain areas by imposing further savings-related requirements on the prescribing physicians. Possibilities of this kind should be exploited, even if the strain on the system cannot be durably relieved in this way. Consequently, the improvement of drug therapy should equally focus on quality.

125. There is no easy way of achieving improvements in outcome-oriented fashion in this multifactorial complex of conditions. Although theoretically desirable, cost-efficient and effective drug therapy that exploits all "savings potentials", in particular, is hardly attainable in practice because of the wide range of influencing factors. It would therefore seem appropriate to draw up a realistic assessment of the savings potential of the rationalisation reserves suspected or theoretically achievable in connection with the prescription of drugs. Feasible ways of rationalising could then be found on this basis. If, on the one hand, modern pharmacotherapy is wanted that reacts promptly to innovations and largely exhausts the health-related potentials of drugs, this will, on the other

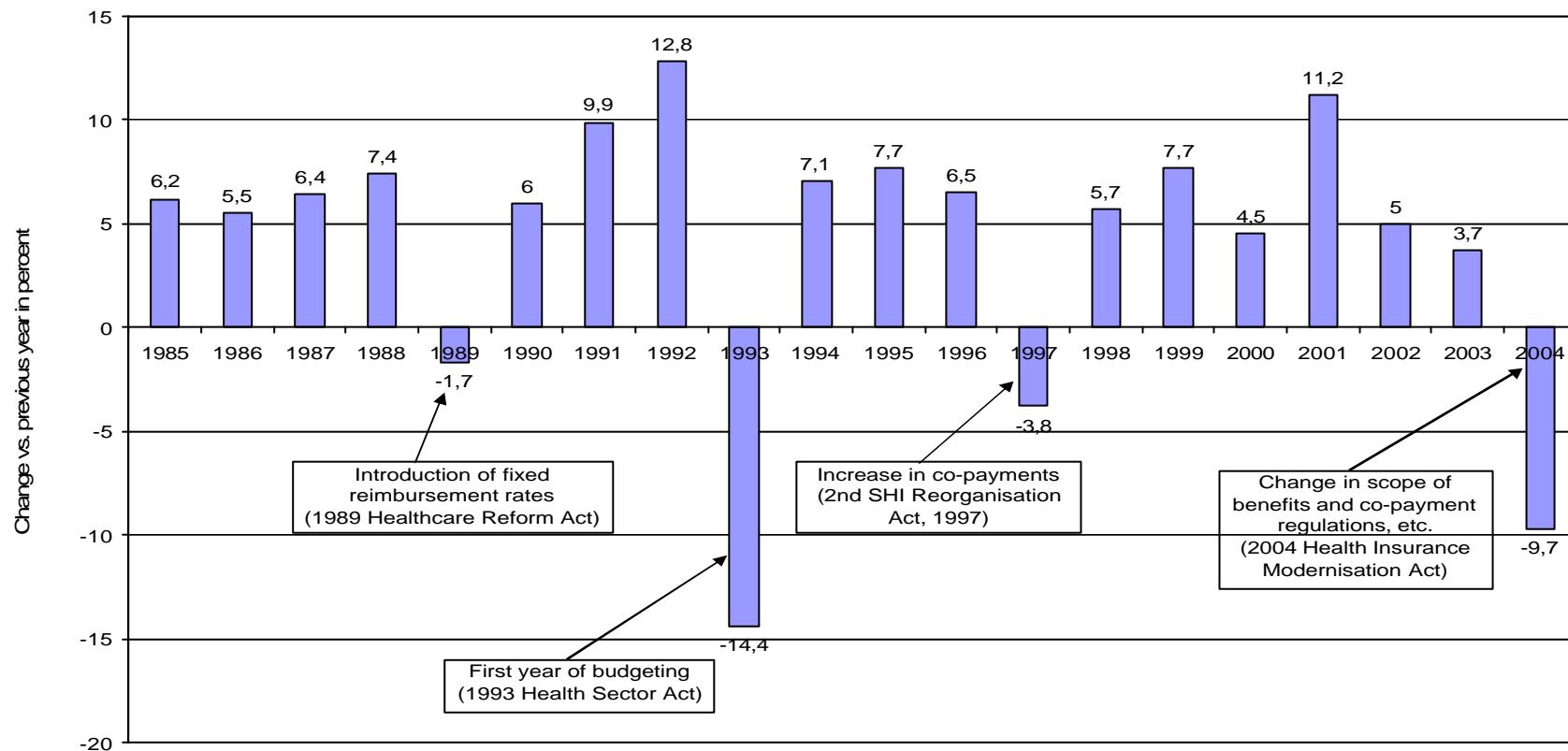
hand, automatically entail a corresponding volume of costs. Nevertheless, the volume of savings achieved in practice must be gauged time and again against the theoretically possible result and realigned, if necessary. Similarly, the realisation of the envisaged target parameters must be subject to constant review based on the criteria of practical achievability.

The German drug market at a glance

126. In terms of sales volume, the German drug market is the third largest in the world. However, if per capita drug expenditure is examined, or the "drug quota" - this being the ratio of expenditure on drugs relative to the total expenditure on health care - the figures tend to be inconspicuous in an international comparison, in terms of both their level and the expenditure trend.

127. Except in 1993, expenditure on drugs in Germany rose continuously in the period from 1992 to 2003. Expenditure in the framework of SHI and that of private households developed reciprocally and usually added up to approx. 90% of the total expenditure. With approx. 70%, SHI accounted for the largest portion of the expenditure on drugs borne by the various agencies. In 2003, the turnover generated by prescriptions in the framework of SHI amounted to more than 60% of pharmacists' turnover. It thus plays a dominant role as regards the development of the German drug market. Since the mid-1990s, expenditure on drugs has accounted for a steadily increasing percentage of total SHI expenditure. Second to expenditure on in-patient benefits, it constituted a larger expenditure item than out-patient treatment by physicians in 2003. A decline in expenditure on drugs was recorded in 2004 as a result of statutory regulations. However, expenditure growth can already be expected again in 2005.

Figure 5: Change in SHI expenditure on drugs per member compared to the previous year (in percent)



Figures for 2004: provisional accounting result, 1st - 4th quarter 2004.

Only the Western Länder up to 1991, Western and Eastern Länder from 1992 onwards.

Source: SHI statistics; own calculations and representation

128. Rationalisation potentials exist in the fields of prescription of controversial drugs, active substances with the potential for manufacture of generic drugs, and me-too drugs. By reducing the prescription of controversial drugs and forgoing medications of unconfirmed therapeutic benefit, SHI-accredited physicians made a substantial contribution to drawing on rationalisation reserves in recent years. A further contribution to the savings volume was made by the fact that, since the beginning of 2004, non-prescription medicines, which include many controversial drugs, can no longer be prescribed for insureds over the age of 12 at the expense of SHI, with just a few exceptions. The savings potential resulting from forgoing controversial drugs will probably continue to decline in the future, partly because of the exclusion of approx. 5,000 preparations from the market in 2003, for which no proof of efficacy was submitted and for which no application for re-registration was filed. In contrast, the expiry of patents is constantly yielding new opportunities for rationalisation through the prescription of generic drugs. With just under 68% in the market for active substances with the potential for manufacture of generic drugs, and over 30% in the total SHI market, Germany has what is probably the largest market share of generic drugs in the world. The price gap between off-patent, single-source drugs and generic drugs is, however, increasingly closing against the backdrop of the market-dominating position of just a small number of manufacturers of generic drugs. A probably greater potential for savings than in the field of substitution by generic drugs currently exists within the generic market segment because, instead of a price competition, an intensive discount competition is in progress there, which benefits not the insurance funds or the contributors, but the pharmacies. Finally, the launch of very expensive, patented drugs can be seen in the overall market. They include a significant proportion of me-too products, many of which have no greater therapeutic benefit than less expensive generic products.

129. The central parameter influencing the growth of expenditure on drugs, the so-called structural component, consists of the inter-drug and the intra-drug effect. The inter-drug effect dominated in recent years, i.e. the substitution, predominantly or on balance, of less expensive drugs by new preparations with higher prices. The intra-drug effect relates to one and the same drug and involves a switch to other pack sizes, dosage forms or potencies. Where the inter-drug effect relates to more expensive drugs with no relevant therapeutic advantages, this drug substitution leads to concealed price increases and inefficient drug therapy. A cost-benefit assessment in the framework of a "fourth hurdle" could fix a maximum reimbursement limit in the framework of SHI for preparations of this kind, e.g. by including them in the system of fixed reimbursement rates.

Expenditure on drugs and production from an international point of view

130. In recent years, the pharmaceutical industry in Europe lost ground on companies from the USA in terms of competitiveness. Germany and Italy, in particular, recorded negative trends in this context. In the early 1990s, Germany was still the world's third-largest pharmaceutical producer, but today only takes fifth place behind the USA, Japan, Great Britain and France. There is no longer a German company among the ten enterprises with the highest sales. This is partly a result of a process of concentration and globalisation in the pharmaceutical industry, which is still continuing and the impact of which on willingness to innovate and the quality of the supply of drugs should be kept under critical observation.

131. It is also in the interests of the patients to preserve and promote successfully researching pharmaceutical companies in Germany, since new preparations are often first launched on a company's home market. Additionally, research and development in connection with new medicines are often accompanied by extensive value-added activities, permit spill-over effects into other branches of industry and create jobs. The pharmaceutical industry in Germany has been recording declining employment figures in recent years. Advanced development, such as that in the American research-based pharmaceutical industry, has not taken place to such an extent in Europe. In the USA, a new structure developed in the industry, which is characterised by small biotechnology enterprises that perform work for the major corporations. The technology market could probably be exploited more efficiently by outsourcing parts of basic research. Networking between universities, private and public research institutions also contributed to creating a research-friendly environment from the point of view of the industry in the USA. This is one of the reasons why European corporations are gearing their basic research towards North America. Apart from a few big players, the industry in Germany consists of numerous small and medium-sized enterprises. The regulation of the German market is of great importance for these businesses, since they do not generally see themselves as being in a position to move parts of research and development or production to locations abroad.

132. Pharmaceutical companies expect stable framework conditions, so that they can plan their research and development expenditure on a long-term basis. However, as evidenced by the example of Switzerland, successful pharmaceutical companies do not necessarily need a domestic market with a high sales volume. The marketing authorisation procedure is today largely carried out in accordance with specifications valid

throughout Europe. Swift implementation of the corresponding directives, regulations and recommendations of the European Commission benefits patients and enterprises alike. This includes, for example, the acceleration of authorisation procedures and the provision of incentives for the development and marketing of medicines for rare illnesses, the elderly and children. Gender-specific differences must be taken into account in this context at all events.

133. A decisive influence on the attractiveness of the German drug market is exerted by the institutions responsible for the prescribability of a drug in the framework of SHI. In this most lucrative segment of the German market, a host of reforms in recent years led to declining transparency, where the short-lived regulatory interventions aimed - with limited success - at containing the increase in expenditure on drugs. From 1997 to 2003, however, new and patented drugs were largely protected against regulatory measures, such as fixed reimbursement rates. However, only little use was made of this additional promotion of research activities. The majority of the new drugs marketed in this period were me-too products, which only rarely had therapeutic advantages or advantages in the price competition with established medicines. In future, the decision regarding the reimbursability of, or the reimbursable amount for, a preparation should thus be geared to lasting, transparent and unequivocal criteria guided by efficiency optimisation and therapeutic progress.

Expansion of decentralised contract negotiations

134. According to Section 130a Para. 8 SGB V, health insurance funds or their associations can reach agreements with pharmaceutical companies on discounts for drugs issued at their expense, in addition to the price reductions provided for by law under Section 130a Paras. 1 and 2 SGB V. To fully exploit the rationalisation potential, these contract negotiations between manufacturers and funds should be increasingly used in connection with medications in the fixed-reimbursement segment. If no contract negotiations are held, or if they fail, the fixed reimbursement rates continue to apply as the maximum reimbursement limits. In this way, the manufacturers' pricing latitude is not exhausted by discounts granted to pharmacies, as in the past, but benefits the health insurance funds, and thus ultimately also the contributors. This is particularly true as regards the generic drugs segment. When issuing the active substance prescribed by the physician, the pharmacist selects a preparation in keeping with the specifications of the respective insured's health insurance fund. The agreed discounts are then refunded to the

funds by the manufacturers on the basis of the prescription accounts. Contract negotiations between health insurance funds and manufacturers counteract the current trend for manufacturers to increasingly focus their discount policy on the pharmacies.

Contracts of this kind relieve the burden on the attending physician when deciding what to prescribe. In the market segment for active substances with the potential for manufacture of generic drugs, for example, he prescribes not the preparation, but the active substance and is thus far less exposed to influence exerted by the pharmaceutical industry. In turn, the contract negotiations procedure can offer the manufacturers greater planning security. It reduces the need for calls by pharmaceutical representatives or other advertising methods to recruit and retain physicians and patients. This takes the focus of the pharmaceutical manufacturers off the individual physicians' offices and saves substantial marketing costs for the manufacturers, which can then ultimately benefit the entire system, or primarily the patients, in the form of price cuts or as research funds. Insofar as they sound out or exploit the manufacturer's pricing latitude, negotiations of this kind can also replace the *aut idem* rule, the implementation of which has so far failed to meet up to expectations.

Negotiating active-substance prices gives large health insurance funds a competitive advantage, since they can offer the manufacturers the prospect of a correspondingly large number of customers. They can pass on the savings resulting from lower prices to the insureds via the contribution rate. In the sense of a decentralised solution, negotiations of this kind can serve as a parameter of competition for individual health insurance funds, particularly in the framework of integrated health care and in disease management programmes. The funds define which medicines or active substances they consider particularly relevant for supplying their patients. However, there is also an obligation to contract for all preparations prescribable in SHI, meaning that the attending physician can, in justified cases, deviate from the negotiated active substances. For many insureds, high-quality, but favourably priced drug therapy should increase the incentive to participate in integrated health care. They gain from lower contribution rates and/or bonus schemes in the framework of integrated health care. Conversely, the insurance funds have greater interest in offering such forms of health care.

135. Contract negotiations between health insurance funds and manufacturers can also be supplemented by negotiations between pharmacies or pharmacy groups and funds that provide for corresponding discounts for the benefit of the funds - e.g. in the case of mail-order pharmacies. Alternatively, pharmacies or associations of pharmacies can en-

ter into discount negotiations with manufacturers and pass on economies of scope to the funds in the framework of a house pharmacy contract. The functioning of the distribution chain via the pharmacies must fundamentally be secured in all these various options. The drugs negotiated and purchased by the respective health insurance fund have to be issued there. Particularly in the case of relatively small funds, distribution chains of this kind can probably only be realised by incorporating mail-order pharmacies, if they are used to deliver drugs for the treatment of chronic illnesses with plannable consumption.

Importance of the family physician sector

136. Since it provides primary medical healthcare, the family physician system constitutes a central element of the health care system. General practitioners and doctors of internal medicine together prescribe approx. three-quarters of all medicines issued at the expense of SHI. Roughly half of all office-based physicians belong to this group. The range of medicines prescribed by them largely matches, suggesting that the patient population is comparable in terms of morbidity (see Table 6). For many people, the family physician is - even without formalised gatekeeper models - the first professional they contact regarding health problems. The role of the family physician will probably become even more important in the future as a result of the embodiment of family physician-based medical care in law and the targeted merging of prescription and diagnosis data.

Table 6: Drug prescriptions of general practitioners and doctors of internal medicine by indication groups (in DDDs per physician for 2003)

Indication group ^{a)}	General practitioners	Doctors of internal medicine
27 (Beta-blockers, Ca-blockers, angiotensin inhibitors)	67,685	60,239
17 (Antihypertensives)	43,938	38,706
36 (Diuretics)	27,601	26,498
12 (Antidiabetics)	23,515	24,613
5 (Analgesics/Antirheumatics)	23,210	15,765
74 (Thyroid drugs)	22,415	18,932
58 (Lipid-lowering agents)	19,784	21,303
79 (Platelet aggregation inhibitors)	17,499	15,042
28 (Bronchodilators/Anti-asthmatics)	15,820	15,255
60 (Gastro-intestinal agents)	15,131	14,764

Arranged according to the 10 indication groups with the most DDDs among general practitioners.

a) According to the Red List system.

Source: Own representation

137. The key features of the complex decision-making situation of a family physician are a generally fairly old clientele characterised by multimorbidity, the direct link to the environment in which the patient lives, and often insufficiently sound knowledge of the best treatment option under these conditions. There is frequently a lack of reliable information on the therapeutic efficacy of drugs or other treatment options in elderly patients. In addition to structural problems of this kind, however, there are also signs of deficits regarding the prescription and use of drugs, which fall under the responsibility of the individual physician. The physician's prescription decision depends on his personal knowledge and experience, as well as on structural framework conditions, such as the existence of guidelines and therapy recommendations, or the specification of the medication when a patient is transferred from in-patient care. Economic framework conditions, influence exerted by the pharmaceutical industry and aspects of the interaction between physician and patient are other important determinants. Therefore, an improvement in pharmacotherapy must be accompanied by a reduction of the complexity of the decision-making situation. The individual physician should not feel that institutional specifications restrict his decision-making freedom, but should see them as assistance. On the other hand, there should be a substantial reduction of all influencing fac-

tors that do not serve transparency, the comparison of therapies and the optimisation of quality and efficiency.

138. There is possibly a connection between remuneration, the duration of consultations and the prescription rate, i.e. the shorter the consultation, the higher the prescription rate. However, no unequivocal results are available regarding the impact of certain remuneration systems on the supply of drugs. There is still a substantial need for research in this quarter.

Requirements of drug law

139. The marketing authorisation of a drug requires proof of its efficacy, safety and pharmaceutical quality. In addition to the national authorisation procedure, there is a central and a decentralised European procedure. The manufacturer alone decides on the indication to be authorised and can, given the high costs for studies and authorisation, thus exclude patients with an economically less attractive indication from effective treatment. An "Off-Label" expert group affiliated to the Federal Institute for Drugs and Medical Devices (BfArM) occupies itself with the potential extension of therapy with authorised drugs to indications previously not authorised. The manufacturer should interpret a positive vote of the group as a call to apply for extension of the authorisation. As regards indication-specific prescribability (see below), greater commitment of the national authorities would be conceivable in this quarter. Although this would constitute the exertion of influence on the manufacturer's decision, since he would also be liable for this non-authorised indication, it would appear to be a possibility, at least if certain time limits are observed (e.g. the lifetime of patent protection), for enabling an additional group of patients to profit from a preparation if it can be justifiably assumed that it has benefits outside the authorised indication.

140. The decision regarding the prescribability of a drug, i.e. whether it is reimbursed (possibly up to a maximum amount) in the framework of SHI, has an extensive impact on its profitability in the German market. Insureds are entitled to pharmacy-only drugs, provided that they are not excluded from prescribability by law or by guidelines of the Joint Federal Committee. Since 1 January 2004, non-prescription drugs have no longer been reimbursed in the framework of SHI, insofar as they are not considered to be the treatment standard for a severe illness. The status of being a "prescription drug" thus represents an important criterion when prescribing a drug. However, the combination of

"prescription-only status" and "prescribability" is not geared to medical requirements and is merely a formal criterion. The (socio)economic and quality-related effects of the new regulations on the obligation to pay for services should be subjected to detailed examination. Those non-prescription drugs that are considered to be the treatment standard for a severe illness were compiled in a list of exceptions and continue to be prescribable ("Short Positive List"). Impartial, quality-assured, readily accessible and comprehensible consumer information is of great importance in this context. This call is directed not only at authorities, but also at physicians and pharmacies, e.g. when giving advice on self-medication.

Economic and structural framework conditions

141. Since the physician does not himself bear the costs of a drug and the health-related effects of his prescription, he initially only considers these effects on the patient or the community of insureds in the framework of his personal knowledge and his interest in the best possible medical treatment. Consequently, regulatory measures attempt both to heighten the cost-consciousness of the physician by means of financial incentives, and also to enhance the quality of prescription.

Since 1993, there have been budgets in various forms for containing the increase in expenditure on drugs in the out-patient sector. On 31 December 2001, agreements on targets for the supply of drugs between the health insurance funds and the Association of SHI-Accredited Physicians replaced the drug budgets, exceeding the limits of which had never been sanctioned since their introduction in 1993. Despite this absence of sanctioning, however, there was an expenditure-reducing effect at the time of introduction effect and an expenditure-increasing effect at the time of abolition. A greater incentive effect on the individual physician is exerted by an individual liability to recourse, as provided for in Section 106 Para. 5a SGB V. Exceeding physician group-specific individual prescription limits according to Section 84 Para. 6 SGB V leads to audits being conducted and possibly to recourse claims if the additional expenditure is not justified by special features of the office. The individualisation of these "budgets", and the possibility of exceeding the budget in justified, exceptional cases, appear to be more sensible instruments than the global agreements on targets. One central instrument of target-oriented budgeting is the provision of information on individual prescription practice. Since January 2003, the KVs have been supplying SHI-accredited physicians with an individual overview of the prescription data of their offices on the basis of the data from

the Joint Monthly Drug Utilisation Information System of the SHI (GAmSi), eight weeks after the month of prescription.

142. A comprehensive health policy analysis requires a more cross-sectoral and cross-therapy perspective of prescription practice. This helps avoid the shifting of expenditure to other sectors of the health system and implement the principle of "saving with drugs, not on them". Many drugs can be used as substitutes for more expensive treatment (e.g. in the in-patient sector). On the other hand, other treatment methods are also capable of replacing inefficient drugs in certain cases.

143. Despite several political attempts, there is so far no general Positive List in Germany. An instrument of this kind is always necessary for increased transparency in the drug market when the authorisation conditions do not guarantee that only drugs of therapeutic relevance gain access to the SHI market. A "fourth hurdle", which links the reimbursability of a drug to proof of a favourable cost-benefit ratio, could, however, replace the effect of such a list in the long term if drugs already on the market were also subjected to this examination. Independently of this, one member of the Council pleads in favour of a general Positive List. In addition, in the framework of integrated health care or as a parameter of competition of individual health insurance funds, decentralised Positive Lists can be a suitable instrument for a high-quality, cost-effective supply of drugs. Lists of this kind, experience with which has been good in the in-patient sector, should, however, always be jointly developed by the affected physicians in the manner of a "bottom-up" approach, and they should enable deviation from the lists in justified, exceptional cases.

144. Integrated health care offers the opportunity of controlling prescription practice better and of reducing incentives to adopt more cost-intensive alternative strategies. In this context, it is not a question of absolutely lowering the expenditure on drugs, but the different approaches to integrated health care and disease management programmes do promise generally higher quality and cost-effectiveness in health care. There is still a substantial need for research regarding the interplay of the numerous incentive instruments when establishing, structuring and implementing integrated health care, as well as their impact not only on expenditure on drugs, but also particularly on the health and satisfaction of the patients. Comprehensive and prompt evaluation of these concepts is recommended in this context. The proposed contract negotiations between pharmaceutical companies and health insurance funds could provide further encouragement for integrated health care.

145. Co-payments of the patient towards healthcare services have a fiscal function and a controlling function. They are intended to reduce the unnecessary utilisation of services and relieve the fiscal burden on the funding agencies in the health care system. The SHI Modernisation Act led to a decline in SHI expenditure on drugs by increasing the direct co-payment towards drugs and by changes as regards prescribability. Introduction of the practice fee had an effect in the same direction, since it brought about a decline in the number of consultations and, consequently, also in the number of prescriptions. Empirical studies should monitor the impact of these regulations on the health of the patients, particularly paying attention to social status. The first figures suggest that patients with a lower social status restrict the number of consultations to a greater extent than members of other groups. Neglecting illnesses could lead to higher healthcare costs in the future. A critical eye should also be kept on substitution effects tending towards prescribable drugs in individual indications. On the patient side, the incentives to buy a cheaper product would be strengthened if the minimum co-payment of €5 were to be replaced by a percentage, i.e. if the patient were generally to pay 10% of the selling price. In this context, adjustment of the maximum co-payment (currently €10 per reimbursable medicine) could ensure that revenue would not be affected. In the case of drugs not subject to retail price maintenance, an additional incentive would emerge to compare prices between pharmacies.

Influence of the pharmaceutical industry on prescription practice

146. Research-based pharmaceutical companies invest substantial sums in research and development. The development of a "new chemical entity" takes about 10 to 12 years. According to information from the manufacturers, the development costs amount to as much as US\$ 800 million (2000 prices). Other calculations arrive at figures in the region of US\$ 240 million. Averaged across all new preparations launched on the market, both the development period and the development costs are substantially lower, since many new drugs are non-proprietary products or additional dosage forms of medicines already available on the market. In Germany, a mere 17 new medicinal substances were introduced into therapy for the first time in 2003. Seven of these substances are considered to be truly innovative, while another five at least represent improvements compared to the existing preparations. More stringent demands on marketing authorisation and a longer duration of the authorisation procedure increase the development costs. Acceleration would be desirable not only from the point of view of the companies, but

also from that of the patients, although the quality of marketing authorisation must not be allowed to suffer as a result. Regulatory activities should create more incentives than in the past for the development of therapeutically relevant innovations by honouring the long-term planning of efficacious and cost-effective medicines by admitting them to the SHI market and making it less attractive to market inefficient me-too drugs.

147. Particularly in relation to customer loyalty, the decisive factors for the profitability of a medicine also include product marketing and advertising. When prescribing, the physician must have information regarding the existence and the mode of action of a preparation. Particularly in the case of non-prescription medicines, this information must also be available to the patient. It thus comes as no surprise that pharmaceutical companies invest a comparably large proportion of their turnover in marketing and advertising as in research and development. The expensive deployment of pharmaceutical representatives ("detailing") and the expenditure on distributing samples to physicians would be reduced if physicians increasingly indicated active substances rather than trade names when prescribing, received manufacturer-independent advice on pharmacotherapy (see below) and contract lists were used in out-patient care. Further expenditure results from "direct-to-consumer" advertising and magazine advertising. The high expenditure on advertising is efficient from the standpoint of the individual manufacturers, but at least partially inefficient from the point of view of the overall economy.

In a market economy, manufacturers have every right to use marketing strategies. However, the legislature should organise the legal framework for these activities in such a way that physicians and consumers receive the most objective possible information. In addition, the aim is to give physicians and patients an awareness and a basis of information that enable them to critically judge the corresponding campaigns of the manufacturers. Pharmaceutical companies attempt - often in cooperation with the medical profession - to increase their sales opportunities by expanding concepts of illness or indications.

In Germany, consumer advertising is only permitted for non-prescription preparations. The contribution towards informing the public and patients contrasts with the danger of distorted consumer advertising. Consequently, there are good reasons for remaining reticent as regards the liberalisation of direct consumer advertising for prescription-only drugs.

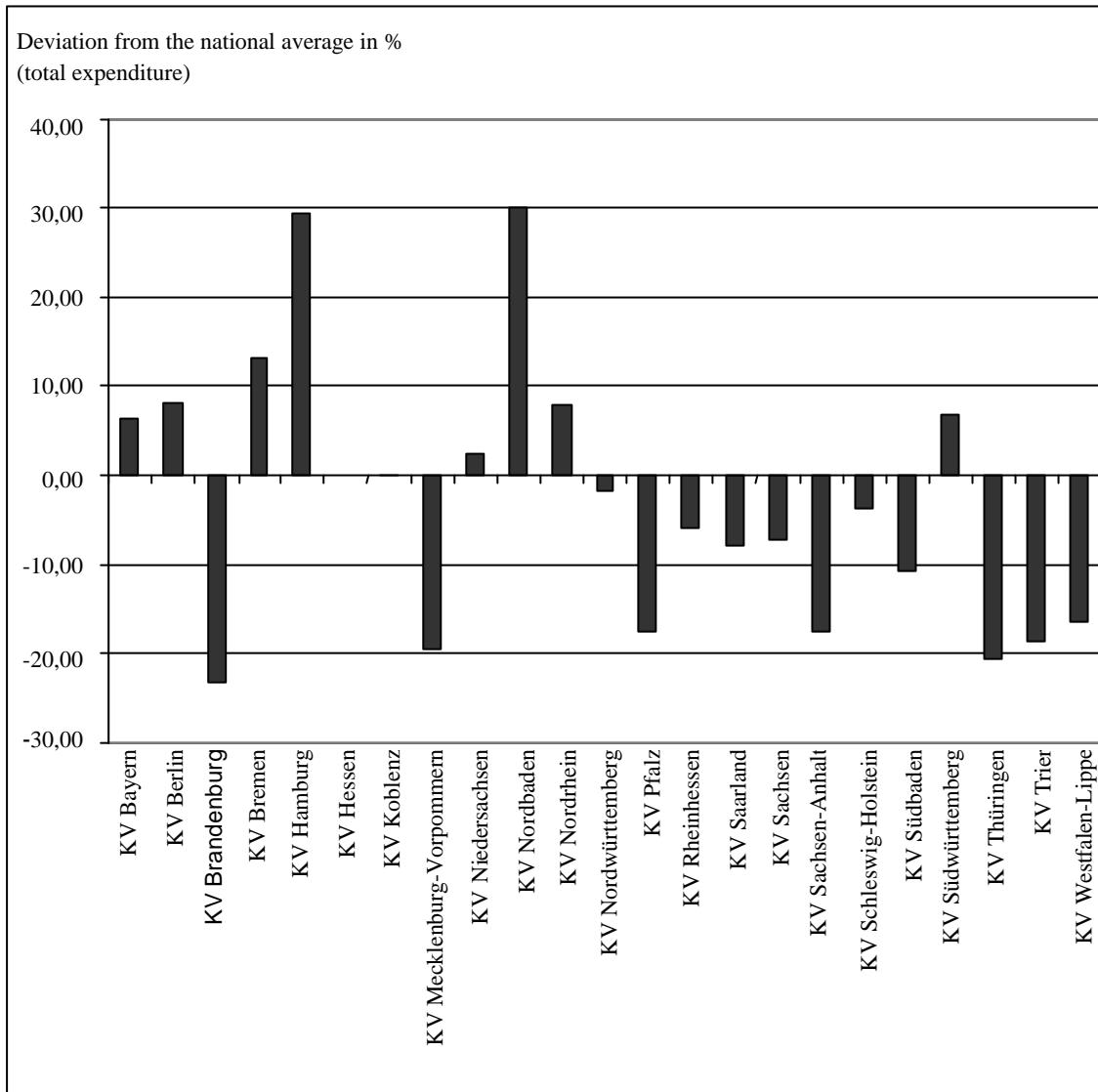
148. When it comes to publishing the results of drug studies, there is a tendency to selectively publish positive study results. This is particularly true of industry-sponsored

studies. In this respect, the disclosure of financial interdependence in connection with the implementation and publication of drug and other medical studies serves to achieve the required transparency. This necessitates the worldwide documentation of clinical studies in study registers and their obligatory - possibly partial - disclosure, provided that there are no objections to this in terms of patent law. This measure would guarantee improved information for physicians and patients, and also help avoid superfluous research in humans.

Patients, physicians and their interactions

149. The prescription of a drug is a medical decision geared to the individual patient and his or her particular medical and social needs. Cost and quality analyses reveal major variations between different physicians' offices and regions that cannot be explained solely by differences in the morbidity, age or sex of the patients (see Figure 6 for an example). The regulatory action taken to date has increasingly led to complaints from patients and the community of office-based physicians. Physicians see the growing financial pressure and the increasing bureaucratic requirements as a threat to their medical decision-making freedom and a strain on the relationship with their patients. The latter frequently complain that they are prescribed fewer drugs in the framework of SHI than in the past. In future, attention should focus on supporting, and reducing the amount of bureaucracy involved in, the joint decision-making process of physician and patient. This would appear to be more feasible if the currently dominant "top-down" approach were to be supplemented or partially replaced by a "bottom-up" component.

Figure 6: Variation in expenditure on drugs by KV regions, illustrated by the example of a substitute fund in 2003



Source: www.gamsi.de; own representation

One concern of a "bottom-up" strategy is the increased involvement of the patient in the therapy decision. Experience shows that this improves compliance. Opportunities for obtaining high-quality information, presented in comprehensible form for medical laymen, may give answers to specific questions regarding the course of certain illnesses, but the patient additionally needs professional advice which, in view of the complex drug actions, only the physician or the pharmacist can provide. However, involvement of the patient in the therapy decision in the spirit of "shared decision-making" does not

aim to off-load the decision onto the patient, but to arrive at a jointly agreed therapy decision following in-depth discussion of the drug therapy, its alternatives and the desired and undesired effects.

This process can be specifically promoted by:

- Establishing communication skills as a central element of basic medical training, specialist training and continuing education,
- Financial incentives for active communication between doctor and patient in the office, and
- Introduction of "shared decision making" as an element of a systematic examination of the quality of practice.

Given the dimensions of the persistence and compliance problem, a fundamental change of view is recommended when it comes to prescribing drugs: compliance and persistence are an element of the physician's mission and thus a quality attribute of medical treatment.

150. Electronic information systems can contribute to avoiding drug interactions, complications and double prescriptions, and also to promoting compliance and persistence once therapy has been commenced. Computer-aided plausibility checks and automated dispensing methods of an electronic patient file or card have the potential to enhance quality, especially if they lead to standard systems. Introduction of the electronic health card should also be accompanied by standardisation of the IT and software systems used by family physicians. This would permit linking to pharmacoepidemiological databases, technical and professional update functions, and integration in the health information network promoted by the EU Commission in the framework of its eHealth programme.

151. Electronic support of the physician's prescription decision must be provided independently of manufacturers and funding agencies. The physician's decision for or against a preparation is often guided by the structure of the office software. If pharmaceutical manufacturers financially support such software, or even distribute it, the drugs listed are usually prioritised in favour of the manufacturer's products. This exertion of influence could be prevented by demanding corresponding certificates or TÜV seals. At the same time, more effort should be put into developing a high-quality, electronic tool - based on independent sources and made available by the health insurance funds and the KVs - for supporting the decision-making process when making out prescriptions.

152. The interfaces between the in-patient and the out-patient sector likewise deserve special attention. Drug prescriptions initiated in hospital often relate to preparations that subsequently cause high costs in the out-patient sector. This is due not only to differences in the prescription practice of hospital and office-based physicians, but also to different financial incentives. In hospital, therapy only has to be financed for a few days, and favourable negotiated prices or high discounts can frequently be achieved, particularly in connection with the launch of new, highly priced medications. This is also in keeping with the marketing interests of the manufacturers. Similarly, expensive medication appears economically justifiable if it permits early discharge from hospital. However, the medication on discharge must not pave the way to the prescription of uneconomical me-too or single-source drugs.

When reading the discharge papers, the physician working in the out-patient field, who is responsible for follow-up prescription and its financial consequences, often cannot see why the drug therapy was changed or initiated and for how long it should be continued. Checking involves a major effort if the discharge papers contain only trade names and not the active-substance designations. In addition, a change of medication to the "state of the art" in hospital shatters the patient's confidence in the quality of the out-patient treatment received so far, making it difficult to make another switch to more economical preparations. Consequently, any adjustment or switch of the pharmacotherapy in hospital should involve the family physician and be justified in detail in the discharge papers - indicating the active-substance designation. When new medication is prescribed, a time or a medical target should be defined at which medication can be discontinued. Close cooperation between hospital pharmacy and referring physicians, which permits joint compilation of a list of efficacious and economical preparations for the hospital, could enable patients to continue receiving the accustomed dosage form.

Quality assurance in the prescription decision

153. Guidelines drawn up according to the established method are fundamentally also important instruments in the specific case of drug therapy, helping to optimise provision. Particular emphasis should be placed on the development of intersectoral guidelines that consider different needs as regards sex, age or social situation. This means that women, children, aged and multimorbid patients should be included in marketing authorisation studies at the earliest possible time, since data on these patient groups, in particular, are generally missing or inadequate.

154. Application of the increasing number of evidence-based guidelines has led to improvements in the prescription practice of physicians, but their influence is still too slight. Personal contact, particularly with an esteemed specialist or clinical colleague, proved to be far more influential than a consensus-based guideline. It is of decisive importance for the prescribing physician that the variety of information and recommendations obtained from different sources adds up to a complete, cohesive picture. It is often expected that centrally defined specifications alone reach the individual physician in unadulterated form and prompt him to change his prescription practice ("trickle-down effect"). However, even scientifically undisputed guidelines can fail if the "top-down" approach alone is relied on (e.g. hormone therapy in menopause, coxibs, AT-II antagonists and others). A logical solution for closing this oft bemoaned gap between theory and practice would appear to be the decentralised elaboration of guidelines that satisfy the general requirements of evidence-based medicine. These guidelines could then also give consideration to the special circumstances of the multidimensional decision of the office-based physician. Conversely, knowledge and questions from practice must be reported back to working groups engaging in specialised research in order to broaden the scientific basis and make it applicable to the situation in practice ("bottom-up").

155. The enormous success of the "face-to-face" marketing practised in the pharmaceutical industry should also be exploited in the interests of high-quality, efficient drug prescription. Expansion of the advisory rights of the health insurance funds according to Section 305a SGB V beyond cost-efficiency issues could create the framework for manufacturer-independent advice of this kind. Using commercial marketing methods, the family physician receives evidence-based, prescription-relevant information in user-friendly fashion and in personal contact with a trained medical or pharmaceutical colleague.

Given the primary interest in cost minimisation, pharmacotherapy consulting provided by the funding agency cannot offer all the advantages of truly independent, impartial consulting. Manufacturer-independent outreach consulting - in necessary cases - would, however, counteract the dominance of the pharmaceutical industry in physicians' offices and substantially improve the breadth and quality of the information offered to physicians. The basic prerequisite for lasting success of this and any other offer to physicians is that they themselves see the advice given as being helpful and meaningful. To this end, it must be ensured that they can discuss their prescription practice with the consultant voluntarily, openly and without having to fear the information given later being used against them in a claim for recourse. This requires strict separation from the audit. Par-

ticipation must be voluntary, even though it may appear attractive at first glance to concentrate on physicians with high prescription levels and offices with disproportionately great potential for achieving savings.

156. The promotion of quality assurance in medicine must be geared to the personal needs and prerequisites of the individual physician. The "peer review" method, which centres on the evaluating discussion between colleagues, proved to be superior compared to guideline-based continuing education according to the classical "top-down" approach. Increasing numbers of medical quality circles have been established in Germany on this basis. Since the nationwide introduction of the Joint Monthly Drug Utilisation Information System of the SHI for physicians (GAmSI-Arzt) in 2003, all office-based physicians have had an impartial and up-to-date overview of their own prescription data at their disposal, which they can use for comparisons over the course of time or with offices working in the same specialist field. However, individual feedback of this kind is in itself generally not enough to trigger a behavioural change. Rather, the results have to be analysed in the context of the problems and special features of the individual office. Pharmacotherapy circles have been able to provide effective support in this quarter. With medical colleagues acting as moderators, therapy concepts and their implementation are discussed and coordinated in a peer exchange between colleagues on the basis of existing recommendations. Promotion of this form of continuing education, which improves both the quality and the economic efficiency of physicians' prescription practice by introducing a decentralised approach, could help exploit efficiency and effectiveness potentials in this field.

157. The information provided by the Joint Monthly Drug Utilisation Information System of the SHI (GAmSI) and the SHI Drugs Index today permits rapid, and also regional, analyses of the German drug market. The possibility, existing since 1 January 2004, of combining the prescription data of the insureds with diagnostic data and examining them in a longitudinal section, enables valid estimates to be made of overprovision, underprovision and misprovision of drugs in Germany. Pharmacoepidemiological databases, which have in the meantime become established in North America, Scandinavia, Great Britain and the Netherlands, permit combination of the routinely collected prescription, diagnostic and benefits data on a personal basis using pseudonyms. Comparison of the status quo of prescription practice with evidence-based guidelines can not only evaluate the quality of prescription practice, but also detect the effects of health policy measures over the course of time.

One decisive advantage of a pharmacoepidemiological database is that it helps improve drug safety. Since the number of cases, the patient population and the observation period are limited in marketing authorisation studies, rare adverse drug reactions are usually only discovered after the market launch. The incidence of adverse drug reactions and the degree of risk compared to therapeutic alternatives can be determined promptly with the help of a database. On this basis, the safety of a drug can be confirmed rapidly and reliably, or recommendations can be developed for restricting the indication, extending the contraindications or revoking the marketing authorisation. The creation of a data pool of SHI data using pseudonyms, introduced with the Health Insurance Modernisation Act (GMG), represents a first step towards creating a pharmacoepidemiological database.

The "fourth hurdle" as an instrument for improving pharmacotherapy

158. In recent years, the structural component was the decisive determinant for the growth of expenditure on drugs in SHI. Within this component, the inter-drug effect, i.e. substitution, predominantly or on balance, by more expensive preparations encompasses the additional expenditure on clearly outcome-improving pharmaceutical innovations. However, this effect is also attributable to the increased use of patented me-too preparations that have no greater therapeutic benefit than comparable, considerably cheaper medications. The "fourth hurdle" aims to assess the therapeutic efficacy of drugs in comparison with their alternatives and to apply the respective benefit differences to the reimbursement of a medication by the SHI system.

159. The "fourth hurdle" predominantly comes into play as a further criterion in the case of patented drugs, alongside the review of pharmaceutical quality, efficacy and safety. It is not a prerequisite for marketing authorisation of a drug, but serves to provide information for fixing the amount reimbursed by SHI. In its framework, cost-benefit analyses of drugs do not aim at minimising expenditure on drugs from one-sided cost aspects and thus excluding the insureds in SHI from participation in pharmacological progress. According to experience to date in other countries, not the goal of cutting expenditure is dominant in approaches and methods of this kind, the focus instead being on the relationship between therapeutic efficacy and the use of resources. As patients do not have to disclose their willingness to pay for drugs financed by SHI, the "fourth hurdle" takes on the task here of estimating the (additional) therapeutic benefit of certain drugs compared to the existing alternatives and confronting it with the respective costs.

160. To ensure that cost-benefit assessment is performed according to unequivocal criteria and in a transparent process, a two-stage procedure would suggest itself as a further development of the Council proposal in the Addendum to the 2000/2001 Annual Report. With the intention of also separating benefit assessment from fiscal aspects in organisational terms, the medical-pharmacological assessment of the benefit of a drug in comparison with its therapeutic alternatives constitutes the first step of the "fourth hurdle". This assessment is the responsibility of a professional body of independent epidemiological, medical and pharmacological experts, where the involvement of patient representatives is open to discussion. However, differential assessment of the (net) benefit of a drug can only be performed on the basis of objectified criteria and may thus also deviate from the subjective assessment of an affected patient. Estimation of the differential benefit of a drug does not require detailed, cardinal measurement in this context. For the purposes of the "fourth hurdle", it is sufficient to analyse whether, compared to the best existing alternative, a drug offers a lesser, identical, marginally improved, noticeably greater or substantially greater therapeutic benefit.

The result of the medical-pharmacological assessment then serves as the basis for the second step of the "fourth hurdle", the fixing of the reimbursement limit in SHI. Only a correspondingly qualified body can be considered for this decision. In contrast to state price-fixing, the companies here have the possibility of setting their prices freely. However, if the price of a medicine exceeds the reimbursement limit, the patient has to pay the respective difference. Drugs that have a noticeably or substantially greater therapeutic benefit are not subject to a reimbursement limit. Decision-making is a problem in the case of medicines which have a significant, but only marginal additional benefit that may possibly extend only to some areas of their range of indications. In these cases, it would be logical to fix the reimbursement limit for such a drug marginally above the existing fixed reimbursement limit of the neighbouring group, or to restrict reimbursement of the drug on an indication-specific basis by means of pharmaceutical guidelines. The "fourth hurdle" procedure should also be applied to drugs already on the market.

161. The therapeutic effect of a drug under the everyday conditions of out-patient care ("*effectiveness*") can sometimes differ considerably from that under ideal, clinical conditions ("*efficacy*"). However, since no information on relevant differences between *efficacy* and *effectiveness* is available at the time of marketing authorisation and patenting of an active substance, both steps of the "fourth hurdle" require accompanying health services research in the sense of controlling. If doubts exist as to the *effectiveness* of a drug under everyday conditions, it could be approved for unlimited reimbursement in

SHI for a defined period of time. The manufacturer would then be required to also demonstrate the *effectiveness* of his drug within this period. Should he not succeed in doing so, or only partially, the first step would be to evaluate the reasons for the lack of *effectiveness*, before then drawing the specific consequences.

162. The current statutory regulations provide for a fixed amount as the reimbursement limit for certain drugs containing patented active substances. Excepted from this are drugs constituting a therapeutic improvement, also because of reduced adverse effects. It is the responsibility of the Joint Federal Committee to formulate the content in detail, although, in contrast to the intentions of the first step of the "fourth hurdle", it is confronted with political savings targets. The current regulation also has the disadvantage that, in cases of doubt, it permits only inclusion in a fixed reimbursement rate group or full reimbursement of the asking price in the sense of a 0/1 solution. These two extreme solutions lead to unsatisfactory decisions in the case of drugs which result in only a marginal and/or indication-specific therapeutic improvement compared to the standard therapy. The additional model of a reimbursement limit which can lie above the fixed reimbursement rate of the neighbouring group, depending on the added benefit of the drug, is capable, like indication-specific differentiations, of more adequately classifying (small-scale) step-by-step innovations and evaluating them in monetary terms.

163. The task of assessing the benefits of drugs is handled by the Institute for Quality and Economic Efficacy in the Health Care Sector, although it requires a commission from the Joint Federal Committee for this purpose. Consequently, there is a danger of the Institute only receiving highly selective commissions of this kind and indirectly likewise being exposed to fiscal constraints in its analyses. Assessment of the quality and efficiency of drug therapy presupposes not only measurement of the benefits, which the law explicitly places in the hands of the Institute, but also inclusion of the cost side. Independently initiated and prepared cost-benefit analyses, primarily of patented me-too drugs and medicines of disputed therapeutic efficacy, can serve as a decision-making aid for fixing the reimbursement limit in SHI.

Appendix

Legal basis for the activity of the Advisory Council on the Assessment of Developments in the Health Care System (since 1 January 2004)

Social Security Code, Book Five

Chapter Five

Advisory Council on the Assessment of Developments in the Health Care System

Section 142

- (1) The Federal Ministry of Health and Social Security shall appoint an Advisory Council on the Assessment of Developments in the Health Care System. The Federal Ministry of Health and Social Security shall establish an office to support the work of the Advisory Council.
- (2) The Advisory Council shall have the task of preparing expert reports on the development of healthcare services, including the medical and economic effects. In the framework of the expert reports, the Advisory Council shall, giving consideration to the financial framework conditions and existing efficiency reserves, develop priorities for the reduction of medical services deficits and existing overprovision, and indicate ways and means of further developing the health care system; it may include developments in other branches of social security in its reports. The Federal Ministry of Health and Social Security may define the subject of the reports in detail and also commission the Advisory Council with the preparation of special reports.
- (3) The Advisory Council shall prepare the report at intervals of two years and submit it to the Federal Ministry of Health and Social Security, generally on 15 April and starting in 2005. The Federal Ministry of Health and Social Security shall present the report to the legislative bodies of the Federal Government without delay.

Members of the Advisory Council on the Assessment of Developments in the Health Care System

Prof. Dr. rer. pol. Eberhard Wille
Chair of Economics
University of Mannheim
(Chairman)

Prof. Dr. med. Dr. med. h. c. Peter C. Scriba
City Centre Hospital
Ludwig Maximilian University, Munich
(Deputy Chairman)

Prof. Dr. med. Gisela C. Fischer
Hanover Medical School

Prof. Dr. rer. nat. Gerd Glaeske
Centre for Social Policy
University of Bremen

Prof. Dr. phil. Adelheid Kuhlmeier
Institute for Medical Sociology
Centre for Human and Health Sciences
Charité University Hospital, Berlin

Prof. Dr. med. Dr. sc. (Harvard) Karl W. Lauterbach
Institute for Health Economics
and Clinical Epidemiology
University of Cologne

Prof. Dr. rer. pol. Rolf Rosenbrock
Working Group on Public Health
Social Science Research Centre, Berlin