



European Health Forum Gastein 1999

Creating a better Future for Health in Europe

Health and Social Security

6 to 9 October 1999

Gastein Health Declaration

International Forum Gastein
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Preamble

From October 6 to 9, 1999 politicians, scientists, industry and business representatives, health experts, non-governmental organisations and representatives of affected groups gathered in Bad Hofgastein to discuss problems of health and social security with the aim of “Creating a Better Future for Health in Europe”.

Renowned personalities from over 30 countries highlighted this event with their participation and contribution. Just to name a few:

Hajdu Gabor, Romanian Minister for Health, **Caspar Einem**, Austrian Minister for Science, **Erwin Jordan**, German Secretary of State for Health, **Fernand Sauer**, Executive Director of the European Agency for the Evaluation of Medicinal Products (EMA), **Marlene Haffner**, US Food and Drug Administration (FDA), Prof. **Rolf Krebs**, Vice-President of the International Federation of Pharmaceutical Manufacturers Associations, **Ulrich Bode**, President of the Austrian Association of Pharmaceutical Industries, Prof. **Spencer Hagar**, London School of Hygiene and Tropical Medicine, Prof. **Albert R. Bakker** International Medical Informatics Association, **Mary McPhail**, European Public Health Alliance, **Albert van der Zeijden**, International Alliance of Patients’ Organisations.

In the numerous contributions made by the various speakers on different perspectives of health and social security in Europe, particular attention was given to the following issues: solidarity for health, the connection of the health industry’s needs with those of social security systems, the WHO concept of “Health for All” as a challenge for the health economy, and the role of non-governmental organisations in the areas of health and social security.

The most important results of the six Forums and an additional workshop that worked on the following topics are presented below:

1. “Improving the Quality of Care”
Main recommendation: access to good health quality for all (in care, treatment, and services) within reasonable time.
2. “Improving Equity in Health and Health Care”
Main recommendation: The existing gap in access, scope, and quality of health must be studied and gradually abolished, whereas certain groups of persons (e.g. migrants and refugees), the adjustment of the membership candidates, and certain areas (e.g. employment possibilities, alcohol, and drugs) require particular attention.
3. “The Role of Public Health and Health Promotion in a Changing Europe”
Main recommendation: The proposed EU-declaration of the rights of citizens must include references to health and public health measures. Further, public health research must be integrated more efficiently into existing structures, both within the EU and in the member states.
4. “Information Technology: Health and Technological Developments”
Main recommendation: A system for certification of HC Telematic products at the European level should be set up, to ensure that these products are medically cost beneficial, technically interoperable and reliable as well as beneficial to the patient (directly or indirectly). The certification is to be carried out by independent neutral bodies.
5. “Rare Disorders and Orphan Drugs: Research without Return on Investment”
Main recommendation: All efforts (public and private) on an European level must aim at combining funds, research programmes, and information initiatives, as well as at reducing relevant taxes and promoting investment in this area for the benefit of those affected.
6. “The Impact of Biotechnology on Health Systems and Health Services”
Main recommendation: Basic biotechnological research will lead to the development of new drugs, vaccinations, diagnostic methods, and medical procedures. In order to derive practical benefits from these achievements for those affected, it is necessary to establish an open dialog and a functioning communication between researchers in biotechnology, other experts, and the general public.
7. Workshop: “European Economic Integration and Health Systems in an Enlarged Europe”
Main Recommendation: Health should be given a higher priority in the accession process and more support should be given to their health reform. Candidate Countries should be more ‘actively’ integrated in the European health arena.

In detail, the participants of the six Forums developed the following scenarios and recommendations, which were adopted and further elaborated upon by the authors of the present declaration.

Günther Leiner,
President of the European Health Forum Gastein

Forum I: Improving the Quality of Care

1. Situation

- 1.1 The quality concept must be defined on different levels and with different targets: politicians, professionals, managers, economists, patients, consumers, etc. must co-operate.

The quality concept is about

- Defining / developing criteria (ideals)
- Implementing / improving good quality
- Measuring / comparing outcomes (effectiveness)

- 1.2 Consensus on main principles

- It is useful to talk about „quality“ in terms of improvement referring to the needs and interests of healthcare users.
- Patients / consumers are the real stake-holders and remain the ultimate point of reference for quality criteria.
- Criteria should not primarily be provider-induced.
- Integral quality-improvement should be based on experience, information exchange and the education of professionals as well as that of patients / consumers.
- Patients / consumers should be called upon to set criteria, put to contribution and participate in the evaluation of the outcome.

2. Recommendations

- 2.1 Recommendations on national level

- Access for all to good quality of care, treatment and, services within reasonable time. Quality should be based on equity.
- Participation of patients / consumers in decision-making on the quality of care and the healthcare system in general.
- Empowerment of individual users in decision-making on their own treatment (integrated approach).
- Support of patient / consumer organisations in providing advice, education, information, etc. to users and providers.
- Training of all professionals in awareness of good quality as a goal, not as a threat. Stress on the importance of effective interaction with patients and awareness-building of their real needs.

- 2.2 EU-targets in quality of care

- EU has the role – within the limits of subsidiarity – of promoting good quality of care
- Why?
 - Four freedoms
 - Promoting equity
 - Identification of best practise
- Obstacles
 - Legal limitations
 - Cultural and economic differences
 - Institutional resistance
 - Unequal starting points
 - Confusion between different levels
- Targets for the EU
 - Encourage the member states to implement national recommendations.
 - Gather and exchange information; networking.
 - Standardise methodology in data collection, measuring and processing, etc., for quality improvement
 - Set indicative standards and objectives for good practise

2.3 Agenda for EU -action

- Develop quality standards and quality targets
 - Promote the establishment of databases on quality outcome, using existing expertise in member states; standard information
 - Use this information to develop indicative standard objectives and targets for good practise
 - Disseminate the information to member states and relevant organisations
- Support patient and consumer groups in getting involved in quality improvement
 - Support existing organisations and bring them together on the European level
 - Provide them with information on quality and benchmarking
 - Promote patient advocacy by training and consultancy
 - Promote the involvement of patients and consumers in meetings on health care
- Support training of health professionals on quality issues
 - Define minimum standards for training and working conditions
 - Provide national authorities and professional organisations with information concerning training in quality awareness
- Promote research on quality improvement
 - Improve existing methodology on defining quality indicators and quality evaluation
 - Promote inventories and the analysis of “patient needs”, related to consumer-induced quality criteria
 - Analyse the effect of cross-cultural differences on the application of quality standards

Forum II: Improving Equity in Health and Health Care

1. Situation

Behind the issue of improving the equity of access to health care lies a vast range of diverging interests. Different financial capacities and competencies in national health care systems as well as the presence of social security systems of extremely varying capacity can be found. Moreover, political and economic interests from various areas collide, each with an impact on the actual health policy situation in a region, a country, or within the EU. Enhancing the social value of “health” by targeted and co-ordinated efforts from the various levels may constitute a remedy. The forum’s objective was to demonstrate how this can be achieved and for whom it would require a change of views.

The majority of the participants stressed the large gap between the access, scope, and quality of national health care systems in EU member countries as compared to those existing in the candidate countries. The identification of regional problem zones in health care as well as a regional or national definition of poverty limits would enable a better targeting of EU interventions and of national or regional efforts. The participants believe that health gaps can be filled by increasingly identifying interfaces of interest with other socio-political areas of action. As a result, both supranational aid, particularly in the area of research, and national policy action could ensure that in future the people affected no longer fall through the social net. By presenting regional examples, various participants pointed to the fact that some parts of the EU are still too slow in combating the link between structural poverty, poor health, and more difficult access to diagnosis and treatment. On an abstract level, health care systems are often seen as distribution systems for funds, and important references to other areas with a direct or indirect impact on the quality of life and health care are not sufficiently understood.

2. Recommendations

2.1 General recommendations

- The creation of employment and the establishment of dignified living conditions constitute political and social priorities. This eminent social responsibility is considered the duty of the Community and of national and regional decision-makers.
- The existing gap in access, scope, and quality of health care must be studied and gradually abolished.
- A social understanding of disease must be established and developed, and the value of moral principles in health matters must be enhanced.
- Disease is not merely a personal state of emergency but is also determined by social factors – particularly among the unemployed and the disabled.

- 2.2 Recommendations on a national level
 - There is need to establish more and better information on the social determinants of disease and to develop health perspectives, particularly for the poor and the elderly.
 - Research on the causes of disease and dissemination of knowledge must increasingly replace the mere treatment of symptoms in the health sector.
 - Interfaces with other social areas of responsibility must be defined and health gaps must be filled.
- 2.3 EU objectives in connection with “Equity in Health and Health Care”
 - Approximation of the candidate countries to EU standards is to be achieved through increasing efforts to enhance the value of health and social policy in those countries.
 - The creation of employment opportunities is of utmost significance.
- 2.4 Objectives for EU campaigns
 - EU standards must be established in the areas of health insurance and old-age pension provision as well as in the area of other social benefits – in particular for migrants and refugees.
 - Health regions with comparable health-related situations must be defined.
 - Social tasks with an impact on the health situation must be identified on an EU level as well as on a national and regional level. A “Think European, Act Local” approach is necessary.
 - There is need to develop information on issues with a high social impact like alcohol, nicotine, and drugs. This information must then be disseminated in a manner which encourages people to act.

FORUM III: The Role of Public Health and Health Promotion in a Changing Europe

1. Situation

- 1.1 The health status of European Union citizens today is better than it has ever been before. However, there is still room and need for improvement, especially considering the big differences between and within member states. These differences are even more striking, when one looks at Europe as a whole.
- 1.2 Public Health, which has been defined as the “organised attempt by society to prevent illness, lengthen life and to promote health on the basis of scientific evidence”, has a key role in meeting this challenge.
- 1.3 Health promotion is an important delivery mechanism for public health activities. It should not be regarded as a cost, but rather as an investment for society, making society more conducive for health and leading to health gain. This will also enable society to support excluded groups and elderly people and to help them to engage in economic activities which would again lead to further economic gain.

2. Recommendations at EU and member state level

- 2.1. There is a need to generate public pressure and to mobilise concerns so that public health issues receive higher priority in Europe – both in the EU and within individual countries. In order to be effective, public health actions must promote change at all levels.
- 2.2. At Community level, the proposed EU-declaration of the rights of the citizens must include references to health.
- 2.3. Health inequalities as a major crosscutting theme could become a major topic of the next European Health Forum Gastein.
- 2.4. Health impact assessments can be an important tool in order to understand the health consequences of certain policy measures. Policies on nutrition are an important example illustrating how a better understanding of policies and actions can influence dietary habits and the quality of foods.
- 2.5. Stronger structural linkages between public health action and public health research – be it in the Member States, be it in the EU – have to be established. Research has a key role in determining and addressing public health priorities.
- 2.6. General objectives and priorities of public health policy should not be subordinated to single-issue concerns and health scares. Work on food safety, communicable diseases and health information must be integrated into a coherent health policy logic.
- 2.7. Public health concerns must play an important role in the enlargement process of the EU. The Community’s public health policy must address the needs and requirements of applicant countries.
- 2.8. NGOs are of crucial importance in public health, in terms of their advocacy work and their involvement in specific public health activities.

- 2.9. Health promotion is a new tool in addressing health issues and problems at different levels. Further investments in health promotion are needed to develop mechanisms to include the societal context into interventions and evaluation of projects. Health promotion should be seen as a learning activity. While there is a pan-European dimension, it is heavily culturally determined.
- 2.10. New fields of action need to be explored and new instruments need to be developed to reach the socially excluded.

Forum IV: Information Technology: Health and Technological development

1. General conclusions and actual situation

Basically the required technology is available, the emphasis should be now on implementation rather than on experiments and prototypes (although there still is a need to develop products based on the knowledge and experience gained).

To harvest the potential benefits of telematics, adaptation of the processes will be necessary (this will probably lead to adaptation of the organisational structures as well; similar effects have occurred in other industries). This could represent an unique opportunity to put the citizen in the centre of the adapted health systems.

To allow for successful application of telematics accompanying measures will often be necessary with respect to: education, financing, infrastructure.

Internet exists and is growing rapidly, with its regulations based on the market. Some special regulations will be necessary in the domain of security. As a minimum Codes of Conduct must be defined.

The countries, which are candidates for enlargement of the EU, may be in a favourable position to take advantage of this new technology because there will be less opposition from existing structures.

2. Recommendations for action

2.1 At the regional/national level

- The definition of the implementation plans should involve all the various partners (health care professionals, HCEs, patients' organisations, technicians) and not only the latter.
- Both initial and continuous education should be organised for all professions and for the patients. This will also contribute to reducing the risk of social exclusion.
- In the implementation plans, the targets to be achieved have to be clearly formulated. Systematic assessment of the degree in which the targets have been met must be established.
- Regulations and legislation should be adapted to allow for the effective use of telematics in health care in all the necessary areas (e.g. electronic signatures, electronic media, coding systems).

2.2 At the EU level

- European co-operation in developing educational programmes should be stimulated.
- The development of tools for evaluation should be stimulated as well as exchange of assessment results.
- A system for certification of HC telematics products at the European level should be set-up, to ensure that these products are medically cost-beneficial, technically interoperable and reliable, as well as beneficial to the patient (directly or indirectly). The certification to be carried out by independent neutral bodies.
- The development of Codes of Conduct for the use of Internet in Health Care and the definition of info-ethical regulations for the use of telematics in health care should be stimulated.
- Standardisation in health telematics should get a higher priority. In addition, a system should be set up to make specifications of products and solutions widely available (de facto standards).

Forum V: Rare Disorders and Orphan Drugs: Research without Return on Investment

1. Situation

Rare diseases are defined in Europe as those which affect 5 in 10,000 of the population or less or those which need special measures to combat their effects because of the small numbers involved.

Although individually a disease may not be rare there are very many different conditions - over 8000 have been identified - so the number of people affected (either directly or indirectly) is large. It has been estimated that in the EU this number may add up to 30 million.

For many patients with rare diseases, hopes for a cure rest on orphan drugs. Orphan drugs are those which, due to the small number of those who need them, are not economically viable to develop under normal commercial consideration and which need special incentives in order for the patients to benefit from their development.

Not all rare diseases need to be treated by orphan drugs. Some will be able to benefit from new uses of existing drugs. Most rare diseases will remain untreatable for the foreseeable future due to a lack of knowledge about their basic biology and the need for much more fundamental research.

In response to the needs of those affected with rare disorders the EU is in the process of introducing two measures, the Rare Diseases Programme and Orphan Medicinal Products Regulations. Rare diseases are also a feature of the 5th Framework Programme.

The Rare Diseases Programme is foreseen for a period of five years. A budget of 6.5m Euro (1.3m/yr) was allocated and three areas of activity were defined, namely the creation of information databases on rare disorders, support for patient groups for those affected and for umbrella bodies and -investigation of clusters of rare diseases.

Orphan medicinal product regulations will give to the European Agency for the Evaluation of Medical Products (EMEA) the power to stimulate the development of orphan products and to approve their use by granting market authorisation. Orphan products will benefit from a ten-year period of market exclusivity, during which time no similar product will be licensed for use in respect of the use claimed by the orphan product. The USA has had orphan drug laws for seventeen years and in that time almost 200 new drugs have been authorised. The FDA's Office of Orphan Drugs has a substantial budget to stimulate research and to waive the fees normally charged for granting market approval. The European Parliament has just approved a budget for EMEA which does not include any funding for the operation of the orphan medicinal products regulations when they come into force early in the New Year. Without proper budgetary provisions the Agency will be unable to be proactive, nor will it be able to waive fees normally charged to applicants.

2. Recommendations

2.1 Recommendations for the EU

- The original budget for the Rare Disease Programme (30m Euro) should be restored in order for the programme to have a significant impact on opportunities for those at whom it is targeted.
- EMEA should be given a dedicated budget to enable it to operate the Orphan Medicinal Products regulations effectively and ensure the speedy release of orphan drugs on the market.
- EU agencies responsible for the rare diseases programme, orphan medicinal products regulations and the Fifth Framework Programme should collaborate with each other and with external agencies such as patient groups, the Engelhorn Foundation and others to ensure the efficient and effective use of resources and best value for money.
- Procedures developed to manage these programmes should stimulate, not stifle innovation, encouraging investment and the creation of new enterprises and new jobs.

2.2 Recommendations for member states

- Tax credits and other fiscal incentives to stimulate R & D of orphan products should be introduced.
- Rules for the prescription and/or reimbursement of orphan products should be such that all those who need them can benefit. Furthermore, products are not to be denied to patients on grounds of cost.
- Medical education programmes should be developed to increase doctors' knowledge of rare disorders.

2.3 Recommendations for others

- Public understanding of the potential benefits of biotechnology and genetic medicine should be encouraged and enhanced through the media and other channels.
- The investment potential afforded by orphan medicinal products from private sector sources should be publicised and promoted.
- Solidarity and the willingness of society to respond to the health care needs of all its members should be emphasised when considering the use of health care resources (and also when working

out the economic, social and human costs associated with not treating when potentially treatment would be possible).

- Patient groups should be recognised and supported in their role of reducing the isolation and improving the services and support for those with rare disorders.

Forum VI: The Impact of Biotechnology on Health Systems and Health Services

1. Situation

Biotechnology and research in genetics will have a large impact on medicine through an increased knowledge base. An important milestone will be reached in about 2 -years, when the whole human genome will have been sequenced.

These data together with bio-informatics are opening up the path for genomics, which in many years to come will expand our understanding of how the human body functions at the cellular and molecular level. Genomics are leading to a constant flow of new drugs, diagnostics and vaccines.

At the same time, new medical procedures such as cellular therapies, bio-surgery, organ transplants as well as gene therapy are being developed and are becoming available to patients. Some of these new (not all genetics based) techniques are increasingly posing novel challenges for the health care system and are raising fundamental questions about the nature and value of human life.

2. Recommendations to be enacted both at national and European levels:

- 2.1 Both basic and problem oriented research need to be increasingly funded. There will be no applied research without continuing basic research. The competent authorities should take note of the fact that government funding for biomedical research is massively on the increase in the USA. Nations ought to have clear ethical and legal guidelines on research. These should be derived from broad societal deliberations. A common European standard is necessary.
- 2.2 The authorities should encourage industries to develop new drugs, diagnostics, vaccines and medical procedures, including those needed by small groups of patients with rare diseases. These rare diseases represent a major health care problem affecting in total approximately 25-30 million Europeans. Such encouragement needs financial backing. The health care system needs to be flexible enough to allow the rapid introduction of new beneficial materials and procedures. National governments will have to ensure that those who need the innovative products and services can afford them.
- 2.3 There needs to be a more open dialogue between researchers in biotechnology, the medical profession and the general public. Without a broad understanding of what science and technological innovation can offer, individuals, groups and political decision-makers may have difficulty in making balanced and informed judgements with the risk that worthwhile opportunities will be lost. Professionals need to take the concerns and worries of patients seriously. They should communicate with the patient and the general public, accepting them as equal partners - communication is a two-way process: each side can and should learn from the other. This is also important in Eastern Europe, where open public debates don't have a long tradition.
- 2.4 Governments are encouraged to address ethical issues raised by the application of new technologies. Society depends on a "contrat social" based on common ethical principles founded on human rights, solidarity and diversity. Many of the ethical issues appear to be novel, and although in some cases there are underlying similarities to issues long discussed (if not resolved), each society, each generation will have to confront them. Again, a good level of understanding and access to information will contribute to resolving differences and balanced use of innovation.
- 2.5 There is an urgent need for the EU to introduce and enact (or adapt) science-based legislation that will allow Europeans to benefit from products and services generated through biotechnology (as discussed in the workshop, it is not biotechnology but its applications that are being discussed). At the same time the maintenance of a high level of safety is imperative. Without a reliable and rational regulatory framework, the European industrial base is likely to erode in this area. This also applies to the area of patenting, where discoveries may not be patented (nobody is attempting to obtain "Patents on Life"). However inventions need the possibility of being patented in order to maintain the incentive for investment in research and development, while ensuring prompt and effective diffusion of the new knowledge and techniques. To further this aim, patents should be available on useful innovations, but not on genetic material (human or other) in its natural state.

Workshop: European Economic Integration and Health Systems in the Enlarged Europe:

1. Situation

- 1.1 All candidate countries make important efforts in reforming their health systems, albeit different in advances and scope.
- 1.2 But the candidate countries' health systems show important flaws giving raise to doubts about their ability to fully participate in the European social security co-ordination: the gap in health status and health systems, insufficient resources devoted to the health sector, over-capacity and ill maintained health care facilities, low motivation of health professionals and lack of communication to and encouragement of participation of the population. All this could lead to migration pressure (health professionals) and the health status gap is a potential burden on the European Union's economic capacity.
- 1.3 Additionally, the future European Member States face similar problems with respect to the increasing economic integration as the present member states, even though these could in some cases even be considered as opportunity: the possibility of "exporting" health services (Kohll/Dekker) to other Member States represents an important incentive for quality improvement and could attract the necessary capital for updating health care facilities.

2. Recommendations

- 2.1 Health should be given a higher priority in the accession process. Special support should be given to the upgrading of health care facilities in the candidate countries.
- 2.2 Candidate countries should take into account the influences of European law when reforming their health care systems and increasingly voice their concerns and interests in the "European health arena".
- 2.3 Many of the issues discussed at the Gastein Forum are very relevant in the context of enlargement. There is a clear role for the Community in the support of quality issues: development of Europe-wide standards (services, facilities, professionals, dissemination of best practices). The candidate countries should be fully integrated in this process.
- 2.4 Active "integration" of candidate countries should include the exchange of professionals, administrators and researchers. Increased communication and easily accessible information systems are essential.
- 2.5 Increasing involvement of candidate countries in health activities at the European level, especially in those meetings which focus on the internal market and health issues.