

# eurohealth

## Perspectives on pharmaceutical policy

**Reforming  
EU health  
competence:  
framing the  
discussion**

**Sustainable  
development**

**Health Impact  
Assessment in Sweden**

**The politics of  
waiting lists**

**Patient-physician  
communication in  
the Czech Republic**



# COMMENT

## Europe at the crossroads

In this issue of *Eurohealth* perspectives on two important issues affecting European health policy are presented. The first of these concerns potential Treaty reform, as well as examining ways in which to improve existing arrangements. Current discussions on reform of the Treaty are taking place in a very different context to those faced in Amsterdam in 1997. The existing Treaty contains a commitment to contribute towards attaining a high level of health protection, but the impact of the EU health policies can now be felt far beyond the confines of public health. Often however these impacts are unforeseen and not taken into account when drafting Directives. Furthermore increasingly judgements at the European Court of Justice, applying existing Treaty principles on the operation of a single market, are influencing the ways in which health care systems across Europe operate, regardless of the long standing principle that responsibility for health care rests with the Member States.

Paul Belcher et al suggest a number of potential areas to explore in addition to Treaty revision in order to move towards developing an appropriate framework for health policy in Europe. This includes the increased use of the open coordination method. They also discuss the balance between the internal market and social objectives such as health. Philip Berman in his article reflecting on potential Treaty revisions refers to the need to consider the guiding principles underlying all European health care systems: universality, solidarity and equity, and argues that given the two divergent objectives of improving the operations of the internal market and ensuring social protection, it may be an appropriate time to reintegrate the Health and Social Affairs DGs.

In this issue there are also a series of different perspectives reflecting on developments in pharmaceutical policy across Europe. Recently the European Parliament debated the Pharmaceutical Review, notably voting against one key aspect allowing for very limited direct to consumer advertising of prescription medicines in a small number of disease areas. A separate development has been the first report of the European Commission's High Level Group on the Innovation and Provision of Medicines (G10). The group put forward 14 recommendations intended to help improve the competitiveness of the European pharmaceutical industry and foster innovation, whilst being mindful of the need for industry to meet public and social objectives. The group is scheduled to meet again in April to review progress. Contrasting perspectives from the pharmaceutical industry, consumers, the European Parliament, health care policymaking and academia on aspects of both these initiatives are presented.

Finally this issue of *Eurohealth* contains two new features: a web watch providing information on useful web sites, and secondly a new publications page. I hope that you will find this information of interest, and will submit suggestions for web sites and new publications that may feature in future issues.

David McDaid  
Editor

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# Reforming the EU health competence

## Framing the discussion



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Discussions leading to revision of the European Treaty in 2004 are taking place in a very different health policy context to that faced by policy-makers at the 1997 Amsterdam Summit. In particular, new European Court of Justice rulings concerning health care and a growing and diverse range of European Union competencies affecting health services have given rise to an atmosphere of confusion and mistrust over future policy objectives and how they might be achieved.

A fundamental starting point for current discussions should be to identify what future national and EU policy objectives in the health sector actually are and to identify the problems and risks attached to them. Once established, it will be necessary to consider how these objectives can be achieved. This may require new policy tools, new definitions of national and EU responsibilities in healthcare and, ultimately, a revision of the European Treaty to better define policy objectives and reduce the risks inherent in their implementation and legal interpretation.

Importantly, discussions should take a unified policy approach to health at the EU level. The limited public health competence of Article 152 is but one of a wide range of Treaty articles and policies which need to be brought into strategic discussions on the way forward for health. Some of the wider issues of concern already identified by policy-makers include the following:

- Is it time to bring EU pharmaceutical policy out of an industrial context into the health policy domain?

- How will EU competition law impact on changing national health systems?
- Is the legal basis secure for existing financial relationships that may be seen as state aid to health services?
- Has the time come for a clear statement of European social principles on health-care to balance the economic rules of the Single Market?

To help frame the discussions now taking place, it might be useful to structure the debate along the following lines: First, recognising the new European policy context; second, identifying national and EU policy objectives and their risks; and third, looking at how these objectives can be achieved and what tools are required.

### **The new European policy context**

Since the last Inter-governmental Conference considered health in its revision of Article 152 in 1997, it has become increasingly clear that the impact of EU policies on health stretches far beyond the confines of the public health competence into many other areas affecting health services.

EU Directives addressing broader concerns can impact on the organisation of health care in ways that have not been fully considered. For example, the Working Time Directive, when applied to junior doctors, will have profound implications for both postgraduate medical training and, in some countries, the survival of the current pattern of hospital services. To provide 24-hour cover, hospitals will have to employ many more doctors yet the opportunity to



*Elias Mossialos*

obtain practical experience will be reduced. If followed through (and informal evidence from several countries suggests that it will not be adhered to) it will inevitably lead to the closure of many small and medium sized hospitals, with consequences for access to care in rural areas.

Other directives, such as the draft directive on free movement of professionals, are undertaken with the goal of furthering the working of the Single Market, as professional regulations are seen as an impediment to its functioning. This should be balanced against concerns about the safety of patients but as it stands, it is difficult to see how this will be achieved given that many of the existing safeguards will be lost. This is taking place at a time when some countries have been reviewing their systems of regulation in light of evidence that they have been insufficiently rigorous. For example, it is increasingly accepted that the award of a medical degree at the age of 22 or 24 cannot ensure that one can practice safely until retirement. Consequently, some countries now require health professionals to undertake continuing professional development and periodically renew their right to practice. There is, however, only the most general recognition of this issue in the draft directive, which displays no understanding of the complex and diverse systems of professional regulation in Europe.

Another example is the directive on data protection, introduced to facilitate the movement of data across frontiers. Although largely resolved following a large scale lobbying campaign by health professionals, this had threatened to bring to a halt much current epidemiological research in Europe. This would have had profound consequences for progress in health care.

One reason for these problems is the way that, notwithstanding the requirement that EU policies ensure a high level of human health, health considerations relating to key pieces of legislation are often ignored. Pharmaceutical policy, for example, is treated primarily as a matter of industrial policy, despite its profound consequences for health. Consequently, important issues such as direct to consumer advertising have been discussed largely in isolation from their potential impact on health care systems.

In addition to the often unanticipated consequences of EU secondary legislation such as directives, rulings of the European Court of Justice (ECJ) have also had a

profound effect on the policy landscape in applying the fundamental principles of the European Single Market to healthcare goods and services. However, the interaction between new legal interpretations and their practical application to healthcare delivery at national and regional levels present great political and administrative challenges.

An example of this is the confusion that occurs when one Member State proactively refers patients to another for medical treatment. The existing E112 scheme is based on individual choice (subject to authorisation) to obtain treatment elsewhere; it does not concern itself with quality, or other clinical issues such as follow up procedures. It simply ensures reimbursement for the patient's treatment at the rate offered in the country he/she is visiting.

*“the impact of EU policies on health stretches far beyond the confines of the public health competence”*

The block referral of patients from one health system to providers in another does concern itself (contractually) with quality, and offers reimbursement at the rate of the referring country. From one interpretation of ECJ judgments, it should be possible for the block referral to be negotiated with an individual hospital at a price agreed between the parties, provided this does not undermine the capacity of the receiving country to treat its own citizens. But experience suggests that receiving countries may feel uneasy and would prefer to keep some centralised control over the terms on which such referrals are made to their hospitals. The hospitals on the other hand may wish to negotiate terms and tariffs directly with the referring agency, and may argue that any attempt to stop them doing so is in breach of EU Single Market law. It has also been argued that such block referrals should be dealt with entirely within the terms of EC Regulation 1408 (E112), but that could overstretch a structure created for quite different purposes.

There is therefore a tension, borne out in practice, between the freedoms that the ECJ judgments have given individuals in accessing healthcare services and the policy desires of Member States to keep national

control in order to maintain the principles of collective solidarity for their own populations. Is this tension so troublesome that something needs to be done to clarify it?

### **Identifying national/EU policy objectives and risks**

The EU's deepening influence on health services is diverse and fragmented. Partly as a consequence of this lack of focus, it often appears to have little overall policy direction, giving rise to fears about the Commission's intentions, particularly regarding health services.

*“Treaty change is just one of a variety of ways to achieve a new policy objective”*

This atmosphere of mistrust needs to be broken through open discussions to establish what the future policy objectives and aspirations of both national and EU policy-makers actually are. Is the Commission really seeking to extend its comprehensive powers over food safety into other health areas? What are the risks involved in any new policy objective? These are just some of the questions that must be answered.

### **Getting from A to B : New tools required**

Once policy objectives have been established, a careful look at how they can be achieved in practice is required. Are there legal barriers to implementation which require a change to the Treaty? Perhaps the barriers are political rather than legal? Does the Commission already possess the necessary levers to act?

Treaty change is just one of a variety of ways to achieve new policy objectives. Discussion is therefore required to match new policy objectives with existing competencies and Treaty articles before considering how gaps might be filled by Treaty revisions.

The least radical approach might involve a reorganisation of boundaries within the

Commission and European Parliamentary committees. This might make it possible to consider more issues with major consequences for health within an expanded Commission Health Directorate. Conversely, it could be argued that there will always be boundary issues and it will be difficult to strike the appropriate balance in practice. An alternative approach might be to increase the ability of, for example, a strengthened health committee in the European Parliament to scrutinise legislation in other sectors. This would, however, create additional boundary problems. Finally, it may be necessary to revise the Treaty, to place the need to ensure health (and perhaps pursue other social objectives) on a firmer foundation. This would be a major task provoking much political debate but it may be necessary if the ECJ, in interpreting the Treaty, is to form judgements that provide a more appropriate balance between the Single Market and social protection.

A system of ‘open coordination’, already used in areas such as EU employment policy, in which there are formally established means to learn from the experience of others while taking account of national circumstances, provides an opportunity to promote best practice and increase the exchange of information on what works, what does not, and in what circumstances. This process respects historical, political and cultural diversity, not forcing a harmonisation of processes that, while pursuing the same goal, are organised in ways that are incompatible with each other. An open method of coordination will also make more explicit some of the healthcare challenges posed by the Single Market. It will also provide a framework within which they can be addressed and appropriate legal responses, including possible Treaty revisions, debated.

Such procedures will take time to develop yet it is clear that some action is needed now. As a matter of urgency, the EU should establish a system that can monitor on a continuing basis the potential impact of EU law on health systems, particularly Single Market rules. We must ensure that future health policy development is proactive rather than reactive to ECJ rulings such as ‘Kohll and Decker’.

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*This discussion paper was commissioned by the European Health Management Association (EHMA) as part of its contribution to the debate on reforming the Treaty and health competence of the European Community. Further information: [www.ehma.org](http://www.ehma.org). Correspondence to: [PaulJBelcher@yahoo.com](mailto:PaulJBelcher@yahoo.com)*

# The EU, Health and Article 152: Present imperfect; future perfect?

*In their article (this edition of Eurohealth), Belcher, McKee and Mossialos flag up a number of areas where the European Union is having a growing influence on health services, but suggest that this influence lacks focus and overall policy direction. They call for open discussions to establish policy objectives and aspirations of national and EU policy-makers, as well as tools to achieve those objectives.*



*Philip C Berman*

There appear, already, to be a number of areas where there is extensive agreement: that Article 152 is no longer sustainable in its current format, that the EU should have shared competency not only for communicable diseases (where there is an indisputable cross-border dimension) but also for certain core elements of health information systems (with Member States developing their own additional elements).

There is also agreement that the serious and largely unforeseen health service problems that have emerged in relation to the working time directive have demonstrated the need for an early-warning system based on the exchange of information between Member States. This is necessary to anticipate the potential impact of EU legislation on the healthcare sector, particularly single market law, as the lessons of Kohll and Decker should have taught us.

## **Amending Article 152**

It appears that there is widespread acceptance that the current Treaty provisions on health fail to reflect reality. Not only have the Kohll/Decker and Smits/Peerbooms judgments of the European Court of Justice (ECJ) clearly moved the agenda beyond the basis for the original subsidiarity arguments, but also public health-motivated legislation, such as directives concerning tobacco, should be able to rely on a clear public health legal basis rather than having to be justified, as at present, under single market provisions.

Although the overwhelming majority of Member States continue to have major misgivings about direct Community involvement in the delivery of health services, nevertheless there is a recognition that Article 152's limited focus on public health competence is no longer sufficient to cope with the aftermath of recent ECJ rulings. So, if the 2004 Inter-Governmental Conference is to be used to revise the Treaty, what changes should be sought, and what safeguards are required, to ensure that health services can continue to be provided by Member States in an appropriate manner for each country, while strengthening the EU's current remit to ensure "a high level of health protection" and improve public health?

## **Principles underpinning European health systems**

Perhaps the most fundamental issue to be addressed is the need to make explicit, within the Treaty, the guiding principles that underpin all European health systems: universality, solidarity and equity. While the Court has referred to these principles in judgments, it should not be assumed that in a head-to-head confrontation with the principles of the Internal Market, these health principles would survive. A recent report on the impact of the Single European Market on health services<sup>1</sup> refers to the paradox that while, at a European level, the Single European Market requires health services to adapt to market rules, at the national level governments seek to adapt these rules to ensure the effective delivery of services within a social model. This paradox highlights the fact that the Community is committed to two divergent models, the European social model and the principle of market forces as embodied in the Internal Market.

The potential threat of the World Trade Organisation's (WTO) interest in health services makes this an even more significant issue. If the Internal Market has created

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tensions in relation to health services within Europe, the WTO will raise many of the same issues magnified many times over on a global scale. Since health services are to be included as one of many services within the ambit of WTO negotiations, it may be increasingly difficult to protect the principles of the European social model from non-European for-profit companies wishing to provide healthcare services based on the careful cherry-picking of customers rather than supporting notions of social solidarity. Who will be taking the lead in negotiating the terms for provision of health services within WTO: not Ministers of Health, and not even the European Commission's Health Commissioner? Responsibility for WTO negotiations rests

make available a sizeable budget, along the lines of the Common Agricultural Policy, to ensure that these principles are delivered?

Health policy-makers must therefore weigh up the issues of the Internal Market, the WTO, and Accession Countries in determining whether or not to embody the principles in the Treaty. On balance it may be considered important to incorporate them in a Treaty revision. This might best be done by amending Article 2, which details guiding principles in relation to both health and social policy. Such an amendment would define the social character of health and social care, ensuring that secondary legislation, particularly relating to the single market, takes these principles into account.

The potential conflict with the Internal Market might, in part, be resolved by including a cross reference to Article 95 (Internal Market) in Article 152 (there is already a reference in Article 95.3 to a high level of health protection) just as there is a cross-reference between Article 153 on consumer protection and the internal market. Although such a specific link between the two articles would not be necessary in a legal sense, it would be politically desirable to underline the need for the Single Market to take health into account and minimise the risks that the internal market might pose to healthcare provision.

### **Coordinating health and social policy**

From the health perspective, the current legal and organisational distinctions between health and social affairs at a European level, particularly within the European Commission structure, are not helpful. In some Member States, social affairs encompass personal health care yet, at the European level, it is becoming increasingly difficult to develop health policies without careful coordination between the two Commission Directorates-General (DG) for Health & Consumer Protection and Employment & Social Affairs. In spite of increased coordination between Commissioners Byrne (Health) and Diamantopoulou (Social Affairs), issues concerning cross-border patient care and the free movement of professionals are primarily the responsibility of Employment and Social Affairs, although they may have a substantial impact on health systems.

It is difficult to achieve effective coordination within the current organisational and

*“There is widespread acceptance that current Treaty provisions on health fail to reflect reality”*

largely with the European Commission's Trade services, raising serious questions on whether health principles are regarded with the same priority as most health professionals and citizens would expect. The value of the consultation process launched by DG Trade, involving external health organisations as well as DG Health and Consumer Protection, has been heavily criticised by a number of European health NGOs as paying little more than lip service to serious health considerations.

A further argument has been put forward that, while the principles of universality, solidarity and equity are admirable and widely accepted within Europe, economic pressures require that they be complemented with a further principle, financial sustainability. Health services are enormously constrained by financial considerations, and consequently activities should only be undertaken if financially sustainable. However, such considerations must be balanced against the necessity to safeguard social rights and equity.

The three principles may have particular implications for the Accession Countries. If these countries are really expected to sign up to them, the cost of putting these principles into practice might be substantial, and thus the additional principle of financial sustainability might assume increased significance. Is the Community prepared to



legal frameworks. One solution attracting increasing attention would be to integrate the Health and Social Affairs DGs, as was the case in the previous Commission but, if this cannot be achieved, there should at the very minimum be a paragraph on health in Article 136 (social policy) with a cross-reference between Articles 136 and 152. It could even be argued that Articles 136 and 152 might be merged within a single chapter of the Treaty. While it might be suggested that such a revision to the Treaty is not legally necessary, there are strong organisational and political arguments for this change.

### Competence for public health, health systems or population health?

European public health experts have long, and somewhat fruitlessly, agonised over the definition of public health. There is clearly a danger that a similar argument might develop in relation to the new Treaty, as Community involvement in the post Smits/Peerbooms era moves beyond the more traditional limits of public health in Article 152.

Most Member States would argue that health services must remain the responsibility of national or local government, if only because of the significance of health service expenditure to national economic policy. It may be acceptable, however, that health systems and health policy should become a European competence, given that while *individual health* is the responsibility of health services, *population health* can be regarded as having a significant European dimension.

An equally difficult debate still needs to be resolved over the form of competence. In the Convention on the Future of Europe, the proposal to 'downgrade' health from a shared national/EU to merely complementary non-legislative competence would reduce the existing limited powers under Article 152 to the weaker provisions of Article 129 (Maastricht).

### Is health to assume a higher profile in Europe?

Health is at a crossroads in Europe and the current debate within the Convention is evolving rapidly. One route might lead to a diminished European role, the other will see competence expanded. Voices calling for a downgrading of health in the Treaty certainly reflect the views of a number of Member States that health, and especially health services, must remain their responsibility. The argument, here, is that cross-

#### BOX 1

##### CONVENTION ON THE FUTURE OF EUROPE

In order to pave the way for the next revision of the European Treaties, EU Governments decided in Laeken in December 2001 that it was necessary to look at ways of improving the functioning of the European Union.

It was agreed to convene a Convention "to consider the key issues arising for the Union's future development and try to identify the various possible responses".

The key issues are divided in the following categories:

- Fundamental questions about the role of the EU;
- Division of competencies in the European Union;
- Simplification of the Union's instruments;
- Functioning of EU institutions and their democratic legitimacy;
- A single voice for the EU in the world;
- Towards a Constitution for European citizens.

The "Convention on the Future of Europe" will be meeting from February 2002 until October 2003. Its work will be divided into three phases:

- It will open its proceedings with a listening period in order to find out what people want and expect from the European Union;
- The second stage will concentrate on comparing the pros and cons of the proposals put forward for organising the European Union;
- The third phase will seek to draw together the different proposals and draft a final document to be presented to the Intergovernmental Conference (IGC) in 2004.

The European Council appointed Valéry Giscard d'Estaing as Chairman of the Convention and Giuliano Amato and Jean-Luc Dehaene as Vice-Chairmen. In addition, the Convention is composed of:

- 15 representatives of the Heads of State or Government of the Member States (one from each Member State);
- 13 representatives of the accession candidate countries (one from each candidate country);
- 30 representatives of the national parliaments of the Member States (two from each Member State);
- 26 representatives of the national parliaments of the accession candidate countries (two from each candidate country);
- 16 members of the European Parliament;
- 2 representatives of the European Commission.

The Laeken Declaration allows candidate countries to take part in the proceedings without, however, being able to prevent any consensus which may emerge among the Member States.

The Presidium has the key role of lending impetus to the Convention and to provide it with a working basis. The Praesidium of the Convention is composed of 12 members:

- The Convention Chairman and Vice-Chairmen
- 2 European Parliament representatives
- 2 Commission representatives
- 2 representatives of national parliaments
- Representatives of the Governments of Spain, Denmark and Greece (countries holding the Council Presidency during the Convention).

Mr Alojz Peteale, former Foreign Affairs Minister for Slovenia, is the "guest" representing candidate countries in the Praesidium.

border care and professional mobility will only affect minimal numbers, which must not determine the expansion of EU competence. Why not simply develop bi-lateral (or multi-lateral) agreements between Member States, rather than imposing the unnecessary complexity of European regulation? If Europe expands its role to achieve some minimum level healthcare quality, then where will its responsibilities end? Any argument based on quality will lead to European involvement in patient safety, effectiveness of treatment, clinical guidelines, and even clinical governance to ensure that systems are in place to guarantee accountability. Consequently the EU would become involved in determining levels of health spending, requiring significant expansion of European policy areas and legislation.

*“This time, the health article must not be thrown together at the very last moment.”*

The opposite perspective is not only concerned with the threat posed by the internal market and world competition, but sees the Community providing real added value in terms of health protection as well as access to health care for all Europeans. Those in the Convention taking this view might also argue that the ‘subsidiarity defence’ can no longer be sustained, given recent ECJ decisions. Ring-fencing national health systems cannot continue in the face of the fundamental principles of the European Union. Better, they would argue, to accept reality and amend the Treaty in a manner most favourable to the principles most Europeans feel are essential to health. EU citizens have valid aspirations to receive effective health services and these need to be reflected in the Treaty. To allay fears over subsidiarity and to avoid direct European involvement in quality and effectiveness issues, non-regulatory mechanisms such as “open coordination” might be used.

### **Impact of Accession Countries**

While the arguments about the future of health in the EU have been debated among the fifteen Member States, negotiations on the new treaty will also involve the ten accession countries. Their priorities may be very different, particularly those countries with health systems that require significant development. It is imperative that their

views about the future of health in Europe should be ascertained at the earliest opportunity. While possibly they will look to the Community for structural funds for health care renewal, will this be accompanied by an approach that favours an expansion of European competence or that maintains more traditional lines on subsidiarity?

### **No change is not an option**

Although there is a wide spectrum of views on the direction health should take, one thing that most experts agree is that the status quo cannot be maintained. While traditional public health work (such as communicable disease surveillance) has benefited from Article 152, the ECJ rulings have made the health service aspects of Article 152 largely redundant.

It is widely acknowledged that, at a minimum, the piecemeal and uncoordinated nature of the article, e.g. its contradictory references to organs and blood products in both providing and minimising an EU competence, needs to be refined and replaced by more generic references moving away from listing specific areas for action. Any attempt to change the article brings its own problems. One suggestion floated is that paragraph 5 (“Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care”) should be removed. To take it out selectively would send a political signal some Member States might consider entirely inappropriate. Yet to leave it unchanged might also be considered inappropriate in light of ECJ judgments.

One thing is certain. This time, the health article must not be thrown together at the very last moment. Time must be found by the Commission and the Member States (including the Accession countries) to think through the issues so that Europe and its Member States will then have an effective legal basis, sustainable for the long-term, to deliver health in the most appropriate way to its citizens.

*NOTE: The author writes in his personal capacity.*

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### REFERENCE

1. Busse R, Wismar M, Berman PC (eds). *The European Union and Health Services: The Impact of the Single European Market on Member States*. Amsterdam: IOS Press, 2002.

# Drug dealing and drug dependency



*Alan Maynard*

*“The distortion or corruption of the evidence base is a problem both for identifying clinical as well as cost effectiveness.”*

Three groups dominate the healthcare industry in Europe:

- Politicians and civil servants who wish to retain power by buying and selling votes.
- The pharmaceutical industry wishing to make profits.
- Physicians who desire both high incomes and continued autonomy.

The behaviour of all three groups is well established and socially accepted by most Western societies. As Ted Marmor has remarked, “what’s regular ain’t stupid!” Acceptance of these familiar behaviours is part of our everyday life.

Against this background, a “high level” group on medicines was established under the auspices of the European Commission. This group is made up of people who make their living out of health care: Ministers of Health and Industry, four drug dealers (from, for instance, Glaxo and Sanofi) and some Eurocrats wanting to expand their power, with increased leverage in the market. It is unlikely that any of these good folk will confront the health-wealth trade-off that characterises all dealings in this market. In particular they probably will not resist the temptation to talk, but do little substantive about the inappropriate use of pharmaceuticals, fuelling the profits of this health creating, resource intensive and too often mischievous industry.

The ethical pharmaceutical industry is a powerful producer of wealth and health. However drug dealing in this legal market poses major ethical, economic and social challenges. In particular the blind drive for wealth evident in some parts of the market, results in the marketing of drugs of marginal or zero benefit, using scarce resources that would produce significant health gains for the population if spent efficiently.

## **Design and reporting of trials**

As a result of marketing in the early 1960s, thalidomide was prescribed to pregnant women who subsequently gave birth to children with major physical defects. This product of a “free”, unregulated market

led to the UK 1968 Medicines Act, and similar legislation throughout Europe. Consequently the testing of new chemical entities (NCEs) was formalised and regulated, now by a pan-EU agency based in London. Any new NCE has first to be tested on animals, and a clinical trials certificate (CTC) is then only issued after careful scrutiny of these trials, enabling a company to proceed to tests on humans.

The purpose of human trials is to demonstrate effect (and the absence of damage to patients). Effect can be demonstrated in relation to a placebo or rival product. The regulator has to be convinced by evidence from such trials before a product licence (PL) is issued. This whole process can take 10–12 years and the industry claims that it now costs \$800 million for each product brought to market. Thus the cost to the firm involved in losing a product just before the issue of CTC or PL is very high.

The design and reporting of trials can be subject to distortion, (deliberate and accidental) which can bias the evidence base and lead to the excessive use of non-beneficial or only moderately useful new drugs. A nice example of this was the testing of a new anti-psychotic in comparison to an older product used to treat schizophrenia. One trial used a very high dose of the old product (haliperidol) so that the new drug was made to have a much more appealing side effects profile for patients.<sup>1</sup> It is also asserted that for this drug, its effects on body mass (it made patients fatter) were not reported in a fully transparent manner.

A remarkable characteristic of this process is that the legal requirement is to show effect, not relative effect, and once marketed, follow up of the effects of drugs are poorly regulated. There are some signs that regulators (for example, the US Food and Drugs Administration) are becoming increasingly interested in identifying the effect of a new drug relative to its rivals i.e. does the NCE have significantly better effects? The evidence shows that many new drugs have only minor advantages,<sup>2</sup> but that their prices may be as much as 350 times as great as existing products.<sup>3</sup>

Once such unremarkable products and the all too few better drugs are in the market place, their effect is not systematically monitored by structured post marketing surveil-

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*“A levy on industrial marketing budgets should be used to fund the education of doctors about what works for which patients at least cost.”*

lance. If this was done, the preliminary conclusions about the NCE when it was first marketed could be developed with great potential advantages for patient health.

In most EU countries the three preliminary “hurdles” which have to be overcome before market certification is permitted (safety and quality in the production process, and efficacy in terms of no damage to patients) are now complemented by reference to the “fourth hurdle” of cost effectiveness. The Australians were the first to implement the requirement that for a new product to be reimbursed by the public health care system, companies had to demonstrate cost effectiveness. This requirement has been emulated to varying degrees in England & Wales (not Scotland<sup>4</sup>), Finland, Spain, France, the Netherlands, Portugal and other countries.

#### **Distortion of the evidence base**

The distortion or corruption of the evidence base is a problem both for identifying clinical as well as cost effectiveness. There are examples of clinical trialists having to continue trials of apparently poor therapies and of biased results being reported in peer-reviewed journals.<sup>5</sup>

There is also evidence that whatever “naughtiness” clinical trialists produce, economists can copy them! For instance Friedberg and colleagues reviewed economic analyses in the field of oncology and concluded, “although we did not identify bias in individual studies, these findings indicate that pharmaceutical company sponsorship of economic analyses is associated with reduced likelihood of reporting unfavourable results”<sup>6</sup>

The marketing power of the pharmaceutical industry is formidable and its influence enormous. Although doctors undergo many years of training before they are fully licensed to practice in the EU, this training does not enable them to distinguish well between the wealth inducing marketing hype of industry and the health inducing obligations to their patients that they have from the Hippocratic tradition.

The industry invests in “conference tourism”, taking practitioners (and sometimes their wives) business class to five star hotels in exotic destinations. Such investments “educate” practitioners about the sponsoring companies’ new products. It has been shown that not only are these trips very effective in placing the product in doctors’ minds, but subsequently they return home and add the products to

hospital formularies. This conference tourism can lead to ineffective and inefficient products being added to formularies.<sup>7</sup>

#### **Rising to the challenge**

The use of drugs varies considerably within the EU. It is recognised that antibiotic use is excessive and highly variable. There is a fourfold difference in the use of antibiotics across the EU with the French using the most and the Dutch the least. This north-south difference is largely unexplained. A close relationship between antibiotic use and antimicrobial resistance has now been demonstrated: the high levels of use in southern Europe will create many new resistant bacteria raising health care costs globally.

Despite the modest to low rate at which novel and highly effective products are appearing on the market,<sup>2,3</sup> pharmaceutical expenditure is rising rapidly throughout the EU and the rest of the world. The French spend twenty per cent of their health care budget on drugs and the rate of expenditure growth there and throughout the EU is high. How can this growth be contained and how can member states target better the delivery of cost effective drugs?

Policy makers both in and outside the EU are confronted by very similar challenges. The three dominant players in this market place are resistant to change. The industry has enormous financial capacity and has developed considerable skills in managing patients (note how most patients groups are “supported” by the industry in line with product lines in which they specialise e.g. Pfizer’s support for men’s groups), the public, the media (note the uncritical ways in which journalists report the often minor but usually exaggerated effects of new products and ignore their costs!) and political market places.

Politicians, according to public choice theory, market their policies to gather votes to either acquire or retain power. The industry can offer financial and other support to politicians, for instance providing places on company boards. Company marketers managed to convince the Governments of England, Australia and New Zealand to reimburse beta interferon for multiple sclerosis, despite their respective regulatory agencies declaring that this drug was not cost effective.

The third element in this trinity is the physician. They are inundated with marketing material from the industry. Their educational and career training is often

largely financed by the industry. The volume of literature appearing in journals is far too large for most doctors to keep up to date and, as a consequence they are vulnerable to the industry sponsored syntheses which may not always be fully evidence based. The naturally curious nature of these professionals makes them interested in prescribing new drugs (i.e. experimenting on their patients), even if there is no systematic evaluation of effect and cost.

The medical profession in Europe is the last bastion of conservative trade unionism. The profession has retained autonomy and is also highly paid generally, and influential politically. Medical practice is characterised by great variation at every level of the health care system, as well as evidence of inappropriate care (e.g. the use of antibiotics). Often proven and cheap therapies such as medication after heart attacks are not delivered to the poor, in part because the industry prefers to market expensive patented drugs (often of marginal effect) rather than cheap proven products which yield low profits. No health care system in the EU or elsewhere has management systems that effectively monitor these practices and oblige practitioners to deliver efficient, high quality care to patients, rich and poor.

### What form should policies take?

There is a considerable risk that the G10 group will produce little of substance. These bureaucrats from Government and industry will not wish to disturb the comfortable equilibrium that ensures that industry acquires profits and the politicians and the medical practitioners are offered nice returns that maintain their power bases and finances. The participants at this particular health care feast are doing nicely thank you, and will resist change that threatens their interests. They can adopt a wide range of policies, many of which have been shown to be totally ineffectual and thus appropriate for those seeking no radical changes in policy.<sup>8,9,10</sup>

But what if there is a reformer in the G10 group who is not only not muzzled but also articulate enough to move the group towards the adoption of policies which are orientated towards increasing population health by ensuring radical change in the pharmaceutical market? What form should policies take?

The first policy needed is the universal adoption of the “fourth hurdle” obliging companies to demonstrate not only that

their products are clinically effective but also cost effective. Reimbursement should be determined by relative cost effectiveness with a “low hurdle” above which the state would not care for the therapy (e.g. a ‘guideprice’ of €15,000 per quality adjusted life year produced). The ideal institution for the Europe would be a Euro-NICE.

Such a mechanism would not reduce expenditure. Indeed the English National Institute for Clinical Excellence (NICE) has added £600 million to NHS expenditure since 1999. The purpose of NICE and similar institutions is to target resources to where they give the greatest health gain per unit of cost.

Expenditure can only be managed by better control of physician prescribing with counter-detailing or counter industrial marketing. A levy on industrial marketing budgets should be used to fund the education of doctors about what works for which patients at least cost. If practitioners make evidence based prescribing decisions, waste will be reduced and patient welfare enhanced. Can the G10 group break the mould and be radically innovative? Don’t hold your breath!

*“once marketed, follow up of the effects of drugs are poorly regulated.”*

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### REFERENCES

1. Geddes J, Freemantle N, Harrison P, et al. Atypical antipsychotics in the treatment of schizophrenia: systematic overview and meta regression analysis. *British Medical Journal* 2000;321:1371–76.
2. National Institute for Health Care Management. *Changing Patterns of Pharmaceutical Innovation*. Washington DC, 2002. Available at [www.nihcm.org](http://www.nihcm.org)
3. Garattini S, Bertele V. Efficacy, safety and the cost of new cancer drugs. *British Medical Journal* 2002;325:269–71.
4. Cookson R, McDaid D, Maynard A. Wrong SIGN NICE mess. *British Medical Journal* 2001;323:743–45.
5. Morgan S, Barer M, Evans R. Health economists meet the fourth tempter: drug dependency and scientific discourse. *Health Economics* 2000;9:659–67.
6. Friedberg M, Saffran B, Stinson TJ. Evaluation of conflict of interest in economic analyses of new drugs used in oncology. *Journal of the American Medical Association* 1999;282(15):1453–57.
7. Chren M M, Landefeld MD. Physician behaviour and their interactions with drug companies. *Journal of the American Medical Association* 1994;271: 684–89.
8. Bloor K, Freemantle N. Lessons from international experience in controlling pharmaceutical expenditure. I: controlling patients. *British Medical Journal* 1996;312:1469–71.
9. Freemantle N, Bloor K. Lessons from international experience in controlling pharmaceutical expenditure. II: influencing doctors. *British Medical Journal* 1996;312:1525–27.
10. Bloor K, Freemantle N, Maynard A. Lessons from international experience in controlling pharmaceutical expenditure. III: regulating industry. *British Medical Journal* 1996;313:33–35.

# The customer revolution:

## *The pharmaceutical industry and direct communication to patients and the public*



*Per Wold-Olsen*

*“Patients and consumers are increasingly demanding more information about their own health and treatment options.”*

We live in a world in which the pace of change is irresistible. The internet brings a wealth of new information to anyone with a computer and a modem. The pace of drug discovery has accelerated. We live longer and healthier lives. More people are treated with more medicines than ever before. Medicines and other health interventions that we use are however becoming ever more complex, for physicians and patients alike, making the status quo no longer tenable. Under the leadership of Commissioners Liikanen and Byrne, the G10 group has explored areas that need change for Europe to realise its vision of an information society that will contribute to the improvement of health for all European citizens.

### **The customer revolution and access to breakthrough medicines**

One important element of the European landscape today is the customer revolution in all aspects of society, including pharmaceuticals. Ten years ago, dialogue on medicines was limited largely to conversations between pharmaceutical companies and members of the medical profession. Today, patients and consumers are increasingly demanding more information about their own health and treatment options. They are eager and willing to take a more active role in managing their health.

One example of modern informed patients are those HIV/AIDS patients who actively search for knowledge on better ways to manage their condition, and demand rapid access to innovative medicines. As a result, when protease inhibitors were introduced to Europe between 1995 and 1996, I was impressed at the speed with which the

medical community and patients adopted this new therapy across Europe. New combination treatments had an almost immediate impact in reducing morbidity, mortality and costs to society. For instance, today in the UK roughly two-thirds of all HIV-positive patients are on anti-retroviral therapy, essentially all of those who should be receiving these treatments. This is an unusually high proportion relative to other therapeutic areas.

Contrast this with an area where patients are not as informed, for example, the case of osteoporosis, a disease that affects more than 12 million middle-aged and elderly women in Europe. Research-based pharmaceutical companies have developed breakthrough medicines proven to reduce the risk of debilitating fractures that plague the lives of women suffering from this disease. Yet five years after these medicines were introduced, only 2.5 million of these women are benefiting from treatment (only one in five of those who should be treated, according to WHO guidelines).

What is right for a modern society, the example of HIV/AIDS or osteoporosis? I think the answer should be obvious. There are many examples, like osteoporosis, that further substantiate the dilemma of under treatment. We are in the midst of a therapeutic revolution in medicine, with new medications for a range of chronic conditions providing physicians with the tools to help their patients both live longer and improve their quality of life.

Consider statins, a new class of medicines introduced roughly 15 years ago to treat high cholesterol. These medicines offered real treatment options for the first time. The results of the Scandinavian Simvastatin Survival Study (4S), a clinical trial of 4444 patients provided compelling evidence of

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more than a 40% reduction in coronary mortality for patients who had suffered from myocardial infarction and angina.<sup>1</sup> Treatment with statins therefore can help individuals live longer, and continue to make productive contributions to both their families and society. Even more dramatically, based on mortality reduction data from 4S and the number of Europeans treated, this year alone an estimated 60,000 – 70,000 thousand lives were saved by statin treatment. That is impressive, but the number could have been twice as great, as only half of those who could benefit from treatment receive such treatment.

Results from the recently published Oxford heart protection study (OHPS) of more than 20,000 patients have also demonstrated the benefits of treatment with simvastatin in people usually viewed as being at lower risk for cardiovascular disease (patients with diabetes, narrowing arteries or who have had a stroke).<sup>2</sup> A report on a BBC television programme, Watchdog Healthcheck, estimated that if, as suggested by the OHPS, all people at risk from coronary heart disease may benefit from statin therapy, approximately 15 million people in the UK could be prescribed statins.<sup>3</sup> Currently only around 2 million people receive such therapy. Speaking on the programme, Professor Poulter, professor of preventive cardiovascular medicine at Imperial College School of Medicine, London, said that budgetary restrictions on access “inevitably mean that people are dying of vascular diseases, that would otherwise not happen if they were on statin therapy.”<sup>3</sup>

Despite the strong clinical evidence for the benefits of statin therapy, pharmaceutical companies are prohibited today from communicating these results to patients and consumers, and asking them to consult their physicians. However advertisements on the cholesterol lowering properties of margarine are published, for instance, one German advertisement promotes “the only margarine that can definitely lower your cholesterol level.”, while in the Netherlands this same product was called a “breakthrough in cholesterol lowering that can lower LDL by 10% in three weeks”. Other examples can be found in Finland, the UK and Germany for various products including herbal remedies claiming to have cholesterol-lowering properties. In contrast pharmaceutical companies cannot even tell consumers that scientifically proven medicines are available, and that they should consult their doctor.

### **The Lisbon Summit and e-health in Europe**

The Commission certainly accepted the need for action to improve the options available for access to health information for all patients and consumers in Europe. When the Commission met with the Council of Heads of State and Government in Lisbon and Feira in March and June 2000, they developed an eEurope action plan; a blueprint for a new European agenda to use e-technology to achieve an “*Information Society for All*”. All Member States agreed on “the strategic importance of full exploitation of new information technologies in the public administration of health, for the benefit of the citizen as consumer of both health care services and health information.”<sup>4</sup>

One of the key targets of this plan was Health Online, which has the primary objective of developing “an infrastructure of user-friendly, validated, and interoperable systems for health education, disease prevention, and medical care.” This commitment to e-health in Europe has been affirmed repeatedly in the intervening months by the Council, the Commission, and the European Parliament. In April 2001 the Parliament’s Report on the Programme of Action in the Field of Public Health noted that “the Community should take into account the right of patients to receive simple, clear and scientifically sound information about their illnesses, available treatments and ways of improving their quality of life.”

Furthermore in July 2001, as part of its regulatory review process, the Commission had proposed to amend the Advertising Directive to allow for a pilot with direct-to-consumer advertising to “ensure the availability of better, clear and reliable information on authorised pharmaceuticals” for patients with HIV/AIDS, asthma, and diabetes. We can now look at some of the broader dimensions relating to information for patients.

### **The role of the informed patient**

Informed patients are discerning patients. There is a growing body of evidence, from cases as varied as benign prostatic hyperplasia, asthma, hypertension, breast cancer, and diabetes, that patients who take an active role in managing their care have better health outcomes and, as such, are cost-effective patients for society.

This stands to reason, as the more a patient knows about a disease and its treatment,

*“Patients who take an active role in managing their care have better health outcomes and are more cost-effective to society”*

## REFERENCES

1. Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study (4S). *The Lancet* 1994; 344(8934):1383–9.
  2. Heart Protection Study Collaborative Group. MRC/BHF heart protection study of cholesterol lowering with simvastatin in 20,536 high risk individuals: a randomised placebo-controlled trial. *Lancet* 2002; 360: 7–22.
  3. BBC Watchdog. *Statins*. Healthcheck reports. 11th February 2002. Available at [www.bbc.co.uk/watchdog/reports/health/index2.shtml?rpt57](http://www.bbc.co.uk/watchdog/reports/health/index2.shtml?rpt57)
  4. European Commission. eEurope. *An Information Society for All. Action plan*. Report prepared for Feira European Council. 14th June 2000. Available at [www.europa.eu.int/information\\_society/eeurope/action\\_plan/pdf/actionplan\\_en.pdf](http://www.europa.eu.int/information_society/eeurope/action_plan/pdf/actionplan_en.pdf)
  5. Rosenthal MB, Berndt ER, Donohue JM, Frank RG, Epstein AM. Promotion of prescription drugs to consumers. *New Engl J Med* 2002; 346 (7):498–505.
  6. Calfee JE. Public policy issues in direct to consumer advertising of prescription drugs. *Journal of Public Policy and Marketing* 2002; 21(2):174–94.
  7. European Federation of Pharmaceutical Industries and Associations. *Guidelines for Internet Websites Available to Health Professionals, Patients and Public in the EU*. October 2001. Available at [www.efpia.org/6\\_publ/Internetguidelines.pdf](http://www.efpia.org/6_publ/Internetguidelines.pdf)
  8. Commission of the European Communities. eEurope 2002: Quality criteria for health related websites. *Journal of Medical Internet Research*. 2002;4(3):e15. Available at [www.jmir.org/2002/3/e15/index.htm](http://www.jmir.org/2002/3/e15/index.htm)
- the more rapidly health can be restored. When certain therapies are prescribed, well-informed patients are more likely to adhere to treatment efficiently with safer and more successful outcomes and more efficient use of healthcare resources. Indeed, non-compliant patients are actually the most costly patients to society and across different therapeutic areas; rates of non-compliance average roughly 50% in today's society. This reinforces the case for better information for patients, making sense for both patients and health systems.
- The Commission proposal to amend the Advertising Directive was a first attempt toward improved patient communication through the media, however the legislative outcome is uncertain. There is another related but different dimension, the use of the internet. Most of the attention in the debate has focused on the former, particularly DTC advertising, in the United States. Despite the claims of critics, there is evidence from consumer surveys and other studies showing that DTC advertising provides valuable information on available treatments (together with risks and side effects); motivates consumers to seek additional information from physicians, pharmacists and other sources; and helps people improve adherence to medical therapies and undertake behavioural changes that lead to better health.<sup>5,6</sup>
- Via the internet, European citizens already have wide access to a variety of sources of health information from third-party suppliers inside and outside the EU. Access is only available to internet users, but they cannot obtain product information from European-based pharmaceutical companies. There is also no certainty that the information supplied is accurate, appropriate, comprehensive, or comprehensible. To ensure that there is both equity in health information, and that European citizens are empowered to play an active role in managing their health, we need new thinking.
- The EFPIA guidelines for websites**
- One such simple change is for patients to have direct access to data provided by European-based companies through the internet. In the spirit of this concept, the European Federation of Pharmaceutical Industries and Associations (EFPIA) has developed a set of guidelines for company-sponsored websites.<sup>7,8</sup>
- These guidelines are entirely consistent with the draft quality criteria for health-related Websites that emerged from the Commission's Brussels workshop in June 2001. The EFPIA guidelines reflect the principle that industry policy will ensure that European consumers receive balanced and accurate information in their own languages, consistent with European summaries of product characteristics when they decide to seek such information. Many patients see this as their right, and indeed it is, under the European Convention of Human Rights.
- Living in an information society**
- For better or worse, we now living in an information society, where most Europeans are swimming in a sea of health information, including the internet, magazine advertising, and broadcast advertisements, with information on both disease conditions and specific products.
- Moving forward we have to find ways to make the information society work for patients and for better health outcomes. The pharmaceutical industry, together with other stakeholders, has an important role to play in achieving this goal both through the internet, and through different forms of advertising.
- Attitudes toward healthcare today are different than those that prevailed in our parents' generation. My mother listened passively to whatever her physician told her, while my wife and I ask why and want to understand what's being prescribed. Our children will go even further. We've already seen this attitude in the activism of AIDS patients and cancer patients in recent years. Those in the next generation will say "medical decisions affect my life, and I'm the best judge of what's most important to me." It is our joint responsibility, including the pharmaceutical industry, to help the new generation gain access to the full range of high-quality knowledge they need to establish productive dialogue with their physicians, and to make informed choices about their health, their treatment options, and ultimately their therapies.
- This is the challenge we face today in realising the vision of a European information society of tomorrow that results in improved health for all – and not just the privileged or well-resourced.
- A version of the paper was originally delivered to the 8th Annual Economist Pharmaceuticals Conference, 14 February 2002, London, England.*
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# Finding a voice for the medicine-takers



Angela Coulter

*“Direct-to-consumer advertising is by far the most controversial topic on the EU’s medicines policy agenda.”*

As a member of the European Commission’s High Level Group on Innovation and Provision of Medicines (G10) Group my task was to represent the perspective of European patients. An academic and director of an independent educational charity dedicated to seeking feedback from patients throughout Europe, my claim to knowledge of the patient’s perspective rests on 20 years experience of researching patients’ views and experiences. Nevertheless, my appointment to the G10 caused considerable controversy because many patients organisations felt they were better qualified for the role.

The question of who can most legitimately speak on behalf of the patients of Europe is a tricky one. There is a plethora of organised patient groups in most countries, but many are small and poorly funded and the majority represent patients with specific diseases. While many of these groups came into being as a result of genuine community action on the part of patients, some were established with funding from pharmaceutical companies as part of their ‘disease awareness’ strategies and others were set up by clinicians to support their efforts to raise funds for research. Few could claim to speak for the vast majority of patients and citizens who do not join organised patient groups but who nevertheless use and pay for health services.

Fragmentation of these interests into small disease-specific groups has left the patient’s voice relatively weak in most policy forums and medicines policy is no exception. My daunting task as a member of the G10 group was to try to ensure that patients’ needs are not forgotten in the high level horse-trading between member states and the pharmaceutical industry.

## **Aims of G10**

Apart from me, the other people around the G10 table represented member states (Ministers of State from Germany, France, Portugal, Sweden and the UK), the

pharmaceutical industry (Presidents of the European Federation of Pharmaceutical Industry Associations, the European Generic Medicines Association, the European Self-Medication Industry, and GlaxoSmithKline Pharmaceuticals), and health insurers (President of the Association Internationale de le Mutualité). The group was jointly chaired by Erkki Liikanen, European Commissioner for Enterprise and Information Society, and David Byrne, European Commissioner for Health and Consumer Protection.

The task we were set was to review the extent to which current pharmaceutical, health and enterprise policies can encourage innovation and competitiveness, while at the same time ensuring satisfactory delivery of public health and social imperatives.

The group consulted widely and took account of the views of many organisations and individuals, including many patient and consumer groups. At the outset it seemed to me that there were a number of issues of importance to patients that required action at a European level (see Box 1 on following page). We managed to consider most of these issues in the run-up to the publication of the first G10 report, but it soon became clear that it would be necessary to focus efforts on only a few areas if progress was to be made. The variety of perspectives represented by the G10 membership meant that achieving consensus was difficult. Nevertheless the group did manage to agree on various recommendations, some of which touch on several of the issues listed in Box 1.<sup>1</sup> Most of the group’s recommendations were couched in general, non-specific terms, but they are now the subject of follow-up action and the G10 group is due to meet again in April 2003 to review what has been achieved.

## **Direct-to-consumer advertising**

Direct-to-consumer advertising (DTCA) is by far the most controversial topic on the EU’s medicines policy agenda. The USA and New Zealand are the only countries where this is currently permitted. Companies are not allowed to advertise

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**BOX 1  
MEDICINES POLICY: KEY ISSUES FOR PATIENTS**

**Ensuring affordable, equitable and timely access to effective treatments**

- pricing, co-payments and reimbursement  
*cost to patients*
- defining 'added therapeutic value'  
*including effect on patient's quality of life*
- evaluating cost-effectiveness  
*including cost to patient, side-effects and quality-of-life impact*
- medicines for neglected diseases  
*i.e. 'orphan' drugs and drugs for use in developing countries, effect of patent protection on developing countries*

**Access to evidence-based information to support informed treatment choices**

- quality standards for patient information leaflets  
*including content, presentation and distribution*
- quality of information on health web sites  
*including standards and accreditation*
- tools for shared decision-making  
*development and dissemination of evidence-based decision aids*
- regulating advertising  
*DTCA and company websites*

**Clinical trials: improving recruitment, design and reporting by involving consumers**

- public education about research methods  
*greater transparency and involvement to encourage participation*
- patient involvement in trial design, implementation and assessment  
*ensuring that patient's perspective influences trial design*
- patient-assessed outcomes and quality-of-life  
*key outcome measures from the patient's point-of-view*
- research ethics and data protection  
*harmonisation of procedures and raising standards*
- publication of trials  
*trial registers and consumer 'watchdog' function*

**Patient safety: reducing risk and monitoring adverse events**

- licensing and regulation  
*including transparency, public accountability, and patient representation*
- drugs for children, pregnant women and older people  
*facilitating research into safety and efficacy for neglected sub-groups*
- packaging and labelling  
*incorporating better safety features*
- post-marketing surveillance  
*harmonisation of procedures and raising standards*

prescription medicines to patients anywhere in the European Union. The pharmaceutical industry has been lobbying hard for a relaxation of the prohibition, supported by a few patient groups who argue that patients should have the right to access any information that drug companies wish to provide. Ranged against them are consumer groups, such as Health Action International (HAI), and professional

groups, including the Pharmaceutical Group of the European Union (PGEU), who are concerned that unfettered advertising of these products would distort the market, drive up costs and increase the risk of inappropriate and potentially harmful prescribing.<sup>2</sup>

In parallel to the work of the G10 Medicines Group, the European Commission conducted a review of pharmaceutical legislation. Their proposed amendments set alarm bells ringing among anti-DTCA lobby because they seemed to signal a relaxation of the prohibition on direct-to-consumer advertising of prescribed medicines. The Commission's recommendation to the European Parliament called for a measure of deregulation to allow companies to provide information to patients with diabetes, AIDS and asthma.<sup>3</sup> HAI issued a press release denouncing the move as 'the thin end of a wedge to open the door to DTCA'.<sup>4</sup> In the event the Pharmaceutical Review Committee's recommendation to relax the advertising ban was rejected at its first reading in the European Parliament following an effective campaign among MEPs.

This move to allow the pharma companies to provide information about their products directly to patients has been incorrectly attributed to the G10 Medicines Group, but the Pharmaceutical Review was an entirely separate exercise. In contrast, G10 recommended that the restriction on advertising of prescription medicines to the general public should continue, but we called for action to improve the availability of good quality, objective information so that patients can be better informed about the medicines they take and actively involved in decisions about their treatment. We also called for recognition and clarification of the distinction between advertising and good quality information.

**Evidence-based patient information**

Insufficient information about their illness, prognosis and treatment options is central to people's dissatisfaction with health care.<sup>5</sup> It comes top of the list of problems identified in patient surveys and is the underlying cause of the vast majority of formal complaints and legal actions. Poor communication and failure to inform leads to optimistic and often unrealistic expectations about the benefits of medical care. Risks and side-effects are often under-emphasised or not mentioned by clinicians, with the result that patients are unprepared to face problems and treatment failures.

They are forced into a position of dependency with little opportunity to help themselves or to participate in decisions about their care.

The quality of clinical communication can have an effect on outcome. Patients who are well informed about prognosis and treatment options are more likely to adhere to treatments, leading to better health outcomes. They are also less likely to accept ineffective or risky treatments. Assisting patients to make informed choices and encouraging them to participate in a therapeutic alliance or partnership with the clinician is now seen as the key to promoting effective medicine-taking.<sup>6</sup>

Informed patient participation in health care choices is impossible without access to accurate, comprehensive, unbiased information about the pros and cons of all available treatment options, including the option of no treatment. Unfortunately much available information does not conform to recognised quality standards (see Box 2).<sup>7</sup> Information provided on company websites or in advertisements is particularly problematic in this regard.

Most patients want comparative information about the treatment options for their particular disease or condition. They need evidence-based statements of benefits and risks derived from credible sources. Patient information should refer to the quality and consistency of empirical studies and should be explicit about uncertainties and controversies. It should present all options (including doing nothing) in a balanced way, and should be well designed, clearly structured and concise.

Inducements to patients to demand specific prescription medicines cannot conform to these standards. Companies whose *raison d'être* is selling products have no incentive to broadcast the existence of products produced by rival companies or to compare and contrast the benefits, risks and side-effects of the alternatives. Advertisements and company disease-awareness campaigns will not meet patients' needs for reliable, evidence-based information.

### The way forward

What is needed is a concerted effort to make evidence-based patient information much more widely available. This important task cannot be left to the pharmaceutical industry alone. Instead it requires a concerted effort by all stakeholders, including the European Commission, national governments, health insurers, industry,

#### BOX 2

#### STANDARDS FOR GOOD QUALITY PATIENT INFORMATION MATERIALS

- **Uses patients' questions as the starting point**
- **Addresses common concerns and misconceptions**
- **Refers to all relevant treatment and management options**
- **Provides honest information about benefits and harms of each option**
- **Includes quantification of likely outcomes**
- **Uses non-alarmist, non-patronising language in active rather than passive voice**
- **Provides checklists and questions to ask the doctor**
- **Is well-designed, structured and concise with good illustrations**
- **Is explicit about authorship and sponsorship**
- **Refers to sources and strength of evidence**
- **Includes the publication date**
- **Includes sources of further information**

professionals, patients and consumer groups. The G10 Medicines Group called for the establishment of a public-private partnership to develop and oversee the process. Quite how this initiative will come about is not yet clear.

The Pharmaceutical Review Committee envisaged a role for the European Medicines Evaluation Agency (EMA) in developing and monitoring standards for patient information, but if the process is to be credible it will require the active involvement of, and accountability to, all those groups with a legitimate interest in the topic, including member state governments.

Demonstration projects should be established and rigorously evaluated against clear quality criteria. A great deal is already known about what patients want, but careful piloting will be required to evaluate different ways of meeting these needs. The information needs of minority groups will require special attention. In particular it will be important to examine mechanisms for disseminating information so that patients can access it at the time they need it and in a form that is comprehensible and useful to them. Information providers will need education and support to improve the quality of materials and clinicians will need training and encouragement to inform and involve patients in decisions about their care.

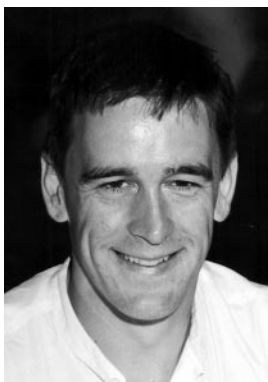
This is an ambitious agenda, but the rewards in terms of more informed medicine-taking and better public understanding of the benefits and limitations of medical treatments could have a profound impact on public health throughout Europe.

#### REFERENCES

1. G10 Medicines Group. High Level Group on innovation and provision of medicines. Brussels: European Commission, 2002.
2. Medawar C. *Health, Pharma and the EU: Direct-to-consumer Drug Promotion*. London: Social Audit, 2002.
3. European Commission. Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use. Brussels: European Commission, 2002.
4. Health Action International Europe. *HAI Europe Criticises EC Move Towards DTCA and Calls for Evidence of Health Benefits*. Amsterdam: HAI Europe, 2001.
5. Coulter A, Magee H. *The European Patient of the Future*. Buckingham: Open University Press [in press]
6. Marinker M, et al. *From Compliance to Concordance: Achieving Shared Goals in Medicine Taking*. London: Royal Pharmaceutical Society of Great Britain, 1997.
7. Coulter A, Entwistle V, Gilbert D. Sharing decisions with patients: is the information good enough? *BMJ* 1999;318:318-22.

# G10

## *An opportunity missed*



*Tony Hockley*

*“As ever consensus has produced an innocuous fudge soon to be forgotten.”*

Every government has a favourite way of kicking difficult issues into the long grass, in which they will either become lost for good or fail to emerge for several years. In the UK this has long been the role of the Royal Commission and in Brussels the role of the *Comité des Sages*. Both serve to lock the protagonists on the subject into the process and its eventual conclusions. Under the snappy title of ‘G10’, befitting its 21st century creation, just such a committee was formed to deal with questions on European pharmaceutical policy, already discussed in five years worth of ‘roundtables’.

Unlike a UK Royal Commission, which is usually enlivened by publication of a minority report alongside the official version, the G10 was guaranteed to spring no surprises by only producing a consensus opinion on the issues at stake. As ever consensus has produced an innocuous fudge soon to be forgotten.

The G10 report amounted to little more than an endorsement of the European Commission’s current work programme; particularly the review of pharmaceutical legislation that was already well underway when the G10 began its work. Tacked onto this endorsement has been a replication of some of the less onerous outputs from the earlier UK Pharmaceutical Industry Competitiveness Task Force (PICTF),<sup>1</sup> most notably the development and use of performance indicators. Extending this UK work to the European level could greatly assist analysis of the industry’s relative competitive position,<sup>2</sup> but will only be of practical value to a Member State that is seriously concerned with attracting major pharmaceutical companies to invest locally.

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### **Unfulfilled promise**

At the launch of the G10 ‘high level group’ in March 2001 the Commission promised an examination of “*how European systems measure up*”.<sup>3</sup> The Terms of Reference set as its first question: “*The medicines industry produces products intended to cure disease and save lives. How does Europe shape up internationally in terms of availability of new effective products meeting Europe’s real health needs?*”<sup>4</sup> In fact it did nothing of the sort. The report did not address this issue sufficiently.

Intriguingly Commissioners Liikanen and Byrne wrote in their preface to the G10 Report that: “*The Group are to be congratulated for not avoiding difficult issues such as cost-effectiveness, information to patients, etc. where, traditionally, it has been difficult for industry and social partners to establish consensus*”<sup>4</sup> Despite this, the recommendations contained nothing of substance on these issues that have not already appeared elsewhere in Commission’s proposals on the review of pharmaceutical legislation. For some reason it was considered worthwhile for one of the recommendations to state the obvious by arguing that the review should: “*consider ways of improving the legislation or the operation of the licensing system to improve the introduction to the market in particular for innovative medicines*”. Hardly a new challenge to the Member States, or to the years of delay that patients face whilst pharmaceutical pricing and reimbursement processes in several Member States drag slowly along.

The report used other recommendations to endorse Commission initiatives on orphan drugs and paediatric medicines, amongst others, and called for activities “*to support the development of a biotechnology strategy in Europe*”, mentioning in a footnote that this would be “*in line with the Communication from the Commission...*”.

### **Prescription medicine advertising**

When attention turned to the contentious subject of prescription medicine advertising the G10 again sheltered behind the review of pharmaceutical legislation. It noted that over-the-counter medicines could already be advertised, and stated that: “*the existing prohibition on advertising medicines available only on prescription to the public should also remain*”, without a supporting argument. The only concession to the challenge of the internet was to ask the Commission to work on the distinction between information and advertising, and

to support this with “*a collaborative public-private partnership*”.

That the group could offer nothing new on this most contentious of issues, was perhaps its greatest missed opportunity. At a time when the EU is seeking to create an information society and tackle social exclusion, endorsing an attitude that information should only be available to those who go in search of it serves neither ambition. It assumes that European consumers are incapable of distinguishing between neutral information and commercial advertising, when they are bombarded with both on a daily basis. The current situation where only a privileged minority can go in search of drug-related websites and other sources of information, will not be affected.

The G10 Report provides a bureaucratic response to questions. It is no surprise, therefore, that its reply to concerns that patient groups might be reliant on funding from one interest group, the pharmaceutical industry, is to suggest that another, the European Commission, should fund such groups. It might then be argued that it would become too easy, for those receiving Commission funding to challenge the credentials of those relying on other sources of funding, notably industry. Problems of EU competitiveness and the lack of a vibrant European pharmaceutical market, stem from an excess of bureaucratic involvement, not too little.

### **Towards a globally competitive European pharmaceutical industry?**

The G10 group so far have added little that will boost the competitive position of the European pharmaceutical industry. With one or two exceptions, Member States have prioritised cost containment within their state healthcare system, rather than reversing the shift of the pharmaceutical industry to the United States. This shift is reinforced with each and every merger and acquisition. It is accelerated as the focus on cost containment becomes ever more severe as fiscal constraints of the Euro-zone impinge on Member States' fiscal policies. The drugs bill has been an easy target for cuts, the victims of which are more often than not foreign-owned companies rather than local interests.

Ad hoc measures taken to tackle the drugs bill have moved European health systems ever further from market disciplines, and thereby ever further from the completion of a Single Market. The G10 were asked to identify how “*the dynamism of the market*

*can be improved*”, yet the report prescribes market mechanisms only for medicines that are neither purchased nor reimbursed by the state, even though this was seen as “*an opportunity to develop a genuine EU-wide single market for non-reimbursed medicines including the possibility of a pan-European price*” The Commissioners may be right in saying that the Group did not avoid difficult issues, but it tackled them only in the extremely limited context of the European private market. The G10 could yet add value to work already underway in the pharmaceutical sector if its members were to begin to ask for the first time whether what they have prescribed for the private prescription and over-the-counter markets might also be applied to the public market. Prescription drugs face increasing competition, not only from direct competitors,<sup>5</sup> but also from increasing reliance on off-patent substitutes. Generic competition is still a novelty in many European countries, but is now spreading fast, creating the scope for ‘innovation’ in drug budgets if finance ministries are willing to pursue this.

The only route to a single market and to a globally competitive European pharmaceutical industry would be through the development of market-based competition. The G10 has left much to be done in pursuit of this, in ways that are consistent with the health policy goals of the EU and its Member States. Attention must focus on the European Parliament and Council of Ministers to analyse and answer questions set for the G10, but left unanswered. But first they should decide whether Europe wishes to provide the pharmaceutical industry with a global base for its activities, or whether it is content to trade today's cost-containment, for the loss of research, jobs and revenues across the Atlantic?

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#### REFERENCES

1. Pharmaceutical Industry Competitiveness Task Force. *Final Report*. London: Department of Health/Association of the British Pharmaceutical Industry, March 2001.
2. Pharmaceutical Industry Competitiveness Task Force (PICTF). *Access and Competitiveness Study*. London: Department of Health/Association of the British Pharmaceutical Industry, 2002.
3. European Commission. *Pharmaceuticals: High Level Group Established to Look at Medicines for Europe*. IP/01/444, 26 March 2001.
4. European Commission. *High Level Group on Innovation and Provision of Medicines: Recommendations for Action*. 7 May 2002. Annex A, p26.
5. Sussex J, Marchant N. *Risk and Return in the Pharmaceutical Industry*. London: Office of Health Economics, 2001.

# The Pharmaceutical Review

*Nearly all of us use pharmaceuticals. Whether we are relying on medication to ease a headache, or something far more serious, we should demand and expect access to products whose quality is assured by the EU.*



*Catherine Stihler*

*“it is vital that we do not confuse information with marketing claims”*

A review of EU pharmaceutical legislation is currently underway. This legislation aims to ensure new, safe and effective products, strengthen competitiveness of the European pharmaceutical industry, and prepare approval and pharmacovigilance procedures for enlargement.

The package relating to human medicine is complex encompassing two reports, a draft directive on medicinal products for human use, and a draft regulation on marketing authorisations and the functioning of the European Medical Evaluation Agency (EMA). There is also a linked report on veterinary medicinal products. The reports drew over 800 amendments in committee and passed the first reading stage at plenary in October 2002. The package will return to the European Parliament in due course for a second reading.

Highly technical matters are at stake: the length of time drug approval by the Commission takes, the way in which Member States can approve pharmaceuticals; and whether there should be a single (EU) centralised system for approval or if member states should be allowed greater flexibility to recognise pharmaceuticals for use. Furthermore the legislation examines reform of the EAEMP (European Agency for the Evaluation of Medicinal Products). Some amendments, rejected by Parliament, argued for an extension to cover complementary and children’s medicines although legislation directly addressing these issues is already before Parliament or in the pipeline.

### **Compromise**

Parliament agreed several compromises. Plenary adopted the European Food Safety

Authority model of management board for EMA, adding a representative of the various social security schemes. Fifteen members will be appointed by the Council in consultation with Parliament, together with one Commission representative, two from industrial organisations, and one each from patients’ organisations, doctors’ associations and social security schemes. On data exclusivity, eight years for authorisation procedures and ten years for production and marketing were carried for both human and veterinary uses. Plenary also voted to allow an initial five year renewal of authorisation followed by indefinite renewal. On expiry of authorisation if a product is not placed on the market within x years, a so-called ‘sunset clause’ of three years, including exemptions in exceptional situations was approved. On expiry of authorisation if there was a marketing gap of y consecutive years, the Commission’s proposal was maintained for human use (two years). A flexible approach, strongly urged by Labour MEPs, was adopted for human but not veterinary medicinal products.

### **Direct to consumer advertising**

However, the most controversial proposal by far was the issue of direct to consumer advertising (DTCA). Commission proposals to introduce a five-year pilot scheme allowing direct advertising for prescription drugs relating to aids, diabetes and asthma proved one of the most keenly debated aspects of the pharmaceutical review. The European Parliament overwhelmingly rejected the proposal and deleted Article 88.2 (494 votes in favour, 42 against, 7 abstentions).

Although some people will argue that this is merely a debate about providing patients with information, I agree with those who say that it is about controlling access to, and prices of, medicines and strongly urge, “Buyer beware”. The United States’ approach to DTCA makes for surreal adverts. Stereotypically, they offer magical solutions in the form of pills available from “all good pharmacies”. The resulting miracle cure is followed by a disclaimer run through at top speed. This is likely to

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inform us that the success rate of the medication is shockingly low, with a range of side effects, and that pregnant women should never (ever) touch such products with their bare hands (and I write this with very little exaggeration). You might think individuals would exercise discretion over what they purchase as medication, but is it surprising that the ten most heavily advertised drugs in the US are the ten best selling drugs? Advertising sells after all.

Patients certainly need information but it is vital that we do not confuse information with marketing claims. We must resist demands for direct to consumer advertising of prescription-only drugs. Medicines are not sold or consumed like ordinary products. Our key goal in the next stage of the pharmaceutical review should be to ensure that patients receive safe, tested and effective medication and reject direct to consumer advertising.

*“the most controversial proposal by far was the issue of direct to consumer advertising”*

## Further Information on G10 and the Pharmaceutical Review

The G10 High Level Group on Innovation and the Provision of Medicines website can be found at <http://pharmacos.eudra.org/F3/g10/g10home.htm>. This provides access not only to the final report at <http://pharmacos.eudra.org/F3/g10/docs/G10-Medicines.pdf> but also information on Terms of Reference, workshops undertaken as part of the process, background reports and other documentation, as well as information on current pharmaceutical legislation.

### Some additional reaction to the G10 report

Association Internationale de la Mutualité

[www.aim-mutual.org/docs/g10\\_%20press\\_release\\_en.pdf](http://www.aim-mutual.org/docs/g10_%20press_release_en.pdf)

Association of the British Pharmaceutical Industry

[www.abpi.org.uk/press/press%20releases\\_02/020507.asp](http://www.abpi.org.uk/press/press%20releases_02/020507.asp)

European Federation of Pharmaceutical Industries and Associations

[www.efpia.org/3\\_press/20020507.htm](http://www.efpia.org/3_press/20020507.htm)

Pharmaceutical Group of the European Union

[www.pgeu.org/01.07.03E%20PGEU10%20FINAL%20G10.pdf](http://www.pgeu.org/01.07.03E%20PGEU10%20FINAL%20G10.pdf)

The Standing Committee of European Doctors

[www.cpme.be/adopted/CPME\\_AD\\_Brd\\_210902\\_16\\_EN\\_fr.pdf](http://www.cpme.be/adopted/CPME_AD_Brd_210902_16_EN_fr.pdf)

### Reaction to the initial consultation document

The initial consultation document is available at <http://pharmacos.eudra.org/F3/g10/docs/g10an1.pdf>

Health Action International – Europe

[www.haiweb.org/campaign/DTCA/response\\_to\\_the\\_G10.html](http://www.haiweb.org/campaign/DTCA/response_to_the_G10.html)

BEUC, the European Consumers Organisation

<http://pharmacos.eudra.org/F3/g10/docs/responses/4.pdf>

The Consumers Association in the UK

<http://pharmacos.eudra.org/F3/g10/docs/responses/resp2/Consumerspharm.pdf>

### Other documentation of interest

UK Pharmaceutical Industry Competitiveness Task Force (UKPICTF) Report, March 2001

Available at [www.doh.gov.uk%5cpictf/pictf.pdf](http://www.doh.gov.uk%5cpictf/pictf.pdf)

UKPICTF ‘One year on’ Report, May 2002

Available at [www.doh.gov.uk%5cpictf/pictfoneyearon.htm](http://www.doh.gov.uk%5cpictf/pictfoneyearon.htm)

Overview of Pharmaceutical Pricing and Reimbursement Regulation in Europe. P. Kanavos. London School of Economics and Political Science.

Available at <http://pharmacos.eudra.org/F3/g10/docs/synthesis.pdf>

LSE Survey on Pharmaceutical Pricing and Reimbursement Structures in the European Union and Worldwide

Available at <http://pharmacos.eudra.org/F3/g10/p6.htm>

Further information on the Review of Pharmaceutical Legislation can be found at

<http://pharmacos.eudra.org/F2/home.html>

# The Wanless Report:

## *What next for public health and what are the European implications?*



*Paul Lincoln*



*Geof Rayner*

The NHS is the UK's most cherished organisation and remarkably the largest organisational entity in Europe. But it is a sad reflection on British public policy that it has taken 54 years since its inception before any serious official attempt to develop a scientific basis for long term planning.

In 2001, the UK Treasury commissioned Derek Wanless, former chief executive of the NatWest Bank, supported by a Treasury 'in house' team, firstly to examine the technological, demographic and medical trends over the next two decades affecting the health service in the UK. Secondly, it sought to identify the key factors determining financial and other resources required to ensure that the NHS could provide a publicly funded, comprehensive, high quality service available on the basis of clinical need and not on ability to pay.

### **Securing our future health**

The resultant document *Securing our Future Health: Taking a Long-term View*, ubiquitously known as the 'Wanless Report',<sup>1</sup> was well received. One of the future planning scenarios presented in the report, the most conservative in terms of future costs, has since been adopted by the government as the official resource model for the next five years. After this period it is anticipated, if recommendations are accepted, that the information, modelling and forecasting will be further reviewed.

The report's central focus is future demand (technological, demographic and public expectations) on healthcare. It also makes some very significant observations about public health, which is the main concern of this article. So significant are these that many believe that the report is a watershed for public health, and is perhaps the best opportunity since the NHS was founded to address some fundamental issues that in the past have received marginal attention.

When the NHS was established, part of its rationale was the contribution it made to national and organisational efficiency. It was hoped that, in circumstances of rising living standards (e.g. better food, and housing), the historic reservoir of ill health in

Britain would be drained away, leading to falling health care costs. Sadly, not only was this wishful thinking, but according to one observer, a "miscalculation of sublime proportions". NHS expenditure has since risen considerably, although it remains considerably below that of some insurance-based systems because of the tight control placed on expenditure. What the report achieves, after decades of official hand wringing on rising NHS costs, is a more accurate calculation of demand and supply issues facing the NHS, and not only that, an interpretation of factors influencing demand from a public health perspective.

### **Report scenarios**

The report establishes three possible scenarios for the NHS leading up to 2020. Two are described below. One scenario presented is that of '*solid progress*' in which individuals become more engaged in relation to their health. Life expectancy rises considerably, health status improves and the population has confidence in the primary care system, using it more appropriately. The health service becomes more responsive and there are high rates of technology uptake. Another scenario is '*fully engaged*'. Levels of public engagement in relation to their health are high. Life expectancy increases beyond current forecasts, health status improves dramatically and the population has confidence in the health system and demands high quality care. The service is responsive and there are high rates of technology uptake, particularly in relation to disease prevention. The projected annual costs for the first scenario are £184 (€ 283) billion, compared with £154 (€237) billion for the second scenario in 2020.

### **Interpretation of headline findings**

Our interpretation of the reports headline findings and observations are:

1. The NHS should continue to be publicly funded as the analysis shows that this is probably the most efficient and equitable way of providing healthcare.
2. It is both desirable and feasible to construct long term planning models for

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the NHS and forecast future scenarios based on an assessment of the most probable major demands. Such analyses can, and should be, utilised to plan the resourcing and type of services made available in the short to long term.

3. The long term planning of health care cannot be separated from considerations about how public health can be improved by the NHS, as well as by other public bodies and through additional instruments.

4. As a consequence of the above, investment in the delivery of public health needs to be stepped up to reduce avoidable demand.

5. For the first time the contribution of public health to the NHS is quantified – estimated as £30 (€46) billion in savings in 2020 alone. This is based on the delivery of national priority public health interventions through the NHS, largely through universal national standards via National Service Frameworks for the prevention of major avoidable chronic diseases, in particular cardiovascular disease, cancer and diabetes.

### Setting an agenda

The key question for UK policy makers and public health specialists is what happens next. In our opinion the agenda set as a consequence of the report includes a need to produce a clear investment plan for public health at national and local levels as an integral part of the NHS modernisation programme. Furthermore the forecasting model developed and used by the Treasury should be published, allowing this to be applied and extended to other areas of public health not yet considered.

The full social and economic benefits, associated with the ‘*fully engaged*’ scenario, should be described and quantified, as the original review only considered the benefits in terms of health and service outcomes for the NHS alone. Equally, the application of such a model for public health investment outside the NHS, especially in tackling the wider determinants of health should be considered. The original analysis did not consider many upstream policy options for public health, especially those that can reduce health inequalities, many of which are beyond the traditional scope of health services.

Links need to be established between the European Commission, the World Health Organisation (WHO) and with experts in individual countries such as the Netherlands, where similar work has been undertaken. This can help develop a

scientific basis for long term planning, for example through health and health service modelling, forecasting techniques and other instruments. It would also fit in with new EU policy focused on the public health framework and WHO efforts to compare the performance and investment in health services and systems. Given the alarming projections on the burden of avoidable chronic diseases, this is all the more pressing for the future health of both European citizens and health systems. At the European Health Forums in Gastein, Austria in 2001 and 2002 there have been recommendations calling for the European Commission and WHO to establish a European Commission on Macroeconomics and Health.

Finally, the public health research and development agenda needs to be developed further to ensure the relevance and quality of information and evidence for policy making at national and local levels. One of the obstacles encountered in the report was a dearth of evidence based policy information on public health. The team questioned why public health research had received so little attention in terms of research and development investment. The development of a new generation of health forecasting models should therefore be a priority; in particular models that can accurately estimate the impact of changes in health determinants on the health of the population.

### Conclusion

It was US management guru Peter Drucker who stated that management decisions about the future should not be put off until tomorrow. This statement carries much weight in the field of health. We must constantly remind ourselves that when we describe the current health status of the population what we are in fact observing is chronic disease trends originating between at least twenty and perhaps more than fifty years ago. We might also reflect that the health indicators for Europeans, particularly children and young people, are progressively worsening and the historic decline of disease trends can be reversed.

In the UK the Wanless Report provides the foundations of a new approach and the rationale for changing our perspectives on health. We have been presented with an opportunity to properly examine the macroeconomic and social consequences of improving and investing in health, and what this means for how we develop and deliver our health services. We hope that this rare opportunity won't be wasted.

*“[There is] a need to produce a clear investment plan for public health at national and local levels”*

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### REFERENCES

1. HM Treasury. *Securing Our Future Health: Taking a Long-Term View – the Wanless Report*. London, 2002. Available at [www.hm-treasury.gov.uk/Consultations\\_and\\_Legislation/wanless/consult\\_wanless\\_final.cfm?](http://www.hm-treasury.gov.uk/Consultations_and_Legislation/wanless/consult_wanless_final.cfm?)

# Health at the heart of sustainable development?



Louise Sarch

*The concept of sustainable development was first popularised by the World Commission on Environment and Development in 1987, headed by Gro Harlem Brundtland, then Norwegian Prime Minister. It soon became a policy priority, coming to world-wide attention at the United Nations Conference on Economic Development in Rio in 1992. Health has always been at the heart of sustainable development and the World Summit on Sustainable Development (WSSD) last September in Johannesburg reaffirmed this position.*

## Where is health within the sustainable development agenda?

Principle 1 of the Rio declaration on environment and development stated: "Human beings are at the centre of concerns for sustainable development. They are entitled to a healthy and productive life in harmony with nature".<sup>1</sup> Furthermore Chapter 6 of Agenda 21,<sup>2</sup> the global programme of action on sustainable development agreed at Rio, focused on action to protect and promote human health. Five key areas were identified: meeting primary health care needs, control of communicable disease; protecting vulnerable groups; meeting the urban health challenge; and reducing risks from environmental pollution. Despite this, health was not generally viewed as a priority for sustainable development. Nevertheless, over the past ten years 'health' has grown in importance as an international [development] policy priority, with an increasing understanding and acknowledgement of the links between health, economic development and the growing burden of non-communicable disease.

Consequently health has gained in status at major international meetings and conferences in recent years, most notably at the Doha Declaration on the TRIPS Agreement and Public Health (2001), and the Millennium Development Goals conference (2000). The World Health Organization report that now for the first

time meetings of the G8, UN Security Council, World Economic Forum and the OECD are explicitly addressing health issues as development and security issues.<sup>3</sup> Finally ten years on from Rio, at the Johannesburg summit health was billed as a central issue.

## The World Summit on Sustainable Development

Health was given prominence by UN Secretary General Kofi Annan under his proposed WEHAB initiative, covering water, environment, health, agriculture and biodiversity, launched in May 2002. Both Principle 1 of the Rio Declaration and the WEHAB initiative highlight the fundamental association of health within the three UN defined mutually reinforcing pillars of sustainable development, namely economic growth, social development and environment protection. As the WEHAB document stated: 'Health is both an indicator of as well as a resource for sustainable development.'<sup>4</sup>

Health is not only a fundamental element and monitor of sustainable development, it is also an overarching objective and essential requirement. Poverty eradication, and changed patterns of production and consumption are not possible without improved health. As Gro Harlem Brundtland

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\* Others include: UN Special Session on Children (2002); International AIDS Conference (2002); International Conference on population and development (1994); World Summit for Social Development (1995) and the World Conference on Women (2000).

wrote: “We cannot achieve the goals of sustainable development in the face of widespread ill health.... Improving healthy life is not only a desirable outcome of sustainable development it is also a powerful and undervalued means of achieving it.”<sup>5</sup>

Critics of the WSSD accused it of failure; many campaigners were dismayed that they worked so hard to achieve so little, and much of the media coverage was [unnecessarily] negative. However, some very positive achievements and highly laudable commitments were made or revised at the summit (some are listed below), which can be viewed as ‘health gains’.

### ‘Health Gain’ commitments

*On poverty:* to halve the number of people living on less than €1 a day by 2015<sup>6</sup> and to establish a world solidarity fund to eradicate poverty and to promote social and human development.

*On water and sanitation:* to halve the proportion of people without access to safe drinking water<sup>6</sup> and access to basic sanitation by 2015.

*On hunger:* to halve by 2015 the proportion of people suffering from hunger and realise their right to a standard of living adequate for the health and well-being of themselves and their families, and promises to increase food availability and affordability.

*For women and children:* to improve their status, health and welfare, and enhance their role in nutrition and food security.

*On chemicals:* by 2020 the use and produce of chemicals will not affect human health and the environment.

*On transport policy:* to promote an integrated approach to reduce adverse health effects, limit urban sprawl, improve urban air quality and health.

While these are only some of the key commitments inextricably linked to health, the WSSD’s Plan of Implementation specifically sets out commitments and actions for health and sustainable development. The text declared an urgent need to address the causes of ill health and to strengthen health-care systems to deliver basic services to prevent, control and treat diseases. Key agreed commitments included: improving health literacy through health education by 2010; reducing the under fives mortality rates by two-thirds and maternal mortality three-quarters by 2015; reducing HIV in people aged between 15 and 24 by 25 per cent in the most affected countries by 2005 and globally by 2010. Commitments were

made to improve availability and access to nutritionally adequate food, and also to develop and strengthen preventative and curative programmes for non-communicable diseases such as heart disease, stroke and cancer and the associated risk factors including tobacco, poor diet and lack of physical activity.

In addition, the *Johannesburg Declaration on Sustainable Development*,<sup>7</sup> reaffirmed the commitment to sustainable development, including a: “particular focus on severe threats to sustainable development. Among these conditions are: chronic hunger; malnutrition; illicit drug problems; natural disasters; illicit arms; trafficking; terrorism; communicable and chronic diseases, in particular HIV/AIDS, malaria and tuberculosis. (para 19)”

A number of partnership initiatives were also fostered. These are specific commitments by various multi-stakeholder partners intended to contribute to and reinforce the *Plan of Implementation* and to help achieve the further implementation of Agenda 21 and the Millennium Development Goals. Over 220 partnerships (worth \$235 million) were identified in advance of the summit and around 60 partnerships were announced by a variety of countries involving governments, businesses and civil society. (See Box 1)

*“at Johannesburg health was billed as a central issue”*

### WHO and sustainable development

The World Health Organisation played an active role at the summit, involved in preparations for the WSSD, participating in the Plenary, holding parallel events and launching their own partnership initiative. WHO’s approach to sustainable

#### Box 1

#### EXAMPLES OF PARTNERSHIP INITIATIVES IN HEALTH

**Healthy Environments for Children: A Global Alliance on Children’s Health**  
*Lead: WHO (Geneva)*

**Global Health and Development Chart**

*Lead: Department of Public Health Sciences, Karolinska Institute, Sweden*

**Migration of Healthcare Workers**

*Lead: Stakeholder Forum (London)*

**Network for therapeutic Solidarity in Hospitals (ESTHER)**

*Lead: GIP ESTHER (France)*

**Transport, Health and Environment Pan-European Programme (THE PEP)**

*Lead: UN/ECE and WHO Secretariats (Geneva)*

Further information on all these projects can be found at:  
[www.johannesburgsummit.org/html/sustainable\\_dev/p2\\_health\\_sd1.html](http://www.johannesburgsummit.org/html/sustainable_dev/p2_health_sd1.html)

**Box 2****THE INDABA DECLARATION<sup>10</sup>**

The declaration which supports a WHO global strategy on diet, physical activity and health, currently in consultation, is based on four principles:

1. Good health is a vital input to, and outcome of, sustainable development.
2. It can be achieved only by addressing the underlying and basic causes of disease.
3. Modifiable causes of health and disease are environmental.
4. The nature and quality of food systems, and therefore of diet and nutrition, are fundamental determinants of human health and welfare, and that of the whole living and natural world.

*“some very positive achievements and highly laudable commitments were made”*

development focused on two main strands: Firstly, health and development: firming up action for better health among poor people. This focus was based on the analyses of the Commission on Macroeconomics and Health, identifying poor health as a drain on the economy and society, while investment in health spurs economic and social growth.<sup>8</sup> The second strand concentrated on health and the environment, with an emphasis on the impact on children's health. Children are especially vulnerable to the impact of environmental degradation, pollution, mismanagement of natural resource and unhealthy consumption patterns.

To this end WHO held a joint event with UNICEF and UNEP on health and environment in the 21st century, *‘Priorities and action strategies to secure our children's future’*, chaired by Gro Harlem Bruntland. They also held a joint high-level conference with the South African Department of Health, addressed by Mrs Bruntland, Carol Bellamy from UNICEF and Manto Tshabalala-Msimang, the South African minister for health. Sessions included a ministerial roundtable on poverty and investment in health, in which Jeffrey Sachs, chairperson of the Commission on Macroeconomics and Health participated. WHO also launched their partnership initiative ‘Healthy Environments for Children’ at the summit.

### **Beyond the summit: The Global People's Forum**

Initiatives were not just confined to official WSSD deliberations. A critical mass of civil society organisations met at the Global People's Forum in Johannesburg at the same time as the WSSD. This forum allowed African and International Civil

Society organisations, especially those from the South, to participate in discussions on sustainable development.

It was reported that at least 20,000 people from more than 3,000 groups in 120 countries registered for the alternative summit. Groups represented included: small farmers, women's groups, indigenous peoples, youth, the scientific and technological community, human rights workers, environment and spiritual groups, aid agencies, trade unions, political organisations, minority parties, the landless, networks of fair traders, anti-globalisation coalitions and the churches.

As well as participating in some of the health partnership initiatives, participants of the Global People's Forum signed up to a civil society declaration and a programme of action including a call for governments to approach health as a human right. It also recommended that the UN develops and implements a comprehensive health plan to ensure universal access by 2015; and that the WHO conduct fact-finding missions in vulnerable communities around the world suffering from environmental and health problems and should document investigations, findings and recommendations.

However, many civil society groups, which were mostly development and environment groups, felt excluded and disempowered by the WSSD. Not only was the People's Forum held 35 kilometres from the official deliberations, making interaction between the two near-on impossible; even those NGO's who had official accreditation to the Summit were only able to observe the open sessions between member states.

### **Stakeholder Forum Implementation Conference**

On the eve of the WSSD, Stakeholder Forum for Our Common Future<sup>9</sup> held an Implementation Conference to facilitate the development of stakeholder partnerships to deliver sustainable projects. The three day event focused on four areas: energy, food security, fresh water and health, involving over 400 people from over 50 countries. The different sectors were organised into 25 workshops charged to develop ‘concrete, agreed and owned collaborative action plans aimed at implementing the Agreement's sustainable development’. For instance, one workshop group focussing on nutrition, prepared the ‘Indaba Declaration’, on food, nutrition, health and sustainable development, which was endorsed by conference delegates,

including representatives from government, industry, academia, the voluntary sector, charitable foundations and the health professions.

The declaration highlighted the triple burden of disease now borne by almost all middle- and low-income countries of nutritional deficiencies, infectious diseases such as HIV-AIDS, and also non-communicable diseases like heart disease and cancer.

### Policy agenda

Increasing globalisation brings with it an increased integration of sectors and policy areas. It is no longer possible to deal with distinct subjects, or confine action to national or continental borders. Trade and health as previously highlighted at Doha, for instance encompass food and nutrition, pharmaceuticals/medical devices, catering and the leisure industry, all of which need to be addressed on a sustainable development footing.

Poverty and health are crucial global issues, endorsed by the Millennium Development Goals. Poverty eradication cannot be achieved without good health. Health is not just about disease or access to health services, but also broader determinants like water, sanitation, housing, energy, transport, air quality, food, agriculture, and educational autonomy. These are also essential elements of sustainable development and poverty eradication. Poorer people are more likely to live in areas of environmental degradation, and they are more likely to get sick. Individuals who are sick are more likely to become poor. The links identified between health, poverty and environment are strong and becoming more apparent.

At the same time there is an increasing realisation of the role poverty alleviation, and thus health protection and promotion, plays in national and foreign policies for civil society and security. World security cannot be attained while huge levels of poverty and inequity persist: disease and hunger lead to economic weakness and political instability.

Meanwhile there is a growing epidemic of non-communicable diseases (cancer, heart disease and stroke for example) caused largely by the globalisation of key risk factors: tobacco use, unhealthy diet and physical inactivity. Increasing urbanisation has been cited as a key factor. Here levels of smoking may be high, unhealthy diets persist with fast and processed foods prevalent, with levels of physical inactivity increasing due to transportation, pollution

and safety fears.

The policy agenda for sustainable development is about all these issues, and more. Not only must they be tackled as integrated and interdependent issues across international boundaries, but also by all sectors, not just the environment and health, but transport, agriculture, trade and education among others, as all can impact on the wider determinants of health.

### Conclusions

Health was clearly on the agenda of the WSSD, much more so than ten years ago at Rio. Of course much more could have been done, but what Johannesburg did was to raise the status of health within the sustainable development agenda. This has given rise to the opportunity for those in the health community to make health a core element and objective of sustainable development, changing the perception that health is merely a by-product of this process.

*“a number of partnership initiatives were fostered”*

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### REFERENCES

1. United Nations General Assembly. August 1992. *Report of the United Nations Conference on Environment and Development* (Rio de Janeiro, 3–14 June 1992) A/CONF.151/26 (vol. I).
2. [www.un.org/esa/sustdev/agenda21chapter6.htm](http://www.un.org/esa/sustdev/agenda21chapter6.htm)
3. Von Schirnding Y, Mulholland C. *Health and Sustainable Development: Addressing the Issues and Challenges*. Geneva: World Health Organisation, 2002.
4. WEHAB Working Group. *A Framework for Action on Health and the Environment*. United Nations, August 2002 p7.
5. Bruntland G-H. Health: a pathway to sustainable development. *Journal of the American Medical Association* 2002;288(2):156.
6. Millennium Development Goals [www.un.org/millenniumgoals/](http://www.un.org/millenniumgoals/)
7. [www.johannesburgsummit.org/html/documents/summit\\_docs/1009wssd\\_pol\\_declaration.doc](http://www.johannesburgsummit.org/html/documents/summit_docs/1009wssd_pol_declaration.doc)
8. Commission on Macroeconomics and Health. [www.cmhealth.org/cmh\\_papers&reports.htm](http://www.cmhealth.org/cmh_papers&reports.htm)
9. Stakeholder Forum Implementation Conference. [www.stakeholderforum.org](http://www.stakeholderforum.org)
10. *Indaba Declaration on Food, Nutrition, Health and Sustainable Development*. Sandton, South Africa, August 2002.

# The politics of waiting lists in Dutch health care



*Hans Maarse*

Long waiting lists for health care were a hot political issue in the 2002 Dutch election. They are generally considered to be highly visible evidence of a crisis in performance of the health care system. Until the mid 1990s waiting lists did not gain much attention in health care policy making. Policy makers were mainly concerned with cost control, efficiency, the appropriate use of care, need for budgetary discipline, and expenditure cuts. The new 'Purple government', on assuming office in 1994, set the annual volume growth in health care expenditures at 1.3 % for the period 1994-1998 compared to 2.3 % in previous years (however the target was never achieved and the real growth rate was 1.9%). It was not anticipated that when reducing inefficiencies, lower growth rates for health care expenditure would impair the quality of care or give rise to long waiting lists. Warnings of an impending crisis were made merely by the prophets of doom, and no one took their warnings seriously.

## A new problem?

The recent character of the crisis raises the question as to whether long waiting lists did not previously exist. A definite answer cannot be given because of poor data. But there are clear indications that they predate the present crisis, for example, in nursing

homes and in residential care for people with a mental handicap. They were also familiar in hospital care. However, waiting lists never really reached the political agenda. What, then explains the current crisis?

There is much evidence pointing to a growth of waiting lists across health care. Also, many patients now on the list are more seriously ill than previously and, according to all standards, in very urgent need of care.<sup>1</sup> Yet, it is too simple to argue that the current crisis and its rapid rise up the political agenda are only a matter of more patients waiting longer. One can also observe a decline in the social acceptance of waiting. Patients are more assertive and less willing to wait. Physicians begin to emphasise the (potential) adverse impact of waiting upon the medical condition of their patients. Employers no longer accept waiting as they have an interest in minimising the costs of absenteeism. In addition, waiting lists have received intense media coverage arousing public emotion. Finally, one should not overlook the impact of the economy. Why waiting whilst the economy is booming?

In October 2001, approximately 244,000 persons were registered as waiting for curative somatic care. Table 1 provides data on hospital care, highlighting a diverse picture with many variations between specialties. Long waiting lists also existed for long-term and home care.

## Problem definition

Policy analysts know that problem definition is basically a political activity foreshadowing advocated solutions. The waiting list problem is an excellent example.<sup>2</sup> Many critics put the blame on under funding and considered waiting lists to be the price paid for years of tight cost control, inducing a gap between demand and supply. They noted that growth in health care expenditure dropped from 21.9 % between 1990-94 to 14% over the period from 1994-98. The health-to-GDP ratio fell from 8.9 % in 1992 to 8.7% in 1998. Under funding caused, for instance, shortages in nursing and physician care, and a lack of beds in residential and intensive care. Salaries did not keep pace with those in the commercial sector. A heavy workload in health care and increased frustration about the quality of care also led to a rise in sick leave, seriously reducing the attraction of health care sector employment.

The problem of under funding suggested a simple approach: halt expenditure cuts and raise the health care budget. This approach

**Figure 1**  
Waiting lists in hospital care

Specialty	Number of persons	Waiting time diagnosis (weeks)	Waiting time treatment (weeks)
Orthopaedics	34.962	5.0	12.6
Ophthalmology	34.232	9.2	12.9
Surgery	34.777	3.1	9.1
ENT	18.212	4.1	6.5
Cosmetic surgery	23.803	11.9	22.5
Gynaecology	11.055	4.3	6.7
Psychiatry	57.800	---	29.0
Cardiology	3.642	5.1	2.3

Source: Prismant, Zorgverzekeraars Nederland

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had much appeal among many politicians who felt an urgent need for a sign of prompt and visible action. As a result, spending began to rise, initially on a small-scale and ad-hoc basis, but soon becoming large-scale and structural. A 2.5% target for growth in health care expenditure was set for the period 1998–2002, increased from the previous projection of 1.3%. Overall expenditure rose from 14% in the period 1994–98 to 25% between 1998–2002. Thus, health care rapidly moved from a climate of strict budget control and expenditure cuts to a period of extra spending. Using this extra spending power often proved difficult, mainly because of labour market problems, consequently budgets sometimes went partly unused.

The view that waiting lists were linked to under funding did not go uncontested. For instance, health care policymakers at the ministerial level often argued that the basic problem was not a lack of resources but a lack of efficiency in health care (whatever this meant). In this vein, the Inspectorate for Public Health reported that waiting lists in open-heart surgery and percutaneous transluminal coronary angioplasty were also due to bad planning, failing human resource management and ineffective use of existing capacity.<sup>3</sup>

Therefore, the solution was not simply to pump more resources into health care but rather to reform institutional structures. Powerful incentives to improve efficiency were needed. Hospital budgets, for instance, should be performance-related. The political weakness of the inefficiency approach was, of course, that reforms would take too much time, the results would be uncertain, and that achieving consensus would be difficult given conflicting interests. More immediate action was required, not only to help patients but also as a form of political damage control.

Furthermore, waiting lists prompted a debate on measurement and registration. Data on waiting lists proved very poor, in part due to failing registration and double counting. Accurate and timely information on available capacity in provider institutions was also missing. Politicians became ever more frustrated about the lack of transparency which, in their view, pointed to poor management. The government's response to the lack of transparency was to intensify efforts in research and registration including the harmonisation of procedures, and also to establish an on-line information network on available capacity. This task was far from easy. Measuring waiting lists

turned out to be an intractable problem, not only because of poor registration but also because norms for acceptable maximum waiting times were absent. Moreover, it was not clear who would be responsible for defining such norms. Provider and health insurance organisations soon took the initiative on defining norms. They introduced social maximum acceptable waiting times for non-acute care which were adopted by the government.

Economists suggested a different approach, drawing attention to the social costs of waiting caused by a loss of welfare, income and production as well as long-term disability. A recent report estimated these costs at €3,200m.<sup>4</sup> According to the authors, these costs warrant a substantial financial effort to combat waiting lists, as long and sizeable waiting lists are socially inefficient.

### The impact on policy making

The waiting list crisis has significantly altered the Dutch health care landscape. Many consider it scandalous, raising new issues in health care policymaking. For instance, there have been reports in the medical press claiming a causal link between waiting and long-term disability (e.g. depression) and even with premature death.

Another question raised is why the Netherlands has waiting lists while neighbouring countries like Belgium, France and Germany do not? Why must Dutch patients go abroad for timely treatment? Many politicians, suffering from amnesia, seem to forget that, until recently, they considered strict budgetary control in health care an absolute necessity as part of a wider policy of keeping public expenditure contained. Waiting lists demonstrate that policymaking success today may easily become tomorrow's failure.<sup>5</sup>

The waiting list issue evolved into a leading topic in health care policymaking in a very short period of time. Emphasis was put upon extra spending and as a result, the culture of cost control lost much of its priority. For many providers, the key issue no longer is the level of expenditure, but rather how to spend budgets effectively and in a timely fashion. Their main concern now is the scarcity of labour.

Waiting lists prompted activity at all levels, both conventional and unconventional. One example of unconventional activity was the formation of a 'Waiting List Brigade' by the Minister of Health to investigate unacceptably long waiting times. Health insurers now use waiting lists for marketing purposes, guaranteeing their

*"The political weakness of the inefficiency approach was that reforms would take too much time."*

*"Waiting lists demonstrate that policymaking success today may easily become tomorrow's failure."*

*“Private centres are suddenly appreciated as valuable instruments in resolving the waiting list crisis”*

policyholders treatment within a defined time period and identifying where they can get treatment quickly (waiting list brokery). In addition, some insurers have begun contracting with hospitals in other European countries.

Another political aspect of waiting lists has been the emergence of policy making by decibel. Health care providers and interest groups discovered that vocal public action on the lack of capacity or the threat of new or longer waiting lists proved very effective in acquiring additional funding. Recently, for instance, this strategy saw hospitals demanding more capacity for intensive care. They viewed the lack of capacity exclusively as the Minister's fault, and conveniently ignored their own responsibility, e.g. the inefficient use or lack of investment in ICUs. The medical profession when arguing for improved remuneration also point to waiting lists.

A rather new phenomenon entails the increased use of litigation in health care. A few patients in urgent need of care on the waiting list, argued successfully in court for immediate treatment. They contended that insurers had to provide sufficient care, and that health insurance would become meaningless if insurers could not organise timely access to health care. Cases also revealed a diffuse accountability structure. Who should be accountable for waiting lists: the Minister of Health, provider institutions, health insurers, others? The court concluded this lay with the insurers, raising the issue of how to reconcile insurers' accountability with the imposition of fixed budgets by the government. Health insurers in charge of the implementation of the Exceptional Medical Expenses Act (AWBZ) promptly claimed that fixed budgets should be lifted, because they could not be accountable while being constrained by fixed budgets. Thus fixed budgets for long-term care, one of the cornerstones in cost control, were converted into open-ended arrangements.

#### **Provision by the private sector**

Waiting lists also provoked a new political debate about so-called 'private clinics'. Until very recently, these centres were considered inefficient and redundant. Hospital managers accused them of 'cherry picking'. Private centres had to cope with unfavourable reimbursement arrangements under social health insurance, a clear proof of repression. Now however, the picture is changing, private centres are suddenly appreciated as valuable instruments in

resolving the waiting list crisis and health insurers have begun contracting with them.

Recently, the Advisory Council on Public Health and Care (RVZ) went one step further by recommending the use of for-profit health care under strict conditions.<sup>6</sup> As yet, social health insurance legislation forbids health insurers from contracting with for-profit providers. The political reaction to the proposal demonstrates, however, that private centres and profit-making constitute highly contested issues in policy-making. There is a widespread fear that private and for-profit activity will increase costs and open the door to a two-tier health care system with optimal access for those who can afford to pay, and more limited access for patients with lower incomes (who must wait). For the same reason, an initiative by some hospitals to set up special diagnostic facilities for employees to reduce sick leave was rejected, despite an initial welcome from the Minister of Health and frequent pleas for more entrepreneurial activity by hospitals and other providers.<sup>7</sup>

#### **Conclusion**

Waiting lists have become a source of increased frustration among politicians and the general public. Following Wildavsky who in 1980 wrote about the pathology of health care, the situation could be described as *'doing more but feeling worse'*.<sup>8</sup> Although waiting lists have fallen in some fields, particularly in home care, there is a sense of a deep crisis in the performance of the health care system. Where has all extra funding gone? Why do waiting lists still exist? What are providers doing? What explanation is there for the significant increase in the performance of neighbouring hospitals in cataract surgery, following the introduction of a contract by a health insurer with a private clinic for cataract surgery? What explanation can there be that despite all the extra funding, sizeable and long waiting lists for cataract surgery did not disappear?

In summary, waiting lists represent a crisis, first and foremost for patients who must wait in pain and anxiety. The crisis has wider ramifications, it is also political, provoking conflicts and panic and, more fundamentally, growing frustration and concern about the government's ability to take care of public well-being within a welfare state. From the public's perspective, it is the Minister of Health and the government who are to be blamed for long waiting lists, which is why they were such a hot topic in the 2002 electoral campaign.

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#### REFERENCES

1. Inspectorate for Public Health. *Annual Report 2000*. The Hague, 2001
2. Mur-Veeman I, Broekman S, Schoneveld M, van der Made J, Light D. *Debating on Waiting*. Maastricht, 2002 (mimeo).
3. Inspectorate for Public Health. *Annual Report 1997*. The Hague, 1998.
4. SEO. *Wachlijsten – een duur Medicijn*. Amsterdam, 2001.
5. Bovens M, 't Hart P, Guy-Peters B (eds). *Success and Failure in Public Governance. A Comparative Analysis*. Cheltenham, 2001.
6. Raad voor de Volksgezondheid en Zorg (RVZ). *Winst en Gezondheidszorg*. Zoetermeer, 2002.
7. Putters K. *Geboeid Ondernemen*. Rotterdam, 2001.
8. Wildavsky A. Doing better and feeling worse: the political pathology of health policy. In: *The Art and Craft of Policy Analysis*. London, 1984.



# Health Impact Assessment: screening of Swedish governmental inquiries



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Health Impact Assessment (HIA) is a method for predicting the potential health consequences of political decisions. The main purpose of HIA is two-fold: to increase awareness of what determines health for sectors outside the health sector and also to provide policy-makers with a more efficient way to make informed decisions. Many countries are already looking at the potential health consequences before making decisions, but HIA provides a systematic approach to predict and estimate the potential impact. This approach usually involves developing a tool and checklist, to screen and analyse potential health impacts in an organised fashion.

The aim of this study is to present current developments of HIA at a national level in Sweden and to introduce preliminary results from a screening process of governmental inquiries (directions to green papers) for all ministries during 2001 and 2002. Screening these inquiries provides a good opportunity to access the decision making process at an early stage long before any proposals and white papers are produced. A full report from this process will be published during 2003.

Many organisations and countries have emphasised the need to develop and use HIA. In the international arena, organisations like the EU and WHO have explicitly promoted HIA as a method of estimating the potential health impacts of different policies<sup>1,2</sup> and many countries are in the process of implementing HIA at the national and regional level. From 2003 impact assessments are gradually being introduced to policy areas covered by the EU's competence, among them the area of public health. A variety of implementation methodologies have been developed such as Environmental Impact Assessment (EIA),

Strategic Impact Assessment (SIA), Human Impact Assessment and the Integrated Impact Assessment (IIA). Several countries have combined HIA with EIA, mainly because EIA is a well-known concept with established methodology for predicting the environmental impact of different policies.

## HIA as a method and process

Generally, HIA methodology can be divided into two parts; first considering how a document (policy, project, program etc) will impact on the determinants of health and second how these determinants, in turn, will affect population health. To conduct a HIA, it is thus necessary to possess knowledge on health determinants and their relationship with health outcomes, as well as data on the distribution of the determinants in the population. Ideally, the results of the HIA should therefore be estimated for the whole population as well as by gender or vulnerable groups.

Conducting a HIA entails four distinctive steps: screening, scoping, appraisal and evaluation. The first step is concerned with document selection and the screening process. A checklist has to be developed based on certain criteria considering possible changes in health outcomes as a consequence of a proposed policy. These criteria are often based on health determinants and take different population group characteristics into consideration. Scoping deals with issues such as when in the policy process HIA should be conducted, by whom and how this should be performed. The appraisal phase constitutes the actual assessment, which can be performed at different levels of depth (a rapid assessment or more in-depth analysis), and the evaluation process should appraise the process itself, i.e. how well the assessment worked and if it has led to any changes in policy or the policy proposal.

## HIA in Sweden

In Sweden, a systematic HIA approach at the local and regional level has been developed and occasionally implemented. The Swedish Federation of County Councils and the Association of Local Authorities

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started to develop a tool for HIA in the mid 1990s. The tool is divided into three parts; “the health question”, “the health matrix” and “the health impact analysis.”<sup>3</sup> Half of all county councils and one sixth of local authorities are using or are in the process of introducing HIA, and a recent evaluation of this HIA approach found that both civil servants and politicians were pleased with the way the process was working.<sup>4</sup>

The first HIA at a national level was conducted in 1995 when Sweden joined the European Union. The HIA assessed potential public health impacts in Sweden of the introduction of EU regulations concerning trade in alcoholic beverages.<sup>5</sup> A second major HIA concerned the health impacts of the EU Common Agriculture Policy.<sup>6</sup> Since then several HIAs have been performed at the national level, e.g. the effects of an age limit on the sale of tobacco. However, these HIAs were not performed in a systematic way, and the outcomes were not always expressed in quantitative terms.

An initial investigation in 2001 to study the implications of using HIA at this level<sup>7</sup> led to the conclusion that the HIA implementation process requires more evaluation in practice.

**The screening process**

The first step towards implementation of HIA as an integrated part of policy making has recently been taken in Sweden. This obligation is further emphasised in the recent white paper on public health,<sup>8</sup> presented to Parliament in December 2002, and currently passing through the legislative process. The aim of the present study at the National Institute of Public Health (NIPH) is to develop the screening element of the HIA process; to create a checklist followed by screening of governmental inquiries (from January 2001–August 2002) in the ten principle Ministries (finance; defence; health and social affairs; foreign affairs; environment; communication, industry and employment; education; justice; culture and agriculture). The reason for choosing governmental inquiries was to try to enter the decision making process at an early stage. Preferably, HIA should be conducted during the process of proposal development in order to have a fair chance of impacting on the policy maker and policy development. The criteria for governmental inquiries are publicly available at [www.regeringen.se](http://www.regeringen.se) and are thus appropriate for systematic screening.

The principle aspects of screening were first to determine the main criteria (based on determinants of health and differential characteristics of population groups) to efficiently screen potential health consequences. Second, to decide how best to use the criteria regarding equity and gender issues.

It was important to look at the determinants of health and health outcomes, as well as how different population groups could be affected by a change in the proposed policy. The proposed national public health goals are based on the major health determinants and were identified by a parliamentary committee (1997–2000) (Table 1). To estimate the potential health impacts on the population, screening examined the whole population as well as looking at gender and vulnerable groups (Table 1).

**Preliminary results**

Preliminary results of the present study indicate that approximately one third of all governmental investigations ought to include a HIA. This is based on the

**Table 1**  
**THE CHECKLIST FOR THE SCREENING STAGE**

1. **Description of the policy**
2. **Does the policy affect any of the ten health targets?**
  - Participation in influence on the society
  - Economic and social security
  - Safe and favourable growing up conditions
  - Healthy working life
  - Sound and safe environments and products
  - Health promoting medical care
  - Physical activity
  - Eating habits and safe food
  - Tobacco, alcohol, illicit drugs, doping and gambling
  - Prevention of infectious diseases
3. **Does the policy affect the population as a whole or some population groups?**

• The whole population	men	women
• Children		
• Adults		
• Elderly		
• Chronically ill		
• People with a handicap/impairment, also allergy		
• People with an addiction, alcohol, drugs etc		
• Unemployed		
• Immigrants		
• Refugees		
• Single-parents		
• People with low income		
• Homeless people		
• Homosexuals		

Other groups:

Motivation:
4. **Will the policy lead to an HIA?**

Yes

No

Motivation:

assumption that if one or more health determinants were affected by an inquiry then HIA should be conducted. Most governmental inquiries were undertaken in the Ministry of Industry, Employment and Communication, Agriculture, Environment, and Finance. However, resource constraints mean that it will not always be possible to conduct a HIA, and therefore it will be necessary to prioritise inquiries. At a later stage of the HIA, it will be useful to use the additional criteria disregarded earlier in the checklist such as “type of policy?” “are the effects of the policy direct or indirect?” and “are there short or long run health consequences?” Use of these criteria will help select inquiries with the largest potential health impact.

Using health targets as the main criteria on the checklist proved to be very useful, as these goals are based on the main determinants of health. The most frequently used targets in the screening process were participation in and influence on society, economic and social security, and healthy working life. These three goals are very broad and consist of several sub-targets and therefore are often affected by policy proposals. Moreover by including such health targets in a screening tool their use can be evaluated. This use of targets in a HIA can provide information about if and how the targets are regarded in policy proposals, and in which Ministries.

The screening process was not considered to be difficult, but tricky. A necessary requirement for the screening process was the formation of a HIA core group. This consisted of a number of experts from the NIPH with different backgrounds. The core group screened some of the inquiries, making it possible to discuss general aspects of the process and suggest improvements. It was important to reach consensus when there were doubts as to whether certain inquiries necessitated HIA. A core group such as this appears to be essential for a successful HIA process.

### Conclusion

HIA is not a discipline or a subject of in its own right, but more of a systematic process for predicting changes in population health status as a result of a specific policy proposal. The aim is to place health on the political agenda of all governmental departments and provide policy-makers with better information. The development of a more regular and systematic HIA has just begun in Sweden and elsewhere, and it is important to continue analysing this

process. The next step as mentioned earlier is to set the conditions on how to prioritise among inquiries that led to a HIA, and with this knowledge, move on to the scoping and appraisal stage. In 2003 the NIPH will present the study to the Ministry of Health in Sweden, and working together to set the direction for the future work of HIA in Sweden.

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### REFERENCES

1. European Commission. *Community Action Program for 2003–2008*. Luxembourg: European Commission, 2002. [http://europa.eu.int/comm/health/index\\_en.html](http://europa.eu.int/comm/health/index_en.html)
2. European Centre for Health Policy. *Health Impact Assessment: Main Concepts and Suggested Approach*. Brussels: World Health Organization, European Centre for Health Policy, 1999.
3. The Swedish Federation of County Councils and the Association of Local Authorities. *Focusing on Health – How Can the Health Impact of Policy Decisions be Assessed?* Stockholm: The Federation of County Council, 1998.
4. Finer D, Haglund B, Tillgren P. *Hälsokonsekvenser i ett SjukvårdsoMrade: En Utvärdering av Praktiskt Utförande och Genomförande*. [The Evaluation of and Experiences of Working with Health Impact Assessment in a County Council]. Stockholm: The Federation of County Councils and Karolinska Institute, 2002.
5. Holder HD, Giesbrecht N, Norström T, Olsson O, Skog OJ, Österberg E. *Effekter av Lägre Alkoholpriser och Slopät Försäljningsmonopol*. [Effects of decreasing prices on alcohol products and abandoning the selling monopoly on alcohol]. Stockholm: Swedish Council for Information on Alcohol and other Drugs and National Institute of Public Health, Report 43, 1994.
6. The National Institute of Public Health. *Health Impact Assessment of the EU Common Agricultural Policy*. Stockholm: The National Institute of Public Health, 1996.
7. The National Institute of Public Health. *Modell och Metoder för Hälsokonsekvensbedömningar*. [Models and methods of Health Impact Assessment]. Stockholm: The National Institute of Public Health, 2001:9.
8. Regeringens proposition 2002/03:35. [Goals for Public Health; Governmental Proposal 2002/03:35], Stockholm.

“Approximately one third of all governmental investigations ought to include a HIA”

# Demand-orientation and demand-driven care:

## *Conceptual confusion in health care*



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Health care is an almost permanent subject of public debate. Aspects of discussions are broad and of a moral, ethical, economical, legal, organisational and administrative nature. This makes the field of health care extremely interesting but at the same time very complex.

Patient choice has become an important touchstone of health care reform across northern Europe. This search for a new role for patients reflects the current period of what might be called a 'paradigm flux', now affecting health service delivery in nearly every advanced industrialised country.<sup>1</sup> In developing health care policy and the organisation of health care services, more and more pleas are being made to introduce demand-orientation and demand-driven care as counterparts to a strongly institutional, supply-oriented approach. This movement can be viewed across all aspects of society, for instance in public housing, education, social services and social security.<sup>2</sup> Janssen speaks of a trend over the next decade, in which client demands will become the departure point, i.e. "demand-driven" health care.<sup>3</sup> The Ministry of Public Health, Welfare and Sports has a somewhat similar point of view that states that "demand-driven care" has become a policy aim.<sup>4</sup>

The turning-point in the health service, from a supply-driven to demand-driven approach, took place in The Netherlands in the late 1980s, beginning with the recommendations of the Dekker Committee. The conceptual cornerstone of this approach is consumer sovereignty, which assumes that it is possible and useful to let supply be steered autonomously by the demand for care.<sup>5</sup> It assumes that consumers are capable of making choices in relation to the use of services, and are highly motivated; they want to choose. The reforms Dekker

envisaged have hardly materialised. The possibility of personal budget financing arose only in 1995, largely because of lobbying by the Disability Board.

Much has been written about the dilemmas of demand driven care, organisational difficulties in the execution of demand-orientation and the financial consequences of the introduction of care based on demand. In contrast, the literature on the clarification of these concepts is quite scarce. Furthermore, the terms have been defined in various ways, ranging from mere client-orientation, to actual influence on supply by client driven demand.<sup>6</sup> To prevent miscommunication, clarification of the different concepts is highly desirable. Definitions are discussed below.

In comparing the various definitions, there seem to be some distinctive and common elements:

*Focus:* what is the main concern.

*Power:* who has final control

*Perspective:* professional, individualistic, administrative, economic perspective or combination of these.

### **Demand-orientation**

Definitions of demand-orientation focus on supply and thus on the actions of care providers. Demand-orientation refers to a procedure that care providers (ought to) use while developing services. One government advisory body report defined it as "A mutual effort of patient and provider that leads to the patient receiving help that fulfils his wishes and expectations and at the same time complies with professional standards".<sup>7</sup> The provider has knowledge of these so-called professional standards, (often in contrast to the client), who therefore tend to control the content and shape of services.

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Another definition of demand-orientation is “Policy and practice that aims at fulfilling the need for public health interventions based on: data concerning the size and severity of population health problems and the needs, wishes and expectations of client organisations as well as individual clients”.<sup>8</sup> This definition balances individual subjective wants and the objective needs of the whole population. Control rests with policymakers and providers, as they decide on the weight of individual versus collective needs and are responsible for financing.

In contrast to these two definitions the Dutch Patient/Consumer Federation uses a more general definition: “Demand-oriented supply is that, which on a collective and individual level, according to the opinion of the user or their representative, contributes optimally towards the problems he encounters”.<sup>9</sup> However, further explanation of this definition reveals that it is similar to that of the RVZ (Council for Public Health and Health Care), as health care suppliers with professional knowledge take account of the needs and wants of users through a process of demand clarification.

In defining demand-orientation, the focus of all the different definitions seems to lie in the process of generating a service that contributes towards the needs and wants of users. Final control is in the hands of policymakers and health care suppliers. Suppliers decide to what extent they are willing to accede to the demands and wishes of their clients. All of this largely occurs from a professional perspective, and because of information-asymmetry health care suppliers retain their status as experts. From an administrative perspective, the deliberations of policy-makers on individual versus collective population needs help play a role in demand orientation.

### **Demand-driven care**

Most definitions about demand-driven care, as well as demand-orientation, indicate a process, but in this case the focus is not so much on the actions of the suppliers or providers but much more on the possibility of choice for users, and thus demand itself. The interdepartmental commission ETTY stated: “The essence of demand-driven care is that the insured himself *can* determine his care. The main concern here is the possibility of choice. The goal of introducing the concept of demand-driven care, is to put clients in a more equal position in relation to suppliers, so that suppliers will work more efficiently and meet more user demands. Clients will have more

influence on care received because they themselves, as much as possible and as far as they desire, can make choices from the available supply, given of course that a choice of care option exists”.<sup>10</sup> The focus here is on the process that service users will go through. A somewhat similar definition of demand-driven care is used by the Ministry of Public Health, Welfare and Sports. “Indicated demand guides the quantity and quality of the required supply”.<sup>11</sup> Both of these definitions contain restrictions: choice is limited to *available supply* and a *formal indication for care* is required.

In contrast to the above, some definitions do not restrict user control: “The patient/consumer needs to be in control, for he is ‘the client’ and also has experiential expertise. Patients and consumers decide on care options. Demand-driven care must be accompanied by solidarity, freedom of choice and preservation of personal autonomy”.<sup>12</sup> Another stated that “Demand-driven care is translated as the ideal of the free market, in which the supply of care is determined by autonomous and responsible consumers/patients making self assured choices on the use of health care services”.<sup>5</sup> The Board for Public Health Care, defines the concept somewhat similarly as “implying that market demand determines the supply of care”.<sup>7</sup> Crucial to all of these definitions is the dependency of supply on demand and thus the dependency of suppliers on patients. This can be further emphasised: “Having supply guided by demand, with demand actually having the means to guide supply”.<sup>9</sup>

The focus of different definitions for demand driven care seems to be freedom of choice for users, i.e. the process by which individuals select services that best address their needs and wants. Control ultimately rests with users (demand). The emphasis in this case is on the individual nature of the demand (individualistic perspective). Individuals determine both the type and provider of care. As every individual has different experiences, each demand can be different. The policy for and nature of supply are thus tuned to demand. Demand affects the nature, quality and quantity of supply. Furthermore, demand-driven care is seen from an administrative perspective, in which hierarchical budget-driven approaches are replaced by more decentralised consumer-oriented perspectives. Ultimately, when users also have the financial resources to ensure that suppliers acquiesce to their demands, the concept can also be viewed from an economic perspective.

*“Patient choice has become an important touchstone of health care reform”*

### Differences in definitions between key-players

Definitions in the literature originate from five different key-players: science and knowledge institutes, government and advisory bodies, care suppliers, client interest groups and others such as commercial organisations. In comparing the various definitions from key players, several differences can be identified.

Firstly, the extent to which restrictions are built into definitions varies. In contrast to others, the government and advisory bodies include restrictions on complying with client needs and wants, freedom of choice and final control. This raises the question as to what extent there is actually a focus on demand. Within the concept of demand-orientation, these restrictions need not be a contradiction. After all, final control rests with suppliers, who ought to attend to clients' needs and wants (demand), but who also from a professional perspective can ascertain what is best for the patient.

However, when control rests with users, as in the case of demand-driven care, these restrictions seem somewhat contradictory to the meaning of this concept. According to a number of governmental definitions, individuals ought to have some choice over services and suppliers, but constrained by available supply and need for appropriate indication for care. To some extent we can speak of freedom of choice, but this is only the case when an individual agrees with the formal indication for care and available supply meets needs and wants. For example if a child is identified as being suitable for 'special education' because of a behavioural disorder, he and his parents would then be able to choose between special schools in the area (available supply). However if the child (and his parents) would prefer to go to a normal school and see a psychologist once a week, demand-driven care would imply that the type of services provided would be dependent on demand and thus the needs and wants of service users. In this case however the needs and wants of the child and his parents would not be met, given restrictions which limit choice to existing supply. There lies the contradiction in recommending demand-driven care.

Another noticeable difference is that many care suppliers do not distinguish between the terms demand-orientation and demand-driven care. When they speak of demand-orientation, the elements found in their definitions are similar to those for the general concept of demand-driven care, and

vice versa. Care suppliers define both demand-orientation and demand-driven care as: "Making the client and his needs and wants the centre of attention."<sup>13</sup> In the explanation of each given definition, sometimes the definition leans more towards the generalised concept of demand-orientation (focusing on the actions of suppliers who maintain control), and in other cases towards demand-driven care (focusing on freedom of choice with patient control). Examples of such nuances include: "addressing more clients' needs" and "individualisation of care" on one side and "service provision tailored to demand" or "more authority for the client" on the other. In all cases definitions provided by the government and associated advisory bodies are the most restrictive in nature, while those of client interest groups maximise the level of control exercised by individuals. This of course is consistent with the nature and aims of these groups.

### Conclusion

Although there is some confusion about demand-orientation and demand-driven care, we can identify some common themes. We can conclude that there seems to be a fundamental difference between the two concepts. Regarding demand-orientation, the focus is on the extent to which those who provide services, take the needs of individual patients into account. Largely this is a matter of professional perspective. In demand-orientation, those supplying services still guide demand.

In the case of demand-driven care, the focus is on freedom of choice, with the individual patient having the final say on the type of care received. Demand-driven care is seen more from an administrative perspective, in which hierarchical budget-driven approaches are replaced by more decentralised consumer-oriented perspectives. The emphasis is on the individual nature of demand. It assumes that only individual patients have the necessary experiential expertise to make informed choices. In some instances patient control is extended even further, giving individuals the necessary financial resources to ensure that desired services are provided. Demand-driven care can thus be viewed from an economic perspective. Supply can actually be influenced by demand. We can conclude that in the case of demand-orientation supply guides demand, while in the case of demand-driven care, demand guides supply.

*"Using demand orientation final control rests with policymakers and health care suppliers"*

## REFERENCES

1. Saltman RB. Patient choice and patient empowerment in northern european health systems: a conceptual framework. *International Journal of Health Services*. 1994; 24(2): 201–29.
2. de Roo AA. Samenwerking als strategische keuze en het koppelen van zorgprocessen in netwerken. In: Boon L (ed). *Zorgdynamiek en samenwerking*. Reeks Ontwikkelingen in de gezondheidszorg. Amstelveen: Stichting SYMPOZ.
3. Janssen RTJM. *Schaarste in de gezondheidszorg: afwegen of afwentelen?* Katholieke Universiteit Brabant, 1997 (inaugural lecture).
4. Terpstra E. Beleidsmatige dilemma's bij de vormgeving van vraaggestuurde zorg. In: Boon L (ed). *Vraaggestuurde zorg*. Reeks Ontwikkelingen in de gezondheidszorg. Amstelveen: Stichting SYMPOZ, 1997.
5. Grinten T van der. Sturing door en stimulering van de vraag. Kanttekeningen bij vraagsturing in de gezondheidszorg. In: Boon L (ed). *Vraagsturing en zorgketens*. Reeks Ontwikkelingen in de gezondheidszorg. Amstelveen: Stichting SYMPOZ, 2000.
6. Garretsen HFL. *Goed geholpen? Over vraagsturing en evidence based werken in zorg en preventie*. Katholieke Universiteit Brabant, 2001 (inaugural lecture).
7. Raad voor de Volksgezondheid en Zorg. *De rollen verdeeld*. Zoetermeer: RVZ, 2000.
8. Dekker E. *De ongeslepen edelsteen, vraaggerichtheid in het volksgezondheidsbeleid*. Artikel Zorgonderzoek Nederland/ De Middenweg, 2000.
9. Goudriaan G, Vaalburg AM. *De vraag als maat; vraaggerichtheid vanuit gebruikersperspectief*. Utrecht: Nederlandse Patiënten/Consumenten Federatie, 1998.
10. MDW-werkgroep AWBZ. *De ontvoogding van de AWBZ*. 's-Gravenhage, 2000.
11. Ministerie van Volksgezondheid, Welzijn en Sport. Modernisering AWBZ. Tweede kamer, vergaderjaar 2000–2001, 26 631, nr. 13. 's-Gravenhage, 2001.
12. Nederlandse Patiënten Consumenten Federatie. Over de NPCF, 2001. [www.npcf.nl](http://www.npcf.nl)
13. ZMOK. Beleidsnota, 2001. [www.zmok.nl](http://www.zmok.nl)

# An overview of the Armenian health care system

*We should strive for a system that covers everyone, although we are a long way from finding a system that can control costs while delivering adequate medical services to all Armenians. We have a sense of determination to deal with the challenges that lie ahead.*



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Like most former countries in the Commonwealth of Newly Independent States (NIS), Armenia has been diverging from a highly command orientated, hierarchical, bureaucratic and unsustainable Soviet health care system model. Under the socialist regime health and social services were financed through general funds and centrally administered. Access was free and universal. Since beginning the transition towards a market-oriented economy, Armenia has faced a number of difficult challenges including a major earthquake, war, a blockade enforced by Turkey and Azerbaijan, an energy crisis, recession and economic collapse. This combination of events has had severe consequences. Economic decline has placed Armenian health institutions in jeopardy, hindering reforms. Public health has deteriorated and life expectancy declined. Thus, gains in freedom have been accompanied by a loss of many basic economic and social services that the population had come to enjoy and expect.

## Health Policies

Armenia undertook significant economic and social sector reforms after gaining its unexpected independence and has witnessed many attempts to reform the health care system. The government is only now introducing a comprehensive reform program, intended to secure stable funding for the health care system, making it more efficient and cost effective, and ensuring access to basic services for the entire population.

Between 1993 and 2002 several measures were undertaken towards structural, managerial and financial reform, which led only to partial improvement, but produced some unexpected results. The Armenian national health system is subject to state control, and until recently has been deprived of any competitive forces. Almost every medical institution is state-owned and directly managed by health authorities. The changing status of medical facilities (first to economically independent state enterprises and then to state closed joint-stock companies) and the new administrative-territorial division of the republic resulted in a substantial weakening of mechanisms of quality control and management within the health care system.

**Table 1**  
**SOME PRINCIPAL INDICATORS IN THE ARMENIAN HEALTH CARE SYSTEM**

Indices	1990	1994	1995	1997	1998	1999	2000
Number of physicians per 10,000 people	41	34.5	33.3	34.0	34.3	33.2	32.3
Number of beds per 10,000 people	86	77.7	76.2	67.4	66.5	62.0	54.7
Average number of medical staff per 10,000 people	98.6	85.1	81.4	70.0	68.0	64.9	62.3
Average number of outpatients' visits per capita	9	5	4.8	3.2	2.4	2.3	2.1
Average annual occupancy of beds (days)	247	162	152	141	123	122	116
Average length of treatment per patient (days)	15.6	16.3	15.2	13.9	12.8	12.8	12.7

The promotion of primary/out-patient-polyclinic health care has not been prioritised sufficiently, and a modernised national system of health care standards and quality control has not yet been introduced. Problems have accumulated, the demand for medical services is four times less than the available supply, and there has been an excess supply of beds. However during the period 2000–2002 hospital capacity was reduced.<sup>1</sup> Thus, the number of hospitals has fallen by 40–45% and bed capacity by 25–30%. Capacity is now approximately 50–55 beds per 10,000 inhabitants, which is close to the low European standard level, and is almost equal to those in the USA. Some principle indicators for the Armenian health care system are shown in Table 1.<sup>2</sup> Furthermore the government is planning to introduce compulsory medical insurance in January 2003 together with supplementary voluntary insurance, in order to increase funding available to health care while simultaneously increasing population coverage.

#### Accessibility and health status

Armenia has previously introduced radical reforms to the health care system, accepting that it was no longer possible to provide free on demand health care to the entire population. The reliance on direct out-of-pocket payments obviously undermines the principle of equity with respect to both financing and access. The government has ensured that a basic package of care is still available to the most vulnerable groups, although funding has usually fallen short of targets, thus requiring patient co-payments even in the case of these targeted groups. Therefore, even the accessibility of the most essential services has become a very serious problem mainly for socially vulnerable groups in the population. Low purchasing power, absence of state medical insurance, the introduction of out-of-pocket payments and the increase in informal payments have resulted in a sharp decrease in timely referrals to doctors at a

time of increased morbidity.

The average bed occupancy rate in the country is about 30% (in some regions it is even lower, about 10–15%).<sup>3</sup> This is very low compared to European standards, due both to the general social-economic status of the population and the low effectiveness of health care management and financing. Bed occupancy rates have fallen more than 200%, and visits by doctors to patients' homes have fallen more than 30%. The number of physicians per capita is twice as large in Armenia as it is in western countries; however, physicians are not distributed in a similar fashion. In the cities there are 65 physicians per 10,000 people while elsewhere it varies between 14–32 physicians per 10,000. Between 1990 and 2000 physician numbers fell, while at the same time, the number of inpatient admissions to hospital decreased from 467,172 to 192,007.<sup>4</sup> Average length of stay and the number of outpatient visits per capita have also fallen (see Table 1).

Although there has been a sharp fall in timely referrals to physicians, this does not reflect a situation, where population morbidity has been increasing. Between 1990 and 2000, the birth rate sharply decreased while the overall death rate remained constant; thus the overall rate of increase in the population has slowed substantially (see Table 2). Deaths from cardiovascular diseases have increased to 55% of total deaths in 2000. Neoplasms accounted for a further 16.5%, respiratory disorders 5.8%, digestive disorders 3.3%, infectious and parasitological diseases 1.2%, other diseases 13.6%, and accidents, injuries and poisonings 4.6%.<sup>5</sup> The infant mortality rate (IMR) has increased slowly since 1995 while the maternal mortality rate (MMR) has shot up to 52.5 per 100,000 live births in 2000 compared with 34.7 in 1995 (see Table 3). The MMR is expected to rise even further in the future due to an increase in the number of unassisted home deliveries and abortions.<sup>3</sup>

*“Given the current social-economic situation, it is clear that an essential increase in the budget for health care cannot be expected in the near future.”*



## Health care financing

The state of health care financing is quite precarious, and it is unlikely to improve in the near future. The slow pace of economic development in Armenia led to decline in funding for the health care system. Resources are very limited, and there has been a loss of public and professional confidence in access to and funding of state guaranteed health care services.

In 2001 the state health budget was just 1.1% of GDP (even in the years of collapse of the NIS this was 3–4%) and accounted for approximately 25% of total health care expenditure.<sup>6</sup> 15% of health care expenditure came from humanitarian aid contributions, with the remaining 60% financed through private out-of-pocket payments. Against a background of rising debt built up between 1997–2001, chronic under financing of healthcare continues. In 2001 the expenditures from the state budget for health care were 13,403.3 billion drams (around \$24.4 million) 65% of which was distributed to inpatient care, 28% to outpatient care and 7% to emergency services.

The Armenian government can only spend \$7 per capita on health services, compared with per capita spending of \$2,000–\$2,500 in Europe, \$1,785 in Canada and \$4,235 in the USA.<sup>7</sup> Total expenditure on health from all sources accounts for only \$50–70 million. Given the current social-economic situation, it is clear that an essential increase in the budget for health care cannot be expected in the near future. An important source of funding in the health care system continues to be direct payments by the population. Investigations undertaken with the support of the World Bank demonstrate that the real financial flows to the hospital sector including direct payments for drugs, food, medical personnel services etc, are 3.5 to 4 times greater than funds allocated from the state budget alone.

Financing mechanisms have also been the subject of change. Regarding hospital care, financing per patient per day was replaced with case based financing, while for ambulatory care a transition from a per visit to per capita mechanism was implemented. A global budget mechanism was introduced to the inpatient and outpatient emergency care system. Despite some positive results arising from the application of these changes, serious problems still were encountered in the process of medical care and services delivery because of the gradual reduction in the budget for healthcare.

Table 2

### DEMOGRAPHIC CHANGE IN POPULATION (per 1000 population)

Indicators	Birth rate	Death-rate	Rate of pop <sup>n</sup> increase
1990	22.5	6.2	16.3
1991	21.6	6.5	15.1
1992	19.2	7.0	12.2
1993	16.4	6.8	9.5
1994	13.7	6.6	7.1
1995	13.0	6.6	6.4
1996	12.8	6.2	6.2
1997	11.6	6.3	5.3
1998	10.4	6.1	4.3
1999	9.6	6.3	3.3
2000	9.01	6.32	2.70

Table 3

### TRENDS IN HEALTH STATUS INDICATORS

Indicators	IMR per 1000 live births	MMR per 100,000 live births
1990	18.5	40.1
1991	17.9	23.1
1992	18.5	14.2
1993	17.7	27.1
1994	15.1	29.3
1995	14.2	34.7
1996	15.5	20.8
1997	15.4	38.7
1998	14.7	25.4
1999	15.4	32.9
2000	15.6	52.5

Source: National Statistical Service, Republic of Armenia, 2001.<sup>5</sup>

## Conclusion

It goes without saying that Armenia is currently facing remarkable challenges that will shape the health system in the country in the 21st century. Results of the Armenian health care reform process so far do not meet all the objectives of health care policy, although some improvements in certain areas can be observed. Public financing of health and public funds for the health sector should though be increased in order to improve the current complicated situation in the health care system. To achieve this, a number of urgent measures have to be introduced. These include

## REFERENCES

1. Country Health Report Armenia, Yerevan, 2000.
2. *Key Data on Health 2000*, Luxembourg: Eurostat, 2001.
3. Hovhannisyanyan SG et al. European Observatory on Health Care Systems. *Health Care Systems in Transition: Armenia*. Copenhagen: WHO Regional Office for Europe, 2000.
4. Economist Intelligence Unit. *Armenia: Country Report*. November 2000.
5. National Statistical Service, Republic of Armenia. Statistical Collection, 2001.
6. Ter-Grigoryan A. *Financing of the Health Care System in the Republic of Armenia*. Yerevan, 2001.
7. Mkrtchyan A. *New Tendencies in the Health Care of Armenia*. Yerevan, 2001.

improving the efficiency with which resources are utilised, introduction of a variety of mechanisms of financial flow management, as well as increased transparency in the use of funds. Furthermore medical institutions need reorganisation, in order to harmonise them with international standards (for example, in Armenia inpatient services currently receive the greatest share of budget expenditures, around 65% of the total budget, compared with 35–50% in more developed countries). Further optimisation within the health care system is required, for instance reducing excess capacity, redistributing human resources and selective contracting for state funded services. The average duration of inpatient treatments need to be reduced, in 2000–2001 these averaged 12.7 days, compared with only 8 to 10 days in highly developed countries.

Encouraging the development of insurance companies, pension funds, and funds for public health care education has not yet been undertaken. There is a need to

introduce multiple types of funding mechanisms, augmented by additional sources of financing (for example, from the state budget, community budget, medical insurance funds, private health insurance schemes services, direct payments, co-payments and other sources allowed by legislation). These need to be complemented by optimal models for reimbursement.

Other measures include more effective and targeted use of funds from charitable and humanitarian aid, as well as improved systematic use of funds obtained from the Armenian diaspora. The role of the private sector in the supply and financing of health services can be strengthened, while also increasing earmarked health taxes, and reducing the tax burden falling on medical institutions. Methods of redirecting resources, currently diverted to the informal economy, to the health care sector need to be examined. Finally realistic annual state health care programmes and budgets need to be developed and approved, taking account of distributional issues.

## Grass-roots initiatives in mental health policy in Eastern Europe



*Paul Cutler*



*Robert Hayward*

### Pathways to Policy

Since the collapse of the Soviet Union and the creation of newly independent states in Central and Eastern Europe, health policy as a whole has been in transition. Within this framework of general health reform, mental health has been relegated to a subsidiary role. Many of the countries do not have an explicit mental health policy and there has been a vacuum of initiatives at state level to tackle both the needs of the still large population of institutionalised hospital patients and the poverty and neglect of those who need mental health services in the community.

Hamlet Trust's Pathways to Policy programme, initiated in January 2002, is an innovative approach to these problems that

seeks to work directly with users, carers and other local stakeholders to fill this void in mental health policy and provide positive alternatives with sustainable outcomes. The programme works in five countries at present: Estonia, Bosnia and Herzegovina, Romania, Armenia and Kyrgyzstan.

The programme raises some fundamental questions about health policy. It asks how policy is made and who should be involved to make it effective in meeting the needs of disempowered groups. The traditional assumption that policy is something that is made by government is being challenged by international organisations, civil society and the private sector. Already there is growing evidence that local people can make a difference to mental health at a policy level.

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## Mental health in Central and Eastern Europe

To be effective, policy initiatives need to link the structural to the personal. Research by Hamlet Trust and partners<sup>1-3</sup> over the last five years highlights a well-documented generic picture of mental health in the region:

- Many people with mental health problems continue to be incarcerated in large, Soviet era psychiatric hospitals.
- Equal numbers of people with long-term mental health needs are accommodated in remote social care homes.
- Funding for mental health is a low priority amongst all governments.
- Users of mental health services have no voice in the provision of services.
- There are few community services.
- Mental health continues to be dominated by a medical model of treatment and there is little space for social and community alternatives.
- Human rights abuses towards users of services are commonplace and often unchallenged.

But often this has contrasted with what users of mental health services themselves say are the policy issues on the ground, (for example, Winn<sup>4</sup>). These consistently are:

- To be treated with dignity and respect and to be listened to.
- To have choice both in mental health care and in society.
- To have jobs and income so as to avoid poverty and deprivation.
- To live in the community in decent housing.
- To have friends and consistent relationships.

### User-involvement

The development of the concept of user-involvement and a voice for users is essential if mental health policy is to meet real needs. Not only are users experts in their own experiences of mental health, they often hold essential knowledge on the inside workings of mental health services and mental health professions.<sup>5,6</sup> Recognising and valuing this expertise challenges the disempowerment of users and in the long-term benefits all stakeholder groups. For example, Hamlet's evaluation of policy initiatives in 2002 has revealed that whilst professionals can find it uncomfortable being challenged by users, they

### THE HAMLET TRUST

Hamlet Trust is a UK based international non-governmental mental health organisation that has worked in Central and Eastern Europe and Central Asia for the last fifteen years.

Hamlet has an explicit value base of promoting active user involvement in all aspects of mental health. It provides training, consultancy and a small grants programme to members of a network that now numbers over fifty-five independent NGOs in seventeen countries.

The main focus of Hamlet's work over the years has been self-help, user-involvement, advocacy and organisational development. The Open Society Institute, the UK Community Fund (National Lottery), the European Union and The UK Department for International Development have been the main funders of this work.

For more information on Hamlet Trust and the Pathways to Policy programme, contact:

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recognise that equal partnerships require assertive partners able to initiate and energise change. Experiences in Estonia and Kyrgyzstan over the last year have shown that users are able to lead new service developments and challenge human rights abuses together with professionals.

The response of the international community to these problems has been mixed, often with contradictory messages given to the new democracies and their citizens. For example, countries engaged in accession to the European Union have been encouraged to prioritise economic and executive reform (for example, the police), pulling funding away from health and social policy issues. At the same time, all the states have come under international human rights law, which is being tested in terms of mental health practices by local lawyers and advocacy groups in all the countries. The organs of global mental health governance (such as the World Health Organisation) have asserted the need for explicit mental health policies and have done much work in articulating what should form the basis of any new policy.<sup>7</sup>

Whilst this blueprint approach to policy has strengths in ensuring that minimum standards can be set<sup>8</sup> and that countries are able to learn from each others experience in an efficient way, there are also problems in this approach that the Pathways to Policy programme attempts to address.

### Policy as process

Mental health policy is not simply something that is produced, it is also a process.

*“Local people can make a difference to mental health at a policy level”*

*“Influencing policy is a far broader objective than simply considering legislation or government budget priorities.”*

Effective policies need to take into account the local environment, culture and history. In Hamlet’s experience, the meaning of policy is negotiated, constructed and challenged on a daily basis by many different groups. Not least, the lack of a language to articulate the differences between terms such as policy, politics and stakeholder and the importation of concepts from the west has meant that policy is a much debated concept. In Pathways to Policy, Hamlet supports users, carers, relatives and other local stakeholders to have a voice in this process and work out their own meanings. The academic underpinning of these ideas has been adapted from the innovative work of writers such as Dreze and Sen<sup>9</sup> and Mackintosh<sup>10</sup> who have articulated a model of policy-as-process in relation to poor and excluded groups. What the Pathways to Policy programme has done is integrate this model to a mental health setting in post-communist Europe.

For example, Hamlet has facilitated much work on mapping of policy environments through workshops and participatory strategic planning exercises. Local stakeholders have identified that in their environments, mental health policy is often as likely to be demarcated by international organisations and trans-national pharmaceutical companies as by government. Influencing policy therefore becomes a far broader objective than simply considering legislation or government budget priorities. In Tallinn the local forum has worked closely with the media (in particular newspapers) to explore the media’s role in Estonian health policy and the setting of agendas.

The programme has deliberately set out to avoid prescribing outcomes that relate to particular policies. Rather, it is predicated on the belief that by institutionalising local policy processes that engage all mental health stakeholders in equal partnerships then sustainable, locally responsive policies can be created by people on the ground. The outcomes sought therefore are:

- New and improved intensity and quality of relationships between local and national mental health stakeholders.
- A raised profile for users of mental health services and their families as active agents in the development and evaluation of mental health policy at a local and national level.
- Successful local action (campaigning, lobbying, awareness raising, research) by partnerships of stakeholders to make

changes to existing mental health policy or local practices.

### Values into action

The main tool available to the programme is the establishment of local and national forums of mental health stakeholders with the brief and resources to pursue these outcomes. The concept behind the forums is that they are developed locally, are representative of all stakeholder groups and have the resources and commitments to meet regularly and undertake local action. For example, in Estonia the Tallinn local policy forum has a membership of over twenty people from groups as diverse as the social ministry, the media, local churches, psychiatrists and doctors, lawyers, NGOs as well as users and family members. The forum meets approximately every six to eight weeks and so far membership has been consistent and strong.

The programme provides a range of support and resources to facilitate the creation of effective forums. Hamlet’s role has been to support the local stakeholders without influencing the contents of the forum and the focus. The only criteria set by Hamlet has been that the forum must be focused on issues of mental health and that users of mental health services are the largest single group of stakeholders in the forum.

Activities over the last year have included:

- The recruitment and training of a local policy coordinator.
- Provision of information and training for local stakeholder groups on issues of policy and mental health (for example, lobbying skills, partnership creation and campaigning tools).
- Large open days where all interested people can come and discuss mental health and contribute to the planning of future activities and the forums.
- Materials and research.
- Study visits to enable the forums to learn from policy experiences and initiatives in other countries.

In the coming year there will be international events and conferences to bring the forums together from each country to evaluate their work and plan future activities.

The local policy coordinator role is an essential aspect of the programme. Hamlet’s research has identified that whilst many stakeholder groups have an interest and commitment to networking and part-

nership creation, finding time and space for this is extremely challenging. Many organisations comment that the expectations of western government donors are that all posts must be prescribed with concrete and specific activities. Whilst this is fine with regard to projects with clear, tangible outputs that can be easily calculated (for example, numbers of patients seen), any project that works in the less tangible area of advocacy and policy struggles to make a case for a post that has the necessary space and flexibility to work in this creative environment.

Hamlet has deliberately taken the risk to fund the local policy coordinator role with a broad brief to build alliances and partnerships and develop the forums in response to local needs. A team of six coordinators have been carefully selected with the skills and attributes to work in the freeform policy arena in a clear and accountable way. The dividends of this have been that the programme has been able to provide local policy support that is flexible enough to respond to local opportunities and pursue unique activities. Evaluation and management has relied on close communication, reflective diaries, focus groups and semi-structured interviews rather than on more straightforward targets and outputs.

Local coordinators are funded by Hamlet and are part of the Pathways to Policy team. However, they are local people and are hosted within a local mental health NGO to ensure local accountability. Two of the team of coordinators are users of mental health services, one is a carer, and another is a doctor by background.

### Policy Outcomes

Already there have been many clear outcomes from the programme. At a national level, users and ministry officials have worked together to evaluate existing services whilst planning new ones in Estonia.

Last year over 80 individuals have worked together to identify key policy priorities for the country. This has created partnerships that have addressed issues as diverse as:

- The lack of low cost transport in urban and rural areas to enable people to access existing services.
- The invisibility and fragmentation of existing mental health research (A surprising amount does exist amongst the diverse stakeholder groups but is not readily accessible). The Tallinn forum is currently looking at collating existing

research into an accessible book to be used to empower advocates, campaigners and decision makers with accurate information and statistics.

- Public awareness of mental health as a key health policy issue has been raised through leaflets, cultural events and open days.

At an international level local coordinators and members of local forums have been invited to international conferences and seminars to share their experiences with global decision makers. In Kyrgyzstan, Hamlet supported and part funded an investigation into psychiatric hospital policy. A range of cross-cutting issues have also been targeted in the programme including the role of the media, gender relationships, ethnicity and technology as factors in driving mental health development. In the coming year the forums will be undertaking research on these key topics and producing position papers for wider consideration.

The challenges for the future are to ensure the local, long-term sustainability of the forums and to create stronger links between the forums and international bodies to support a flow of information and learning between actors and organisations at different policy levels. Engagement in policy requires openness to learning as Hamlet and partners work closely with the varied groups who have an interest in mental health. The dissemination of this learning becomes itself a policy activity.

*“The programme has been able to provide local policy support that is flexible enough to respond to local opportunities and pursue unique activities.”*

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### REFERENCES

1. Cutler P, Hayward R, Shears J. *Building for the Future: Making Organisations Stronger and More Effective*. London: Hamlet Trust, 2002.
2. Hayward R, Nica R. *Gaining Ground*. London: Hamlet Trust, 2001.
3. Mental Disability Rights International – MDRI. *Human Rights and Mental Health*. Washington: MDRI, 1997.
4. Winn L (ed.) *Power to the People*. London: Kings Fund, 1990.
5. O’Hagan M. *Stopovers on my Way Home from Mars – A journey into the Psychiatric Survivor Movement in the USA, Britain and the Netherlands*. London: Survivors Speak Out, 1993.
6. Lindow V. *Self-Help Alternatives to Mental Health Services*. London: MIND, 1994.
7. Jenkins R, McCulloch A, Friedli L, Parker C. *Developing a National Mental Health Policy*. London: Maudsley Monographs, 2002.
8. World Health Organisation. *World Health Report 2001: Mental Health New Understanding, New Hope*. Geneva: WHO, 2001.
9. Dreze J, Sen A. *Hunger and Public Action*. Oxford: Clarendon Press, 1991.
10. Mackintosh M. *Development Policy and Public Action*. Oxford: Oxford University Press, 1992.

# Communication: an important factor in patient decision making



*Lukas Prudil*



*Pavlina Kanova*

*“The human element in physician - patient relationships should not be undervalued.”*

The negative legacy from the socialist regime in the Czech republic included poor population health, a run down health care system, lack of status for health care professionals, poor respect for patients, a passive society in which individuals waived any responsibility for their own health status, and poor doctor-patient relationships. Thirteen years have passed since fundamental political changes in the Czech republic. Changes in the current health system now reflect those more generally taking place across political, economic and social dimensions of society.

The status of patients in any health care system corresponds with the status of citizens in society. The former totalitarian regime, which restrained human rights generally, equally did not permit freedoms to patients requiring health care. However in the early 1990s, human rights gained a higher profile, including the establishment of a charter on patients' rights, an ethical code for the Czech Medical Chamber and a biomedicines convention.

The right to free choice of physician and health care facilities is often perceived as one of the most fundamental patient rights. This entitles patients to choose any physician within any speciality or any health care facility in the Czech Republic. The system has been criticised as open to abuse and inefficiency as general practitioners do not act as gatekeepers, thus patients can directly seek specialist care. It is also possible to change the chosen physician within a three month period under the public health insurance scheme. Equally under certain conditions the physician or facility can refuse to treat a patient, for example, having capacity constraints.

## **Information for patients**

Although patient choice of physician or health care facility is stated, there is a lack of information comparing the quality of health care services provided. Where

information is available, this typically is insufficient for evaluation. Thus there is a contradiction between an almost unrestricted choice and an absence data on which to base decisions. We therefore conducted research on the type of information influencing patients, and whether they have access to sufficient information to make informed choices.

Almost everyone probably agrees that communication is important in our lives. Health has traditionally been highly valued in Czech society<sup>1</sup> and we consider adequate communication to be an important component of the medical care process. It is though difficult to measure and quantify this level of importance. No scale of 'communication importance' exists with measurable values. However the majority of patient complaints to the Czech Medical Chamber, have their roots in inadequate communication rather than on medical aspects of physician work. Depersonalised and dehumanised physician-patient relationships were one of the most important aspects of dissatisfaction with medical care in the health care system under the socialist regime. Relationships however between physicians and patients have been moving more towards partnership in the 1990s, and the nature and process of this transformation manifests itself in physician behaviour and communication with patients.

Our research team focused on communication between different groups of physicians and their patients. To evaluate the importance of communication we prepared a questionnaire where the importance of communication was placed alongside other informational factors that we believe influence the decision making process of individuals when choosing a physician or health care facility.

## **Methodology**

The target group were individuals aged 18 years or older in the city of Brno, the

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second largest city in the Czech Republic with a population of approximately 400,000. Four hundred respondents were sampled from census data on the basis of four characteristics: age, sex, education and economic activity. Data from the 1991 census (education, economic activity) and preliminary data from the 2001 census (sex, age) were used in the study.<sup>2,3</sup> 53% of respondents were female and 32% were not economically active. 25% had only primary school education, 30% had been to apprenticeship training centres, 30% secondary schools, and 15% university.

Participants completed a written questionnaire in October 2001, including three key types of question. Where do individuals look for the information when choosing a general practitioner, specialist or hospital? What types of information are available to individuals? What information is important to individuals? Participants could select one or more options from a list collated following a pilot study. Additional responses could also be given, but with some exceptions few were provided.

We looked at different dimensions of the quality of health care services. Individuals were asked to what extent they take into consideration the communication abilities of physicians and their behaviour, i.e. communication abilities in broader sense. We asked about the importance and accessibility of information patients received about their diagnosis and treatment options, and also more generally about interaction with physicians.

## Results

Overall 82% of respondents did not have access to adequate information to help choose either a physician or health care facility. Only 10.5 % felt sufficient information was available. 58.5 % believed access to information was important, compared with 37 % for whom this was not an issue. When asked where information was obtained when choosing either a general practitioner, specialist or hospital, the principle sources were friends and relatives, followed by information provided by physicians. The third most important response in the survey was simply that patients did not attempt to search for information but went to the nearest physician or health care facility.

When choosing a general practitioner 78% of respondents considered physician behaviour to be important, while 61% felt their ability to communicate was important

(Table 1). 79% and 64% respectively believed that there was adequate access to information on GP behaviour and communication skills. Behaviour was significantly more important to older respondents (over 55 years) and less important to those between 18 and 34. Women, in general, were significantly more sensitive to the communication skills and behaviour of GPs.

A lower level of importance was attached to communication skills and physician behaviour when searching for a specialist. 65% and 59% of respondents respectively considered physician behaviour and communication skills to be important. (Table 2). As with GPs older people valued these attributes more highly. 62% and 54% of respondents respectively believed that this information was available. 75% and 49% of respondents respectively considered physician behaviour and communication skills to

**Table 1**

**RESPONDENT VIEWS ON THE ACCESSIBILITY AND IMPORTANCE OF DIFFERENT TYPES OF INFORMATION ON GENERAL PRACTITIONERS**

	Accessibility (Rank)	Importance (Rank) (%)
Accessibility of consulting room	1	3 (64.3)
Consulting hours	2	9 (25.0)
<b>Physician behaviour towards patient</b>	<b>3</b>	<b>2 (78.0)</b>
Consulting and waiting room friendliness	4	10 (9.0)
Communicating information on diagnosis and treatment options	5	4 (61.8)
Information on physician's professional skills	6	1 (81.5)
Privacy	7	8 (27.5)
Technical equipment	8	6 (47.0)
Treatment success rates	9	5 (53.0)
Contacts with specialists	10	7 (34.0)

**Table 2**

**RESPONDENT VIEWS ON THE ACCESSIBILITY AND IMPORTANCE OF DIFFERENT TYPES OF INFORMATION ON SPECIALISTS**

	Accessibility (Rank)	Importance (Rank) (%)
Accessibility of consulting room	1	6 (50.5)
Consulting hours	2	9 (18.8)
<b>Physician behaviour towards patient</b>	<b>3</b>	<b>2 (65.0)</b>
Consulting and waiting room friendliness	4	10 (6.3)
Communicating information on diagnosis and treatment options	5	5 (59.0)
Information on physician's professional skills	6	1 (85.5)
Treatment success rates	7	3 (64.8)
Technical equipment	8	4 (64.0)
Privacy	9	8 (24.3)
Contacts with other specialists	10	7 (25.3)

**Table 3**  
**RESPONDENT VIEWS ON THE ACCESSIBILITY AND IMPORTANCE OF**  
**DIFFERENT TYPES OF INFORMATION ON HOSPITALS**

	Accessibility (Rank)	Importance (Rank) (%)
Accessibility of hospital	1	6 (45.0)
Hospital friendliness	2	7 (36.3)
<b>Attitude of hospital staff towards to the patient</b>	<b>3</b>	<b>2 (75.3)</b>
Successfulness of treatment	4	4 (62.8)
Communicating information on diagnosis and treatment options	5	5 (48.8)
Information on physicians' professional skills	6	1 (85.5)
Technical equipment	7	3 (72.8)
Privacy	8	8 (20.0)

be important when determining which hospital to use (Table 3). Fewer people believed that there was access to this information, 56% and 45% for behavioural and communication skills respectively. Women reported these attributes to be more important, but age was not important.

It is important to note that we cannot generalise our results to all of the Czech Republic. The research was carried out in the city, and may be comparable to that found in other urban settings, however we do not know whether the situation in rural areas is similar. We would expect that other factors like geographical access to health care facilities play an even more important role, and we would like to conduct future research in rural settings.

### Discussion

We found that, when speaking about communication in the broader sense, i.e. communication and behaviour, the communication abilities of physicians are extremely important factors in individual choice of physician or health care facility. They are significantly higher priorities compared to

other factors such as the availability of equipment at a facility. The human element in physician – patient relationships should not be undervalued.

Patient empowerment is an issue not only in former communist states, but an important theme of wider health care system reforms that are under way in all democratic countries. The range and quality of published information on the quality of health care plays an important role. In addition to patient empowerment, increased disclosure of such information can improve accountability and help improve health service quality.

The greatest amount of information is published in the USA, but experience indicates that such information has not been used as expected. Principle reasons for this can include incomprehensibility, lack of public interest or distrust of information, problems in updating information, and less opportunity for patient choice.<sup>4</sup> Previous studies have shown that patients often don't understand medical care quality indicators and are not able to interpret them correctly. The public may be more interested in the behaviour of the health care workers, whether treatment is adequate and information on quality of life, rather than information on surgical complications and hospital mortality rates.<sup>5</sup>

The question remains as to how we can measure and evaluate the level of communication and physician behaviour towards patients. There are attempts to published information on physician attitudes to patient based on surveys of patient satisfaction in some countries such as the USA. This type of information should be published together with objective measures on the professional quality of care provided, as satisfaction surveys may be misleading.

Reshaping the physician-patient relationship will take time. Pre and post-graduate medical education can play an important role, and more attention in training needs to be placed on physician patient communication. We believe however that actual medical practice is more influential. Young physicians are confronted with the habits and practice of their older colleagues. Typically they more or less voluntarily adopt the work culture that obviously reflects moral and cultural norms in society as whole. Thus the transformation of physician attitudes towards patients will proceed at a similar pace to changes in interpersonal relationships in society as a whole.

### REFERENCES

1. Mozny I. *Ceska spolecnost. Nejdulezitejsi fakta o kvalite naseho zivota*. [Czech Society. The Most Important Facts about the Quality of Our Life] Port: Prague, 2002.
2. *Preliminary Results of the 2001 Population and Housing Census*. Czech Statistical Office, 2001. [www.czso.cz/eng/census/results.htm](http://www.czso.cz/eng/census/results.htm)
3. *Population and Housing Census 1991*. Prague: Czech Statistical Office, 1992.
4. Salajkova I. Verejne publikovani informaci o kvalite zdravotnickych sluzeb [Publication of Information on Health Care Quality]. *Zdravotnictvi v Ceske republice* 2001;4(3-4):159-60.
5. Schneider E C, Lieberman T. Publicly disclosed information about quality of health care: response of the US public. *Quality in Health Care* 2001;10:96-103.



**The Commission on the  
Future of Health Care in  
Canada**

[www.healthcarecommission.ca](http://www.healthcarecommission.ca)

The Commission was set up in April 2001 and charged with making recommendations to sustain a universally accessible, high quality, public administered health system that balanced investments in prevention and health maintenance with those directed to care and treatment. In addition to the final report published in November 2002, a series of discussion papers and summary reports on a wide variety of topics in health care and health policy were commissioned and can be viewed on the website. These were prepared by independent health researchers, experts, and academics from across Canada, and were subject to peer review. All 40 discussion papers are available on-line, many of which discuss issues which are equally the subject of debate in Europe. Comparison is also made with European and other international experience in a number of papers. This site is available in both English and French.

**Health Equity Network  
(HEN)**

[www.ukhen.org.uk](http://www.ukhen.org.uk)

HEN's aims are first to encourage active and fruitful collaboration between specialists from different disciplines in addressing issues of equity and inequality in health; second, to promote the translation of evidence and analysis into policies for tackling inequalities in health. It also helps facilitate the public policy debate on equity and inequality in health. The website provides information on past and future HEN seminars and workshops, and links to publications from these events. In addition, information is provided on a wide range of international events, and health and equity related links. A directory of individuals with an interest in equity in health and information on the health equity network mailing list are also provided.

**The Hellenic Presidency**

News and information on the Greek Presidency.

[www.eu2003.gr/en/cat/0/index.asp](http://www.eu2003.gr/en/cat/0/index.asp)

**Association Internationale  
de la Mutualité (AIM)**

[www.aim-mutual.org](http://www.aim-mutual.org)

AIM is a group of independent health insurance and social protection bodies operating according to the principles of solidarity and non-profit-making orientation. It includes 44 national federations covering 31 countries, providing coverage to more than 155 million people, either through the management of compulsory health insurance or by supplementary, alternative or substitute coverage. The association provides a forum for exchange and debate concerning social protection. A number of different resources are provided on the website including a newsletter, responses to EU reports and legislation, and a publication ordering facility. The website is available in English, French and German.

**NHS Economic Evaluation  
Database**

[http://agatha.york.ac.uk/  
nhsdhp.htm](http://agatha.york.ac.uk/nhsdhp.htm)

The NHS Economic Evaluation Database developed and maintained at the NHS Centre for Reviews and Dissemination at the University of York, provides free access to structured information on published economic evaluations of relevance to the UK NHS. Thousands of articles are available on-line and the detailed search engine provided allows complex searches to be undertaken. In addition two other databases – DARE – the Database of Abstracts of Reviews of Effects and the Health Technology Assessment Database can also be searched.

**CODECS – Connaissances  
et Décision en Economie  
de la Santé (Knowledge  
and Decision Making in  
Health Economics)**

[www.inserm.fr/codecs/  
codecs.nsf](http://www.inserm.fr/codecs/<br/>codecs.nsf)

CODECS is the first French language database for Economic Evaluations in Health Care, and has been developed by the French College of Health Economists in collaboration with the National Institute of Health and Medical Research (INSERM). It is similar to the NHS Economic Evaluation Database. Access to the database is free, and there are both French and English language search facilities. The aim of the database is to provide information on all published economic evaluations of health care technologies with relevance to the French context. This is already in excess of 550 articles.

**CREDES – Centre de  
Recherche d' Etude et  
de Documentation en  
Economie de la Santé**

[www.credes.fr/Default.htm](http://www.credes.fr/Default.htm)

The CREDES website available in both French and English provides a wide variety of information on publications in the field of health economics and health policy, with a particular emphasis the situation in France. A number of background documents have been produced on the French health care system. Its multidisciplinary team monitors and analyses trends in the behaviour of consumers and health care professionals from a medical, economic, geographic and sociological perspective. Information on forthcoming events and a good collection of links to institutions and information resources in France in particular are available.



# NEW PUBLICATIONS

This issue of *Eurohealth* sees the introduction of a section on new publications that may be of interest to readers. Contact David McDaid [d.mcdaid@lse.ac.uk](mailto:d.mcdaid@lse.ac.uk) if you wish to submit a publication for potential inclusion in a future issue.

## **Valuing Health in Practice. Priorities, QALYs, and Choice**

*Douglas McCulloch*

2003. Ashgate. Hardback. 138 pages. £39.95

ISBN 0-7546-1867-6

This book explores issues in health care choice, and in particular focuses on the use of the quality adjusted life year (QALY) as a tool for priority setting within the health care sector. It provides examples of how methods of priority setting are developed, and reflects on approaches adopted across the European Union.

Professor Alan Maynard, Department of Health Sciences, University of York said of the book, "Dr McCulloch provides a clear, topical and useful account of the use of economics in priority setting in the NHS. His book offers a nice guide to the uninitiated and sets out clearly the challenges both in developing this approach and then using its results to change clinical behaviour."

**Contents:** Priorities, QALYs, and choice; The quality-adjusted life year; Two QALY measures; Testing a QALY measure; Comparing procedures using QALY values; Using QALYs in practice; The case of Alzheimer's disease; The ASTEC evidence; Review; Appendices; Bibliography; Index.

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## **Foundations for Health Improvement. Productive Epidemiological Public Health Research 1919–1998**

*Walter W. Holland*

2002. The Stationery Office. Hardback. 236 pages. £21.50

ISBN 0-1170-2994-7

This book documents the history of epidemiological and public health research in the UK and the USA over 80 years since the end of the First World War. It examines the type and quality of research undertaken, and how this has been organised and funded. The complex relationships between the development of epidemiological and public health research and the political environment in the two countries are also examined.

**Contents:** Epidemiological public health research 1919-1939; Epidemiological public health research 1945-1998; Where is epidemiological public health research done and who pays; Trends in UK and US society, and politics 1919-1998; What has influenced epidemiological public health research; Conclusion; Annexes; Index.

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## **EU Law and the Social Character of Health Care**

*Elias Mossialos and Martin McKee*

*In collaboration with Willy Palm, Beatrix Karl and Franz Marhold*

2002. P.I.E – Peter Lang. Softback. 259 pages. £13.00.

ISBN 9-0520-1110-9

European law is an increasingly important factor in the development and implementation of national and local health policy. The situation with regard to laws impacting on health care is especially problematic as consequences arise from policies designed primarily to address problems in other sectors, which then establish general principles whose applicability to health care only becomes apparent once interpreted by rulings of the European Court of Justice. This book provides a comprehensive assessment of the main implications of EU law in certain key areas of health care.

Professor Jos Berghman, of the Catholic University of Leuven, has previously said of the publication "This is a timely book that brings together in both an accurate and critical way the various aspects in which health care and European legislation have become intertwined."

**Contents:** A European Social Model?; The theoretical basis and historical evolution of health policy in the EU; Free movement of professionals; Free movement of patients; Pharmaceuticals and medical devices; Voluntary health insurance; EU competition law and health care systems; Information technology law and health care systems; The way forward; Bibliography; Index.

## EUROPEAN PARLIAMENT SUPPORTS COMMISSION PROPOSAL ON EUROPEAN – DEVELOPING COUNTRIES CLINICAL TRIALS PROGRAMME

On January 22 the European Parliament's Committee on Industry and Research gave its support to a new European Commission proposal intended to help develop cost effective drugs for HIV/AIDS, malaria and tuberculosis in the developing world. The European-Developing Countries Trial Programme (EDCTP) would provide additional Commission support under the Sixth Framework Programme to European and developing countries working together to develop effective interventions. €200 million would be provided by the Commission, to be matched by con-

tributions of €200 m each from participating Member States (Norway also eligible) and the private sector. This represents a substantial increase over the €100 million allocated to this area under the Fifth Framework Programme.

MEPs amended the proposal to increase the transparency of intellectual property rights, stating that "A transparent approach to intellectual property rights, in the public interest, must be one of the principles underlying any of the EDCTP's

*Further information is available at*

[www.europarl.eu.int/meetdocs/committees/itre/20030122/485749en.pdf](http://www.europarl.eu.int/meetdocs/committees/itre/20030122/485749en.pdf)

activities." In particular they want the rules on intellectual property rights to guarantee that people in developing countries have easy and affordable access to any new medicines produced through the programme. Interventions also need to be simple and appropriate for developing country conditions, and in the longer term other diseases should be included in the scheme. The revised proposal falls under the co-decision (first reading) procedure and will be considered in February in Strasbourg.

## PARLIAMENT VOTES ON PROPOSED PHARMACEUTICAL DIRECTIVE

In October the European Parliament voted on the European Commission's proposals to reform European legislation on pharmaceutical products. These wide-ranging proposals, introduced just over a year ago, concern in particular the Regulation that provides the legislative framework regulating medicinal products, a Directive on human medicines and a Directive on veterinary medicines. The main aim of the proposal is to strike a balance between a high level of health protection for European citizens and the need to boost the competitiveness and innovative capability of the European pharmaceutical industry. The proposal has undergone 850 amendments since it was first introduced.

The main results of the Parliament's first reading were:

- Support for a central authorisation procedure, via the European Agency for the Evaluation of

Medicinal Products, for all new medicines;

- Rejection of the initial Commission proposal for a pilot project to allow advertising of drugs to treat diseases such as AIDS, asthma and diabetes
- Support for a 8+2 years data protection proposal, meaning that generic medicinal products would be eligible to apply for authorisation 8 years after the reference medicinal product is approved, while the production and marketing of the generic medicinal product authorised on this basis would have to wait an additional 2 years.

The vote was the first of two readings of the European Parliament under the co-decision procedure (First reading). The proposal must now be endorsed by the EU's Council of Ministers before the European Parliament can complete its second reading.

*For additional information please consult:*  
<http://pharmacos.eudra.org/F2/home.html>

*A press release by the Pharmaceutical Group of the European Union is available at: [www.pgeu.org/02.10.23E\\_05PR\\_Pharmaceutical\\_Review.pdf](http://www.pgeu.org/02.10.23E_05PR_Pharmaceutical_Review.pdf)*

## PROPOSED NEW DIRECTIVE ON PROFESSIONAL QUALIFICATIONS

The European Parliament is currently discussing the Commission's proposal for a Directive to clarify and simplify the rules in order to facilitate the free movement of qualified people between Member States. The proposed Directive, which would replace fifteen existing Directives on the recognition of professional qualifications, constitutes the first comprehensive modernisation of the Community system since it was conceived forty years ago. Under the proposal, health care professionals from any EU country would be allowed to work for up to four months a year every year in another member state without being registered with the national regulators in that country.

*Additional information on the proposed Directive is available at [www.db.europarl.eu.int/oeil/oeil\\_ViewDNL.ProcViewCTX?lang=2&procid=5998&HighlightType=1&Highlight\\_Text=Professional\\_QUALIFICATIONS](http://www.db.europarl.eu.int/oeil/oeil_ViewDNL.ProcViewCTX?lang=2&procid=5998&HighlightType=1&Highlight_Text=Professional_QUALIFICATIONS)*

## TOUGH EU RULES ON MANUFACTURE, PRESENTATION AND SALE OF TOBACCO PRODUCTS TAKE EFFECT AND ARE UPHELD BY ECJ

The Directive on the Sale, Marketing and Manufacturing of Tobacco Products came into effect on 30 September. The Directive sets out rules based on scientific advice on key issues such as additives, addictive substances, health warnings and misleading claims, such as categorising cigarettes as 'mild' or 'light'. It also reduced the maximum levels of tar, carbon monoxide and nicotine in cigarettes. The new legislation puts the EU in a leading position worldwide on tobacco control and ensures the same standard of protection in all Member States.

British American Tobacco Ltd and Imperial Tobacco Ltd challenged the Directive claiming that it conflicted with the EU's Single Market

laws, as the Directive was more concerned with public health issues rather than the free movement of goods within the internal market. However in December the European Court of Justice upheld the validity of the directive. It ruled that the new harmonising directive would help prevent the emergence of obstacles to the free movement of tobacco products within the EU that would otherwise be created by the adoption of different national rules laying down different requirements as to the manufacture, presentation and sale of tobacco products. The Court also ruled that it was correct to ban descriptive terms which might mislead consumers, and that such action was appropriate for attaining a high level of health protection.

Further information: <http://curia.eu.int/en/cp/aff/cp0299en.htm>

More information about the new Directive is available at:

[www.europa.eu.int/comm/health/ph/programmes/tobacco/publication.htm](http://www.europa.eu.int/comm/health/ph/programmes/tobacco/publication.htm)

## CAMPAIGN TO PROMOTE BREAST FEEDING

Health Commissioner Byrne has launched a campaign to promote breast-feeding. As part of this campaign, the Commission will spend €600,000 on a study to find the best examples of breastfeeding promotion in the EU. The results will help health agencies develop strategies and action plans at national and local levels. The two-year scheme is the latest in a long line of EU efforts to make mothers aware that breast feeding gives babies the best start to life, even if some mothers have to turn to formula milk when they return to work. An existing EU Directive forces infant formula milk manufacturers to indicate the superiority of breast-feeding on packaging. The Istituto per l'infanzia in Trieste, Italy, is coordinating the project.

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## EUROPEAN YEAR OF PEOPLE WITH DISABILITIES LAUNCHED

37 million Europeans have some form of disability and can be subject to much stigma, discrimination and limited opportunities. The European Year of People with Disabilities (EYPD) is intended to promote greater awareness of the challenges faced by the disabled, and move further towards ensuring equality. The year was launched in Athens on January 26, under the Greek Presidency of the EU, supported by the European Disability Forum and the Greek Confederation of Disabled People. One of the focal activities is an EYPD march across all Member States, beginning in Greece, led by a specially designed bus.

Speaking at the launch Commissioner Diamantopoulou (Employment and Social Affairs) stated that 'Member States are not doing enough to give disabled people in Europe equal rights with the non-disabled. The rights we are

talking about can be summed up as rights to 'access': access to a job, access to buildings, access to e-mail and the internet. These rights may already exist on paper, but not in reality. The European Year of People with Disabilities must mark the start of lasting change for our 'invisible citizens.'

It has been estimated that less than 40% of people living with a disability are in employment, compared with nearly two thirds of the able bodied. There is therefore scope to improve employment prospects and more generally integrate individuals in society. It is anticipated that a directive barring discrimination within the workplace will be implemented by the end of 2003, employers will then be obligated to take reasonable steps to meet the needs of disabled employees.

The EYPD website can be accessed at [www.eypd2003.org](http://www.eypd2003.org)

## NEW REPORT ON EUTHANASIA AND ASSISTED SUICIDE

The Council of Europe Steering Committee on Bioethics has published a study on laws and/or practices concerning euthanasia and assisted suicide in 34 of the Council's member countries and in the United States, which has observer status with the Organisation.

Results of a questionnaire on which the study is based found that euthanasia is only legally possible in Belgium (9 countries did not give specific replies). Assisted suicide is a legal possibility in two further countries, Estonia and Switzerland (10 countries did not give specific replies). The study was prepared following Recommendation 1418 on the protection of the human rights and dignity of the terminally ill and the dying, adopted by the Council of Europe's Parliamentary Assembly in 1999.

A copy of the study is available at: [www.coe.int/euthanasia-report](http://www.coe.int/euthanasia-report)

## POLITICAL AGREEMENT REACHED ON PROPOSED DIRECTIVE ON ADVERTISING AND SPONSORSHIP OF TOBACCO PRODUCTS

The Employment, Social Policy, Health and Consumer Affairs Council meeting in December reached political agreement on the proposal for a Directive of the European Parliament and of the Council on advertising and sponsorship of tobacco products, with a view to enabling adoption in 2003.

### NEW WHO HEALTH REPORT

The WHO Regional Office for Europe has released The European Health Report 2002. The report analyses a decade of evidence on health in the Region, which embraces 51 WHO Member States with some 870 million people. It describes trends in health and the most important health problems, lifestyle and environmental determinants of health and health care systems.

While overall levels of health in the WHO European Region are among the highest in the world, the report describes widening gaps between and within countries. It thereby confirms the strong links between socioeconomic development, health and equity in the Region: "The great differences in health status observed across countries and among groups within countries have highlighted the fact that all major determinants of health are linked to social and economic factors."

The report also builds on the view that health policies cannot be isolated from other policy sectors: "One central task in improving health is to reduce socioeconomic inequalities, thus placing health in the context of human development." The link between health and employment, income maintenance, social welfare, housing and education is crucial in all European Member States.

*The full report, including the annex of statistical tables comparing countries in the European Region, can be found on and ordered from the WHO Regional Office website [www.who.dk](http://www.who.dk)*

Previously in November in a plenary session of the European Parliament, MEPs fully endorsed the European Commission's proposal. This draft Directive took full account of the judgement of the European Court of Justice of October 2000, which annulled a previous Directive 98/43/EC on tobacco advertising. In this vote, MEPs rejected all but one of the amendments introduced by Parliament's Legal Affairs Committee, which would have restricted the scope of the Directive. An amendment stating that Member States retain the competence to regulate matters relating to tobacco advertising that are not covered by the Directive, such as indirect advertising or sponsorship without cross-border effects, was accepted.

The Directive aims to harmonise national regulations on tobacco advertising in the press, radio, and other information services, in addition to regulations on the sponsorship of transnational events. This complements existing legislation on television advertising and the sponsorship of events by tobacco products. The proposal is based on articles 47 (2), 55 and 95 of the Treaty.

### EMCDDA SURVEY ON SCHOOL-BASED PREVENTION PROGRAMMES IN THE EU

This Report by the European Monitoring Centre for Drugs and Drug Addiction analyses and discusses information gathered, on the basis of a pilot questionnaire survey, from 50 school-based prevention programmes across 9 EU member states. The purpose of the project was to identify indicators that describe and compare prevention policies. Amongst the findings of the report is that training of professionals is key to prevention and that professionals must have specific and concrete theoretical knowledge rather than a general understanding of health promotion. This will increase the degree of intensity, concreteness, clarity and evaluation of programmes. In addition, coherence between program theory base, resources and evaluation are critical, and it is important that programmes be thoroughly evaluated on the basis of good indicators.

*The survey is available at [www.emcdda.org/multimedia/project\\_reports/responses/schools\\_survey\\_2001.pdf](http://www.emcdda.org/multimedia/project_reports/responses/schools_survey_2001.pdf)*

### NEW REPORTS FROM WHO REGIONAL OFFICE FOR EUROPE:

#### Highlights on Health and a Health Status Overview for Countries of Central and Eastern Europe

These reports provide an overview of the health of the ten central and eastern European Countries that are candidates for accession to the EU. The Health Information and Evidence Unit of the WHO Regional Office Europe produced these documents with the support of the European Commission and of the Ministry of Health of Finland.

Among the findings of the overview are:

Overall death rates began to fall in 1990s and life expectancy increased, although dramatic economic and social changes were associated with

low birth rates, net emigration and falling populations, particularly those of working age. Demographic change has increased the proportion of elderly people, though not as dramatically as in the EU.

Men's health is particularly poor compared both with the EU and with women in the candidate countries. Exceptions are where women are increasingly adopting harmful behaviour, such as smoking, where they are victims of violence, or where they are only now gaining full access to modern family planning services.

*The full report is available at [http://europa.eu.int/comm/health/ph/programmes/monitor/pub/index\\_en.html](http://europa.eu.int/comm/health/ph/programmes/monitor/pub/index_en.html)*

## SIXTH FRAMEWORK PROGRAMME: LAUNCH AND FIRST CALL FOR PROPOSALS

The Sixth Framework Programme for Research (FP6 2003–2006) was launched in November at a major conference in Brussels, which brought together more than 9,000 participants from 61 countries, of whom more than 1,000 were from accession and candidate countries. In addition to providing a forum for scientific debate and exchange of best practice, the conference provid-

ed an opportunity to present the objectives and priorities of the Framework Programme and explain eligibility criteria. Amongst the three pillars of EU research policy is a long-term project: the creation of the European Research Area (ERA). FP6, with a budget of €17.5 billion, aims to feed into the ERA initiative by networking research centres across Europe and achieving a criti-

cal mass of European scientific excellence.

On 16 December the European Commission announced its first Call for Proposals under FP6. This first allocation of €3.4 billion will be targeted largely to seven key priorities, which include the health related section on 'Life sciences, genomics and biotechnology for health'. Funding will also cover policy relevant research on public health, healthcare services and health determinants. 70% of this first round of funding will focus on new funding schemes such as Networks of Excellence and Integrated Projects. Deadlines for the first call are in March and April 2003.

*Further information see*  
[www.cordis.lu/fp6](http://www.cordis.lu/fp6)

### INTERIM REPORT ON PUBLIC HEALTH MONITORING PROGRAMME

The general aim of the Community action programme on health monitoring, adopted in June 1997, is to contribute to the establishment of a Community health monitoring system by producing comparable information on health and health-related behaviour of the population, diseases and health systems. The programme was based on commonly agreed European-wide indicators with regard to definition, collection and use.

The interim report, which covers the implementation period from 1997 to 1999, is based on an external evaluation and includes excerpts from this report. Amongst the

findings are that 60% of the programme's objectives were, by 1999, covered by actions supported through the programme. Existing networks of experts had substantially developed throughout the course of the programme. Much expert capacity exists in Member States which can be approached for support regarding specific problems and tasks within public health and health monitoring. Nevertheless, the external report found that the establishment of a Community-wide health monitoring system is still incomplete and there is a need to limit the number of indicators for practical use in policy making.

*The report is available at*

[http://europa.eu.int/comm/health/ph/programmes/monitor/pub/index\\_en.html](http://europa.eu.int/comm/health/ph/programmes/monitor/pub/index_en.html)

### FIRST CONFERENCE OF THE INTERNATIONAL FORUM ON COMMON ACCESS TO HEALTH CARE SERVICES

The International Forum is intended to allow politicians, administrators and researchers from different countries an opportunity to exchange knowledge, experience and ideas for public health services provided according to need, taking equity considerations into account. The Forum will arrange international meetings and conferences, as well as promote research in order to develop ideas of common access to health care services.

The first conference of the International Forum took place in Stockholm on 30–31 January. Ministers for Health from seven countries (Chile, Germany, Greece, New Zealand, Slovenia, the United Kingdom and Sweden) met for two days. In addition to these deliberations over access to health care services, delegates were also informed on specific topical issues by leading researchers from across Europe.

*More information is available at*  
<http://social.regeringen.se/inenglish/forum/index.htm>

### EU DRUG AGENCY REPORT ON THE DRUG SITUATION IN EUROPE

The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) has launched an 'Annual report on the state of the drugs problem in the European Union and Norway'. The Report reveals that candidate countries face a major challenge in tackling narcotics abuse and warns that there is a clear gap in most accession countries between the availability of drug services and demand by those needing treatment. Amongst the Report's other conclusions are that cannabis continues to be the most popular drug in the EU; consumption of synthetic drugs is a major cause of concern, and the rate of drug related infectious diseases, such as HIV, is rising. In the past

year, almost 9 tonnes of heroine were seized – a third of this in the UK, which has the single largest drug problem in the EU.

*The Report is available in 12 languages with press releases that summarise the main findings at*  
<http://annualreport.emcdda.eu.int/en/home-en.html>

The EMCDDA also recently published a 'Handbook for surveys on drug use among the general population', which summarises the guidelines for the key indicator 'Extent and patterns of drug use among the general population'.

*More information is available at*  
[www.emcdda.org](http://www.emcdda.org)

# News in Brief

## New Public Health Programme

The EU Public Health Programme (2003–2008) has been published in the Official Journal of the European Union and is now available on the Europa website.

[www.europa.eu.int/eur-lex/pri/en/oj/dat/2002/l\\_271/l\\_27120021009en00010011.pdf](http://www.europa.eu.int/eur-lex/pri/en/oj/dat/2002/l_271/l_27120021009en00010011.pdf)

## EU Framework Programme Independent Experts Database

The European Commission has published two calls for experts, one for individuals and one for institutions, to be added to an independent experts database. Experts will be asked to help in the evaluation of research proposals, and also in monitoring new and existing projects within the Sixth Framework Programme (and previous framework programmes as appropriate). The deadline for applications is 31 December 2006.

Further information: [www.cordis.lu/experts/fp6\\_candidature.htm](http://www.cordis.lu/experts/fp6_candidature.htm)

## Call for Expressions of Interest

DG Sanco recently published a Notice of call for expressions of interest. DG Sanco will transmit an invitation to tender and the specifications to all or some of those who have expressed an interest when it requires specific services. Lists will be drawn up in the areas of Consumer Protection, Food Safety, Public Health (Section 3-III) and Other Fields. These lists will be open for a period of three years, and eligible expressions of interest will be included throughout this time.

More information is available at [www.europa.eu.int/comm/health/ph/tenders/index\\_tenders\\_en.html](http://www.europa.eu.int/comm/health/ph/tenders/index_tenders_en.html)

## EU activities on nutrition

A status report is now available on the European Commission's work in the field of nutrition in Europe. It provides a comprehensive overview of specific projects funded by the Directorate General for Health and Consumer Protection as well as nutrition related actions in other EU policy areas such as the Common Agricultural Policy.

[http://europa.eu.int/comm/health/ph/programmes/health/reports/nutrition-report\\_en.pdf](http://europa.eu.int/comm/health/ph/programmes/health/reports/nutrition-report_en.pdf)

## Meeting of nutrition experts

National experts in WHO Europe's nutrition and food security programme will evaluate current progress in formulating national food and nutrition action plans at a meeting in Athens in February. The planned WHO global strategy on diet, physical activity and health will also be debated.

More at [www.who.dk/eprise/main/WHO/Progs/NUT/ActionPlan/20020729\\_1](http://www.who.dk/eprise/main/WHO/Progs/NUT/ActionPlan/20020729_1)

The global strategy is available at [www.who.int/hpr/NPH/docs/GlobalStrategy.pdf](http://www.who.int/hpr/NPH/docs/GlobalStrategy.pdf)

## New EU Directive limiting noise at work

The European Parliament and the Council have agreed on minimum health and safety standards for noise exposure at the workplace. The Directive brings in new, stricter limits on noise at work but ensures that this imposes no unnecessary new burdens on business.

The agreement is available on the Conciliation Committee website: [www.europarl.eu.int/code/backgrou/default\\_en.htm](http://www.europarl.eu.int/code/backgrou/default_en.htm)

## European Convention and Health

The new Convention Working Group on Social Europe published a working document on 10th December calling for the European Social Model of healthcare and social protection to be included in Article 3 of the preliminary draft Constitutional Treaty. The Working Group should finalise its report at the end of January.

The working document is available at: <http://european-convention.eu.int/docs/wd11/6222.pdf>

## International Conference on Poverty, Food and Health

The Institute of Preventive Medicine, at Lisbon University has organised an international conference on Poverty, Food and Health in Welfare: current issues, future perspectives from July 1 to 4, 2003.

More information: [www.pfh2003.org](http://www.pfh2003.org)

## New Directive on the Regulation of GMO's comes into Force

A new version of the 1990 Directive on the regulation of Genetically Modified Organisms in Europe came into force on October 17. The new Directive updates and strengthens the previous Directive by extending the labelling requirements to all food and ingredients produced from GMO's and genetically modified feed material.

More information on GMO's, including the document "Questions and answers on the regulation of GMO's in the EU" is available at: [http://europa.eu.int/comm/food/fs/gmo/gmo\\_index\\_en.html](http://europa.eu.int/comm/food/fs/gmo/gmo_index_en.html)

## "Goethe Challenge Trophy" for Europe-wide smoking prevention

EU Commissioner for Health and Consumer Protection, David Byrne, was awarded the Goethe Challenge Trophy for Smoke-Free Environment at the 5th European Health Forum in Bad Hofgastein in September. The "Goethe Endowment for Non-Smoking" presents the award every year to institutions, university departments and individuals who have made outstanding contributions to ensuring a smoke-free environment. David Byrne is the first politician to receive the trophy.

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