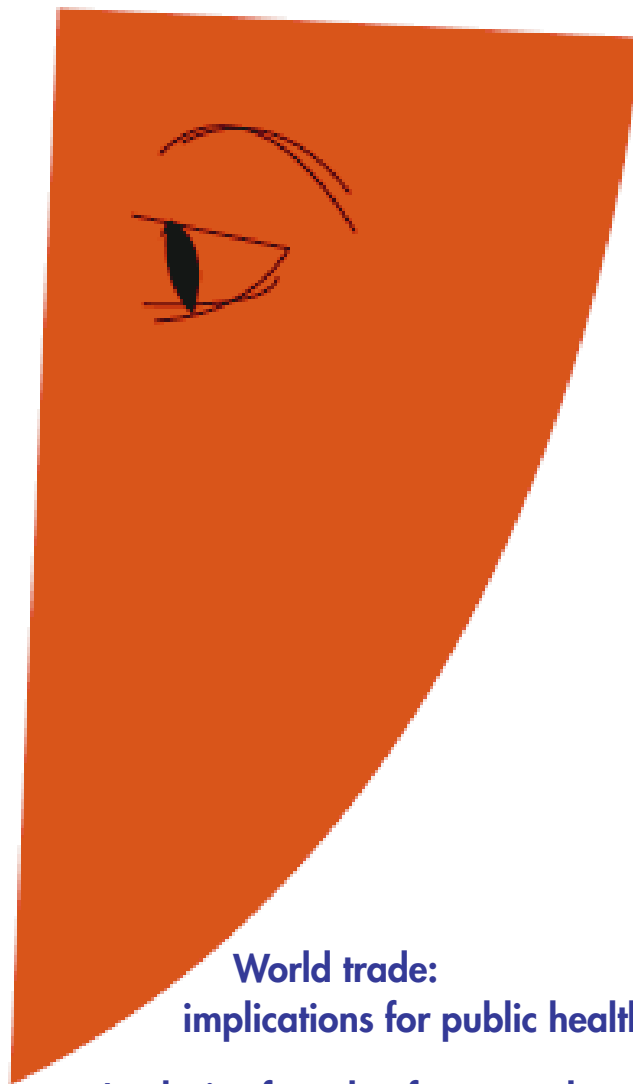


eurohealth

Public health priorities for the French Presidency of the European Union



World trade:
implications for public health

Analysis of market forces and
healthcare systems

Gastein Forum:
focus on the Commission's health strategy

P r e f a c e

It has been a summer of three steps forward and two steps back for European public health. The recent decision of the European Court to annul the Tobacco Advertising Directive is a serious set-back for all those who put so much effort into getting it drawn up and agreed by the institutions. It is perhaps part of a learning curve that will ensure that future legislation is put on an incontrovertible public health footing from the outset. In this issue Andrew Hayes discusses the fall of the Directive and the implications for the future of policy in this area.

There have also been positive developments in public health. As this issue's editorial points out, a consultation process is to be launched to determine the shape and competencies of a European Health Forum that will involve the primary stakeholders in the field of public health in the development of policy.

This year's conference season enabled significant debate on the Commission's new health strategy – an issue that formed one of the five principal areas of discussion at the European Health Forum Gastein, held in Austria during September. A report from the conference on the new strategy is presented here, as are two perspectives on it – from an accession state, Estonia, and from a European region, Catalonia.

Our major section in this issue discusses the link between public health issues and the World Trade Organisation. These articles provide informed perspectives on the role of the Union in respect of agreements at the global level. They discuss, in part, the extension of intellectual property rights through the TRIPS agreement – an issue of central importance to the European Union and its place in a knowledge based global economy. In addition, they point to the problem of medicine supply in the developing world as an essentially political one. Commissioner Lamy begins this section with an article that shows how trade policy can assist in the achievement of health objectives.

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Roast duck for Christmas?

Paul Belcher

Senior Editorial Adviser, Eurohealth

The EU health community is currently awaiting the announcement before the end of this year of a consultation process on the welcome proposal from Health Commissioner Byrne to establish a new consultation mechanism, the 'European Health Forum'.

This Forum is part of the new EU health strategy announced in May and aims "to give the public health community at large an opportunity to play a role in the development of health policy."

Commissioner Byrne has championed this as a "vital part" of the new EU health package and he has gained much support for his commitment, particularly among the stakeholder groups already identified by him as potential partners: voluntary bodies, health professionals, academic and patients' organisations etc.

As the Commissioner stated in the last edition of Eurohealth, "It cannot be right that there is currently no formal procedure by which civil society organisations can make their views known on policy issues or on preparation of legislation in the health field." Indeed, as the Commissioner points out, it already happens in other areas such as EU social and development policies. However, questions over the achievements of the annual Social Policy Forum are causing many to prefer a more permanent process in the health field.

By launching a consultation, Mr Byrne will be taking the first, concrete, steps to achieving what was dismissed by some observers as a 'political slogan' two years ago, when it was first raised as a possibility by Former Health Commissioner Pdraig Flynn, at the European Parliament Public Hearing on Health. Although welcomed, few expected that it would lead to any practical follow-up. I recall a Chinese proverb, quoted by

a senior EU health lobbyist present during Flynn's 1998 speech, which encapsulated the feeling at the time:

*"Just because mouth is open,
roast duck does not fall in!"*

We now appear to be in a new, more positive phase. Commissioner Byrne has won praise for demonstrating his commitment to this project; not only in speeches, but also by building the Forum into his health strategy package. In response, stakeholder groups have launched preparatory discussions in readiness for the forthcoming consultation.

In October over 40 mainly non-governmental health organisations met in Brussels for a wide ranging discussion on the way forward. It was organised by the European Public Health Alliance and attended by national bodies and EU umbrella networks such as the European Health Management Association, the European Network of Health Promotion Agencies, and the European Standing Committees of Nurses and Doctors (see www.eph.org). The following points were among the issues raised:

- The Forum should be a formal, permanent structure, not just an annual conference.
- The Commission's consultation document should include a possible model for the Forum, rather than simply putting forward a list of questions.
- The Forum should be coordinated independently of any of the stakeholder groups, perhaps within the Commission with assigned staff and resources.
- The Forum should not only respond to the Commission's existing agenda, but also initiate consideration of new issues to contribute to future EU health policy development.
- The Commission should respond to, rather than simply receive, the reports, opinions, recommendations

etc. that the Forum might develop.

However, amid enthusiasm for the Forum, there are some rumblings of concern in the non-smoked filled rooms of the Brussels health lobby. Firstly, given the haste with which the Council of Ministers and European Parliament are having to approve the Commission's proposal to prolong the existing health programmes before they cease at the end of this year (necessary given that the new programme will not be in place until 2001), there is concern that the consultation document might also take more time to emerge from the Commissioner's services. There is a particular worry that this might lead to a fast track consultation process of less than the minimum three months envisaged.

Indeed, while Commissioner Byrne has promised to launch the consultation before the end of the year, the lack of any concrete information from the Commission as we enter November might suggest that a delay is likely. There is certainly a heated debate among policy makers at the moment, both within and outside the Commission, on how open or controlled the Forum should be. Some Member State representatives have already voiced their concern at allowing this consultative body any influential role in EU health policy development and there may be similar concerns within the Commission itself. In addition, organisations already represented in the EU Economic and Social Committee and Committee of the Regions may regard the Forum with suspicion. As well as causing a delay, dealing with such differences may lead to a proposal that is more of a political balancing act than a radical approach to consultation. While roast duck is now firmly on the political menu within the Commissioner's Cabinet, serving a timely and, importantly, substantial dinner by Christmas might require a little more commitment elsewhere.



Dominique Guillot Minister of Health of France

Les priorités de santé publique de la Présidence Française

Public health priorities for the French Presidency

On the eve of the 21st century, the European Union is facing significant challenges in the field of health.

We live in a world in which health is a privilege that the majority of people do not enjoy, whilst the minority, to which we belong, continue to develop new technologies which revolutionise healthcare, at ever increasing cost. The European Union cannot continue to ignore the tens of millions of deaths caused by malaria, tuberculosis, and AIDS each year whilst we dispose of the necessary preventive measures. France has called upon the United Nations to organise a conference on these issues. The European Union, at the proposal of the European Commission, shall consider a new strategy in this area, on the basis of the findings of a forum that was held on the 28th September on the European Commission's initiative. Funding mechanisms in support of this action should be sought.

The French Presidency also attaches the greatest importance to the World Health Organization's (WHO) Framework Convention on Tobacco Control. The European Union has already adopted directives which seek to limit the impact of tobacco dependence, whilst

A l'aube du XXIème siècle, l'Union Européenne est confrontée à de grands défis dans le domaine de la santé.

Nous vivons dans un monde où la santé est un privilège dont ne dispose pas la majorité des être humains, alors qu'une minorité, à laquelle nous appartenons, développe chaque jour de nouvelles techniques qui révolutionnent les soins, pour des coûts de plus en plus élevés. L'Union Européenne ne peut ignorer les dizaines de millions de morts causés dans le monde chaque année par la malaria, la tuberculose et le SIDA, alors que nous disposons des traitements et des moyens de préventions nécessaires. La France a demandé à l'Organisation des Nations Unies la tenue d'une conférence sur ces sujets. L'Union Européenne, sur proposition de la Commission, va étudier une nouvelle stratégie dans ce domaine, à partir des travaux du forum qui a eu lieu le 28 septembre à l'invitation de la Commission Européenne. Les moyens financiers à mettre en place à l'appui de cette volonté devront être envisagés. .

Dans le même esprit, la présidence attache la plus grande importance au projet de convention de l'Organisation Mondiale de la Santé (OMS) pour la lutte contre le tabagisme. Nous avons déjà adopté dans l'Union Européenne des directives qui, tout en permettant la libre circulation des produits du tabac, tentent de limiter les conséquences du tabagisme pour la population. Les Etats-Unis d'Amérique ont aussi pris des mesures en ce sens. Mais nous sommes extrêmement inquiet de la situation dans les autres pays. Les jeunes des pays d'Afrique

allowing for the free movement of tobacco products. The United States have adopted similar measures. We are however extremely worried about the situation in other countries. Young people in Africa and Asia seem to constitute the primary target for the development of tobacco products markets, using practices which have been forbidden in the European Union, such as the distribution of free cigarettes at the school gates. We shall therefore actively support, and if necessary strengthen the WHO's framework convention.

As regards the European Union's internal policy in the field of health, the French Presidency has taken over at a decisive time. The Treaty of Amsterdam strengthened the powers of the Community in this domain. The first proposals of the European Commission seeking to lay the foundations of a new strategy have been, or shall shortly be, forwarded to the Council. The agenda of the next Health Council, which shall be held in December, thus acquires particular importance.

The public health programme should serve as a framework for the implementation of the new strategy. Like the European Commission, we believe that health monitoring, the detection of threats to health and rapid response to these threats, as well as measures on health determinants, constitute priorities. Particular focus should however be placed on the integration of health protection requirements into other policy areas, as the most effective vehicle for promoting human health protection. The new programme should encourage closer cooperation between the Member States, with the support of the Commission, on topics of common interest or problems of common concern, such as resistance to antibiotics, the impact of new technologies or the problems of quality in the field of health.

“We live in a world in which health is a privilege that the majority of people do not enjoy.”

Health monitoring presents a particular problem. All agree that it should draw upon the resources of the networks of public health agencies in the Member States, as well as on resource centres such as Eurostat, the OECD and the WHO. Experience has however shown that the networks are unable to operate without the assistance of a coordinating body. This body would contribute to the adoption of common definitions and methodologies, train teams responsible for data collection and establish networks for data collection, which would collate and disseminate the information. The accession of new Member States, where public health cultures often differ considerably, will render the creation of such a body all the more important. We therefore call for the provision of funding for a coordinating body under the new programme.

On the initiative of the French Presidency, the

et d'Asie semblent constituer des cibles privilégiées de développement des marchés des produits du tabac, avec des pratiques interdites chez nous, comme la distribution de cigarettes gratuites à la sortie des écoles. C'est pourquoi nous soutiendrons activement, et si nécessaire nous renforcerons le projet de convention de l'OMS.

Pour ce qui concerne la politique interne de l'Union Européenne en matière de santé, la présidence française intervient à un moment décisif: le traité d'Amsterdam a renforcé les pouvoirs de la Communauté dans ce domaine, et les premiers textes de la Commission pour mettre en place les éléments d'une nouvelle stratégie sont sur la table du Conseil, ou y seront dans les jours qui viennent. De ce fait, l'ordre du jour du prochain Conseil santé, au mois de décembre, sera particulièrement important.

“Nous vivons dans un monde où la santé est un privilège dont ne dispose pas la majorité des être humains.”

Le programme en santé publique doit servir à mettre en place une nouvelle stratégie. Comme la Commission, nous pensons que la surveillance de la santé, la détection des menaces pour la santé et la réaction rapide à ces menaces ainsi que l'action sur les déterminants de santé constituent des priorités. Mais un accent particulier sera mis sur la prise en compte de la santé dans toutes les politiques, ce qui constituera l'instrument d'action le plus efficace pour la santé des populations. De plus, le nouveau programme permettra une coopération accrue entre Etats membres, avec l'appui de la Commission, sur des sujets qu'ils souhaitent étudier ensemble ou sur des problèmes communs, comme la résistance aux antibiotiques, l'impact des nouvelles technologies ou les problèmes de qualité dans le domaine de la santé.

La surveillance de la santé pose un problème spécifique. Chacun s'accorde à considérer qu'elle doit s'appuyer sur les réseaux d'instituts de santé publique des Etats membres, ainsi que sur les centres de ressources que sont Eurostat, l'OCDE et l'OMS. Mais l'expérience actuelle montre que les réseaux n'arrivent pas à fonctionner sans un coeur, sans un organisme de coordination qui aide à adopter des définitions et des méthodologies communes, à former les équipes chargées du recueil des données, qui mette en place des circuits cohérents de recueil des données, qui regroupe l'information et la diffuse. L'arrivée des nouveaux Etats membres, où les cultures de santé publique sont parfois très différentes, rend d'autant plus utile la création d'un coeur de réseaux. C'est pourquoi nous proposons d'inclure le financement de cette structure de coordination dans le nouveau programme.

Le Conseil santé de décembre se penchera à l'initiative de la présidence sur plusieurs problèmes importants.

December Health Council shall examine a number of important issues.

The first of these is nutrition, which constitutes a major health determinant, alongside tobacco dependency and alcoholism, but has been somewhat neglected over the last few years. Poor nutrition is a major contributor to premature deaths from cardiovascular diseases and is responsible for a high percentage of cancers and it is known that the influence of European policy on the nutritional habits of European citizens is considerable. It also provides the opportunity to talk about nutrition in a positive light, as eating can be both pleasurable and beneficial to health. This is the message that our country wishes to put across, and we hope it shall be heard.

The second issue concerns medicinal products for children. Very few medicines have been adapted for children. Doctors and parents are obliged to use adult medication, diluting or fractioning it in order to administer it to children, without adequate prior safety tests having been carried out. With the support of the European Commission, we shall be presenting a resolution proposing action in this field, to ensure that our children are not being put in danger.

“Young people in Africa and Asia constitute the primary target for the development of tobacco products markets.”

We also attach the greatest importance to the development of measures against alcohol abuse. We are awaiting the European Commission's proposal for a recommendation on the health of young people and alcohol and shall press, together with the future Swedish Presidency, for its adoption. Like Sweden, we believe that a strategy should be developed at European level in this area, as was the case in the fight against tobacco dependency.

On the legislative front, the future directive on blood products will be extremely important. It will be the first text on substances of human origin to be based on the new Article 152, and should enable the definition of ethical norms and of the conditions for ensuring the safety of these products.

The significance of the agenda of the forthcoming Council meetings show that we have moved into a new phase in the development of the European Union in the field of health, following the adoption of the Treaty of Amsterdam. The next few years should see the implementation of the measures necessary for the well being of the populations for which we have responsibility. This will only be possible if the Member States are mobilised, if the services of the European Commission responsible for health are strengthened and if all the players in field of health are involved in the formulation and development of this policy.

Le premier est celui de la nutrition, déterminant majeur de santé, au même titre que le tabagisme et l'alcoolisme, et qui a été un peu oublié ces dernières années. Une mauvaise alimentation est à l'origine de l'essentiel des décès prématurés par maladies cardiovasculaires, et d'une proportion importante de cancers, et les politiques européennes jouent un rôle important dans les choix alimentaires de nos populations. C'est aussi l'occasion de parler d'alimentation de manière positive, car manger peut être à la fois un plaisir et une activité bénéfique pour la santé. C'est le message que notre pays souhaiterait transmettre, et nous espérons qu'il sera entendu.

“Les jeunes des pays d'Afrique et d'Asie semblent constituer des cibles privilégiés de développement des marchés des produits du tabac.”

Le second est celui des médicaments pédiatriques. Très peu de médicaments ont une forme adaptée aux enfants. Les médecins et les parents sont obligés d'utiliser des médicaments pour adultes, et de les diluer ou de les couper pour les administrer aux enfants, sans que des essais aient été faits au préalable dans des conditions de sécurité acceptable. Nous présenterons une résolution, avec l'appui de la Commission, pour proposer une action dans ce domaine, et éviter de mettre en danger nos enfants.

Nous attacherons aussi la plus grande importance au développement des actions contre l'abus d'alcool. Nous attendons de la Commission une proposition de recommandation sur la santé des jeunes et l'alcool, et, avec la future présidence suédoise, nous nous attacherons à faire aboutir cette décision du Conseil. Comme la Suède, nous pensons qu'il serait nécessaire de développer une stratégie européenne dans ce secteur, comme cela a été fait pour la lutte contre le tabagisme.

Dans le domaine législatif, la future directive sur les produits sanguins sera extrêmement importante. Ce sera le premier texte sur les produits du corps humain basé sur le nouvel article 152, et il devra permettre de définir nos principes éthiques dans ce domaine, ainsi que les conditions pour assurer la sécurité de ces produits.

L'importance de l'ordre du jour des prochains conseils montre bien que nous sommes entrés dans une nouvelle phase de construction de l'Union Européenne dans le domaine de la santé, à la suite du traité d'Amsterdam. Les années qui viennent vont permettre de mettre en oeuvre les activités nécessaires pour le bien-être des populations dont nous avons la responsabilité. Cela ne sera possible que si les Etats membres sont mobilisés, si les services de la Commission chargés de la santé sont renforcés, et si tous les acteurs de la santé sont associés à la définition et au développement de cette politique.

Public health or private profit?

Implications of the recent judgement on the EU Tobacco Advertising Directive



Andrew Hayes

“This whole sad saga strikes at the heart of international decision making.”

The European Court of Justice (ECJ) has recently dealt a blow to health protection in Europe. On 5 October 2000, it announced judgement in the case brought by Germany and various UK tobacco companies against the Directive on tobacco advertising that had been adopted by the Community in July 1998. The Directive was due to take effect progressively from January 2001 onwards and would have banned all tobacco advertising except at points of sale, prohibited brand stretching and restricted publicity surrounding tobacco industry sponsorship of sporting and cultural events.

The decision to annul the Directive betrays the efforts and good intent of the three Community institutions, of politicians from all Member States, of officials working at EU and national level, and of the health community throughout Europe. Above all, it ignores the health protection interests of EU citizens. Instead it defends the right of an industry to continue promoting a product which, when used exactly as intended, leads directly to the premature death of one in two regular smokers.

Tobacco is the single biggest cause of preventable death in the world. In the EU, more than half a million people die each year as a result of tobacco related disease. In Europe as a whole, the figure is more than one million. These figures alone justify public authorities in taking whatever action may help to eliminate, or at least reduce, the tobacco epidemic. Indeed, public authorities that take no action to challenge the tobacco industry who are guilty of negligence on a massive scale. Every one of the 1350 daily tobacco deaths in the EU results directly from the production and marketing strategies of the tobacco industry, but indirectly from governments' failure to protect the health interests of their citizens.

The public health context

The Directive on tobacco advertising was conceived as part of an overall cancer prevention and tobacco control strategy for the EU, the 'Europe against Cancer' programme, adopted in 1987. This was the Community's first initiative in the field of health, and pre-dates the EU's limited

health competence originally introduced by the Maastricht Treaty and slightly strengthened by the Amsterdam Treaty.

From the outset, the cancer programme pursued a legislative approach: Directives were adopted to ban tobacco advertising on television (1989), to label tobacco products with agreed health warnings (1989) and to limit the maximum tar content of cigarettes (1990). At the same time, the Commission proposed the introduction of a wider ban on advertising. The initial response of the European Parliament was to demand a stronger version of the proposed ban. The Commission duly obliged, and the Directive was eventually approved by the Parliament at first reading in February 1991. A blocking minority in the Health Council then delayed progress for several years. The Directive was finally adopted by Council in July 1998.

Germany announced that it would challenge the Directive, and subsequently did so: its case was submitted to the ECJ on the Kohl government's last day in power. The incoming Schröder coalition subsequently considered whether to withdraw the case but decided not to, in order, according to new Health Minister, Andrea Fischer, to test a point of law. Eventually the case submitted by Germany was joined by several UK tobacco manufacturers. Other commercial operators also submitted challenges to the European Court of First Instance, but these have been dismissed.

The Court judgement

The ECJ judgement annuls the Directive on the basis that Article 95 of the Treaty, which regulates the internal market, was not appropriate for a measure whose objective seems primarily to be health protection. In reaching its decision, the Court was guided by the opinion and recommendations of Advocate General Fennelly, published on 15 June. Fennelly had accepted some of the arguments presented by the applicants, and dismissed others. He considered that the Directive breached the principle of proportionality, the right to property and the right to pursue a professional activity. On the other hand, he had concluded that the principle of subsidiarity

was not applicable to the Directive, that it was perfectly legitimate to pursue two simultaneous objectives, namely the removal of trade barriers and the protection of human health; and that a comprehensive prohibition of advertising tobacco products would not breach the right to freedom of expression. Moreover, Advocate General Fennelly agreed that there were reasonable grounds to believe that the comprehensive prohibition of tobacco promotion would result in a significant reduction in consumption levels, probably corresponding to the saving of thousands of lives (as many as 38,000) each year.

The Court opted in favour of the tobacco industry, claiming that the *raison d'être* of Article 95 – harmonising the free movement of goods and services in the internal market – could not be used to remove completely one particular commercial activity. This despite the fact that there are now advertising bans in seven EU Member States (B, F, IRL, I, P, FIN, S) and that a further three (DK, NL, UK) have announced their intention to transpose the provisions of the Directive into national law. If the market is to be harmonised, when most Member States have already committed to ban a particular activity, it seems in all logic impossible to imagine how this can be done without introducing a total ban. Perhaps the Court senses something of a contradiction here, for it has suggested that Article 95 could be used to bring forward a much more limited proposal – namely banning the advertising of tobacco products in periodicals, magazines and newspapers. This could be justified in order to ensure the free movement of press products across national boundaries.

So now we have no advertising Directive at EU level, and the Court decision has put the Commission on the spot. Commissioner Byrne and his colleagues will have to decide whether to bring forward a new but severely limited proposal: one that is unlikely to satisfy the health lobby, for it will leave massive loopholes that the tobacco industry will be sure to exploit.

Broader implications

However, there are wider issues at stake than just the advertising Directive (however important many of us believe that to be). This whole sad saga strikes at the heart of international decision making, the role of the EU in health protection, and the failure of the body politic to respond to the needs and the concerns of the public.

First, we had a political commitment. As far back as the mid 1980s, the EU Member States committed themselves jointly to the fight against cancer. But when political commitment had to be translated into political action, some Member States began to capitulate to pressure from the tobacco industry. During the years of delay, thousands have continued to die because the interests of industry were put first. We need to bear this lesson in mind, as the Member States of the World Health Organisation begin to work on the detail of the proposed Framework Convention for Tobacco Control.

Second, the EU's co-decision process is one of consideration, negotiation and agreement between Parliament and Council, based on a proposal by the Commission. In the case of the advertising Directive, this lasted nearly ten years: much too long, but done properly. The three Community institutions – Council, Parliament and Commission – all consulted their own legal services on the appropriate legal base. All confirmed that it was right to use internal market legislation to control the advertising of a product placed on the market – taking account, at the same time, of a high level of human health protection.

Eventually, there were some winners and some losers. The losers refused to accept the decision and instead chose to challenge the majority political consensus. They did so by going to Court, thus requiring the Court to issue a legal interpretation which risked undermining a political commitment, properly reached following the application of agreed decision making procedures. This, in the event, is what happened.

Where now?

So we have a Court decision which implies that health protection is of little concern in the EU: commercial interests have to come first. A similar philosophy operated in the UK just a few years ago, when the political establishment hid the possible risk of BSE leading on to human disease. The commercial interests of the meat industry were considered more important than publicity intended to protect consumers' health.

Good governance, in the public interest, implies priority for the health and well-being of citizens. This is true both nationally and internationally. If the EU wishes to win the hearts and minds of its citizens, it has to put their interests first. In terms of tobacco control, this now means finding a way to reverse the damaging consequences of the recent Court judgement.

“Good governance, in the public interest, implies priority for the health and well-being of citizens.”

The Third European Health Forum Gastein on 27–29 September 2000 discussed five principle topics in its major fora: the citizen and communication in healthcare; implications for healthcare systems of eHealth; health targets as a tool for developing health strategies; patients' rights and citizen empowerment; and the new EU health strategy.



We focus here on the last of these – the EU's new Health Strategy. In the first article, Tapani Piha, a Counsellor on health issues in the permanent representation of Finland to the European Union, summarises the debate and conclusions of the Parallel Forum I on EU Health Strategy, sponsored by the European Commission.

In the two subsequent articles two contributors to the forum restate their perspectives on the new strategy. Eduard Rius I Pey, the minister of health for Catalonia, gives a view of the relevant issues and implication of the strategy for Europe's regions, particularly those, like Catalonia, that have a significant or even dominant role in the delivery of healthcare. Jaanus Pikani of the University of Tartu in Estonia discusses the strategy from the perspective of a Candidate Country, identifying the issues that face prospective member states in the healthcare field.

The new EU health strategy:

Moving forward through communication and debate



Tapani Piha

The European Commission's proposal of May 2000 for a new health strategy consists of several important and interlinked elements:

A proposal for a new action programme for public health;

Other measures and instruments in the health field; and

Discussion on how health is handled across all policy areas.

Proposal for a new health strategy and programme

The multi-layered structure of the Commission's proposal makes it very interesting and profound. The proposed strategy is the first overall approach to health across different policy areas in the Community.

The proposal for an action programme is a new implementation system in the making. The Parliament and the Council of the EU will elaborate and decide upon its details

during the coming months, probably before summer 2001.

The stakeholder panel in the forum welcomed the Commission's proposal for a new health strategy and action programme on public health. It was considered to be 'a qualitative leap' and 'a turning point'. But they also maintained that health still deserves a higher priority in the EU. Health is part of the European social model which can and will be our competitive advantage in the world markets.

Despite the budget of 300 million euros for the action plan over six years, health still lacks money in the European Union, especially when compared to other issues, such as subsidies to tobacco growing. The six years' duration is adequate for the action programme but a longer-term perspective is still needed.

A few specific issues were raised in the discussion:

(1) Networking and exchanging information are key elements in the strategy. The proposed EU health forum will create transparency and responsiveness in European policy making. The health forum may take many forms but to create

The Forum was chaired by Nick Boyd, Department of Health, UK, and the stakeholder roundtable moderated by Clive Needle, European Network of Health Promotion Agencies.

enhanced dialogue and networking in the European Community we shall also need other mechanisms as well.

(2) Tackling health determinants through health promotion and disease prevention is the essential third strand in the proposed public health programme. Health promotion is an essential part of the programme. For European partners, the value of exchanging experience, networking and mutual learning should not be underestimated even though these actions are not readily reflected in health statistics.

Particular attention was drawn to issues such as:

- ageing;
- mental health promotion;
- nutrition (a priority for the French EU Presidency in the second half of 2000);
- action on tobacco;
- health-oriented alcohol policy (a priority for the Swedish EU Presidency in the first half of 2001).

(3) There is a notion that inequalities in health are growing both in and between Member States. The accession of candidate countries to the EU will exacerbate this situation.

(4) The health minister of Catalonia, Eduard Ruis I Pey, made a forceful case for involving European regions in EU health policy development. (See his article in this issue of *eurohealth*.) In some countries regions have wide powers in health, not the national governments.

(5) The Tartu University Clinic in Estonia carried out a survey among members of parliaments, public health officials and professionals from EU candidate countries to learn more about their experience of EU cooperation in health. Jaanus Pikani reports on the findings of the study in more detail in this issue. Some highlights of the findings were:

- Candidate countries had participated in the EU cancer, drugs, health promotion and AIDS programmes but not in the health monitoring and rare diseases programmes. The management and funding procedures of the Phare programme were felt to be cumbersome and not conducive to participation.
- Interestingly, the respondents considered that health tourism would not be a problem.
- Candidate countries shared some issues, such as the need to develop health sys-

tems and tackle communicable diseases.

A key question is whether the new public health programme and strategy meet the needs of the EU candidate countries.

(6) Gender equality was raised by one stakeholder: mainstreaming means that the gender perspective should be kept in mind in health policy, too.

The single market and health

A harmonisation of healthcare services is excluded from Article 152 (public health) of the Treaty but healthcare is an important part of the European economy. A recent study by the European Health Management Association has found that more than 250 regulations, directives, recommendations and rulings referring directly to healthcare have been introduced since 1958. One third of them originated from the European Court of Justice. Therefore, it is justified to claim that the European dimension in healthcare does exist.

The current situation highlights the leadership challenge for health policy makers in the healthcare sector. Who leads the dynamic processes influencing healthcare in the Community?

One speaker asked whether we can move away from the situation where the Commission and Member State reactions to vital decisions of the European Court of Justice are absent and there is no consensus. Could policy-makers create extra benefits from cross-border access to healthcare?

There was a broad consensus that high quality care and equal access to it should be included in the Charter of Fundamental Rights, as advocated by the 1999 Gastein Forum. Indeed, the draft for the Charter includes a reference to preventative and medical care.

The representative of doctors made a forceful case for the right of patients to choose health services throughout the EU and emphasised their initiative on the inclusion of this aspect into the Charter.

No one challenged the continuing responsibility of Member States to organise healthcare but it was recognised that this would be modified by economic and social integration in the Community. One member state representative highlighted the real limits to the Community's capability to tackle even small issues. Prudent caution is needed.

There was a heated debate on the need for

“inequalities in health are growing both in and between Member States. The accession of candidate countries to the EU will exacerbate this”

minimum requirements to avoid a two-tier healthcare system in the EU. The opinions ranged from 'necessary' to 'not necessary nor possible'. As a compromise, guidelines and benchmarking were suggested. Several speakers maintained that a two-tier system is already emerging in Europe.

Whatever the solutions are, solidarity is badly needed in the Community now and in the future.

One stakeholder emphasised the importance of nursing in health strategies. There is a need to provide nursing education at university level in all countries though this depends on available resources. Outcome criteria need to be agreed on nursing and nursing education, including health promotion.

How healthcare issues are tackled at EU level will be one of the hot topics in the discussions in the Parliament and Council. The Commission's proposal for a new health strategy includes several elements on healthcare. The strategy acknowledges the

effects of the single market, and the action programme will provide for an information system that includes healthcare aspects.

Integrating health into all Community policies

Ensuring health protection in all Community policies and activities is an obligation clearly written into Article 152 of the Treaty.

The Commission suggested starting with key areas and put forward three elements:

- From 2001, the Commission will explain the health implications of key proposals.
- Coordination within the Commission will be increased.
- The new action programme will provide tools for piloting and better analysis.

Stimulating evidence on health impact assessment was presented from Wales and the Netherlands. Their experience suggested that serious investment in practical action is needed to make progress. It was useful also to create a permanent capacity for assessment.

Health impact assessment can aid decision making. Its uses include:

- Ensuring that health consequences of policies and actions are not overlooked.
- Showing how different policy areas can add to opportunities to improve health and increase partnerships in health.

Experience has also given lessons on the challenges:

- The enormous number of decisions makes the issue of selection a demanding and important task.
- All issues do not present themselves for assessment, for example because of lack of data.
- To be useful, the assessment must provide explicit conclusions, vague statements do not help.
- The policy process will roll on, policy makers can't wait for assessment results. Therefore discipline and strict deadlines are essential.

The emphasis on health impact assessment needs to be on its practical application rather than on theory. Managing the political consequences of the assessment results is essential. Political commitment is needed so that even the unpleasant study outcomes influence decision making. This may be facilitated if researchers can provide alternative solutions.

KEY RECOMMENDATIONS

The Commission's Communication on health strategy deserves further attention by all stakeholders; this will not be completed as part of the decision making process on the new health action programme.

All stakeholders should continue looking at the details of the new action programme, including the budget, as they will be decided by the Parliament and the Council over the coming months. Later these observations will benefit its implementation.

The Commission's forthcoming consultative proposal on the organisation of the EU health forum will need to be studied and commented on carefully by all stakeholders.

Further thinking is needed on how health inequalities should be addressed in the new action programme. One obvious task is to develop and collect indicators.

Decision makers at different levels have to be involved in implementing the European health strategy. This applies especially to regions.

Candidate countries should make stronger efforts to increase their participation in Community activities but this needs to be more than matched by Commission and member state actions on, inter alia, better information dissemination, broader partnerships and streamlined administrative procedures.

It is important to be proactive in assessing the impact of the single market on health services and to develop more sophisticated approaches.

Solidarity in healthcare as a key characteristic in the European social model and needs to be included as a component in the EU health strategy.

Capacities for health impact assessment need to be created at all levels (EU, country, regional, local) and practical assessment studies carried out.

European collaboration on health impact assessment should be strengthened by networking of research centres and policymakers which is a suitable task to be included in the new action programme.

The new EU health strategy and the regions

In May this year, the European Commission put forward the new European Health Strategy. This strategy seems to be a decisive step forward in putting health higher on the European political agenda and will provide a space for the exchange of experiences on the way health systems are dealing with today's challenges. This is a matter of particular concern to the regions, many of which, like Catalonia, have full competencies in health matters.



*Dr Eduard Rius I Pey
Minister for Health,
Catalonia, Spain.*

European health systems today face many challenges. And although health systems are different, with different levels of service and different funding mechanisms, they all face similar problems. They all have to deal with the 'three transitions' – demographic, epidemiological and technological – be it at Member State level or at regional level. The budget available to meet these challenges is limited. European economic and monetary integration, and compliance with the so called Maastricht criteria, and the economic discipline they impose, call for major efforts from all Member States and at all levels. The resulting budgetary restrictions and the need to reduce public deficits and debt have had a significant impact on all administrations and all areas of the welfare state. But the effects have been more noticeable and have been felt more strongly in the health area than in other areas of social protection.

Reforming health systems

These two quite contrary developments have sparked off a series of reforms and counter-reforms of health systems aimed at improving quality and efficiency and balancing revenues and expenditure. Although economic criteria are fundamental for the construction of a solid, competitive and balanced European Union, it would be a mistake to neglect the social aspects that have always characterised European countries – in contrast to the United States. Social cohesion is one of the pillars of the European Union, and health is a central element of social cohesion. It is also an important economic driver and can seriously affect productive sectors of the economy. In short, there is no question of the

importance of health and the health sector in the construction of Europe, yet, so far, health has not been given the priority it deserves in European policy.

The 1993 Treaty of Maastricht and the more recent Treaty of Amsterdam add a new dimension to health at the European level. However, as David Byrne, the Commissioner for Health and Consumer Protection, stated recently, "the potential to improve citizens' health is highly under-exploited". The new health strategy put forward by the European Commission thus represents a qualitative leap in European health policy. It points very clearly to an increasingly important role for health in the construction of the European Union. The new strategy will open up a new space for discussion, debate, and activity. It will facilitate the exchange of experience, networking, and mutual learning. It is a comprehensive approach to European health issues that allows for flexibility in implementation. This is a clear advantage over the previous programme, as Commissioner Byrne has pointed out on several occasions.

Objectives of the Strategy

The first objective of the public health programme, *improving information on public health*, is particularly important. It is impossible to take really informed decisions in matters of European health and health systems without better information on the similarities and differences between health systems, particularly given the growth of the internal market. Closer cooperation between the regions and Member States could be extraordinarily positive when it comes to dealing with the challenges mentioned above, as well as many others. We must learn from successful experiences in the different regions and Member States to constantly improve our health systems.

The second objective, *enhancing the capabilities of rapid response to health threats*, is a necessary response to crises such as BSE, the disappearance of borders between Member States, the free trading of goods and services, and the increased movement of people for personal or professional reasons. A health threat in one country or region is potentially a health threat for any other. This demands the development of

“The participation of the regions will be a key success factor in ensuring flexible, agile and effective implementation.”

rapid and agile warning and detection systems, and the preparation of action plans to control any possible threat to the health of our citizens.

The third objective, *addressing health determinants*, seems to continue several of the individual lines of the still ongoing public health programmes, while placing them in a broader health perspective. This more comprehensive approach is welcomed as it allows for a flexible approach to the many factors that have an influence on health, while still taking up major diseases like cancer and AIDS.

Article 152

The other important point is the *general* European Union Health Strategy. The European Commission is starting to take on the specific role assigned to it in Article 152 of the Treaty of Amsterdam ‘to ensure a high level of health protection in the definition and implementation of all Community policies and activities’. Here the European Union will have to build on the experiences with health impact assessments and the mechanisms for coordinating policy areas developed at different levels, including the regional level.

The new strategy, being more comprehensive and flexible, is both very ambitious and very challenging. It can only succeed if all participants make a special effort and the programme is well managed and coordinated. Besides its explicit goal – to influence health in the European Union – there is no doubt that sooner or later, directly or indirectly, it will influence European health systems. Decision makers at the different levels need to be actively involved in managing the future programme.

Implications for the regions

This is particularly important for the regions, especially those with full health competencies, like Catalonia. It is vital that they be actively involved in decisions on implementation of the strategy if its full potential for health in each region is to be realised and the regions themselves are to contribute fully at EU level. The participation of the regions will be a key success factor in ensuring flexible, agile and effective implementation.

We in Catalonia are also debating the role the regions and stateless nations should play in the framework of Community institutions – in the context of closer cooperation. The regions are steadily taking on greater responsibility for health issues. They are the ones closest to the citizens

and best able to detect and evaluate their specific problems and needs. That is why health (at least as far as organisation and management are concerned) is increasingly a local issue, with a less state-centred, more regional focus.

Catalonia, for instance, has had competence for health issues since 1981. The transfer of powers and capacity of action has allowed Catalonia to develop a health system model that differs significantly from those of other autonomous regions in Spain. The separation of financing and provision; a private-public mix and the integration of not-for-profit organisations in healthcare provision; tools such as the Catalan Health Plan; programmes such as ‘Vida als Anys’ (Life to Years); and the advanced interface with the social sector (home care and long-term care): these are features that define our health system model. They have enabled it to respond more effectively to health needs in Catalonia, such as those deriving from an ageing population, which has become an EU-wide challenge.

A moving target

On the other hand, as we have seen, the challenges to health and health systems will grow, especially in connection with the freedoms of movement within the Community. These freedoms will have an increasing impact on health systems and their main elements: financing and provision. This must be taken into account in the overall design of EU health policy. If the EU is unable to assure the coverage of EU citizens – when travelling within the Community, for example – then it will have failed in its mission as stated in Article 152 of the Amsterdam Treaty ‘to ensure a high level of health protection’. There is a clear role for the Commission in facilitating coordination between the different EU health systems. Stronger coordinating mechanisms and improved information on health and health systems will be a first step in the right direction, together with the other proposed measures to actively promote health protection in key areas of Community activity.

Catalonia has been, and still is, actively involved in a wide range of existing EU health projects. We look forward to taking full advantage of the new EU health strategy, and we are well equipped to contribute to its implementation – with our experience and with our human and other resources. However, this strategy can only succeed if the EU regions are actively involved in the construction of a healthy Europe.

“Social cohesion is one of the pillars of the European Union, and health is a central element of social cohesion.”

The view of the candidate countries



Jaanus Pikani

“a more positive attitude to enlargement would be very welcome at various institutional levels within the Community”

The new EU Public Health Strategy has been received with great interest in the ‘health arena’ in Europe, and also in the accession countries. Indeed, the strategy places particular emphasis on the importance of enlargement for public health policy in Europe in the future. It points out the specific and often more serious health problems in the candidate countries, and the limited resources they have available to devote to health.

We wanted to find out the candidate countries’ opinions on the new health strategy: how it meets their needs and expectations, how they have participated so far in the various EU health programmes, and any positive experiences or concerns they might have. To do this, the Tartu University Clinics in Estonia conducted a survey of politicians, public health officials and health professionals in candidate countries. Through this rather informal survey we were able to learn more about their experiences in ongoing EU health programmes and obtain their views on the new strategy. The questionnaire was mailed to various people in all the candidate countries, and responses have been received from a total of nine: Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Slovenia, and Slovakia.

The existing EU programmes

Existing EU public health programmes have been open to candidate countries since 1998, but the opportunity to participate has been taken up only very slowly. In the crucial Health Monitoring programme, in particular, the participation so far is nil – and Estonia is no exception here. The reason for this is not, however, lack of interest. The main difficulty lies in earmarking the necessary funds in state budgets, and overcoming unfamiliarity with the bureaucratic hurdles of the programmes themselves. Another important factor was pointed out, namely the problems of communication and information flow with the Commission. On the other hand, the fact that the Commission has shown flexibility, especially with respect to the involvement of candidate country representatives in programme committee meetings, was acknowledged as a positive point.

Despite the general feeling that participation in the programmes is at a very early stage and that it is too early to draw meaningful conclusions, some common benefits gained from participating in programmes were mentioned. The overwhelming opinion was that active cooperation in Community public health programmes has brought a measurable increase in knowledge, experience and skills among the experts in candidate countries. In particular, the growing exchange of information between candidate countries themselves was mentioned as a significant gain.

Assessment of the new strategy

Candidate countries’ initial assessments of the European Community’s New Health Strategy use adjectives such as ‘innovative’, ‘realistic’, ‘comprehensive’ and ‘instructive’. The document was described as broad, detailed and comprehensive, involving nearly all health sector activities. At the same time it was seen to reflect an awareness that public health is not the responsibility of the health sector alone but is influenced by other areas. The strategy document will be useful as a base for candidate countries’ own strategies. It provides tools and information they can use to catch up with European standards and ‘ways of doing things’ in the different areas of public health. It is also a good basis for tackling the challenges created by the single European market. The commitment to involve NGOs such as patient organisations and other health-related associations in health policy at the European and national level in the search for better health and greater cost-effectiveness and quality of health systems in Europe was seen as very positive.

The existence of Community public health programmes helps to underpin the importance of health programmes at the national level, especially as regards the allocation of funds in restricted state budgets. All countries have limited funds, but in the case of the candidate countries the economic transition led to a massive economic downturn from which they are only slowly recovering, some faster than others. Along with the benefits of EU membership, accession to the EU will bring further limits on

I would like to thank Krista Kruuv, Tartu University, for her help in carrying out the survey and all those in the candidate countries who took the time to respond to it. Particular thanks to Magdalene Rosenmöller, IESE, for comments on an early draft of this paper.

public spending if the candidate countries want one day to satisfy the Maastricht criteria. Additionally, for some countries, actual or projected NATO membership has meant having to allocate extra funds to defence.

Cooperation at the European level, through participation in EU programmes, can make national programmes more effective and easier to implement. For this reason, the plan to extend ongoing public health programmes, assuring continuity of actions, was welcomed.

Participation

Although all three key areas of the new strategy were considered to be of great importance, the first objective, improving health information and knowledge, was cited most frequently as an important area in which to participate. One 'heritage' the candidate countries have to deal with is the fact that, in former times, statistics were only ever compiled for the sake of collecting numbers, not to support policy making. It is extremely important that they continue improving data collection methods and the use of information for policy making. Collaborating with EU Member States and regions will help them do this. There are big differences between the healthcare systems of the accession countries, so enlargement will increase the diversity of health system models in the Union. Therefore, it is very important to focus on information that will allow comparisons between the different models at EU and candidate country level, particularly in view of the challenges posed by the internal market.

As far as the second objective is concerned, threats to health know no borders, neither within the EU nor between the EU and future Member States. The alarming increase in resistant forms of tuberculosis (TB) and the arrival of AIDS in central and eastern Europe are the most noteworthy factors calling for collaboration, coordination and mutual learning.

With regard to the third objective, the candidate countries welcome the move away from the previous illness-focused approach towards a broader concept of health determinants. The accession countries have already participated with some success in previous programmes. Although health and health systems in candidate countries are usually treated as if they were all the same, in fact there are big differences between countries and many problems are country specific. If the strategy is to be successful, a more country-specific analysis and a will-

ingness to deal with issues specific to each country would be a great advantage. For this to happen, the countries concerned need to be much more actively involved.

Amsterdam and the accession process

The general strategy – ensuring respect for health issues in EU policy – fulfils the Treaty of Amsterdam mandate “to ensure a high level of health protection in the definition and implementation of all Community policies and activities”. So far, this has been rather neglected in the accession process, in which economic criteria, and the ‘hard’ *acquis communautaire*, have taken precedence over health. This will have to change if the commitments of the Amsterdam Treaty are to be taken seriously. Indeed, the main concern voiced in our survey was that in the general accession process health issues are not considered a priority. There is a big gap between candidate countries and EU member states in health status, economic situation, and health systems. This could be a source of major problems in the future, even though all candidate countries are actively engaged in reforming their health systems, at varying speeds and with varying degrees of success. In this context, an interesting finding from the survey is that there is an unambiguous feeling among candidate countries that ‘health tourism’ and an ‘outflow of doctors’ will not be a serious problem in the accession process.

The accession process itself is not easy. But there are plenty of unnecessary hurdles, such as when countries are required to meet certain criteria – in the specifications of chemical substances, for example – and yet access to the corresponding database is ‘for members only’. How can candidate countries meet EU standards or *acquis communitaires* if they do not have access to the necessary information? Here, a more positive attitude to enlargement would be very welcome at various institutional levels within the Community.

Implementing the new strategy will be a great challenge because it is so comprehensive and so flexible. Great efforts will have to be made on all sides. And it is important that candidate countries are involved early on in the implementation process if the strategy is to be successful and achieve the ambitious goals that have been set. Properly implemented, the new EU strategy will help to reduce potential ‘threats’, and improve health and health systems in countries across Europe, including the candidate countries.

“If the strategy is to be successful, a more country-specific analysis ... would be a great advantage.”

Health services and international trade: the role of the European Commission



Pascal Lamy

*“the panorama of the
healthcare sector is
progressively
changing”*

Universal access to healthcare services may be considered as one of the most significant features of a social system based on the principle of solidarity. In fact, the direct impact that health services have on the welfare of the population makes this sector a foundation of the social system of any country,

a key element that makes a fundamental contribution to the quality of life.

In line with the health chapter of the Amsterdam Treaty, this strong conviction has led the European Union to adopt as a primary objective of its policy the attainment of a high level of health protection for Europe’s citizens. In its recent Communication on the health strategy of the European Community, the Commission set out how it is working to achieve a coherent and effective approach to health issues across all Community policy areas. It is essential that all the Community’s activities that can affect health contribute to the overall strategy, and that health is given due weight in developing and implementing policies and actions. The trade aspects of that policy are of course only one important element among others. However, I am quite convinced that trade policy may play a significant role in contributing towards the achievement of these objectives through two different channels: first, the international negotiations on services under the GATS (General Agreement on Trade in Services) and second, as an important part of the more global Commission initiative for better access to health worldwide, especially in the developing countries.

International negotiations in services

We are in a situation where the panorama of the healthcare sector is progressively changing. It is becoming more dynamic in terms of interactions between an increased number of actors and of the technological potential that can move medicine closer to the patient.

One of the consequences of this process is that possibilities in offering the supply of health services across borders are increasing. This is particularly evident in the case of e-health, where cross border trade may offer countries various advanced care services and the services of professionals from other parts of the world, which could enhance the general quality of care.

In view of these developments we must pay an increasing attention to the regulatory framework applied to the trade of health services under the WTO system, and in particular under the GATS, which establishes a set of rules for trade in services and creates a ground for WTO members to undertake commitments for the opening of their market to foreign suppliers.

The European Community and its Member States, within the framework of the Uruguay Round negotiations, have made commitments with regard to health services, in particular with regard to the provision of hospital services by foreign suppliers in the territory of the European Union.

In practice, this means that foreign operators can establish private hospitals in the Community and that such hospitals will be treated as if they were owned by Community nationals. This being said, the EU has reserved its right to subsidise its public sector without any commitment to extend this benefit to private operators.

For the GATS 2000 negotiations, the main focus will most probably be movement of consumers and development in the field of e-health. E-health or telemedicine already accounts for an estimated six per cent of the European information technology market and two per cent of the European healthcare market. Its development could improve the quality of healthcare, in particular in cases where a doctor – generalist or specialist – will request a specialist, who can be located in a foreign country, to give a second opinion on his or her diagnosis. This could be most helpful in areas, either remote or where population is scarce, where hospitals cannot offer a full range of specialists.

It must be underlined that this has not and will not impede EU countries in establishing and defining the safety and quality of the health sector in the manner that they consider the most adequate. All WTO members, even for areas that have been opened to foreign suppliers, maintain their sovereign right to regulate the activities within their territory and to guarantee the achievement of legitimate public objectives.

“It is essential that all the Community’s activities that can affect health contribute to the overall strategy... we are quite convinced that trade policy may play a significant role.”

The right of each European country to define a specific and appropriate regulatory system for the health sector includes also the possibility of determining an adequate system of subsidy to the public health sector. This may be necessary to maintain or increase the quality standards and the social objectives that are at the basis of their health system. Such principles are clearly in line with the Communication on services of general interest, recently adopted by the European Commission. This Communication gives each EU Member State the ability to ensure the guaranteed access of each citizen to much needed services, which are essential to the realisation of economic and social cohesion.

During the new process of negotiations in the field of services that was initiated in January 2000 (GATS 2000) in accordance with the built-in agenda agreed at the end of the negotiations of the Uruguay Round, the specific characteristics of the health services will be taken into account, in order to guarantee that further opening will not serve as an instrument for the mere promotion of the commercial interests, but rather represents an opportunity for ensuring the improvement of health conditions and the development of new health technologies. Improving the conditions of access to the markets cannot be dissociated, in particular in the health sector, from the objective of contributing to the enhancement of the quality of life and wealth of the population.

Improving worldwide health access

In line with the G8 orientations taken in Okinawa last July, the European Commission has decided to tackle the issue of access to health services in the develop-

ing world, with a special emphasis on HIV/AIDS, malaria and tuberculosis. We are convinced that the international community needs to step up its efforts, both at public and private level, to find the appropriate solution to this intolerable situation of human suffering.

Following the adoption of a global Communication on health access, the European Commission recently organised a Round Table with all the parties interested. We have now reached a consensus in particular on the need to increase the affordability of key pharmaceuticals. There was also a clear acknowledgement that effective progress is only possible through a comprehensive global approach including streamlined efforts of development aid and increased focus of public and private research and development activities on these diseases.

As far as trade matters are concerned, our objective is to continue to work in several directions:

- first, to explore together with industry whether voluntary licensing constitutes an adequate and appropriate method of obtaining increased access to medicines;
- second, to contribute to the facilitation of tiered or equity pricing systems, whilst avoiding re-importation of the cheaply exported products;
- third, to further examine the impact of import duties and taxes in developing countries on the price of key pharmaceuticals;
- and last, to aim at a full implementation of the TRIPS agreement, including those disposals that give the necessary flexibility to address public health concerns and emergency situations.

Health is increasingly recognised as a public good. Given the level of public concerns in this field, I consider it very important to maintain an open and continued dialogue with all those organisations and institutions that have an active interest in health aspects of trade policy. It is in fact only through active cooperation with all interested parties (representing third countries, involved international organisations, industry, consumers and professional associations) that it will be possible for the European Community and its Member States to carry out a well focused and adequate policy for health services in the on-going GATS negotiations and to address the urgent needs of health access in the developing world.

“effective progress is only possible through a comprehensive global approach”

Global trade liberalisation: challenges and opportunities for world health



Elke Jakubowski



Henry W. Wyes

“WHO has the mandate to make public health a priority in trade agreements.”

Trade in goods and services plays an increasingly prominent part in the economies of both rich and poor countries and for several decades the value of trade has grown at least twice as fast as the world economy. It now accounts for a quarter of the world's GDP. Trade has come to be an essential source of income since the creation of the General Agreement on Tariffs and Trade (GATT) in 1947, and thus has been integral in the positive correlation of economic growth and health.

Recent developments have led to an increasing liberalisation of trade at the global level. The international community has adopted a rule-based approach under the aegis of the World Trade Organisation (WTO). The WTO is a membership organisation established in 1995. It determines multilateral trade policies and provides a political framework for further trade liberalisation through its ministerial meetings. A number of trade agreements have direct implications for health:

- Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)
- Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)
- Agreement on Technical Barriers to Trade (TBT)
- General Agreement on Trade in Services (GATS)
- GATT 1994, which contains the main exception for public health in article 20B, and its progenitor the GATT 1947

The entire policy area of import and export subsidies for tobacco, as covered by the Agreement on Agriculture, also has direct effects on health.¹ During the current Millennium Round of trade talks, it is expected that WTO's General Agreement on Trade in Services (GATS) and the Trade Related Aspects of Intellectual Property Rights (TRIPS) will be revised with major implications for healthcare and health.^{1,2}

The expected trade revisions run parallel to a debate on the public health implications of trade. Evidence on the extent to which liberalised trade is affecting health is not readily available, though global trade

determinants of health and possible areas of research have been identified by Bettcher et al.¹ A number of observations and positions on the world health impact of liberalised trade can be identified.

Health impact of world trade

Among the direct public health benefits of liberalised trade is the expansion of the global market for health goods including drugs, medical devices and telemedicine products, which could lead to a global increase in the availability of health goods. This may already have affected decisions regarding which diseases receive national and international resources, enabling, for example, a global consensus on eradication or elimination of certain diseases representing global threats.

Health on the global agenda

In addition, health has been firmly established on the global policy agenda as it has been acknowledged that with increasing economic globalisation phenomena such as the liberalisation of trade, domestic action alone can no longer ensure people's health locally. It is also well understood that achievements in health are critical to the fulfilment of international development goals, and the liberalisation of trade agreements has allowed more foreign investment in health services.

Health has found an entry into the G8 discussions, the Davos Summit, the UN Security Council, and the European Union. It was an integral part of the millennium discussions in many countries. Although it is too early to draw conclusions, it can be argued that enhanced international, governmental and intergovernmental health protection activities will contribute to the improvement of the world's health.

However, there are also some substantial health risks deriving from liberalised global trade.² For example, there are some direct health risks resulting from the movement of goods, people, and services, most evident in relation to international trade in contaminated foodstuffs, living substances, illegal goods, and trade of harmful goods such as tobacco.³

We would like to thank Douglas Bettcher and Franklin Apfel for comments on earlier versions of this article.

Liberalised trade can lead to more imports of health goods into healthcare markets, in particular in light of vast electronic communication practices. For example, the pharmaceutical industry might be stimulated towards market introduction of drugs that have limited therapeutic value. This can result in increasing pharmaceutical sector expenditure. Liberalised trade also increases the danger of introducing pharmaceuticals that do not comply with international efficacy and safety standards. It might equally lead to the unhampered dissemination of medical technologies.

Health implications of trade in (non tangible) health services are not yet perceived to be a major issue but carry the potential to impact on the public-private mix of financing. An increase in the level and role of private financing can for example be expected in the context of many European healthcare systems where public finance in social health insurance systems and national health systems so far predominates. This might raise concerns about equity.

Amongst the most compelling arguments calling for a global protection from the health risks of trade liberalisation is the fear that liberalised trade will enhance the world health divide, with rich populations having access to effective vaccines and antibiotics that are financially or logistically inaccessible to many poor populations. Fifty per cent of people are already deprived of essential drugs in the poorest parts of Africa and Asia.⁴ Such concerns have fuelled developing countries' hesitation to sign the TRIPS agreement. They fear that applying strict patent protection regulations would lead to an escalation of costs of essential medicines and would have an increasingly negative effect on access to medicines and manufacturing technologies.⁵

To combat these concerns, a number of measures have been suggested for reducing the risk of public health exclusion or marginalisation of poor populations. These include the exclusion of a set of life-saving and essential medicines from privatisation and trade liberalisation and effectively from certain TRIPS rules.² Potentially, for the development of such a list, WHO's essential list of drugs could be a starting point. Among other measures suggested is the simplification of the development of generic drugs.

The role of WHO

WHO's role in the debate is ubiquitous as WHO has the mandate to make public

health a priority in trade agreements.⁶ The Organisation has started to utilise its constitutional authority to promote the development of international law to protect world health. In May 1999 the 192 member states of WHO endorsed a resolution, which set the negotiation of the Organisation's first legally binding convention in motion: the Framework Convention on Tobacco Control.³ The framework convention is expected to provide an international framework for tobacco control policies and to set standards that countries can adopt to control advertising, prevent smuggling and facilitate the global exchange of knowledge.⁴

WHO has also developed and achieved international consensus on norms, standards, and guidelines in the area of pharmaceuticals that could serve as the basis for international trade agreements. In the area of food, the international body of the FAO/WHO Codex Alimentarius sets the international trade standards.

Furthermore, WHO handles and disseminates health information as a public good, such as essential information on the rational use of drugs and best practices in cost-effective treatments of basic conditions. The Organisation calls for stakeholders to regard essential drugs and their research and development as public goods, in order to benefit both the patent holder and the public, and it strongly supports development of mechanisms for preferential low prices for essential drugs in lower income countries.⁴ In addition, the Director General of WHO has recently invited "governments, industry, NGOs and other partners to establish with WHO an appropriate mechanism for monitoring the actual effect of new trade agreements."⁷ There are also new and promising institutional developments within WHO, such as the WHO Commission on Macroeconomics and Health, launched in January 2000, and the Massive Efforts programme on communicable diseases.

It is hoped that these measures will increasingly come to advise trade disputes that have environmental and public health implications.

With respect to the challenges and opportunities for world health deriving from global trade liberalisation, WHO has been called upon as an independent provider of knowledge and evidence to expand and share knowledge on the effects of globalisation on health and to outline appropriate public health policy responses to trade, investment and development work.

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Trade in health services: In whose interests?

Trade negotiations have direct and indirect implications for health systems and service provision. However, healthcare and health related markets are not typical markets and health related goods cannot be traded in the same way as other services and goods. It is of the utmost importance that this is recognised and it has particular relevance to current trade negotiations. In terms of overall national and European interests, properly functioning, accessible and equitably financed healthcare systems are more important than sectoral commercial interests in health and healthcare products.



Meri Koivusalo

The organisation and financing of health services varies between European countries but for most of them a common feature is their universal coverage and solidarity in financing. However, in practice health service provision in most European countries is not a pure public service, but involves private actors or contractual relationships making services potentially tradable in most countries.

Globalisation and emphasis on global seamless service provision has created both the supply of and demand for more commercial interests in healthcare markets, as well as mechanisms to deliver these through telemedicine and internet services across borders and 'globally'. It has been estimated that the health services sector in the OECD countries alone accounts for US\$3 trillion annually.¹

The saturation of healthcare markets in the United States has also created the need for service providers there to expand into other markets. This has been made explicit in statements by the United States services industry with the first priority aim for the negotiations being to achieve maximum liberalisation in all modes of supply across the widest possible range of services, as soon as possible. A second priority is to fully embrace important new sectors in the liberalisation efforts, including education and health.²

Negotiations on trade in services will have direct implications for health policies governing movements of persons supplying services, movement of consumers, foreign

commercial presence and cross-border trade in health services. However, in practice negotiations on trade deal as well with broader aspects of healthcare such as trade in pensions, insurance, home care, community care, nursing services, laboratory services, rehabilitation and other related services such as hotel services, catering, computers and hospital building and management. In addition, trade negotiations in other areas, such as government procurement practices, trade related intellectual property rights, competition, subsidies and investment may have substantial and largely unanticipated implications for healthcare.

In most European countries health systems are still considered mostly in the national context, with little concern for trade and investment policies. This means that the influence of trade agreements on regulatory measures, organisation and resources in healthcare is often driven by trade, rather than health related or public interests. This process can be defined as 'trade-creep', as much of the decision-making and priority setting is made outside the health sector.

Trade agreements are legal international agreements and a key issue is to understand fully their policy implications at national level. These agreements set the regulatory framework for global trade in goods and services and set rights and obligations for governments and commercial actors. It is thus of importance that decisions made in the context of trade or interpretations of these commitments do not undermine the functions and organisation of health services, health related regulatory efforts or the priority of public health considerations over commercial rights.

GATS and trade in services

In health systems and service provision commercialisation tends to increase costs and decrease equity. In most European countries there is a reluctance to let transnational commercial actors establish an increased role in service provision, yet

“Ministries of Health may not understand fully the legal implications and details of trade agreements”

there seems to be little discussion on how these concerns can be respected and taken into account in trade negotiations.

In the General Agreement on Trade in Services (GATS), specific concerns relate to definitions and interpretations of issues such as public services and progressive liberalisation. The agreement on trade in services is committed to progressive liberalisation of services, thus implying a regulatory framework of progressive opening of healthcare markets. The text in the Agreement on trade in services makes a clear exception for public services stating that a service supplied in the exercise of governmental authority means any service which is supplied neither on a commercial basis, nor in competition with one or more service suppliers. The main question is how this is interpreted in practice.

In most European countries decentralisation, public-private partnerships and contractual arrangements in service provision have changed how public services are delivered and, technically, the practice of purchasing services may well imply that these can be considered in competition with private commercial suppliers. In many social and health insurance based systems in Europe private providers are a crucial part of the health system.

Thus, in practice, in most European countries, health service provision is in direct competition with commercial providers owing to decentralisation and public management practices or healthcare organisation based on insurance. However, while private sector actors and non-governmental organisations may be used frequently in service provision in many countries, national and regional governments and service purchasers may not be aware of the potential implications of opening such markets to global competition. In addition, even if government contracted services would be excluded, they may be considered in the context of multilateral negotiations on government procurement practices.

Regional and local governments or social insurance organisations may not be aware of the detailed contents of international commercial contractual policies governed by agreements on trade at global level. The questions to be raised deal with, for example, contracting from, and subsidies to, local non-governmental private providers if access to market and similar benefits are requested by the more commercial transnational service provision industry.

There is a danger that trade agreements

could bind the provision of health services to practices designed to serve the interests of commerce. In most countries no proper analysis has been undertaken of the potential impacts of trade agreements on health service costs and organisation at national and local levels. Furthermore, it is unclear to what extent equity in access to services, financing healthcare or maintenance of quality or costs of services and health technologies are considered agreed aims for domestic regulation in trade negotiations. Health services are not like telecommunications or bus services and the quality of health services is far more difficult and complicated to measure and to regulate. In addition, when international actors are involved in service provision the scope for reversing the policies or imposing government regulatory action may become severely limited and result in the increasing presence of private sector and market interests in healthcare provision.

Health and European trade policies

In the Treaty of Amsterdam the European Community is committed to maintaining a high level of health protection and integrating health considerations into all Community policies. Decisions regarding the financing and delivery of social and health services are also established as a national level mandate. At European level the European Commission deals with negotiations on trade and, so far, intends to start from a broad agenda. The questions are whether health issues may become compromised in this process due to other more vocal interest groups and how to ensure that national decisions on health services and systems are duly respected in the course of trade negotiations at the European level.

The Agreement on Trade-Related Intellectual Property Rights (TRIPS), in practice, increases pharmaceutical costs by raising the prices of patented medicines. Peter Drahos has pointed out that in practice TRIPS was not the product of coordinated economic analysis. Rather it was the manifestation of the rent-seeking desires of those multinationals that saw opportunities for themselves in redefining and globalising intellectual property rights.³

Pharmaceutical costs are paid by the sick or through health budgets. Any enhancement of TRIPS protection will have implications for costs and practices in healthcare and especially in the area of pharmaceuticals, diagnostics and other health technologies. This means that negotiations on TRIPS

“health systems are still considered mostly in the national context, with little concern for trade and investment policies”

related issues need to be accountable, in terms of their health and health policy consequences. Otherwise the benefits to the industry might overtly bias the European negotiation stance on trade-related intellectual property rights. This becomes even more important as pharmaceuticals are mostly dealt with in the context of industrial policies at European level. Special efforts are needed to ensure that health considerations, including pricing, trademarks and access to information, are adequately addressed.

In terms of governance, issues of accountability, transparency and policy priorities are of concern at European level. Ministries of Health may not understand fully the legal implications and details of trade agreements, and the national focus in health policy is evident in European level policies. Health policies have not been adequately considered during previous trade negotiation rounds. The European Commission is currently organising civil society consultations, with the only contribution so far on health services being from the European Health Care Management Association

(EHMA). European trade policies have to be aware of conflicts between health policy priorities and commercial interests. European governments and decision-makers need to ensure that health concerns and public interests are not compromised during trade negotiations.

NOTE: A longer document on WTO and 'trade creep' as well as reports on integrating health in other policies in Europe are available from the publications section as downloadable occasional papers in GASPP web-pages: www.stakes.fi/gaspp.

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The WTO-TRIPS Agreement: areas of dispute and implications

Under the WTO-TRIPS Agreement, Member States must grant patents, for a minimum of 20 years, to any invention of a pharmaceutical product or process that fulfils the established criteria of novelty, inventiveness and usefulness. The Agreement represents a major step towards the establishment of global recognition of intellectual property rights. At the same time, it poses a number of questions, which are not dealt with fully in the text of the Agreement and may generate significant friction in the near future.



Panos Kanavos

“intellectual property rights protection is a necessary condition for allowing new treatments to reach the global market place”

Four areas are likely to attract a great deal of attention in view of their ambiguity within the context of TRIPS and the number of cases already presented in the WTO's dispute panels.

- Compulsory licensing (Article 31).
- Parallel imports (Articles 7, 8 and 30).
- The facilitation of accepting application for and granting exclusive marketing rights (Article 70.9).
- Roche-Bolar provisions (Article 30).

Compulsory licensing

Compulsory licensing by the judicial or administrative authority refers to the legal right to grant a license to produce a product without permission from the patent holder, on various grounds of general interest. While the TRIPS Agreement does not refer to compulsory licensing, article 31 does address “Other use without authorisation of the right holder”, and sets out the minimum conditions that must be met in countries to allow for other use. Article 31 of the TRIPS Agreement details the set of conditions under which licenses can be granted. These are:

Public health and nutrition or other reasons of public interest.

National emergency and extreme urgency.

Public non-commercial use.

The presence of anti-competitive practices.

Dependent patents.

Environmental protection.

Refusal of a voluntary license .

Other grounds based on domestic law.

Compulsory licensing presently exists in the UK, France, Israel and Germany, but it is very rarely invoked. Canada abolished it

in 1993 with the introduction of Bill C-91. In principle, article 31 does not limit a country's right to use compulsory licensing as they deem it warranted on the basis of the conditions outlined. The use of such a measure is inexorably linked to the process of pharmaceutical pricing in different countries. If a pharmaceutical product cannot be afforded by a number of countries, then it seems plausible to introduce compulsory licensing on several grounds, including public health, anti-competitive practices, etc. Likely candidates include, in the first instance, many middle income countries, for which the arguments of benefits accruing in terms of technology transfer do not really apply, due to their weak production linkages. Interestingly, however, the issue of affordability has also sparked a debate in the US through the discussion of the Affordable Prescription Drug Act (Sept 1999) in the US House of Representatives to address the high cost of prescription drugs and their high price increases (by 84 per cent between 1993 and 1998).

Parallel imports

In this case, the imported product is available at a lower price than is available from the domestic patent holder. The TRIPS agreement does not *explicitly* prohibit parallel imports. Article 30 of the TRIPS Agreement sets out exceptions to the exclusive rights of patent holders and these are subject to the conditions that they must:

- be limited;
- be duly justified;
- not negatively affect the patentee's interests.

Articles 7 and 8 (in particular paragraphs 8.1 and 8.2) also address the types of exceptions open for consideration. Particularly article 8.2 legitimises appropriate measures taken to prevent the abuse of intellectual property rights that unreasonably restrain trade or adversely affect the international transfer of technology.

Each of these articles contributes a basis for the appropriateness of parallel imports. They balance the interests of consumers and the patent holder, address the need for social and economic welfare in the application of the Agreement, and they can be used

to protect public health and promote international technological advancement. Of course, significant variations are present in the acceptance of parallel imports for pharmaceuticals by trade or economic areas such as NAFTA, where parallel imports are not allowed, and the EU, where parallel imports are legitimate. The possibility of resorting to parallel imports due to cost differences can be expected to intensify the debate about the extent to which these should happen. One such case is the Philippines' parallel importing from Thailand, on the basis of lower market prices in the latter that would benefit the former.

Exclusive Marketing Rights

Article 70.9 of the TRIPS agreement establishes the right of a patent holder to obtain 'exclusive marketing rights'. This would allow companies who have filed an application for a patent in a WTO member country, to market their product without market competition for a period of five years, or until the patent application is decided. Article 70.9 states that pending the granting of a patent, exclusive marketing rights shall be granted during the transitional period to patent recognition, as from the time the invention receives marketing approval. The conditions are that a marketing authorisation for that same product must have been obtained in another WTO member state, and a patent for the product must have been granted in that same state.

The reason for debate on this Article is that it does not mention the content and scope of 'exclusive marketing rights'. Several issues remain unaccounted for and in need of a resolution. These may include one or more of the following:

- To what extent could the holder of such rights prevent others from marketing the product concerned?
- What recourse would the patent holder have against infringement?
- Would the provisions on granting compulsory licenses be applicable?
- What procedures would be available to third parties wishing to use the invention, for example, for experiments, test, marketing approval, etc?

'Roche-Bolar' provisions

In the US, Canada, Australia and other countries, experiments and tests required to secure regulatory authorisation to market a generic drug can take place, and applications for approval submitted, prior to patent expiry, without the consent of the

patent holder. This patent infringement exemption is termed a 'Roche-Bolar' provision. Such provisions were first introduced into US legislation as part of the 1984 Hatch-Waxman Act. They allow generic firms to compete in the post-patent market almost immediately following patent expiry.

Due to the provisions of Article 28, providing that a patent confers on its owner certain exclusive rights, and Article 30, allowing exceptions to the exclusive rights, it is not clear whether Bolar provisions are in compliance with the TRIPS agreement. In particular, what constitutes a legitimate exception is not set out explicitly. This ambiguity favours generic medicine manufacturers in countries where Bolar provisions do exist (e.g. the USA, Canada, but not the EU), and are a bargaining platform for the generic industry in countries where Bolar provisions are not permitted. That is, the generic industry in these countries may argue that adopting Bolar provisions would not infringe international regulations for intellectual property. The EU-Canada dispute over stockpiling within the context of Roche-Bolar provisions, highlights some of the issues involved.

Final remarks

There is no question that intellectual property rights protection is a necessary condition for allowing new treatments to reach the global market place. It is not a sufficient condition though, as cost elements and affordability may hinder many countries from allowing access to new medicines. One argument in favour of patent recognition, often cited by industry, is its positive impact on the transfer of technology to recipient countries. This may nevertheless be counter-intuitive, as the benefits to the multinational pharmaceutical industry from transferring technology are far from clear. By contrast, manufacturing facilities of foreign subsidiaries may be dismantled after the introduction of pharmaceutical patents. In this case, medicines are imported into the country in finished form, and subsidiaries act as distribution centres only.

This is implicitly recognised by the WTO-TRIPS Agreement, and *in principle* it has a number of provisions in place that potentially enable parallel importing, compulsory licensing, and limitations on market exclusivity, and it is ambiguous enough about Bolar provisions. However, the testing of these provisions on a large scale may highlight some of the limitations of the Agreement *in practice*.

"The Agreement represents a major step towards the establishment of global recognition of intellectual property rights."

Europe is beginning to address the crisis of global access to medicines

One third of the world's population lacks access to essential drugs. In the most impoverished parts of Africa and of Asia it is more than 50 per cent. Killers such as tuberculosis (TB) and malaria continue to claim millions of lives in the developing world. Over 75 per cent of the world's population live in developing countries but they account for only eight per cent of pharmaceutical sales worldwide. The AIDS epidemic is also exacerbated by lack of access to medicines. Ninety five per cent of the 34 million people with HIV/AIDS remain without access to treatment.



Ellen 't Hoen

Many factors contribute to the problem of limited access to essential medicines. Unavailability can be caused by prohibitive prices, logistical supply and storage problems, substandard drug quality, irrational selection of drugs, wasteful prescribing and use, inadequate or abandoned production, and insufficient drug research and development (R&D). A main concern are the repercussions of the World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in the pharmaceutical field.¹

Pharmaceutical patents and prices

The TRIPS agreement sets out minimum standards for the protection of intellectual property rights, including a minimum 20 year patent term. Implementation of TRIPS will lead to further drug price increases and will affect developing countries' capacity to produce affordable, generic versions of life saving drugs. It is unlikely that the TRIPS agreement will encourage adequate R&D in developing countries for diseases such as malaria and TB. Developing countries are now under the obligation to provide patent protection but they do not get the full share of the bargain since global R&D investments continue to be geared towards priorities and market opportunities in the more affluent countries.

TRIPS safeguards

The TRIPS provides for safeguards against negative effects of patent monopolies. Compulsory licensing is one of those safe-

guards that can help to remedy the negative effects of patent monopolies where a license is granted to a third party without the patent holder's consent. Another option is parallel import of cheaper patented branded products from other countries.

Whether these provisions can be effectively used remains to be seen. Developing countries are under pressure to refrain from implementing them.² In 1998 the then vice president of the European Commission, Sir Leon Brittan, wrote to vice president M'Beki of South Africa in response to its proposed medicines act, which included a provision for compulsory licensing and allowed for parallel import: "... the law in question would appear to be at variance with South Africa's obligations under the WTO Agreement on TRIPS and its implementation would negatively affect the interests of the European pharmaceutical industry". Both compulsory licensing and parallel import are legal under the TRIPS agreement and parallel import is a legal and common practice within the EU.

Patent protection is meant to encourage R&D and to protect those that invest in innovation. True innovation should indeed be encouraged and protected by a solid intellectual property rights system. Industry stresses the role of patents to protect the R&D investments, but fails to mention that a substantial part of the financing of research and development of important medications comes from public sources. In the USA an average of 55 per cent of the cost of clinical trials for 14 HIV/AIDS drugs presently marketed, is funded by the government.³

Europe's role

The EU is a powerful voice in trade issues and the European Commission plays an important role in representing the Member States in international trade policy. The trade representatives of the European Commission intervened on a number of occasions in international and national

health policies when these policies threatened to affect the interests of the European pharmaceutical industry. Unfortunately for the developing world, until now the European Commission's loyalties have been with industry. But there are signals that this may be changing.

A year ago at an international conference on Access to Essential Medicines in Amsterdam organised by Médecins Sans Frontières, Health Action International and Consumer Project on Technology, the European Commission representative Mrs Hvid said: 'Intellectual property rights are vital to correct the market failure of supply of essential drugs to developing countries and to create a growing market for drugs to combat life threatening diseases. Allowing essential drugs to be excluded from patentability would be a short sighted solution and would have serious long term consequences.' She questioned the usefulness of compulsory licensing because "the right holder needs to be paid adequate remuneration" and said that as parallel imports do not lead to the creation of new effective innovative products against diseases such as malaria, TB and HIV, their long term benefits are doubtful. The Commission failed to acknowledge any negative effect of patent protection on drug prices and on the capacity to produce new essential medicines locally.

The box above gives an overview of other actions of the European Commission.

Changing winds

Recent developments give reason to believe that the winds are changing. Commissioner Lamy has outlined a path for tackling the access issue and has invited NGOs to have input into this process. It will: identify the diseases and medicines of concern; analyse the precise barriers to access to medicines in these specific cases; outline the requirements in terms of technical assistance for TRIPS implementation for the least developed countries; define the type of action and targets for stimulating R&D of drugs for neglected diseases; and cooperate with NGOs, the pharmaceutical industry and donor agencies.⁴

At the G8 summit in Okinawa in July 2000 the Commission supported an ambitious agenda to tackle infectious diseases, including measures to increase access to medicines. On 28 September the Commission convened a high level round table, following which Mr Lamy said that policy orientations were being considered

EUROPEAN COMMISSION'S ACTIONS THAT SHOW THE FAILURE TO ADDRESS HEALTH NEEDS

European Commission DG Trade representatives objected to the WHO publication *Globalisation and Access to Drugs*

In 1998 the European Commission joined the US in putting pressure on South Africa to abandon its medicines act.

In 1998 in response to the draft World Health Assembly resolution on the Revised Drug Strategy and referring to considerable concern among the pharmaceutical industry DG trade concluded: No priority should be given to health over intellectual property considerations

In Seattle the Commission proposed to issue compulsory licenses for drugs on the WHO Essential Drug List. Since there are only a handful of patented drugs in the WHO list, this proposal would have limited the use of compulsory licensing to the extent that it became useless.

The European Commission requires CEE countries applying for EU membership to eliminate Bolar type provisions, which allow generic manufacturers to do research and prepare for regulatory requirements before a patent expires, ensuring fast introduction when the patent term runs out. Bolar provisions are not against EU law.

on pricing, tariffs and taxes of key pharmaceuticals for malaria, tuberculosis and HIV/AIDS. Other areas to examine were tiered pricing, voluntary licensing arrangements for local production, and the possibility for authorities to use Article 31 of the TRIPS agreement to have drugs manufactured in the public interest.

The Commission adopted a communication 'Accelerated action targeted at major communicable diseases within the context of poverty reduction'. The communication will now go to the Council and the European Parliament. The document specifically addresses the need for action to increase access to essential medicines and the need for investment in research and development of global goods. The Commission brought to light the possibility of using compulsory licensing to override patents on medicines in poor countries. This is a radical shift from earlier statements.

The European Commission has a major role to play in addressing the access crises. In order to be effective the Commission will have to be prepared to confront the European pharmaceutical industry instead of acting as its advocate. If the Commission is truly committed to increasing access to drugs, it will have to give priority to health objectives over the commercial interests of the large European pharmaceutical companies. Traditionally, the relationship between the European Commission and the industry has been a very comfortable one and while cooperation is needed, so are confrontation and the building of compromises.

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The lack of TRIPS acceptance by the EU and how it impedes European generic firms

The most recent development in TRIPS (the Agreement on Trade Related Intellectual Property Rights) for the future of generic pharmaceutical products is the clarification by the WTO Panel of the entitlement of advanced generic registration. These provisions allow generic manufacturers to perform clinical trials, test, and experiment to generate data while the original product is under patent protection, and thus permit generic companies to market their product soon after patent expiry. This paper discusses how early development and testing provisions foster balanced pharmaceutical policy and improve economic conditions in the European Union.



Greg Perry

WTO Panel Case

The WTO Case provides significant insight to the importance of advanced testing provisions for European generic manufacturers. Early testing and development provisions are permitted in several industrialised nations, such as the United States, Canada, Australia, and Israel, though not in the EU. In 1984, the US Congress granted generic firms development and testing provisions, known as the 'Bolar' provisions, to balance the special market exclusivity extensions granted to originator companies. However, no such provisions were granted to EU generic manufacturers when the Supplementary Protection Certificate Regulation 1768/92 was introduced. This regulation enabled EU originator companies to benefit from 15 years market exclusivity, one year more than in the USA. But the development and testing provision was not given to generic manufacturers in the EU, thus not creating harmonised pharmaceutical industrial policy.

One of the principal reasons for not supporting 'Bolar' provisions in Europe was the belief that they were inconsistent with TRIPS. The WTO Panel Case (WT/DS114/R) brought by the EU against Canada claimed that conducting development work before patent expiry on the originator drug was against WTO legislation. In March 2000 WTO upheld the Canadian law. However, the Panel also held that stockpiling of generic products during the patent period is not compatible with TRIPS and indicated that production stock made during the patent period and used for the provision of samples for regu-

latory purposes should not be sold for commercial purposes.

The WTO Panel held that:

- (a) Testing, development and the production of samples are compatible with TRIPS.
- (b) This right is not dependent on a patent extension, for example, an SPC.
- (c) Testing, development and the production of samples for export are compatible with TRIPS.

Significantly the panel stated that the additional period of de facto market exclusivity created by using patent rights to preclude submissions for regulatory authorisation should not be considered normal. *"The additional period of market exclusivity in this situation is not a natural or normal consequence of enforcing patent rights. It is an unintended consequence of the conjunction of the patent laws with product regulatory laws, where the combination of patent rights with the time demands of the regulatory process gives a greater than normal period of market exclusivity to the enforcement of certain patent rights. It is likewise a form of exploitation that most patent owners do not in fact employ"*. Consequently, since these legal issues have been clarified there appears no reason why the European Union would wish to oppose the insertion of such provisions into EU law.

The importance of 'Bolar' in Europe

It should also be noted that the European Union did not appeal the case, so it may be assumed that the legal findings of the Panel are acceptable to the EU. There are several compelling economic arguments for providing a development and testing provision in European legislation.

1. Development and manufacturing in the EU

At present generic companies carry out their development and testing work for new generic products predominantly outside the EU. Preliminary calculations, produced by the European Generic Medicines Association (EGA), estimate that EU companies spend almost 1 billion euro outside the EU each year. Moreover, these investments will increase over the

I would like to thank Nisha Shah for her assistance.

next few years as the EU markets expand as a result of patent expiries.

The effect on manufacturing can be shown in the specific case of APS/Berk (part of the TEVA Group), which holds over 20 per cent volume share of the UK market. Restrictions on product development work in the UK led to the decision to cease manufacturing in the UK. The company has relocated its development and manufacturing to Hungary which has a well-established manufacturing and scientific base, and where development, testing and experimental work prior to patent expiration may take place.

2. Ensuring EU generics benefit from the growth of the global generic market

The global generic market is currently expanding at 14 per cent per annum, as many pharmaceutical patents come into the public domain. According to one source, by 2001 the top ten generic markets alone will be worth 22 billion euros, with the USA representing 60 per cent of the market.¹ By the year 2003, according to another source, the total global market is expected to be worth 38 billion euros.²

However, if development and testing work is prohibited under EU law, European companies, both in the active pharmaceutical ingredient sector and in the finished product sector, will only be able to benefit from this market expansion by carrying out development and testing work outside the European Union, particularly in countries with well-established generic manufacturing sites and clinical research laboratories.

3. Ensuring a stable EU accession

The accession of countries such as Hungary, Poland, Slovenia and the Czech Republic to the EU will significantly increase the size and importance of the EU generic industry. Maintaining provisions for testing and experimental use for registration purposes is critical to the generic industries in these countries.

EGA companies from this region have estimated that 14,000 jobs would be lost in Accession countries if they were forced to transfer pre-patent-expiry development work and first-wave manufacturing from these countries to countries outside the expanded EU. These jobs would be lost from the future employment of the European Union.

4. Protecting EU generic API industry

Traditionally, Europe has a highly respected generic active pharmaceutical ingredient (API) industry, but this is now suffering

badly from competition from non-EU manufacturers who benefit from testing and experimental use provisions. The production and supply of active pharmaceutical ingredients in batches of industrial scale are necessary for testing and experimental purposes by generic medicine manufacturers.

This point was well documented in the conclusions of the European Commission's own study of December 1998 undertaken by NERA - "Policy Relating to Generic Medicines in OECD Countries", where it is cited that 13,000 jobs in the EU API industry alone will be lost if no testing and experimental use for registration provision is introduced into the existing EU.

5. Securing supply of generics by EU companies

Currently European health systems import generic medicines from regions which allow early development and testing provisions and from regions which lack strong property protection. The lack of 'Bolar' not only inhibits the development of a generic manufacturing industry in the EU, but also creates a dependency on imports from other regions. Experience from the United Kingdom, Germany, and the Netherlands illustrate that soon after a patent expires generic products, from outside the EU, are introduced into EU health systems. A more favourable situation would be if EU health systems would purchase affordable generics produced in the EU. If 'Bolar' provisions existed in Europe then European generic firms could guarantee supply to European health systems.

Thus fostering advanced registration of generic medicines would harmonise European pharmaceutical policy. If pharmaceutical products had permanent patent protection, no incentives would exist to develop new drugs. Europe protects pharmaceutical patents more than any other region, yet our rate of innovation and has diminished in the past two decades. The outcome of the WTO Panel Case proves that the 'Bolar' provisions are compatible with the TRIPS Agreement. Since the decision, the EGA has approached several European institutions to amend current policies, such as national patent laws, the Pharmaceutical 2001 Review in the European Union, and the European Community Patent, in favour of implementing 'Bolar' style provisions. As presented, such provisions would foster competition, provide employment opportunities in Europe, and improve access to affordable medicines to the population.

"The accession of countries such as Hungary, Poland, Slovenia and the Czech Republic to the EU will significantly increase the size and importance of the EU generic industry."

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Access to medicines: a role for industry

The pharmaceutical industry is acutely aware that many people in developing countries do not have ready access to basic health-care services, including safe and effective medicines. We believe this situation must be addressed, and that the industry has a role to play in doing so. Clearly, however, while medicines are part of the solution they cannot provide all the answers.



*Dr Jean-Pierre
Garnier*

A number of complex issues interact to influence access to medicines and any proposed solutions must address all aspects of the problem. Much of the recent debate has focused on the cost of medicines, and the impact this has on access to treatments – this is the focus of this article.

Pricing structures

To understand the pricing of medicines it is useful to look at how we run our business in developing countries. Unlike Europe, most developing countries do not have a comprehensive, government funded health-care system. Medicines and vaccines supplied for use in these countries can therefore arrive through three different routes:

- the private market which services the affluent and covers predominately the urban areas;
- charities and aid organisations such as UNICEF, to whom we give significantly discounted prices. These organisations ensure delivery to the patient through their healthcare programmes;
- on tender to governments, competing for the business with other companies and pricing our products accordingly.

The prices frequently quoted by our critics are those used in the private sector. The prices we negotiate through tender with national governments, charities and agencies, are significantly lower. For example, we are selling our patented vaccine against hepatitis B, Engerix-B, to UNICEF at 10 per cent of the list price. This flexible, global approach to pricing, which takes into account the very different healthcare systems, government policies and pharmaceutical markets in the developing world, enables us to make a significant contribution to making medicines affordable in developing countries. In other words, used properly, industry pricing differences

improve access to medicines in developing countries, rather than denying access as is often portrayed by critics.

Types of medicine

Affordability of medicines is, however, clearly still an issue. There are broadly three distinct baskets of pharmaceuticals to consider when looking at medicines costs:

Firstly, 95 per cent of the drugs on the WHO Essential Drugs List have no patent and are available as generics. These drugs can be purchased from multiple sources at extremely low prices. For instance, SmithKline Beecham is involved in an initiative to improve the affordability, availability and quality of generic medicines in Africa. SmithKline Beecham offers dozens of such products that are on the WHO Essential Drugs list and are aimed at the areas of greatest need. SmithKline Beecham is able to guarantee an uninterrupted supply of high quality products at low cost. This is particularly important in Africa where, according to the World Health Organisation, up to 60 per cent of products in circulation can be counterfeit.

The second basket contains vaccines and other medicines such as albendazole for the treatment of lymphatic filariasis or elephantiasis. Here again, high quality products and patent protected vaccines are available in large quantities at extremely low prices. This is made possible through successful partnership arrangements with organisations such as UNICEF, MSF and the Red Cross.

SmithKline Beecham is able to provide large quantities of patent protected vaccines at very low prices because our programmes are built upon three basic principles:

Partnership: We get orders from our partners such as UNICEF, specifying what they need and when and where they need it for planned vaccination campaigns. We can, therefore, organise our production accordingly and benefit from economies of scale.

Product Protection: Movement of the product is controlled all the way from our manufacturing plants to the point where the patient receives it because it is used through partnership arrangements and as part of a planned programme. There is little or no risk of the product being stolen and diverted or re-exported to a higher priced market by parallel traders.

Pricing Protection: The key European countries tacitly accept the principle of two tier pricing for vaccines. Indirectly, they

This article is based on a presentation by Dr. Garnier to the European Commission High Level Round Table meeting on accelerated action targeted at major communicable diseases, 28 September 2000.

support the economics of such a system, where we generate revenue for R&D in Europe, United States and Japan, while transferring the benefit of this research, basically for free, to the developing world.

These three principles constitute a favourable framework for dual or tiered pricing.

The third basket of drugs, which comprises the patent protected pharmaceuticals, is the biggest challenge. These products are still at the early stage of their lifecycle and are generating revenue to fund the R&D essential to the discovery of new medicines for the future. A possible way of assisting developing countries to have access to these medicines could be the institution of differential pricing for the most critically required products. However, in the case of these pharmaceutical products we do not have the benefit of the favourable framework which makes it possible to do this successfully with vaccines – partnerships, product protection and pricing protection.

A framework for low prices

Control over the movement of pharmaceuticals to avoid re-exportation, and respect for intellectual property rights, are essential to create the conditions for large scale supply of low cost, high quality, patented pharmaceuticals in the developing world. The industry can only offer even lower prices to developing countries if these prices are confined to the countries for which they are intended. International parallel trade erodes the revenue that we must generate so that we can continue to invest in the costly research and development necessary to find new treatments. This is particularly important given the challenges of communicable diseases in the developing world. The developed world has to be willing to pay reasonable prices for medicines in order to cover costs for developing countries. Effective healthcare and access to medicines requires political commitment and adequate financial and personnel resources everywhere.

The international community, together with the pharmaceutical industry, charities and aid organisations, needs to develop further the principles of partnership, product protection and pricing protection if we are going to see any significant inroads made into the problem of access to medicines in the developing world.

SmithKline Beecham is convinced that with the help of our partners, governments and other interested parties, and with the sup-

port of the European Union, a workable framework can be created. However, it is not a framework that can be created by isolated, individual countries, nor is it a framework that one stakeholder group alone can achieve. International cooperation and leadership is needed, as is the willingness to act. The partnership of the five leading AIDS drug manufacturers with five UN agencies to accelerate access to HIV/AIDS care and treatment illustrates the willingness of others, besides SmithKline Beecham, to aggressively attack this problem.

We also know that people in developing countries will not see improved access to medicines without significant improvements in public healthcare infrastructure, sufficient financing of healthcare needs and the political will of national governments to provide treatment. Absence of these critical factors creates significant barriers to providing effective healthcare services and medicines as a part of this. Using HIV/AIDS treatment as an example, the success of anti-retroviral therapy against HIV/AIDS assumes that the necessary healthcare infrastructure exists to support the appropriate administration of the drugs, monitoring of the response, managing any side effects and ensuring patient adherence to complex regimens for the duration of the illness. This poses difficulties even for patients in the developed world within well developed healthcare systems. In many developing countries healthcare infrastructure to adequately support anti-retroviral treatment exists, if at all, in only a few facilities in major cities.

The absence of national healthcare policies due to weak political commitment and poor healthcare infrastructure are all linked to the unfortunate fact that many developing countries are unable to afford adequate healthcare and treatment for their populations. Little is affordable in a country that spends less than \$5.00 per person per year on healthcare, as is typical of countries in sub Saharan Africa. Massive investment by governments and financial institutions in poverty alleviation is essential for sustainable improvements in the situation.

No one organisation can resolve the problems of access to healthcare and medicines in developing countries. There are no easy answers. Governments, European institutions, multilateral agencies, charities and industry all have a responsibility to address this problem, playing their appropriate role. Effective partnership is essential. Where this is in place we have seen that significant inroads can be made.

“The developed world has to be willing to pay reasonable prices for medicines in order to cover costs for developing countries.”

“in Africa, up to 60 per cent of products in circulation can be counterfeit”



Calum R. Paton

Since the late 1980s, many public or largely collectivised health systems in Europe, and beyond, have been ‘reformed’ according to the rhetoric of market forces. The reality of reform has varied hugely both within and beyond the European Union, yet there have been generic factors leading to pressures for reform.

The two articles here summarise the results of the report, *The Impact of Market Forces on Health Systems. A Review of Evidence in the 15 European Union Member States*. The project was financed by the European Commission and conducted by the European Health Management Association. Besides the authors of the two articles here, Martine Bellanger, Philip Berman and David Hunter were members of the core group responsible for the report.

Analysis of market reforms in Europe

“market reforms can be seen as less significant in their introduction of new payer/provider relations than in the creation of an overt purchaser per se”

Reasons for reform

One must distinguish between *underlying* and *immediate* causes of reform, as well as between types of reform. Cost containment bridges the divide between underlying and immediate causes. The development of global capitalism is a general reason for cost-control: ‘advanced’ nation-states seek to remain internationally competitive through (relatively) lower wages; lower taxes, both to attract or retain capital and to mollify the effect of lower wages; and, therefore, limitations upon the welfare-state, including health-care. Additionally, the domestic political economy of individual countries may lead to an immediate emphasis upon cost-containment.

The latter factor does not however always operate in an obvious manner. For example, why did the UK – with its record of cheap and cost-effective healthcare (some would say, too cheap!) undertake the most radical policy of ‘internal markets’ witnessed in any of the ‘Beveridge’ systems, allegedly geared to increasing productivity and controlling costs?² Only later did the more expensive, corporatist, ‘Bismarckian’ systems, such as Germany, join the search for system-wide reform – and even now, such reform is still aspirational rather than actual.

One must add other factors in order to explain the paradox. Growing expectations by citizens and consumers have occurred in

the context of widening economic and social inequality, both domestically and internationally. The autonomy of professions has been challenged. The healthcare industry is both a source of expense for public health systems, as with the pressure to adopt new drugs and technologies, and yet sometimes also a source of employment and exports for countries.

All in all, public health systems are required to do more, with pressures upon both solidarity and costs. As a result, most European pressures for reform have led to attempts to reconcile a limited equity, defined in terms of a standardised package of services, or common basket available publicly, with both ‘macro’ cost-control and ‘micro’ incentives for greater productivity and also, in some cases, new priorities.

Types of reform

Market forces in healthcare arguably had their ideological heyday, in Europe, in the late 1980s and early 1990s, although the ‘pro market’ stance is still current in some European countries such as Germany today. It makes sense to distinguish between the national health services (NHS or Beveridge countries) and the social insurance systems (‘Bismarck’ countries), principally because the respective prevailing structures led to a different locus for the introduction of market forces.

One can distinguish between the *collector of finance* or *insurer*, the *payer*, and the *provider*. In NHS systems such as the UK, Sweden and Spain, the collector, through taxation, is either national or local govern-

More detailed results as well as individual country reports will be published as a special issue of *Health Policy* in 2001.

ment. Prior to 'market reform', this revenue was generally distributed to public authorities (payers) which organised their own provision. Following market reform, a 'purchaser/provider split' was developed such that the recipient of government revenue (the payer or purchaser) made contracts with separate, or autonomous, providers – with market forces more or less operating in the process. Thus the main market force has been between payer and provider.

In the European social insurance systems, there was greater variety in both collection and payment. For example, in the Netherlands, collection was, and still is, by quasi-taxation. Only after that process is the revenue allocated to the payers (sickness funds and insurance companies) within which citizens have enrolled.

In Germany, however, the state, or quasi-state institutions, have had a much smaller role in this area. Individuals or employees join sickness funds that receive revenue from individuals and employers. The state's role has been limited to regulating levels of contribution according to income levels and so forth – though, until recently, without the 'revenue equalisation' in line with measures of enrolees' or populations needs that has characterised the Dutch system as well as some national health services in allocating to payers.

The main 'market force' in social insurance systems has thus been introduced – unlike in NHS systems – between the individual and the payer, although this has led to new payer/provider relationships in pursuit of both cost control and, in fewer cases, increased quality or, more likely, standardisation of quality. See Figure 1.

A cautionary note

Similar sounding reforms may have been very different in practice. These differences may have reflected different domestic priorities (for example, cost-control versus patient choice) or the politics of designing and implementing reforms.

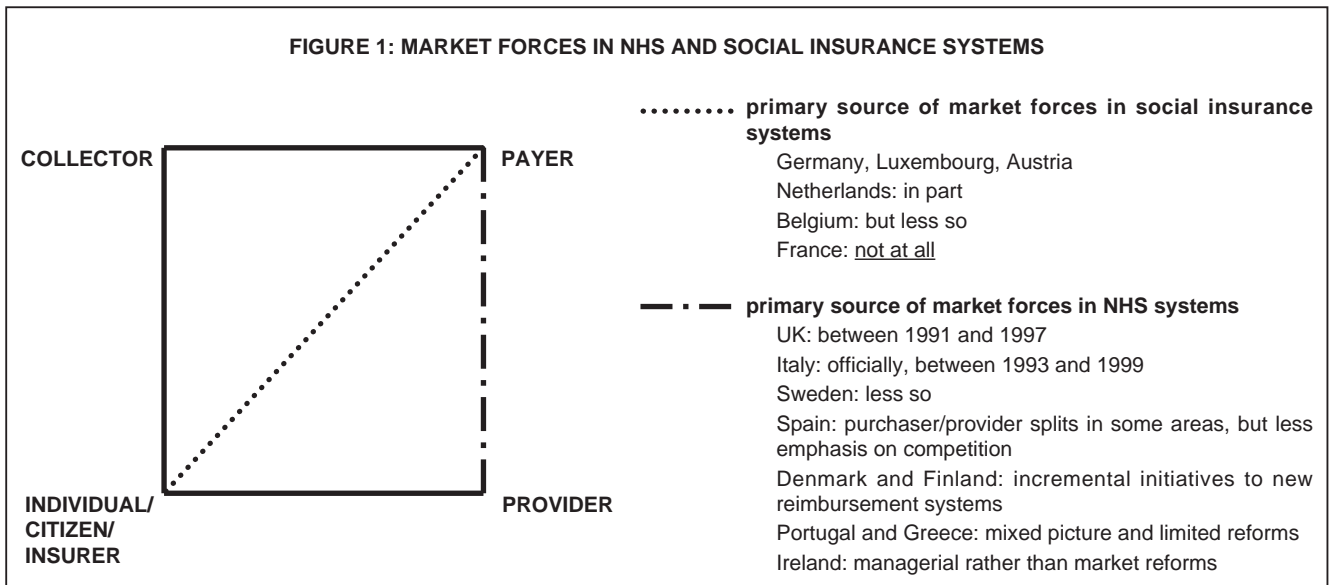
For example, the UK stressed central control to achieve both cost-control and, paradoxically, the achievement of 'citizens' charters' concerning matters such as waiting times and feedback to patients from doctors; whereas Sweden stressed citizen choice of provider. To describe both as 'markets' would obscure a lot. The UK reform subjugated a pre-existing choice of provider by the traditional GP to new contracts made by health authorities (or by the new cash-limited GP fund-holders). Yet in Sweden, increased patient choice of provider (in itself, not conducive to cost control) was the motive for new forms of contract between payer (county council, or sub-division thereof) and hospital. In other words, the 'causality' between contract/reimbursement and patient flow was the other way around. While both reforms may or may not have increased efficiency through contracting, they had very different implications for patients.

New structures?

Have reforms simplified or complicated health systems? Partly through 'managed competition', some social insurance systems are seeking a 'standard package' of publicly funded services with additional services to be purchased privately. This then allows a 'level playing field' on which sickness funds/payers can compete to attract enrolees, if this is desired. Additionally, 'revenue equalisation'

“Market forces in healthcare arguably had their ideological heyday in the late 1980s and early 1990s”

FIGURE 1: MARKET FORCES IN NHS AND SOCIAL INSURANCE SYSTEMS



between funds becomes necessary.

The question therefore arises: would it not be simpler to move to larger scale, geographically based payers which then work or contract with providers. ‘Consumerism’ and choice of sickness funds “means a system without large-scale purchasers which have the power to plan services according to the needs of geographical areas.”¹

Additionally, it may make sense to ‘cut out the middleman’ of the quasi commercial payer, the existence of which may diminish the benefits of the single payer model in healthcare – not least if both economy and equity are threatened by multiple payers and a public/private divide, some of which may result from the undifferentiated application of the Single European Market to

healthcare.

In addition, in NHS systems, the spectre of rationing (a standard package with increasing formal exclusions) is also a ghost at the feast. While decision making by the medical profession and less-than-perfect resource allocation have in the past prevented full equity or full comprehensiveness of service, the abandonment of comprehensiveness even as a goal in countries such as the UK or Sweden would be a milestone.

In this connection, ‘market reforms’ can be seen as less significant in their introduction of new payer/provider relations than in the creation of an overt purchaser per se, part of whose job is to make, or implement centrally made, exclusions or ‘hard choices’. In this regard, there is a similarity between the key trends in reform across both NHS and social insurance systems, whether or not driven by market forces.

In the longer term, candidate members for the EU, as well as other countries with public health systems, may see this as the key outcome of the ‘reform mania’ at the end of the last century.

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Impact of market forces: six hypotheses and limited evidence



Reinhard Busse

The evaluation of the impact of market forces on healthcare systems poses several methodological difficulties. One major problem is the fact that healthcare reforms are usually introduced without any planned evaluation of their effects: an ‘ideal’ situation with control groups consisting of parts of the country or parts of the population not undergoing reform are therefore almost never available. Quite to the contrary, often not even solid pre and post reform data are collected. Even where they are, owing to multiple other changes occurring at the same time, such as the introduction of new technologies, they do not allow robust conclusions to be drawn. Another difficulty is the choice of indicators to measure impact. In our report for the European Commission we investigated the evidence according to six pre-formulated hypotheses. Two relate to economic impact, public health and health system development. In

the following article, the hypotheses and a summary of the findings are briefly summarised.

Hypothesis 1: Market mechanisms increase productivity.

One of the main arguments brought forward in favour of the introduction of market forces is that they increase the productivity and therefore efficiency of the system. However, there is no unequivocal evidence that market orientated reforms have increased productivity although a few studies claim that this happened as a result of reforms in the 1990s. In the UK, to the extent that there is consensus about measurement, the increase in productivity in the NHS since its creation in 1948 has been similar in each decade, although possibly the rate of increase in acute care productivity has been higher in the 1990s, with day case surgery and shorter lengths of stay

probably the main reasons for this. Whether or not technological innovations that increase productivity have been adopted more rapidly because of 'market forces' is open to debate.

One generalisation is that Bismarck type systems – which tend to be generously funded, combining solidarity for citizens with pluralism in financing and payer/provider relations – have more scope for unique improvements in efficiency or cost control which cannot be repeated. The most generously funded systems may therefore have scope for both cost reduction and increases in productivity, particularly in the early stages of reform.

This phenomenon has also occurred in Sweden, where in the mid 1990s, a stabilisation or even reduction in total funding was achieved alongside both significant lowering of waiting lists/times and increased patient choice. Waiting lists for elective surgery had virtually disappeared by the end of 1992. Hospital managers and staff throughout the country showed greater concern with attracting patients from outside of their catchment area and retaining their own patients. They reported increased awareness of considerations of cost and productivity, more constraints on their activities, and greater efforts to do more with fewer resources. More generally, available performance data pointed to improvements in hospital productivity and efficiency. However, Sweden did not only rely on market forces but used 'anti-market' instruments such as budgets as well.

Data from Spain point to the fact that its increase in constant expenditure per weighted healthcare unit came to a standstill in the mid 1990s (i.e. after the introduction of contracting-like relationships between payers and hospitals). Between 1994 and 1997, expenditure per unit decreased by 0.7 per cent.

The German healthcare system has experienced efficiency gains in recent years in both the hospital and ambulatory care sectors. Efficiency gains in the hospital sector can be observed since 1996 if the unit of evaluation is per case, but an analysis per bed or per diem does not yet support this conclusion. The 'turn around' in expenditure per case coincides with the introduction of prospective payment per case or procedure but also with the introduction of institutional benefits from long term care insurance. A warning has to be added to these observations. Increased efficiency per case does not allow any conclusions about

wider cost effectiveness, since both the number of hospital cases and total expenditure for hospital care have increased. These may correlate with decreasing thresholds for admission to in-patient care, both as a result of treating patients with lower 'benefit' and also possibly because of the temptation to fill empty beds. The public is much more aware of efficiency gains in ambulatory care since physicians protest against these, viewing them not as efficiency gains but as a decrease in income. Again, the reason is not market forces but the opposite – the rather successful budgets in this sector.

Hypothesis 2: Market mechanisms are costly to operate.

Significant reforms involve two types of 'management cost' – first, the costs of change; and second, the costs of the new system, once established, as opposed to the old. Market reforms may introduce 'transactions costs', i.e. the costs of contracting and other market relations as opposed to the previous, often hierarchical, procedures. Such costs, if they are higher than in the 'old system', must be set against benefits which are even more difficult to quantify.

Systematic data are not easy to find, although there are some detailed case studies available from the UK and there is a widespread perception that the management costs of purchaser/provider systems are significant. In Spain, the introduction of managerialism and management by contracts has been quite significant. In NHS hospitals, management and administration personnel growth between 1989 and 1995 was 94 per cent while the average increase was only 20 per cent. In Germany, on the other hand, the visible expenditure share of administration has not increased. There are many reports, however, that the time that both nursing personnel and physicians have to devote to administrative purposes has increased dramatically. For nurses, the main extra burden was the introduction of 'nursing time standards' in 1993, which necessitated a daily record of required nursing for every single patient. The obligation was abolished in 1997 to give hospitals greater managerial freedom, but documentation is still carried out in most hospitals. Nursing time standards were, however, a regulatory 'anti-market' instrument introduced to overcome the potential threat to 'downsize' nursing numbers after allowing hospitals to make profits.

Overall, there is no country in which a 'balance sheet' of economic gains and losses from market reforms can be clearly

“there is no unequivocal evidence that market orientated reforms have increased productivity”

“In NHS hospitals, management and administration personnel growth between 1989 and 1995 was 94 per cent.”

presented. There is, however, no conclusive evidence that market forces have increased efficiency, yet there is evidence of increased management costs. Advocacy of market reform as a means to increase efficiency should therefore be treated as suspect.

Hypothesis 3: Policy for public health has been made separately from market reforms, which have been concerned with other objectives.

Public health has been absent from most debates about the introduction of market forces into public, or publicly regulated, systems. This has been the case in both Bismarck and Beveridge systems, even though it might be thought that ‘government control’ in the latter would result in more systematic addressing of public health objectives. Whether or not the assumption is true, there is definitely no link to market forces. Indeed, ‘market reforms’ have generally been restricted, moderated or ‘abolished’ (in part) as a response to concerns about equitable access to good health outcomes. In a number of countries, the market is seen to be a barrier to equitably distributed health gain. In Ireland, for example, safeguarding the healthcare of the elderly has been used to counter market based arguments for the introduction of unrestrained market forces in private health insurance. In the Netherlands, the introduction of market forces through ‘managed competition’ has frequently been seen as in conflict with ‘solidarity’ in healthcare, and by implication with wider public health objectives. It is believed that the inclusion of several types of long term care and mental healthcare in a competitive health insurance market may cause serious problems.

Only in Germany, health objectives and targets attracted attention as a result of sickness funds seeking new tools to be used in competition. A senior manager of the federal association of company based sickness funds proposed that sickness funds set their own individual healthcare targets, which they should try to achieve through ‘managed care’ and ‘disease management’ tools. Another case in which public health arguments were used by proponents of market forces was the exclusion of surgical dental care and dentures from the statutory benefit package for persons born after 1978. It was argued that these benefits were no longer necessary since dental prevention had been included as a benefit in 1989 and that therefore there was no longer a reason for covering surgical treatment publicly (i.e. that it should be paid for privately).

Due to the unpopularity of this move, however, it was reversed by the new parliamentary majority in 1998.

Hypothesis 4: Separating purchasing and provision as well as various forms of contracting have led to greater emphasis on public health.

There has been, in Beveridge countries, much rhetoric about the purchaser/provider split being geared to new priorities, principally primary care. There is no evidence that, in those countries which have created new forms of purchaser/provider split, equitable health gain has been the primary objective or that, where it has been retrospectively defined as such, equitable health gain has been achieved. In Spain, for example, the 1991 Abril Report was concerned with reorganisation of the system, including market orientated reforms such as a purchaser/provider split. The role of purchasers was defined, however, not in terms of the maximisation of population health but “to guarantee the quality of healthcare services and patient satisfaction”. At the same time, responsibilities and activities for public health and healthcare were in some regions separated as a result of devolving the former but not (yet) the latter. This reinforces the conclusion in response to the previous hypothesis that market forces and public health have been separate agendas.

Hypothesis 5: Market reforms have reduced the autonomy of professionals, especially doctors, by creating or ‘sharpening’ the purchaser/provider split.

A key consequence of health system reform has been a change in the relationships between payers, managers and the professions – especially the medical profession, which has traditionally been a powerful actor in all health systems. This change has applied to most types of health system, but has occurred in different ways. In many cases, diminishing the autonomy of the medical profession has been an overt objective of reforms, and the transfer of ‘risk’ to professionals at the ‘local’ level has been a common means of changing power relations. In France, the power of the professions has been allied to the power of the sickness funds, which have been controlled in a corporatist manner. The opposition to reforms has therefore come both from trade unions and professional associations, which have identified more restrictions upon previously liberal reimbursement and less autonomy for ‘social partners’ at the

“In a number of countries, the market is seen to be a barrier to equitably distributed health gain.”

local level in overseeing and managing healthcare. In other Bismarck countries such as Germany or the Netherlands, the logic of 'managed competition' has involved new or formalised systems of contracting which are likely to compel a new dialogue between the providing organisation, e.g. hospital, and the clinician. Mechanisms include the increased use of guidelines and other managerial means of influencing or directing clinical practice.

In Beveridge systems, the general rule has been, 'the more market, the more clinical autonomy is diminished'. It is still an open question, however, as to whether 'the market' or direct performance monitoring and management is more effective at changing behaviour. The 'purchaser/provider split' has varied significantly in form, but has generally been associated with limiting the autonomy of professionals in the context of contracts. Overall, it is best interpreted as a means to 'discipline' professionals, especially doctors. Contracts mean that providers have to ensure that doctors 'deliver'.

Hypothesis 6: Market reforms have restricted access to services in the public sector, yet universal access has been maintained and policy has emphasised shorter waiting times.

Access may refer to the services for which all are covered in the public sector, and to speed of access to such services; the categories of the population covered publicly; or the degree of choice of provider by an insured person.

In the UK, 'internal market' patients 'followed the contract' made between payer/purchaser and provider. This was a diminution in free choice of provider – by patient or by referring GP (except when the latter was a fundholder). Additionally, market reform in the UK has created (temporarily) differential speed of access. For example, GP fundholding in the UK is reputed to have introduced a 'two tier service', with patients of fundholders receiving quicker treatment. Yet in other Beveridge countries, free choice of provider and equitable access were central aims of reform. Sweden in particular sought both shorter waiting times and increased patient choice of provider, with cost control sought through restrictions in reimbursement rates. Denmark implemented a waiting time initiative. In Ireland, access to free consultant services was extended to the Irish population in 1991.

Restricting access to 'cost effective' care is an aspiration in most systems, but examples are so far limited. Most 'rationing' has so far been informal. In no system has rationing of access to public services by income or ability to pay been the key reform. Indeed, the trend in Bismarck systems has been to standardise the benefit package, so that all have access to one system. For example, in the Netherlands, the Dekker proposal for competing sickness funds/insurers was part of a wider reform involving access by all to a standard package of publicly financed services. The restriction in actual services has been limited to dental care for adults and to part of the physiotherapy service. In practice the application of the criteria of the Dunning Committee on priorities has been problematic, and the government decided to transfer dental prostheses back to coverage within the social insurance system (as in Germany).

Such attempted exclusions of services from the publicly funded services are, at least partially (i.e. besides the cost containment aim), the result of an intention to increase both consumer choice and satisfaction as well as to get private money into the system (to support the medical industry) – both factors which should be seen as a result of increasing market forces in health systems.

The introduction of cost sharing and user charges is another policy that may affect access. Market reforms have mostly been distinct from consideration of user charges in Beveridge systems. Indeed a political argument for 'market forces' in the UK was that the increase in efficiency would diminish the need for user charges. It was further argued, by some proponents of the internal market, that applying user charges to non competitive public services was inappropriate.

Increased patient choice of payer in Bismarck-type systems as currently occurring in Germany has been the hallmark of 'managed competition', but it is an open question under such reforms as to what happens to direct choice of provider by citizen or patient. Traditionally in Bismarck-type systems there is free choice of provider by the patient (although access is controlled by the primary doctor in the Netherlands). It is too early to tell whether, as a result of 'managed care' by sickness funds, a long term trend will be a removal of this right in order to allow full financial and other control of providers by payers.

"In France, opposition to reforms has come both from trade unions and professional associations."

e-procurement and health in Europe



Mike Tremblay

*"...more than a third of European companies are applying e-commerce to procurement, logistics, finance, and even product development. Within five years, 90 per cent expect to use e-commerce in sales and marketing and 83 per cent in procurement."*¹

There is no doubt that health systems cost a considerable amount of money. Often spending on health is looked at in terms of total aggregated spending, with the realisation that about 70 per cent of total spending goes on labour costs, a large amount on buildings and on medical and surgical supplies, the rest on various items.

However, we should not ignore the possibility of considerable – potentially massive – savings which can accrue from adopting the emerging practices of private industry in responding to its own supply chain costs. It is increasingly accepted that the gains in economic productivity in the United States are being driven by investment in information technology, and that this may have caused major structural changes to economic performance, such as raising the non inflationary ‘speed’ of the economy, reducing the unemployment level at which labour shortages affect the economy and so on.

Meeting the investment challenge

In health, we have not fully embraced the potential benefits from the new economy, although efforts to adopt telemedicine for instance have been around for a long time. There has been long standing under investment in information technology by hospitals and other health service providers.

This means that as we look at the health economy across Europe, we see an industry that has yet to invest in the technology and organisational innovations that are driving forward reform across all other sectors of the economy. Indeed, the close alliance between health system and central government and public services is keeping these technologies from being adopted, owing to the more conservative methods of the public sector itself. Those countries that will most quickly realise the tremendous potential gains that are possible will be those whose governments encourage the uptake of leading edge technologies. These will be gains such as:

- improved speed of access to health services, health professionals and diagnostic and therapeutic information for patients, consumers and health professionals;
- reduced transaction costs, of supply procurement, of claims processing, and of regulatory and other reporting;
- improved performance of the health supply chain through reduced bureaucracy, duplication, time costs and duplication of effort;
- increased value for money to tax payers as improved performance and productivity offer the opportunity to reinvest savings in health or reduce unwanted expenditures in the first place.

In the case of electronic procurement in health, it has been described as the ‘Eldorado’² of applications of the internet, since health is both a major consumer of products, and has real difficulties in productivity improvement.

The revolution running through our economies today, unleashed by the internet, is knocking at the door of our health systems. The last issue of Eurohealth looked at some of the policy implications being driven forward by the internet. Key amongst these implications were the changes the internet brings to access to information about health. Another key implication will be changes to the ways we deliver health services, and to the underlying support systems of the health industry – the structure of the health supply chain itself.

The internet is changing business relationships; new terminology is emerging to describe these changes, such as the ability of the internet to change the structure of relationships within traditional supply chains. That is to say, the internet can make it easier for buyers and sellers within a commercial context not only to find each other, but to do business together. This is business to business (B2B) e-commerce and represents what is seen as an area where the greatest gains in both productivity and cost savings can be made.

A role for Europe’s institutions

Hugo Paemen, of the European Commission, has laid out the key agenda for the Commission in reforming legislation to take account of the internet, namely: “We want to repeal provisions buried in antiquated legislation that do not make sense for the Internet Age.”¹

At present, EU contracts are valid only with hand written signatures. But there is more: the whole public procurement process floats on a sea of paperwork and procedures,

designed to ensure that all potential contractors are aware of potential public contracts, and that they have time to prepare appropriate bids.

Procurement rules were specifically designed to open up the public market place, in effect to create an open market within which all contractors had an equal opportunity to bid. What we now find with the internet is that this procedure is becoming the norm for all business commerce as it speeds up all aspects of procurement, from finding contractors who meet the required specification to ensuring timely fulfilment of the contract to electronic contract management. Yet, what reform to the procurement rules is necessary? For the public sector, the stringent procurement rules make all procurements complex and costly processes, adding time and thereby costs to activities that could be replaced with more efficient electronic procurement through the internet.

Believe it or not, e-procurement of medical equipment and supplies in the United States will exceed \$27 billion by 2004.³ The average hospital in the US in 2000 will conduct 2.6 per cent of its total procurement transactions on the Internet. By 2001, that should rise to 25 per cent making e-procurement a fast growing industry. Hospital procurement professionals indicate that, by 2003, they expect to perform 64 per cent of their purchasing of medical products, capital equipment and other supplies online.

To create e-procurement, the internet has spawned B2B exchanges as a response to buyers and sellers wanting to realise productivity gains through the internet. These B2B exchanges are often anchored within a specific industry, such as Covisint, backed by Ford, General Motors and Daimler Chrysler, designed to be the primary platform for car makers to do business with their suppliers. Other exchanges are not industry owned, but act as market makers between buyers and sellers, as 'neutral' exchanges.

A recent report by Morgan Stanley Dean Witter noted: "Acting as an electronic hub, these B2B Internet companies have a substantial oppor-

tunity to bring value to groups of motivated buyers and sellers by providing them with a liquid market, new distribution channels, greater product/service selection, competitive pricing environments and, most important of all in healthcare, reduced transaction costs ... The key to winning in the market will be critical mass."⁴

At present, the European Commission's view is that exchanges appear to be pro-competition; they do not restrict trade or create artificial barriers to restrict contractors from presenting their wares to buyers. They increase transparency and they could be significant in bringing down prices. The risk, of course, is that industry exchanges, as opposed to neutral exchanges, will behave like cartels or start to exchange pricing information and it is here that Community vigilance is needed.

But the health industry can enjoy these benefits, too. In Europe, exchanges in health are in their early development, probably a couple of years behind the United States. But significant health exchanges are set to change all that. In the UK there is Healthxchange.com; in the Netherlands there is Eumedics; in Germany GloMediX; in France, Galerie Medicale, and a host of other players seeking to establish themselves in the health markets of their respective countries. Only time will tell if a single European health market will emerge for these players, of the scale that seems apparent from exchanges in the US.

Savings in e-procurement

Supply chain inefficiencies in health (and hence the focus of attention for savings) arise from three key areas:⁵

1. The costs of moving supplies around account for 60 per cent of inefficiencies.
2. The costs of information about products, suppliers, account for 25 per cent of inefficiencies.
3. The costs of managing contracts, including ordering and tendering, account for 15 per cent of inefficiencies.

What e-procurement does for hospitals is permit them to realise savings against these drivers. In particular, B2B exchanges offer specific benefits such as:

- ready access to a wide range of suppliers. For instance, it has been estimated that it can take up to 18 months to identify a new supplier;
- electronic contract management, including specification, tendering, price setting (auction, reverse auction etc.); these benefits here could be compromised by the current paper based public procurement system;
- improved fulfilment strategies become possible, such as procedure based inventory management to link supplies to specific clinical procedures and guidelines.

Industry savings of the order of up to 13.5% have been estimated from e-procurement as shown in Table 1.

Table 1 ESTIMATED SAVINGS FROM E-COMMERCE IN HEALTH⁶

Area of potential savings in e-procurement supply chain	Estimated saving
Savings from minimised supply duplication; better management of demand for supplies; improved stocking linked to use of clinical guidelines	2.0 to 4.0%
Savings from consolidated purchasing, group purchasing, paperless order management	2.5 to 4.0%
Savings from consolidation of supplier base, and improved paperless with specification	0.5 to 2.0%
Savings from improved use of delivery capacity and other service enhancements	0.5 to 2.0%
Savings from automated point-of-service distribution; just-in-time and continuous replenishment strategies	0.5 to 1.5 %
Total potential savings	6.0 to 13.5%

However, the greatest impediment is under investment in appropriate and sophisticated information systems. This is compounded by some specific features of the health industry:

- difficulty for health service organisations having access to appropriate expertise in health technology,
- problems accessing investment financing to acquire the technology,
- reluctance to disturb well established relationships with suppliers.

Existing exchanges

Table 2 identifies some of the exchanges currently in the market.

health systems, there will be differential opportunities to innovate in health and encourage the take up of these new forms of commercial practice. While some countries may be encouraging a proactive and progressive position on e-commerce, there still remain specific difficulties:

- while the EU procurement rules have merit, the time limits reflect a paper based approach to procurement which hampers development of novel contracting and price setting arrangements between buyers and sellers. It is now timely to review whether public procurement in health is hampered by these rules, and that the disbenefits of the present procurement system are greater than

resistance to realising benefits to national health systems from European level approaches.

Finally, it is important to realise that the pace of change being driven forward by key agenda setters in the e-commerce world is faster and more dynamic than the pace of regulatory reform or indeed existing bureaucratic processes within more traditional health systems. The way forward appears to rest on two of key considerations:

1. Novel organisational arrangements to facilitate hospitals and other health service organisations to realise the benefits of e-procurement are needed. There are various forms of group purchasing across Europe, but little commerce actually flows through them for various reasons. Group purchasing consortia are gaining ground in the UK's National Health Service for instance driven by ready ability to share the benefits of group purchasing. In other European countries, individual hospitals appear yet to be unable to realise these benefits and adopt the necessary technology.

2. Different European countries offer different opportunities for B2B exchanges. The larger markets, such as the UK, Germany and France offer the greatest commercial benefits. UK NHS hospitals are required to realise 3% annual savings on supplies by 2001, while Dutch hospitals are required to realise savings of 0.2% of total spending in 2000. These incentives along with these two countries being leaders in the use of the internet suggest these are likely to be the role models for the rest of Europe.

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Table 2 B2B EXCHANGES OPERATING IN HEALTH⁷

Exchanges in health	Industry partners
Newhealthxchange.com	Apparently neutral exchange run by AmeriSource Health Corporation, Cardinal Health, Fisher Scientific, McKesson HBOC
Healthxchange.com	Neutral exchange for health buyers and suppliers
Global Health Exchange	Becton Dickinson, Boston Scientific, Guidant, Johnson and Johnson, Baxter International, Abbott Laboratories, Medtronic, GE Medical Systems, Tyco
Sightstreet.com	Eyecare community, Jobson Publishing
"laboratories"	PricewaterhouseCoopers, Ventro Life Sciences
Other example Industries	
Aerospace Exchange	Boeing, BAe, Lockheed Martin, Raytheon
Band-X	Neutral exchange for wholesale telecoms capacity
e-cement	Neutral exchange for global cement industry
GFX	Neutral exchange selling air cargo capacity
Goindustry	Neutral exchange for buyers of surplus office equipment
Ispat	Steel marketplace
Leatherxchange.com	Global leather industry
Metique	Procurement portal for metals and mining industry
Proxchange	Second hand professional goods
Paperxchange.com	Pulp and paper products
Steelscreen	Steel trading
Unipharma.net	Pharmacies and wholesale medical suppliers

Next steps

While individual governments may be examining the merits or otherwise of the internet and in particular what sort of regulatory environment is appropriate, the benefits of moving forward quickly in keeping with the pace of innovation and development within the new economy generally puts specific pressures on health systems. Depending on the extent to which different countries more or less centrally control their

the possible benefits of moving to B2B health exchanges;

- significant benefits exist where B2B market makers can aggregate specific markets across Europe, yet there is still considerable resistance to parallel imports and a single market in health products. We need to understand how to develop a single market in health and how to energise individual countries to embrace such a market, when there may be

Health targets in the United States: innovation and ambition



Nanci Healy

“The US has had health targets longer than any European country and has acquired experience that could be valuable to other countries.”

The countries and regions of Europe, if they have elected health targets as a policy direction, have followed either the World Health Organisation model or a more limited construct (the approach taken by England). Experience sharing among countries on the effectiveness of their various programmes has just begun and, even within countries, measuring progress toward targets is sporadic and often difficult. At several conferences held last year in Europe – the first ones to be held on health targets – almost no one mentioned the United States as an example of a country that has chosen an entirely different approach to health targets.¹ Yet the US has had health targets longer than any European country and has acquired experience that could be valuable to other countries.

With 275 million people, the US has probably encountered every problem and opportunity related to health policy and health targets that has been experienced by the combined countries of Europe. And for the US, as for Europe, establishing priorities in healthcare is now recognised as a pressing agenda item for federal governments as well as for communities, business and the general public.

While both candidates for the US Presidency argue loudly about prescription drug coverage for older Americans, work has gotten under way in a quieter atmosphere to implement the objectives of *Healthy People 2010*.² *HP 2010* is the third programme of health targets in the US. The first, with 226 objectives for the year 1990, was introduced in 1979, even before the WHO launched Health for All. The second US programme, *Healthy People 2000*, consisted of 319 objectives in 22 priority areas to be met by the year 2000. Its goals were threefold:

- to increase the span of healthy life for Americans;
- to reduce health disparities;
- to provide access to preventive health services.

Progress toward objectives is mixed

The most recent review of progress toward the year 2000 targets, *Healthy People 2000*

Review, 1998-99, indicated mixed results:³

- Fifteen per cent of the objectives have been met, including those for nutrition, maternal and child health, and heart disease.
- An additional 44 per cent of targets are moving in the right direction, including those for breastfeeding, dental visits and immunisations.
- About 20 per cent of the targets are moving in the wrong direction. There are more obese people and, not surprisingly, fewer people exercising, for example.
- For eleven per cent of the objectives there were not enough data to assess progress.

Progress reviews of *HP 2000* are supported by extensive, detailed and reliable data, but it is still difficult to know whether the positive results are attributable to specific interventions and public health programmes or whether they would have occurred as a matter of course. This often-cited criticism is one of the problems faced by many countries and regions trying to measure progress toward health targets.⁴

The framework for *Healthy People 2010*

The development process underlying *HP 2010* was both participatory and transparent. More than 11,000 Americans offered their comments by mail or the internet. A Healthy People Consortium of over 350 NGOs and 270 state agencies conducted regional meetings on the programme. The final document, several thousand pages long, has two straightforward, ‘overarching’ goals:

- to increase quality and years of healthy life;
- to *eliminate* health disparities.

HP 2000 had as one of its goals to *reduce* disparities, but *HP 2010* goes one step further in seeking to eliminate them.

The programme takes a systematic approach to improving health composed of four elements: goals, objectives, determinants of health, and health status. The relationship among them starts with the two

“Eliminating health disparities may be even more challenging than increasing life expectancy.”

goals noted above that in turn guide the development of objectives. The 467 objectives are derived from the determinants of health, identified as the physical environment, individual behaviour and biology, and the social environment. The plan fully recognises the social and economic determinants of health, which is one reason why many agencies outside the health sector share responsibility for implementation.

To achieve the first goal of increasing life expectancy, *HP 2010* has a major task ahead, for the US ranks number 24 in the *World Health Report 2000*. Further, the measure known as ‘years of healthy life’ indicates that years of optimal health did not keep pace with actual years of life during the past decade in the US

HP 2010’s second major goal is to eliminate health disparities, whether they occur by gender, race or ethnicity, education or income, disability, living in rural localities, or sexual orientation. Today in the US women live six years longer than men, the infant death rate among blacks, American Indians and Alaska Natives is double that for whites, and Hispanics are twice as likely to die from diabetes as non-Hispanic whites, as examples. Eliminating health disparities may be even more challenging than increasing life expectancy. Gradients seem to persist in virtually all countries, whatever the health system and demographics.

Leading health indicators

That health indicators are vital to any effort to measure and improve population health is borne out by several major projects on two continents. The Council of the European Union in 1997 adopted a five

year programme to monitor the health of Member States, including an initiative to develop health indicators. In Canada, the provinces and territories have been formulating and using indicators for a number of years and now the federal government is spearheading the Canadian Indicator Project.

In preparation for *HP 2010*, the US Department of Health and Human Services (HHS) asked the Institute of Medicine (IOM) to develop at least two sets of indicators for consideration, in a process designed to be both inclusive and consensual. The effort also acknowledged that *HP 2010* is so comprehensive that “it has the potential to overwhelm and perhaps discourage individuals, voluntary organisations, community organisations and businesses from participation.” The leading indicators would help make the programme manageable and provide a balance that had been elusive during the 20 year history of *Healthy People* – that between a “comprehensive set of health objectives and a smaller set of health priorities.” Further, since the two previous versions of *Healthy People* had failed to engage the general public, the IOM was asked to develop communication strategies for the indicators to inform the lay public as well as traditional public and private healthcare communities.

In April 1999, *Leading Health Indicators for Healthy People 2010 Final Report* was issued. Leading indicators are defined as “a small number of key health and social issues that can be brought to the attention of the nation, motivate actions to exert positive influences over these leading health indicators and provide feedback concerning progress. ... Furthermore, a small set of leading health indicators can create a national identity for the full scale implementation of *Healthy People 2010* and expand the traditional *Healthy People*.”⁵ The hope is that the leading indicators will bestow a kind of identity on *HP 2010* overall and capture public and media interest. The indicators are not intended, according to the report, to provide a mechanism to monitor and evaluate the healthcare delivery system in the US There are other tools for that purpose.

The criteria used in guiding selection of the leading indicators examined each of six issues:

- Is it worth measuring?
- Can it be measured for diverse populations?

HEALTHY PEOPLE 2010 FOCUS AREAS	
¥ access to quality health services	¥ immunisation and infectious diseases
¥ arthritis, osteoporosis, and chronic back conditions	¥ injury and violence prevention
¥ cancer	¥ maternal, infant, and child health
¥ chronic kidney disease	¥ medical product safety
¥ diabetes	¥ mental health and mental disorders
¥ disability and secondary conditions	¥ nutrition and overweight
¥ educational and community-based programs	¥ occupational safety and health
¥ environmental health	¥ oral health
¥ family planning	¥ physical activity and fitness
¥ food safety	¥ public health infrastructure
¥ health communication	¥ respiratory diseases
¥ heart disease and stroke	¥ sexually transmitted diseases
¥ HIV	¥ substance abuse
	¥ tobacco use
	¥ vision and hearing

- Can the people who need to act understand it?
- Will the information galvanise action?
- Are the actions for improvement anticipated and feasible?
- Will measurement over time reflect results of action?

The full complement of leading indicators includes physical activity, overweight and obesity, tobacco use, substance abuse, responsible sexual behaviour, mental health, injury and violence, environmental quality, immunisation, and access to healthcare.

For each leading indicator, specific objectives taken from *HP 2010* will be used to monitor progress. The federal and state governments will issue 'report cards' on progress as well. For example, in the area of overweight and obesity, the objective is to reduce the proportion of children and adolescents who are overweight or obese from eleven per cent to five per cent by 2010. For tobacco, the goal is to reduce cigarette smoking by adults from 24 per cent to twelve per cent. Perhaps most interesting, the objective for the 'access to care' indicator is to increase the proportion of persons with health insurance from 86 per cent to 100 per cent by 2010. This appears most unlikely; some projections on insurance coverage predict more rather than fewer uninsured people in the next ten years.

Tracking progress on *HP 2010* and funding

Inadequate and inaccurate data continue to plague many countries and organisations as they attempt to measure health status and health improvements. In this respect, the US is fortunate because it has huge amounts of good data, although there are still considerable gaps. Data to monitor *HP 2010* objectives come from over 200 data sources at federal, state and local levels and are contained in the Data2010 system. This interactive system allows users to query an updated database and construct customised tables. Although it will be several years at least before reports measuring progress are issued, data are available now for a number of areas. For each objective, data are or will be available by population sub-groups, including American Indian, Alaska Native, Black or African American, Cuban, Mexican American, Asian and White, as examples.

According to Dr. Randolph Wykoff, Deputy Assistant Secretary for Health and

one of those responsible for overall implementation, *HP 2010* is "intensely data driven. The extent to which this process is based on solid science and driven by data has made it something that can be accepted by all political parties in our country and by people across the political spectrum."

No special funding has been allocated to implement *HP 2010*, according to Dr. Wykoff. "The plan is being built into and absorbed by the public health agencies. They are re-targeting and working *HP 2010* into their existing performance plans." The main challenge, he added, is coordinating the efforts of all the people and organisations necessary for implementation.

He noted that one of the great strengths of the *HP 2010* process is its "built in accountability." Each of the 28 focus areas has a lead agency that must elaborate on the objectives, measure them, and report periodically. "A variety of steering committees help accountability" also, said Dr. Wykoff. It is "a non-political issue, data driven."

Although relatively little commentary has so far appeared about *HP 2010*, an editorial in the *British Medical Journal* by Ronald Davis sums up the criticism by calling the programme "impressive but unwieldy." Mr. Davis points out the poorly defined role of the federal government in implementation as well as inconsistencies across focus areas. Further, "the enormous scope of *Healthy People 2010* threatens to divert too many resources from health improvement activities to tracking. ... Better tracking is such a challenge that one objective is to increase the frequency of tracking all the other objectives."⁶

Compared to European health target programmes and even to the World Health Organisation's Health21, *HP 2010* is encyclopaedic. As Mr. Davis asks, "which approach is more effective in achieving improvements in the public's health – developing a comprehensive set of health targets or a more focused one? ... A careful study of the different approaches used throughout the world would help us answer those questions."⁷

As implementation of *HP 2010* begins, public health officials and policy experts in other countries will be observing with a critical eye. In the US as well, opinions of *HP 2010* diverge, but the final word will come as progress reports begin to measure results in the next few years.

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EUROPEAN COURT OF JUSTICE RULES AGAINST THE EC TOBACCO ADVERTISING DIRECTIVE

The European Court of Justice decided on 5 October that the tobacco advertising and sponsorship Directive of 1998, which was adopted by the Council and the European Parliament, violates internal market trade and competition rules and should be annulled.

The Court, however, confirmed that public health protection is a constituent part of other Community policies and stated that a prohibition on certain forms of advertising and sponsorship could be adopted, such as sponsorship events or magazine advertising. The Court ruling is not expected to affect the proposed new Directive on tobacco products that aims to reduce tar, nicotine and carbon monoxide levels and increase health warnings on cigarette packages (see Health Council section).

In response to the Court's decision, the Commissioner for Public Health and Consumer Protection, David Byrne, stated that he is determined to bring forward new measures to tackle the pernicious effects of tobacco smoking, particularly for children and young people. He noted that most Member States supported the Directive to limit tobacco advertising and that many have already taken national measures to

restrict it. The Commissioner stated that he expects Member States and the European Parliament to support new initiatives to reduce the death toll from smoking. He welcomed the International Motor Sport Federation's announcement that it will be imposing a worldwide ban on tobacco advertising as of the end of the 2006 season.

More information on tobacco advertising can be found in the document 'Frequently Asked Questions on Tobacco Advertising in the EU'. It covers areas such as the current legislative situation in the EU on tobacco products, Member States' laws on the prohibition of advertising, and the nature of Community competence to prohibit advertising in general. The document also discusses the contradictory issue of why the EU funds tobacco farmers. *It can be found at: http://europa.eu.int/comm/dgs/health_consumer/library/press/index_en.html*

Commission adopts a Communication on the fight against HIV/AIDS, malaria and tuberculosis

The European Commission has adopted a new Communication, 'Accelerated Action Targeted at Major Communicable Diseases in the Context of Poverty Reduction.' The Communication stresses the need for effective global action to combat HIV/AIDS, malaria and tuberculosis which are killing over five million people every year and causing over 300 million episodes of illness. The Communication outlines the policy framework that the Commission will use to improve its response to these diseases in the developing world.

On 28 September 2000, the Commission hosted a high level international Round Table to discuss the EU's policy to combat HIV/AIDS, malaria and tuberculosis and to reduce poverty.

For more information on the Round table see: www.europa.eu.int/comm/development/sector/social/table_en.htm

The Commission proposes a new EU public health programme and adopts a communication on the health strategy of the European Community

The Commission will replace the eight existing EU public health programmes with a single public health programme, which will run from 2001 to 2006. This new programme will revolve around three key objectives: improving information systems; ensuring a rapid response to health threats; and addressing health determinants. An action programme with a proposed budget of 300 million euros, was presented by the European Commission in May and discussed by the Council on 29 June. The French Presidency is supporting the idea of creating a 'European Health Watch Institute' to ensure that all of the objectives proposed in the Commission's draft programme are pursued.

The European Commission

announced on 31 July that it would extend until 2002 some of the EU public health programmes that are due to expire this or next year, since the co-decision procedure on the new public health programme may not be completed before the expiration of existing programmes. The programmes to be prolonged are those on health promotion, health monitoring, pollution related diseases, and actions to combat cancer, AIDS and certain other communicable diseases and drug dependence. This will ensure continuity between the past and future programmes.

More information regarding the Commission's public health strategy can be found at: www.europa.eu.int/comm/health/index_en.html

Parliamentary hearing on public health and consumer policy aspects of enlargement

The European Parliament held a public hearing on Public Health and Enlargement on 11 July. During the hearing, Commissioner Byrne noted that a number of important initiatives have already been taken to address the public health situation in accession countries. In May last year, the Commission published a working paper on conditions relating to health in candidate countries. The Commission, in close cooperation with the WHO, is also preparing country profiles of all applicant countries, which give an overview of the health situation in each country in a comparative context.

More information on the Parliamentary hearing is available at: www.europarl.eu.int/dg7/hearings/en/default/btm

RESEARCH

New report calls for stronger impetus behind EU research

A new evaluation report on research in the European Union warns that there is a danger of Europe falling behind other economic areas and losing its place as a centre of excellence for the creation of knowledge if European leaders do not prioritise research. The report was drawn up by a panel of eleven high level independent experts from eleven EU countries that assessed the implementation and achievements of Community research and technological development programmes over the period 1995–99.

The report, addressed to EU Research Commissioner Philippe Busquin, states that EU research programmes alone will not be enough to meet the challenges faced by European research and that demographic changes and decreas-

ing research budgets will make a major policy review necessary. The report also calls for greater flexibility to meet new challenges such as new disease and food scares. Commissioner Busquin is expected to unveil plans this autumn to focus funding for research and development on large scale strategic projects in a range of key areas such as biotechnology and aeronautics. The Commissioner has stated that EU funding, currently 15 billion euros under the Fifth Framework Programme that runs until 2002, is spread far too thinly on small scale projects, and believes that funds under the Sixth Framework Programme must be given to fewer, bigger projects. *The evaluation report into research in the EU is available at: www.cordis.lu/fp5/5yr_reports.htm*

EU-US Biotechnology Forum

The first of at least three planned meetings of the recently established EU-US Biotechnology Consultative Forum took place on 12 September in Brussels. The forum was established as a follow up to a joint initiative announced by European Commission President, Romano Prodi, and US President Bill Clinton during the EU-US Summit on 31 May. The purpose of the forum, which will bring together twenty eminent independent experts from the EU and the US, is to discuss the broad range of issues concerning biotechnology, including health, safety, economic devel-

opment, food security and environmental issues. The forum will also address broadly inter-related issues such as the role of science, the ethical dimension, consumer information, public perceptions, risk analysis and intellectual property rights. The members of the forum will carry out much of their work by email and internet discussion, and their assessments will be reported to EU and US leaders. *Further information about the work of the forum will be made available on the European Commission website: http://europa.eu.int/comm/dgs/external_relations/index_en.htm*

Greater collaboration between the WHO and the Commission

The emergence of major communicable diseases such as HIV and the resurgence of malaria and tuberculosis, especially in the world's least developed regions, are raising the demand for research at a time of rapid advances in molecular medicine and biotechnology. Research results are critical to policy making processes and to the development and monitoring of health systems. EC Research Commissioner, Philippe Busquin met with Dr. Brundtland, Director General of the WHO, to discuss how the Commission and the WHO can reinforce each other's actions. Improving research and development activities calls for improved coordination of policies and a better dissemination of research results. WHO and the Commission's Research Directorate General will aim to foster new partnerships amongst networks of excellence, public health services, industry, hi-tech entrepreneurial businesses, NGOs and governments.

Dr. Brundtland also met with Commissioner Byrne to discuss the creation of a **WHO Framework Convention on Tobacco Control**. The Convention will address key issues such as cross border advertising and tobacco sponsorship. The European Community will participate actively in these negotiations that began in Geneva on 16 October. EU Member States have mandated the Commission to negotiate on their behalf in areas of Community competence.

Europe on the Move! Database Report 1999–2000

The European Network for the Promotion of Health-Enhancing Physical Activity has produced a Database Report 1999–2000 profiling its member organisations in EU Member States as well as 11 other European countries and Israel. *More information is available at: www.noc-nsf.nl/europe/*

New agenda on social policy

The European Commission has adopted a new Social Policy Agenda that will run up to 2005. The Agenda is based on objectives that were laid down during the summit in Lisbon in March 2000, and addresses the challenges and opportunities ahead regarding employment, enlargement and internationalisation/globalisation. The Agenda can be regarded as Social Affairs Commissioner Anna Diamantopoulou's mission for the remainder of her term in office.

The Social Policy Agenda and the European Parliament's reactions to it are available at: www.europarl.eu.int/dg7/hearings/en/default.htm

HEALTH COUNCIL

The Health Council met on 29 June 2000.

The most prominent item on the agenda of the EU Ministers' meeting in June was the draft for a **new Directive on tobacco products** proposed by the Commission in 1999. The new Directive aims to strengthen and extend EU measures against the dangers of tobacco consumption, in particular concerning labelling requirements and the tar content of tobacco products. The Council proposed to increase the size of labels to at least 25 per cent of the front and back of the cigarette packet. It thereby rejected the European Parliament's call to have 35 per cent of the front of cigarette packets and 45 per cent of the back to be devoted to health advice, including photographs graphically depicting the ill effects of smoking. The Health Council did agree that classifications such as 'light' and 'mild' must be forbidden, as they lead smokers to underestimate the dangers of such products and that maximum values for tar, nicotine and carbon monoxide content of cigarettes should be lowered. Furthermore, the addition of

ammonium to cigarettes should be banned as it enhances the nicotine's effect. The Council reached agreement by a qualified majority, with the German delegation voting against the proposed Directive and Austria, Spain and Luxembourg abstaining. Parliament and the Council will each have a second reading to reach an agreement. The new Directive is expected to enter into force in December 2003.

On the topic of tobacco regulations, the Council also took note of a report by Commissioner Byrne on the progress of the World Health Organisation Convention on Tobacco Control.

The future of EU health policy could not be discussed in detail as Health Council members received the Commission's proposal for a new health action programme only a few days before the Council meeting. All Member States, however, welcomed the proposed new health strategy and a more detailed discussion will be held at the Council's meeting in December.

The Council adopted a **resolution on health determinants** as a follow up to the European conference on this topic held by the Portuguese Presidency in March 2000 in Evora, Portugal. It welcomed the importance given to health determinants in the Commission's new health strategy and stressed the need to reduce health inequalities. In addition, tobacco, nutrition and alcohol were specifically identified as important health determinants.

The Council adopted a **resolution on medicinal products and public health** as a follow up to the Portuguese Presidency's conference on this topic that was held in Lisbon in April. The Council underlined the importance of ensuring broad accessibility to medicinal products and of innovation and the exchange of experiences between Member States regarding medicine and public health.

The Council adopted a **common position on the pending reform of the EU Directive on blood products**.

FIRST STATISTICAL GUIDE TO HEALTH IN THE EU

Eurostat, the Statistical Office of the European Communities, has published the first edition of '*Key Data on Health 2000*', a reference guide on health in the European Union. The Guide covers all 15 Member States as well as Iceland, Norway and Switzerland. The Report brings together all relevant data sources at the international level – Eurostat, the OECD, the WHO, the International Agency for Cancer and the AIDS Surveillance Centre. The publication presents data on population, lifestyle issues (nutrition, smoking, drug use, AIDS risk, etc.) health risks associated with the environment, working conditions, leisure and traffic morbidity and it gives an overview of healthcare systems.

The following are some of the statistics included in the publication:

- EU citizens feel fairly satisfied with their healthcare services. When asked to evaluate their health services, 70 per cent of respondents in Finland, 71 per cent in Austria, 70 per cent in the Netherlands, 60 per cent in France and 56 per cent in Belgium claimed to be fairly or highly satisfied. Dissatisfaction however, prevails in Portugal (73 per cent), Greece (53 per cent) and Italy (50 per cent).
- Greece has the highest ratio of specialist doctors to total population.
- France has the highest number of psychiatrists per million inhabitants, while Spain and Greece have the lowest.
- Kidney transplants are the most frequent type of transplant in the EU. For every million EU citizens, there were 31 kidney transplants in 1998. Most kidney transplants were performed in Spain, Austria, Belgium and Luxembourg while the fewest number were performed in Greece.

The publication should constitute a valuable tool for all those interested in health problems: politicians, health managers, members of the medical community, health economists, researchers and the public at large. *More information about the Guide can be found at: www.europa.eu.int/comm/eurostat*

NEWS IN BRIEF

Europe Against Cancer week: focus on nutrition

This year's Europe Against Cancer week, held from 9–15 October 2000, focused public attention on proper eating habits as a means to preventing cancer. There is strong evidence to show that diets high in vegetables and fruits decrease the risk of many cancers. The Europe against Cancer Week is an annual event, supported by the European Commission, national health authorities and cancer prevention organisations. *More detailed information can be found at: www.europa.eu.int/comm/health/ph/programmes/cancer/index_en.htm*

Nutrition Report

France has identified Nutrition as a key issue in the field of health during its Presidency of the EU. On the basis of a request by the Commission, the Crete University of Medicine coordinated the EURODIET project. The EURODIET group presented its conclusions at a conference in Iraklion, Crete, in May 2000. The French Society for Public Health (SFSP) has coordinated a report on nutrition in Europe which has been prepared by fifteen experts (one from each Member State, mandated by their governments). The SFSP Report will serve as a basis for a resolution by Health Ministers. *The SFSP's report on nutrition in Europe is available at: www.sfsp-france.org*

European Conference on Youth Suicide Prevention

Each year, nearly 43,000 deaths in EU Member States result from suicide, while 700,000 people attempt suicide. Under the French Presidency France a Conference on youth suicide was held in Nantes on 19–20 September 2000. Its aim was to generate an exchange of information and experiences regarding suicide prevention practices. *(See the opening speech by Commissioner Byrne.)**

European Health Forum, Gastein

The European Health Forum, which has established itself as an important focus for high level discussions on key health issues facing Europe's decision makers, was held in Bad Hofgastein, Austria on the 26–29 September 2000. The Forum brought together decision makers from policy and administration, science and industry as well as key advocates of patient and citizen concerns.*

European Conference on Gender Equity in Public Health

A European Conference on Gender Equity in Public Health was held in Trinity College, Dublin on 10 September 2000. Public Health Commissioner Byrne said in his speech to the conference that the new Community health strategy, will address in a more comprehensive and strategic fashion issues of common concern across the Community.*

European Breast Cancer Conference

The second European Breast Cancer Conference was held in Brussels on the 26 September 2000. It was noted how organised screening programmes in Scandinavian countries have led to a remarkable reduction in the number of deaths resulting from breast cancer. The Europe Against Cancer Programme is currently establishing, developing and disseminating best practice in screening for cancer throughout Europe.*

Parliament suggests 'debt for AIDS' programme

In a resolution on AIDS in developing countries adopted on 7 September 2000, the European Parliament called for reducing developing countries' debt in order to help them fight AIDS and other diseases. It suggested a 'debt for AIDS' programme to the G8.

World heart day

Heart disease remains the leading cause of death in both developed and developing countries. It is the largest single cause of death for people in the EU, accounting for 16.6 per cent of all deaths in 1996. World Heart Day on 22 September, an initiative of the World Heart Federation, sought to promote the message that simple lifestyle changes, such as moderate exercise, can halve an adult's risk of heart disease. The initiative is supported by WHO and UNESCO. *More information on World Heart Day is available at: www.worldheartday.com*

Interim report on future pharmaceutical reform

The Commission published an interim report on future pharmaceutical reform. The report, amongst other things, discusses the shortening of the mutual recognition procedure for pharmaceutical marketing authorisations in the EU. Some observers expect that the Commission will propose to ease the current ban on direct-to-consumer-advertising of prescription drugs. The interim report is available at: <http://dg3.eudra.org/pharmacos/docs/Doc2000/sept/audit0600.pdf>

Commission assistance for Kosovo

The European Commission is contributing 35 million of the 240 million Euro that has been earmarked for the reconstruction of Kosovo to health care reform. Assistance will be implemented mostly by EU health experts, who will work in association with UNMIK, WHO and Kosovar professionals.

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Commissioner Byrne's speech to the conference is available at: http://europa.eu.int/comm/dgs/health_consumer/library/speeches/index_en.html