

# SUSTAINING ACCESS TO MEDICINES IN EUROPE: THE COMING CRISIS

*Report of the HAI Europe/Medico  
International Seminar*

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*Health Action  
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**ABOUT HAI**

Health Action International (HAI) is an informal network of some 150 consumer, health, development action and other public interest groups involved in health and pharmaceutical issues in 70 countries around the world. HAI actively promotes a more rational use of drugs through advocacy, research, education, and action campaigns.

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## INTRODUCTION

The problem of access is usually portrayed as a crucial issue facing developing countries in the South. However, the evidence shows that access to essential medicines is becoming a growing concern in industrialised countries as well. Increasing drug prices, a lack of pharmaceutical innovation, the changing role of regulatory agencies, growing reliance on market-based solutions and new trends in drug promotion all contribute to the growing concern about sustaining access to needed medicines which is felt by many stakeholders involved in European health care.

As part of the international campaign on access to crucial medicines, HAI Europe and Medico International challenged public health stakeholders to identify key areas to be addressed in order to ensure sustainable access to medicines within Europe. The organisations' joint seminar on this issue provided an opportunity for European public health groups and other stakeholders to confront the coming crisis and discuss ways to ensure access to needed medicines in Europe in the coming years.

The seminar's speakers highlighted some of the central issues affecting access in Europe. Some spoke about recent developments in the European Community, others described their own national experiences. Speakers relayed how proposed EU policy on pharmaceuticals related to generics, fast-tracking and advertising may affect access in both the short and long-term. Another presenter emphasised how decisions made in Brussels may affect access in countries outside of the EU.

The seminar aimed to explore the various pressures and priorities facing insurers, governments, consumers and the pharmaceutical industry. It also examined how various influences from outside the EU such as direct-to-consumer advertising and the International Conference on Harmonization play a significant part in the regional access debate.

The event's audience was mixed and comprised many different stakeholders involved in this debate: representatives of governments, consumers, insurers, public health advocates, NGOs, the brand name and generics pharmaceutical industry and academicians. All were encouraged to share their perspectives on the day's theme.

By the end of the seminar it was clear that the meeting had raised many more issues related to access than it could answer. It also found a number of parallels to the access problem already existing in many developing countries.

The seminar marked the first time that the HAI Europe network examined the access issues gathering in its own backyard in addition to cooperating with NGOs and governments to address the already overwhelming access crisis in the South. It marked the beginning of a new awareness among many stakeholders of the growing magnitude of the problem and the rapidly mounting need to take well-chosen steps to address it before it jeopardised public health in Europe. It also sparked a new effort within the network to explore how current access issues will affect the countries of Central and Eastern Europe.

During the next few years, HAI Europe and other stakeholders involved in this debate will work to raise awareness about the growing access crisis in Europe. They will urge policy-makers at both the national and regional level to take action in order to help change or diminish the negative consequences that current economic and political choices will have on the public's continuing access to essential medicines.

## PEOPLE'S HEALTH NEEDS VERSUS COMPANIES' MARKETING RIGHTS by *Andreas Wulf, Medico International, Germany, seminar co-organiser*

*Andreas Wulf is a physician working with Medico International in Frankfurt. The topic of access to needed drugs in developed and developing countries is one of the primary focuses of his current work. Andreas Wulf opened the seminar on behalf of Medico International by examining German government efforts to maximise access to the most needed drugs while respecting companies' right to promote their products.*

The focus of this conference, sustaining access to medicines in Europe, and the issue of financing healthcare and especially the increasing costs of medicines, was a hotly debated topic in the German political arena throughout 2001. This debate was fuelled by the dismissal of the country's former health minister from the Green party. This action led to a loosening of tight controls and threats about the budget for ambulatory care providers by her replacement, a Social Democrat.

The increasing drug costs that followed shortly after the lifting of these controls were justified by the pharmaceutical companies as necessary to support research and development of new, innovative drugs. In the same way, doctors accepted the increased prices as a way to bring about needed improvements in drug treatment. Statutory sickness funds raised concerns that such price increases would lead to higher insurance contributions by the insured and employers--something the government's health policy wanted to avoid at all costs.

### ACCESS: RELYING ON THE MARKET

Before other speakers talk in detail about different aspects of access, I would like to shed light briefly on the concepts and ideas that have dominated and are still dominating the health policy debate in health politics. These topics are namely privatisation, competition and market solutions. I will try to sketch out some of their implications for health policy goals such as safeguarding people's health needs. Strategies to sustain access to medicines must be linked to the same goals and therefore should be kept in mind during the seminar's discussions.

Market-oriented reforms in public services and, specifically, in the health sector, gained international dominance in concepts used to relieve the effects of the 1980's prolonged recession. Private sector management was considered superior due to its emphasis on cost containment and increasing efficiency brought about by competition and economic incentives. After the collapse of the socialist-planned economies, these principles of liberal economy seemed to be highly confirmed. Market mechanisms and competition were introduced in the public sector. For example, experts believed market relations should be governed by contracts which would specify performance targets and employ input/output accounting for more effective monitoring and greater transparency.

**MORE IMPORTANTLY IS THE "SOCIAL BLINDNESS" INVOLVED IN THESE DEVELOPMENTS, THAT IS, THE TENDENCY TO DISCOURAGE OR EXCLUDE MARGINALISED PEOPLE WITH LITTLE ECONOMIC POWER FROM ACCESS TO THESE PRIVATISED SERVICES.**

On the other hand, consumers (or patients) in the health sector, needed to be equipped with the best possible knowledge of those markets so that their interests could be realised through the forces of demand and supply. Following this concept, patients

are considered responsible for their own health. They are regarded as conscious consumers of health services, no longer held captive by insurance bureaucrats and physicians' unquestionable decisions. The role of consumer interest groups in this area will be highlighted later by Clara MacKay of Consumers Association.

At present it is becoming more and more clear that privatisation of public services including health care, water supply, sanitation, telecommunications, public transportation, and education, often cannot bring about the expected improvement in quality and profits. A recent example is the privatisation of the British Railway, which has led to serious problems in service and safety.

More importantly is the "social blindness" involved in these developments, that is, the tendency to discourage or exclude marginalised people with little economic power from access to these privatised services. This is not only true for consumers in impoverished, developing countries in the South, it is a problem in Europe too. However, in the South, it means that sometimes more than half the population has no regular access to health care.

Even as some recent World Bank publications acknowledge the dire necessity of securing at least a basic package of public services to assist poverty alleviation, the trend towards privatisation and free trade of services is still supported strongly in the international arena. Notably, it is the core issue of the World Trade Organization's (WTO) negotiations on the General Agreement on Trade in Services (GATS).

There are three major concerns raised by the market-oriented concept of health care which should be discussed today:

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#### MARKET-FAILURE: SUPPLY-DRIVEN DEMAND

Back in 1993 the World Bank's *World Development Report* – a source not really suspected of criticising capitalism – drew attention to a "market failure" in health care systems, because providers (mostly physicians) base their decisions about their range of services mostly according to their own interest. What seems to be typical for the health care market is that, contrary to liberal economic assumptions, nearly all supply creates its own demand. In fact, (and it doesn't come as a surprise in a world of commodities) health care providers as well as patients often equate "more medicine" with "better health" and consider "expensive medicines" favourable to cheaper ones.

Now let's look more closely at pharmaceuticals in terms of the seminar's topic, access. Innovative medicine is one of the most apparent and articulated needs that patients demand from a modern health care system. However, this need can be compromised by the profit interests of drug suppliers. There has already been a lot of debate on intellectual property rights and the consequences for access to medicines. Under the current system, patent protection keeps the price of new and innovative drugs high in order

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to safeguard the patent owner's profits for a long period of time (20 years of patent protection are demanded in the TRIPS Agreement). However, such prices place these medicines out of the reach of public health systems (and even many private insurance contracts) in most developing countries. As a result, the poor living in most countries of the world, who can't afford to pay for these drugs themselves, have no access to them.

More worrying is the fact that the major health problems experienced by poor people (and in poor countries in general) are of no interest to the research and development efforts of for-profit pharmaceutical companies. Very few new drugs have been discovered for important health problems including tuberculosis, malaria or sleeping sickness because of the weak market power held by the people and countries concerned.

The idea of cross-financing research on these types of diseases with the profits made from “blockbuster” drugs in developed countries can’t be reconciled with shareholders’ interests and transnational companies’ exchange rates.

However, it is not only the health needs of people living in developing countries that are endangered by market forces. Reality shows that the number of really innovative drugs is nothing compared to the amount of new “inventions” which flood the market every year in Western, industrialised countries. Peter Schoenhoefer will present many more details on this issue in his seminar presentation.

Given this fact, manufacturers’ promotion of similar products (“me too” drugs) to bid for the same market segment has become increasingly important. Later during this seminar Charles Medawar will take a critical look at new drug promotion policy proposals within the European Union and their possible consequences for people’s health.

Competition for a winning market share has also led to industry calls for faster access to the market. However, the recent case of Lipobay (cerivastatin) has raised concerns about safety and new drug approval procedures and their surveillance in clinical practice outside strictly controlled studies. John Abraham will paint a detailed picture of the problems arising from the European Union’s increasing push to “fast-track” medicines.

Another topic involved in the drug innovation debate is the demand for a “fourth hurdle” when governments consider approving new drugs. The “fourth hurdle” (used in Australia) demands that in addition to safety, efficacy and quality, the drug provide a substantial improvement in treatment (the so-called “need” clause). It also holds a limit on the number of well-established and useful drugs reimbursed by the social security system. This dampens manufacturers’ interest in bringing a close copy of existing drugs to market. Obviously this will damage drug companies’ profits as the number of new drugs approved will probably be lower and a manufacturer’s “share of the cake” might be smaller. However, through the fourth hurdle, the safety of drug therapy might improve substantially and it might be easier for doctors to gain a good view of available drugs.

How national health policy can move between various stakeholders’ demands and the need to safeguard quality as well as costs will be presented at this seminar by Hermann Schulte Sasse.

## OPERATING EFFICIENCY – SELECTED PROVISIONS IN HOSPITAL CARE

My second example comes from the transformations of hospitals into profit centres. Hospital care costs make up the biggest piece of expenditures by statutory sickness funds.

Understandingly, there is an interest in cost reduction through increased operating, economic and administrative efficiency in hospitals. To achieve this goal, hospital privatisation and corporatisation on the agenda of liberal health policy are not the only issues on the agenda. In addition, proponents call for internal “structural adjustments” to transform hospital substructures, administration departments, and internal services such as laundries, kitchens, and clinics into profit centres. These profit centres are supposed to account for their own financial balances within the framework of the hospital.

These profit centres are also supposed to offer their services directly to their patients/customers and take into account their demands. They can also use their profits for reinvestment or profit-sharing among the staff. Of course, there are some advantages: greater transparency and improvements in the organisational flow of the profit centre as well as more highly motivated and self-reliant staff – possibly resulting in a more patient-friendly atmosphere.

However, serious risks have to be kept in mind. Social welfare-oriented health policy goals, intending to secure access to hospital care for citizens, are not easily reconciled with profit centre structures. By establishing such structures and new financial measures (instruments such as diagnosis-related groups), which are no longer supposed to cover fixed day tariffs but rather reimburse tariffs for standardised treatment cases, important possibilities for cross-financing and subsidising other areas within the hospitals will be halted.

Only some expensive cases can seriously disturb the operating efficiency of a profit centre, thus the logic of avoiding cost-intensive treatment (and patients) is systematically produced. In Germany, one can find evidence of efforts made by hospitals with strict business administration to reject these and other “expensive patients” in spite of an existing “contract of provision” for all hospitals in Germany. A more hidden way to prevent such costs is not to offer treatments that cannot be sufficiently standardised. In the United States, this type of experience has been extensively documented by the public interest organisation called Public Citizen. They have reported on such illegal practices as “patient-dumping” and denial of treatment in hospitals in all regions of the country, both in for-profit or non-profit companies. Thus, it reveals the “structural logic” of risk selection and “cherry-picking”.

## ABOLITION OF SOLIDARITY-FUNDING MECHANISMS

With the establishment of statutory sickness funds in Germany in the late part of the nineteenth century, a solidarity mechanism was introduced into the health insurance system for workers. The system charged premiums according to the worker’s income level while guaranteeing an equal level of care for all insured people and their families.

Increasing competition for clients within the sickness funds has fuelled movements towards the abolition of these solidarity funding mechanisms, even if some instruments of redistribution between the statutory sickness funds have been implemented. However, competition will always prefer “better risks” over “bad risks”, that is, those clients who

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**THOSE INHABITING THE BOTTOM OF THE SOCIAL STRATA ARE MORE EXPOSED TO ILL HEALTH AND DISABILITY BECAUSE OF THEIR LIVING AND WORKING CONDITIONS AND WILL BE DISPROPORTIONALLY AFFECTED BY THESE DEVELOPMENTS.**

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cost less than their premiums against those who cost more. A specific social gap will also widen with these concepts, as it is commonly known that those inhabiting the bottom of the social strata are more exposed to ill health and disability because of their living and working conditions and will be disproportionately affected by these developments.

You don’t have to look as far as Chile which systematically promoted the competition of private health insurance to the general social insurance during the 1970’s dictatorship. This was done following the advice of neoliberal economists from the Chicago school.

Private, for-profit health insurance companies recruit young, better-paid, policy holders with favourable premiums (in their income group) while poorer, especially larg-



er families won't find affordable contracts with private insurance companies. They must depend on public insurance with income-related contributions.

Private insurers extensively use the strategy of “cherry picking”, and must do so according to the logic consequently serving predominately people in the “higher” segment of society which are already “better off” with fewer risks of ill health given their higher social status. Debates in Germany actually reveal similar strategies between competing sickness funds following the already mentioned introduction of competition mechanisms. Namely, flexible, modern, wealthier members of the middle class who are open to healthy lifestyles are courted. They increasingly leave the big traditional sickness funds and move into new, innovative sickness funds which offer modern telecommunication instead of expensive personal service to their clients. The money saved is then “invested” into a more generous reimbursement of new therapies such as acupuncture or nature courses or used to offer lower premiums.

Thus, social redistribution resources decline placing the remaining funds under pressure. The same funds are already stressed by income reductions due to high numbers of unemployed policy holders using lowered tariffs paid by unemployment insurance.

Strategies of statutory sickness funds to ensure good quality health care under these constraints will be explored in greater detail by Angelika Kiewel, representing the Association Internationale de la Mutualité (AIM).

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## CONCLUSIONS

By illustrating three aspects of market mechanisms, I have tried to outline how the introduction of privatisation and competition in health care systems impairs patient needs especially if we see equity and solidarity as important health policy goals. These dimensions are an important way to minimise the existing social gaps related to ill health and premature death. Health systems which feature competition and management efficiency as the main operating principles for the agents involved, be it pharmaceutical companies, hospital profit centres or sickness funds, will systematically benefit those, who are already better off. They will help those who take care of their health in specific ways and who can achieve a better “market-overview”.

In addition to the big companies and their shareholders, these clients will be the ones who will profit from the commodification of health care. Others who are more dependent on social systems' redistribution mechanisms will be systematically excluded and further marginalised. These tendencies of undermining the principle of solidarity make it necessary to use redistribution mechanisms within health politics to secure equitable access to health care for all. Of course it is not a sufficient way to turn “health as a human right” from rhetoric into practice. Within such a framework, a discussion on cost-containment and the quality of health care services, especially of pharmaceuticals, will be of greatest benefit.

**PROMOTING PRODUCTS OR HEALTH?***By Charles Medawar, Director, Social Audit, UK*

*In his presentation, Charles Medawar, a long-standing activist on public health issues, took a critical look at the implications of the European Commission's proposal to ease advertising rules for prescription drugs within the Community, and importantly, the politics behind this move. He suggested that the introduction of direct-to-consumer advertising (DTCA) within the EU would have a huge impact on drug prices and health budgets within the region and beyond.*

It seems vulgar to talk about access problems in Europe when Southern countries are facing such a crisis. However, the truth is that access is becoming a growing issue for Europe too. I recently did a consultancy for the Australian Ministry of Health which enabled me to examine its health care system. The fact is that its system is unsustainable in its current form. The choice will have to be made to drop drugs from the reimbursement list or drop recipients. The same kind of problem is familiar in most industrialised countries. Perhaps if we can begin to find a solution for our situation we can also find ways to help ease the problems in the South.

At this seminar I would like to talk about direct-to-consumer advertising of prescription drugs as a feature of health policy, rather than looking at it specifically as a method of promotion. Today this type of advertising is allowed in the US (by design) and New Zealand (more by accident). Both countries have now had about five years' experience with it. After two public enquiries, New Zealand has just decided not to ban it. In the US it remains controversial, but it is generally accepted that it is there to stay.

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Currently, companies spend about US\$ 2½ billion a year on it. Direct-to-consumer advertising is a problem in its own right. One-quarter of the ads appearing in the US are in violation of that country's advertising law. Imagine the impact of that on countries lacking the resources the US Food and Drug Administration employs on detection and enforcement. While many ads may include some useful information, what happens when commercial information becomes the staple part of the information diet?

Advertising is by its nature partial and superficial; it is almost invariably used to promote branded products which are usually more expensive as they are under patent. Everyone denies that advertising influences them, but acknowledges that it works on others. The existing evidence suggests that direct-to-consumer advertising in Europe will do no more for consumers than advertising has done for health professionals. It is a major threat to public health. Such advertising will turn us into a nation of healthy hypochondriacs. People will be looking for things that could be wrong with them and they will be searching for a pharmaceutical solution. This is the key to the relationship between direct-to-consumer advertising and access to medicines.

Big pharma is a US creation and the States is its spiritual home. Industry is not greedy, but rather in a state of perpetual crisis. It is no longer sustainable because it cannot now innovate at the required rate. Roughly speaking, in order to sustain average industry growth, a pharmaceutical company needs to bring to market, each year, one new "blockbuster" product that can generate sales of at least US\$500 for every 1% to 1.5% it has in the world pharmaceutical market. A major company like Pfizer would

need to develop perhaps six new products a year; in fact it develops about two. All the major companies are in the same boat. Being unable to innovate at anything like the rate required to meet investors' expectations – and increasingly threatened by purchasers requiring more and more better evidence of value for money – the industry has tried to protect its position by agglomeration and aggressive market penetration and expansion. Mergers buy time, but they don't lead to increased R&D productivity – though in the longer term they might be expected to reduce competitive pressures. So, in the meantime, direct-to-consumer advertising of prescription drugs is seen as part of the answer to the innovation crisis, because it allows companies to expand markets greatly, and sustain high drug prices at the same time.

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THE EXISTING EVIDENCE SUGGESTS THAT DIRECT-TO-CONSUMER ADVERTISING IN EUROPE WILL DO NO MORE FOR CONSUMERS THAN ADVERTISING HAS DONE FOR HEALTH PROFESSIONALS. IT IS A MAJOR THREAT TO PUBLIC HEALTH.

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The recent growth of direct-to-consumer advertising in the US has exacerbated a problem that has confronted the industry for some time. In short, the health return on financial investment in medicine has been getting smaller, and the absolute costs too high to bear. The great investment in medicine made in the second half of the 20th century has led to massive improvements in standards of treatment and levels of understanding, but with relatively small improvements in general levels in health. Provision of the essentials of medicine leads to substantial health attainment, but substantial national investment generally produces only marginal gains.

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## PRESSURE FOR DTCA IN EUROPE

This summer, the European Commission published proposals – after a pitiful round of consultation – that would for the first time allow pharmaceutical companies in Europe to promote some drug treatments directly to consumers. The Commission insists that it is not allowing direct-to-consumer advertising; it is proposing to allow companies in future to promote drug treatments for diabetes, asthma and AIDS for a trial period of five years.

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THE EUROPEAN COMMISSION, AND THE G10 HAVE BEEN RESPONSIVE TO THE INDUSTRY'S PLEAS FOR DIRECT-TO-CONSUMER ADVERTISING, MOSTLY BECAUSE THEY ARE WORRIED ABOUT THE DECLINE OF THE COMPETITIVENESS OF THE EUROPE-BASED PHARMACEUTICAL INDUSTRY IN RELATION TO THE US INDUSTRY.

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The move towards direct-to-consumer advertising has been driven not by the vestigial EC Directorate for public health but by the trade and competition (Enterprise) Directorate. As well as being responsible for the licensing and regulating of pharmaceutical companies, it is also concerned with the promotion of the competitiveness of the industry.

A group called the G 10 is also pushing for this change. The G 10 committee, which describes itself as a high level group of “the top decision makers on medicines in the EU” sees its task as producing a report which will try to reconcile health and trade interests. The group includes two EC Commissioners (one each for trade and health), four senior members of the pharmaceutical industry and one consumer representative. Their aim seems to be to make the Commission's proposals more politically acceptable to the European Parliament and the media.

The European Commission, and the G10 have been responsive to the industry's pleas for direct-to-consumer advertising, mostly because they are worried about the decline of the competitiveness of the Europe-based pharmaceutical industry in relation to the US industry. The Commission believes the US pharmaceutical sector is better at innovation. However, the Commission has judged the value of innovation solely in economic terms. Almost unbelievably, its analysis takes no account of the therapeutic significance of innovation, nor its value as a response to medical need. The Commission's measure of success in innovation mimics the industry's own: blockbuster drugs that make lots of money.

The industry says it needs an increasing amount on money to undertake R&D for new drugs. But what kind of innovation are we all paying for? How valuable are these new drugs for public health? We take for granted that without innovation, health will suffer. However, we could do more for health on the global level by making better use of the drugs we have now. How much should be invested in innovation? Should it be in the hands of Big Pharma to decide? Inevitably, it will turn to blockbuster products. Only a few drugs can give ample return.

It seems clear that the trade directorate is not thinking about treatment success. It is much more concerned about the competitiveness of the EU against the US. This blinkered perspective underlines the need to move pharmaceutical policy out of the trade directorate and into the health directorate (Sanco).

The current proposal allows companies to provide consumers with information about three chronic illnesses. Because more and more patient groups are supported by industry it seems inevitable that other patient groups will start demanding that the Commission allow companies to deliver information about their disease too.

## THE EFFECT OUTSIDE EUROPE

Direct-to-consumer advertising is very much an extension of the American way of doing things. This should be borne in mind when contemplating the coming of direct-to-consumer advertising in Europe - let alone in many poorer countries in the world. There cannot be many countries whose people would gain by embracing the American way of health. The per capita cost of health in the US is more than twice that in the EU Member States: it would be unaffordable for any national community. European health systems tend to prioritise general health needs. The American model makes a sharp distinction between "health winners" and "health losers" and is hard driven by market imperatives and needs. At least 40 million Americans have no health insurance at all.

The European Commission has proposed some measure of statutory regulation for the DTCA experiment it has proposed, but ultimately it is looking to self-regulation by the industry. That would be the only option for two-thirds of the world's countries that still lack laws to regulate drug promotion or do not enforce existing laws.<sup>1</sup> Whether one can trust an industry fighting for its survival to "encourage the rational use" of its products by presenting information about them "objectively and without exaggerating" their properties, seems very doubtful indeed.<sup>2</sup>

Direct-to-consumer advertising and all the baggage its brings presents clear risks for the European community. It might be expected to promote higher drug prices and tighter health budgets, to distort priorities in innovation and in meeting medical need.

<sup>1</sup> Mintzes, B. *Blurring the boundaries: new trends in drug promotion*, Amsterdam: Health Action International Europe, 1998.

<sup>2</sup> These are the requirements of the current EU drug advertising laws, codified in the UK as Statutory Instrument 1999, No 267, The Medicines (Advertising and Monitoring of Advertising) Amendment Regulations 1999.

## FAST-TRACKING OF MEDICINES: IMPROVING ACCESS WHILE ENDANGERING PUBLIC HEALTH?

Speaker: John Abraham, Professor of Sociology, University of Sussex, UK

*John Abraham has carried out extensive research on the process of drug regulation in Europe. Using data collected during a survey of stakeholders involved in the regulatory process in this region, he examined the European Union's policy on the fast-tracking of medicines and analysed its consequences for access and public health.*

As part of the International Conference on Harmonization (ICH), EU regulations on pharmaceuticals must be harmonised with regulations used in Japan and the US. Although ICH's membership is limited to the governments and research-based industry associations in these three regions, the process has worldwide implications. Although they are largely excluded from the ICH process, it has important consequences for developing countries and their capacity to produce medicines. In the past few years, the ICH has become a symbol of the emerging globalisation of safety and quality standards. In fact, the World Health Organization now wants to disseminate ICH standards.

The ICH process has affected Europe in a number of ways. Currently, there are a number of structural features in the way medicines are regulated in Europe that are important for our discussion about access, safety and quality. For example, fees for regu-

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THERE IS A GROWING CONCERN THAT THE PUBLIC INTEREST MAY BE NEGLECTED AS AGENCIES FEEL PUSHED TO APPROVE DRUGS QUICKLY AS MANY SEE THE PHARMACEUTICAL COMPANIES AS THEIR "CLIENTS".

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latory "services" are playing an increasingly important role. The last decade has seen a sharp increase in the amount of funding industry pays to regulatory agencies in Europe to carry out their work. Reduced public revenue for pharmaceutical regulation has made regulatory agencies much more dependent on industry fees than they were a decade ago.

There is increasing inter-agency competition for "regulatory business" with an associated emphasis on the acceleration of approval times. With in the EU system, national regulatory agencies must compete with each other to be named the reference member state (under the mutual recognition procedure) or as rapporteur (for centralised procedures). In this role, they receive most of the fees paid by a company when a drug is being considered for approval. There is a growing concern that the public interest may be neglected as agencies feel pushed to approve drugs quickly as many see the pharmaceutical companies as their "clients".

Countries often feel pressure to approve new drugs unless there is a glaring reason not to do so. Member states often approve drugs based on the fact that there is no direct evidence of real risk of harm. This certainly takes attention away from evaluation of a drug's true efficacy and benefit.

The mutual recognition procedure is shielded by almost total secrecy. The centralised procedure allows discretionary provision of information, but gives citizens no right to access the information. The most information available about approved drugs can be found within the European Public Assessment Reports (EPARS) which have been criticised by consumer groups and health professionals for not providing adequate information to make a complete and accurate assessment about the drug.

## WHAT RESEARCH REVEALS

As a central player in the ICH system, would the EU likely experience a levelling down of safety standards? Or has it already happened? We undertook some research with regulators and representatives of the research-based industry to find out. In summary, industry informants said no, while a slight majority of regulators said yes.

TABLE I

*There is, or is likely to be, a levelling down of safety standards*

Informant	Number	No (%)	Yes (%)	Unsure (%)
Industry	27	24 (89)	2 (7)	1 (4)
UK regulators	2	1 (50)	1 (50)	0 (0)
German regulators	4	2 (50)	2 (50)	0 (0)
Swedish regulators	7	1 (14)	4 (57)	2 (29)
EU regulators	2	2 (100)	0 (0)	0 (0)
Totals	42	29 (69)	10 (24)	3 (7)

In our interviews, the industry view on safety standards generally followed the argument set out in this following quote from one of the informants:

Harmonisation will lead to less ridiculous requirements hopefully. Normally my experience is that they [regulators and other standard-setters] do not agree on a lower standard. The requirement is always higher than before. What is also a fact is that the

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HOWEVER, SOME RESPONDENTS SPOKE OF CONCERNS THAT THE EU APPROVAL SYSTEM WOULD DROWN DRUG MARKETS IN COUNTRIES LIKE SWEDEN, WHICH HAVE WORKED TO LIMIT THE NUMBER OF PRODUCTS AVAILABLE AND TO ENSURE THE SAFETY OF THOSE DRUGS.

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unnecessary burden of safety testing is reduced. So we don't have to do what we did in the past just because it was a requirement, rather than because it is scientifically justified. This is not a risk to public health.

However, some respondents spoke of concerns that the EU approval system would drown drug markets in countries like Sweden, which have worked to limit the number of products available and to ensure the safety of those drugs. As a regulator there mentioned "Sweden is much tougher for the companies than some other European countries. We are afraid that the Swedish market could be flooded with a number of drugs that we do not really want to have because we do not know enough about their pharmacokinetics, adverse reactions in patients, interactions with other drugs and so on."

One interview highlighted this point in the following exchange:

Interviewer: Are you saying that there are instances where either this authority [BfArM] or other national authorities in the EU have had to, or have accepted a product which, under their own national procedures, they would not normally have done?

BfArM2: Of course

Interviewer: Which then, potentially anyway, does lead to a lowering of safety standards, by definition?

BfArM2: Of course.

Another German regulator emphasised that improved safety was not the goal of European harmonisation. He said “Harmonisation on the drug level is part of the commercial part of the EU – the single market – DG III [the EU directorate for trade and industry] is dealing with the problem. It’s about access to the market, not about benefit to safety.”

Interestingly, half of the regulators included in the study said that competition between member states was a threat to public health. The industry respondents did not

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#### THE RESULTING PRESSURE FROM INDUSTRY SEEMS HARD FOR REGULATORS TO IGNORE AND THE RISKS COULD BE SIGNIFICANT.

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agree. One said: “I think the competition is to be welcomed because [regulators] have to prove that [they’re] better not just faster. And companies are going to choose that Member State that not only gets them a fast opinion but that ensures that that is acceptable throughout Europe.”

The resulting pressure from industry seems hard for regulators to ignore and the risks could be significant. One German regulator admitted that reduced time frames mean placing more trust in the manufacturer. He said: “If you try to assess complicated products in a very short time, in most cases you must believe what is written down by the companies. If you have a company working correctly, it’s not a problem, but if you have companies which are not, there will be a problem. To find these companies out you must have time. I think there will be a risk for safety in the future.”

A Swedish regulator called on all EU countries to stop pandering to industry’s demand for fast approvals so that public safety was not put at risk. In his interview, he said, “It’s a pity if we as agencies start running in a race which the industry might like. Agencies are there to make sure that safe and effective drugs are on the market – as consumer protection. The health care systems are less interested in 56 or 86 days, they’re more interested in the quality of the assessment. And I think it’s a bit unfortunate that we, together with all the other agencies, have not been able to say: OK, time is now decided at 210 days. That’s what we have to work with, we accept that, but let’s not race faster than that. Let’s make the best out of those days. Instead of competing, let’s make the best evaluations instead of the quickest ones.”

Are regulators’ concerns justified? Or is the industry response reasonable? One can consider a number of regulatory standards that have already been adopted by the EU as part of the ICH process.

- **REPORTING OF POST-MARKET ADVERSE DRUG REACTIONS (ADRS):** The EU decided not to harmonise upwards to the US FDA’s standard calling for quarterly reports and instead agreed on reports every six months. It also decided to demand fatal and life-threatening ADR reports within seven instead of five days due to objections by the Japanese Pharmaceutical Manufacturers Association (JPMA).
- **SHORTENED TRIAL TIMES:** Marketing applications and approval may be made with just six month trial data (previously one year) even though research available to the ICH showed that about one-quarter of serious ADRs in one-year clinical trials occurred after six months and one-eighth first occurred after six months.
- **REDUCED TESTING FOR CARCINOGENICS:** Completed rodent carcinogenicity tests are not needed in advance of the conduct of large-scale clinical trials (the ones that last from six months to a year), even though it is recognised by ICH authorities

that carcinogenicity testing is required for drugs to be used for more than three to six months.

- Carcinogenicity testing may be reduced from two to one lifespan carcinogenicity test, even though such testing remains the crucial way of screening for cancer-inducing drugs.
- **SHORTER TOXICITY TESTS:** Chronic toxicity testing in animals is reduced from 12 to six months, even though the US Food and Drug Administration concluded that unforeseen toxicities are being detected after six months of chronic testing in non-rodents.

What all of these examples suggest is that, in fact, opportunities to harmonise upwards are often not taken. The amount of testing is often being reduced or its time span shortened. One-half of the regulators we interviewed believe that fast-tracking is in the EU dangerous to public health. The material we analysed certainly show that the EU has developed a consistent trend of lowering standards.

## RIISING HEALTH CARE EXPENDITURES AND DECLINING REGULATORY QUALITY: WHAT HAS THE PHARMACEUTICAL INDUSTRY CONTRIBUTED TO SUSTAINING ACCESS TO NEEDED MEDICINES IN EUROPE?

by Peter S. Schoenhoefer, co-editor, *arznei-telegramm* and Professor Emeritus of Clinical Pharmacology at Bremen's Central Hospitals

*Dwindling quality of licensing procedures, useless pseudo-innovations, falsified studies, manipulated drug information, abused (corrupt) opinion leaders, these are just some of the "contributions" Peter Schoenhoefer said have been made by the multinational pharmaceutical industry. If these are the advances the industry is offering, how can it portray itself as a serious partner in the rational use of medicines, he asked.*

The thalidomide disaster changed our views on drugs. Before then, most people thought that drugs allowed on the market were completely safe. We also thought that companies would never try to market (and keep marketing) a drug that could have such serious consequences for health. We were wrong.

### A RECENT EXAMPLE OF THE PROBLEM

Cerivastatin (Lipobay) was rapidly licensed by the European mutual recognition procedure as a "me-too" preparation based on surrogate criteria, small size trials and short-term clinical studies. Bayer withdrew it from the market in August 2001 even though the EU's Committee on Proprietary Medicinal Products (CPMP) had declined to take action at its 29 June 2001 meeting, following increasing number of reports of serious adverse

### THE QUALITY OF REGULATORY AGENCIES IS DECLINING QUICKLY.

effects (rhabdomyolysis) induced by doubling tablet strength to fulfill the claims of superior efficacy made by Bayer's marketing mainly in the US. The affair shows the extent to which industry lobbying and pressure have already eroded the quality of the drug licensing procedure, increasingly endangering patients and consumers.

### THE DECLINING QUALITY OF REGULATORS

The quality of regulatory agencies is declining quickly. *The Lancet* called the US Food and Drug Administration "a servant of the pharmaceutical industry" and the EU Commission's DG Enterprise touts itself as "a promoter of the drug industry." Scandals with drugs such as Lipobay appear to emphasise this problem. There are public warnings. The producer – after some delay – takes the drug off the market. The drug regulatory authorities remain inactive. In some cases, weeks pass before the regulatory authorities show any reaction at all. In the Lipobay case, the manufacturer was the first to act, but lost all credibility with incompetent risk management. Shareholders were the first ones to be informed of the market withdrawal which was published in the press before pharmacists and doctors were informed.

This was followed by the usual "who is the bad guy" procedure of the bureaucrats. The German Ministry of Health said it was going to fine Bayer for not reporting a study

REGULATORY AGENCIES IN EUROPE LICENSE BETWEEN 150 AND 300 PHARMACEUTICAL PRODUCTS EACH YEAR WHICH DO NOT ADVANCE TREATMENT OR IMPROVE THE QUALITY OF MEDICAL SUPPLIES.

on adverse events but this was only window dressing to divert attention away from its own failure to act. Bayer had in fact presented new risk data to the responsible licensing authority, the MCA in the UK in June. These data were presented to the responsible European Committee (CPMP) later that month. Neither the German nor any other national regulatory authority demanded market withdrawal of Lipobay. The event is symptomatic for the worldwide decline in the quality of the drug licensing procedures and for the lack of an efficient system to monitor drug safety after market authorisation.

## LOOKING FOR INNOVATION

Drug development and research have changed in the pharmaceutical industry. Today there is more copying of known therapeutic principles. Successful products of the competitors induce the management to develop a similar compound in order to take away some of the market. This results in pseudo-innovative (“me-too”) drugs rather than innovations. Less money is spent on basic research and therefore, fewer new therapeutic approaches are found. Only one or two interesting new products in clinical medicine are made available each year, and only one such drug comes along every two years for general practice. At the same time, regulatory agencies in Europe license between 150 and 300 pharmaceutical products each year which do not advance treatment or improve the quality of medical supplies.

These pseudo-innovative drugs do not succeed on the market due to therapeutic quality, but rather because of marketing tricks such as falsified scientific data, exaggerated therapeutic claims, destructive information about therapeutic standards and abuse of medical opinion leaders sponsored by the manufacturer. In general, opinion leaders with financial ties to the drug industry are becoming a threat to the quality of medical care due to false expert statements and hidden influences at meetings, in medical publications, guidelines, institutions and medical societies.

The pseudo-innovative drugs are highly prized because they produce sufficient shareholder value. They usually increase treatment costs about tenfold without any additional therapeutic gain as compared to the standard. But they threaten to destroy health care systems by ruining the financial basis. In Germany, pseudo-innovative drugs increased the total expenditures for drugs financed by the statutory sickness funds by more than 10% or more than Euro 2 billion in 2000. Attempts to control the rising costs through drug information failed in view of the financial means in the hands of pharma marketing.

## SCIENTIFIC OR MARKETING BREAKTHROUGHS?

The COX-2 inhibitors celecoxib (Celebrex) and rofecoxib (Vioxx) were the most successful introductions of new drugs selling for more than US\$11 billion during the first two years. Now we learn the studies VIGOR and CLASS describing better tolerability were falsified by deleting, selecting and distorting data. For example, the CLASS study

### INFORMATION IS BECOMING MORE AND MORE MANIPULATED BY MARKETING.

showed that celecoxib was less toxic than standard NSAIDs after six months of use. What the published data didn't say was that this advantage disappeared by the one year mark. This information was suppressed and the six months were simply calculated for one year. The VIGOR study for the drug rofecoxib showed only favourable data and did not contain data that rofecoxib produced more and not less cardiovascular side effects and other serious adverse reactions than traditional NSAIDs such as naproxen.

## THE CONSEQUENCES

An increase in drug expenditures depends on the continuing introduction of pseudo-innovative drugs. If these drugs were replaced by standard treatments in Germany it could drastically reduce drug costs by more than 20%.

Recent press reports have shown that medical journals are also experiencing problems. They have discovered cases of articles manipulating information about a drug in order to get it published and brought to the attention of health professionals.

There are a number of recommendations which would help bring about more rational use of medicines. These include:

- The quality of drug regulation has declined worldwide due to industry pressure, allowing more and more useless and unsafe drugs to reach patients. Licensing has to be performed without time pressure, surrogate criteria, small and short-term studies. Long-term safety studies have to be performed for at least five years if a drug is indicated and licensed for long-term treatment.
- Drug information must be free of all hidden influences of the drug industry at all levels of professional training of physicians and other health care professionals.
- Links of experts or opinion leaders to the pharmaceutical industry and financial ties have to be disclosed during professional meetings and in medical journals.
- Manipulation of data in favour of the manufacturer has to be prosecuted and punished.

## THE IMPACT OF EU POLICIES FOR EASTERN AND CENTRAL EUROPE AND OTHER REGIONS

By *Graham Dukes, Professor of Drug Policy Studies at the University of Oslo, Norway*

*As a physician and a lawyer, Graham Dukes has held senior positions in the pharmaceutical industry, national drug regulation and the World Health Organization. For this seminar, Graham drew on his own experiences in helping to implement and improve drug policy to outline the consequences that EU decision-making on pharmaceuticals can have on countries outside of the region.*

A little less than 48 hours ago, I landed back in Europe after helping to tackle a drug policy problem in east Africa – in Ghana. A day or so before that mission started I was chairing a rather controversial conference in Sarajevo (Bosnia-Herzegovina) of drug policy people from the countries which formerly made up the Federation of Yugoslavia. And one week before that I had been in Britain, dealing with two quite different aspects of drug policy – one relating to abuse of tranquilisers and the other to what I can only term administrative failure – two matters in which an EU country is struggling with problems which EU regulation has done little or nothing to solve.

Now when you are called upon to provide help in situations like that, what you try to do is to direct your attention to the sort of standards which either do exist or should exist in the public interest as regards drugs and the drug policy field in that particular country.

That is precisely the same thing that my colleagues and I found ourselves doing thirty years ago when we set out to develop and interpret drug law in a manner which we believed was best for the people of our country – The Netherlands. In retrospect, the Netherlands Medicines Act – passed in 1958 and progressively enforced and extended in the 1960's and 1970's – was for that very reason a tremendously successful one which has been influential ever since. We did not do that work while constantly looking across the borders, though we did try to learn from – and adapt – what had been done elsewhere. America was ahead of us in some respects, but we found its approaches egocentric, somewhat theoretical, and only capable of being enforced by a vast army of civil servants which no other country could possibly muster. Sweden provided us with some good ideas, but we turned them down when they did not suit our situation. France we found positively idiosyncratic with its reliance on medical testimonials and Germany considered at the time that the drug market would sort itself out and that virtually nothing needed to be done at all – a point of view which we in The Netherlands equally firmly rejected.

Thirty years on I am inclined to look back at the situation in which we found ourselves in Holland at that time as an enviable one. We had the freedom to do what we thought best in our own situation; we had just about enough human and financial resources to do it properly (with about 100 staff involved in drug control). And there was no one around, anywhere in the world, pressing us to follow their example; nor were there strong political or supranational forces seeking to put the public health interest in these matters in the shadow of the interests of industry or commerce. And that is the difference between what I experienced this week in West Africa, the week before in the Balkans and the week before that in Britain.

It is difficult to try and explain to public health students or others, what is meant today by drug policy. I know that in my own experience, after a great deal of discussion

and debate we end up with a complicated scheme which includes: new drug approvals, adverse effect monitoring, research financing, advertising, medical education and dozens of other elements which, taken together and interacting with one another, make up drug

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**ARE THOSE POLICIES, HOWEVER WELL DEvised AND WELL TESTED, REALLY WHAT THIS PARTICULAR COUNTRY NEEDS?**

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policy. But having said that you also have to admit and explain that no country on earth really succeeds in operating that entire complex of policies; most do not even try to do so, and a lot really do not even need to do so, because some problems do indeed more or less take care of themselves. You set priorities in drug policy because certain matters appear vital, but also because you do not have an army of experts, advisers and bureaucrats at hand to tackle everything. The number of drug policy staff in the US, when I first looked at it, was in the neighbourhood of two thousand people. In Holland, we had about one hundred. In Macedonia, my best estimate at present is about eight people. And in Montenegro, which is now going its way, I can find only three, including a deputy minister. Even Ghana is substantially better off.

Now in those circumstances you are, as a nation state, in a position where – through sheer lack of resources – you are very likely to find yourself tempted to follow foreign examples. And if those examples are put to you forcefully either by emphatic foreign consultants or are displayed before you as the keys which will open the doors to entry into some form of international brotherhood such as membership in the European Union – that is the way you are likely to go. And when you see that happening you are bound to ask – are those policies, however well devised and well tested, really what this particular country needs?

If we now look at the thinking and priorities which underlie drug policy and regulation in the European Union what do we find? The drug policies of the EU, such as they are – and they are still far from complete – grew up to serve the needs of a group of very prosperous and highly industrialised countries. The original policies date essentially from 1965 – the date of the first relevant Directive – and a date at which the continent was still shaking from the thalidomide disaster four years previously. One high priority therefore was bound to relate to instituting an approval procedure for new drugs, especially with regard to safety. Others related to:

- quality
- efficacy
- provision of complete data
- free movement

Establishing common standards necessarily led to compromises in view of differing traditions and interests in what was regarded as good medicine. Some parts of the continent found their standards being raised to reach a European mean, but others found themselves lowering their earlier ideals in the interests of attaining consensus, as we have seen in the examples described at the seminar by John Abraham.

The region's powerful competitive pharmaceutical industry was bound to have an effect on what was essentially seen as a free market economy and industry was quick to challenge any obstacles to free movement of products and services.

One result was that the well-known “need clause” was not permitted. This progressive element used in Norway, was said to undermine industry. Low prices, generic com-

petition and parallel import were heavily challenged. There was also a single lack of enthusiasm for guidance in good prescribing or in the use of essential drug lists and advertising.

And quality standards were taken up in the new International Conference on Harmonisation (ICH) with research-based industry as a full partner – setting standards which were arguably not always necessary or even where public health was having to be provided under economically unfavourable conditions, and weak industries were still playing a positive role in supply of simple drugs. All that happened and alongside it the Community fell under the pernicious influence of Thatcherism pushing as it did the public interest firmly into the background.

The difference between the situation for which the EU laws and regulations were devised and the situation in countries at a lower level of development is palpable. Getting drugs to the people in reliable and affordable form is all that matters in the poorest countries, backed up by sporadic measures to eradicate abuses (e.g. in clinical trials).

In a country like Macedonia, the famous “need clause” has found its way into the law – if the law is applied. As you can imagine, this has received very little understanding from the EU. In many other mid-level countries, rigid price controls must have high priority. Talking recently to drug controllers in various of these countries I found them setting priorities for drug regulation which looked very different from those inherent in the EU approach.

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#### *Some drug policy priorities for countries outside the EU (2001)*

##### IN THE COUNTRIES OF FORMER YUGOSLAVIA:

- countering of drug smuggling
- “need” criterion in regulation
- price controls on drug approval and prescribing
- prescribing education
- drug information systems

##### IN MUCH OF SUB-SAHARAN AFRICA:

- essential drugs principles
  - efficient central medical stores
  - means of ensuring financial access
  - simple formularies for non-professional prescribers
  - integration of traditional medicine
  - controls on promotional expenditure
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## CONCLUSION

During the last quarter of a century, a largely homogenous structure of drug law, regulation and policy has grown up in the European Union, and there have also been ever closer links to policy development in the US and Japan. It is evident that with such a large volume of codified policy this is likely to have a strong influence on the approach adopted in other countries in this field. That is especially the case in Eastern Europe, where countries aspiring to future membership of the European Union are easily persuaded to adopt the Union’s standards and directives almost literally.

This powerful influence on developments elsewhere in the world has both favourable and potentially unfavourable aspects.

- A positive element is the fact that a consistent line is introduced into drug policy. The many new countries emerging from the former Soviet Union, Czechoslovakia and Yugoslavia are drawing up entirely new national legal systems and it is good in a matter such as drug regulation that they are encouraged to develop in parallel and to benefit from longer experience elsewhere.
- A potentially negative aspect is the fact that the drug policies of the West and Japan have primarily been developed to serve countries where the economy is strong and growing, where there is a well-established drug manufacturing industry including research-based multinationals, and where society has long developed both explicit and implicit checks and balances on a free competitive economy. How appropriate is this form of policy to countries at a lower – and sometimes much earlier – level of development? Do these policies meet the needs of poor developing countries where the main challenge is still to get drugs to the people and to keep costs at a minimum? How do they affect a physician or public who/which has never had the chance to become immured to aggressive advertising or a massive inflow of competing brands? How do they impinge on a struggling generic manufacturing industry which fulfills a real need?

There is much reason to argue that many of these countries, while seeing the EU standard as something to which they could aspire within a generation, should for the present be looking to their own policy needs and those of their neighbours, and setting the priorities which their own particular situation demands.

## THE PRESSURES FACING NATIONAL GOVERNMENTS: BALANCING THE NEED TO CONTAIN COSTS WITH STAKEHOLDERS' DEMANDS: A PERSPECTIVE FROM GERMANY

by Hermann Schulte-Sasse, Former Head of the Department for Health Care and Health Insurances in the German Ministry of Health

*Hermann Schulte-Sasse is the former head of the department of health care and health insurances at the German Ministry of Health. After leaving government service, he was appointed professor at the University of Bremen. In his presentation, Hermann Schulte-Sasse drew upon his experience as a Ministry official to describe some of the pressures affecting European governments regarding access. He also suggested ways to make prescribing more rational and equitable.*

Germany and most other European countries are facing a sharp increase in health care expenditures. In fact, between 1990 and 1997 Germany's health care expenditures increased by 23%. Drug expenditures are a major part of this growing cost. The rising costs of social expenditures have also strained governments' budgets.

One can address the problem of rising costs in two ways. First, there is the theory that costs are driven by the demand of patients/consumers. These costs are often contained through a co-payment system or by reducing the benefits package. Other experts believe that costs are driven by the supply side. Under this theory costs can be contained

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IN MANY COUNTRIES THERE ARE BIG DIFFERENCES BETWEEN WHAT IS INCLUDED IN THE BENEFITS OFFERED BY THE NATIONAL HEALTH SERVICE AND THOSE OFFERED BY THE PRIVATE SECTOR. THIS RAISES WORRYING QUESTIONS ABOUT EQUITY AND SOLIDARITY

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by forcing health care providers to use budgets, financial incentives, controls and guidelines. In the same way, providers of medical technologies must base their choices on health technology assessments, drug lists, price controls and reimbursement mechanisms.

When considering these theories it is important to note that there is currently no proof that co-payment reduces demand. This may be due to the fact that the problem is not severe enough. However, it certainly does bring additional money into the system. In the same way, reducing benefits does not seem like the right answer to controlling costs. Already in many countries there are big differences between what is included in the benefits offered by the national health service and those offered by the private sector. This raises worrying questions about equity and solidarity. In countries such as Germany it is not socially acceptable to do this. To date, there is not enough discussion on this topic.

Germany also must reconcile its drug needs with a national drug market that is loaded with many old, obsolete or ineffective drugs which have never had to pass an official evaluation process assessing their safety and effectiveness.

Factors such as these suggest there is a need to introduce controls and guidelines that will lead to better decision-making about treatments. For example, the introduction of a limited list of drugs, a so-called "positive list" is a key step in promoting rational prescribing practices. Germany introduced such a positive list in 1993. I also believe that the introduction of standard treatment protocols, used in conjunction with standard symptom/disease definitions, should be made compulsory.

*Barriers to good decision-making*

$$P = \frac{M \times C}{B}$$

P = performance

M = motivation

C = competence

B = barriers

For governments to make good decisions about medicines, they need a solid information basis on new treatments. Policies should be introduced that make it obligatory to have critical information available to all that need it.

At present, Germany also uses a fixed price system that covers all medicines except patent-protected drugs. The industry has brought lawsuits against the sickness fund because of its pricing rules. In fact, in recent months, the case of Ciprobay has revealed growing doubts about respecting patent protection, even in the United States, in the case of a health emergency.

We must remember that drug studies show efficacy for special groups of patients. It is never completely known if the same results will also appear in the general population. There should be more studies on the effectiveness of drugs. Health care providers should always consider a medicine's benefit and risk profile, the disease's prevalence and the resources available. However, doctors should still have room to decide treatment in special cases. Prescribing decisions are filled with personal values.

We need much more evidence-based medicine. Now there is never one answer to a given problem. Different doctors give different answers. I believe opinion-based decision-making should be discouraged and evidence-based choices should become the norm. As C.A. Sirio wrote "Medical practice requires that we tolerate uncertainty. Evidence-based medicine is an approach for applying available scientific data to clinical problem-solving to minimize this uncertainty" (1997).

*The Five E's of Rational Prescribing*

EFFICACY	Does the treatment work?
EFFECTIVENESS	How well does it work in practice?
EFFICIENCY	Is the maximum output obtained for the minimum input?
EQUITY	Are those most in need receiving priority?
ECONOMY	Is the expense justifiable compared with the opportunity costs?

Governments need to think more about the provider's motivation. Many health care professionals feel that their work is overregulated. There needs to be more discussion

WHAT WE ARE LEARNING IS THAT SUSTAINABLE HEALTH CARE IS NOT SO MUCH A QUESTION OF INJECTING MORE MONEY BUT RATHER DECIDING HOW TO SPEND THE MONEY ALREADY AVAILABLE.

about the professional basis of medicine. We need to introduce much more motivational politics. Doctors' competency starts in university. Doctors who lack training in evaluating medical information need to receive an orientation on this from other doctors.

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**CONCLUSION**

What we are learning is that sustainable health care is not so much a question of injecting more money but rather deciding how to spend the money already available. It is not easy to achieve this task. Governments certainly cannot solve these problems alone. However, it is difficult for them to find allies when using abstract ideas.

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In America, as in almost all developed countries, health care already has far, far more at its disposal than, truly redesigned, it would need to achieve its social aims effectively.” – Donald M. Berwick, 1998

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Addressing the access problem is not a question of a free market or more regulation. We have to remember that no country in the world has an entirely free market, there is always some measure of regulation. What we need to discuss is how much regulation is needed in the market. That discussion will help us find allies. And maybe that long-needed debate can lead us to the situation described by Donald Berwick which we hope to reach:

“With firm intention, we can achieve levels of safety, service and health status outcome that we have never yet achieved or even imagined anywhere in our current system – anywhere in the world. Furthermore, we can have those levels of quality at a cost far lower than we are now paying in the developed world” (1988).

## THE ROLE OF GENERICS: HOW THEY CAN ASSIST ACCESS AND THE THREAT FROM NEW EU PROPOSALS

By Greg Perry, Director General, European Generic medicines Association (EGA), Belgium

*The EGA promotes the generic industry's interests at the European level. Its membership includes more than 400 companies involved in the manufacture and supply of generics. At the seminar Greg Perry highlighted the positive contribution that generics can make to improving access in Europe while explaining the current obstacles that sometimes limit their use within EU Member States. In his presentation, he also examined generics in relation to the EU Commission's new pharmaceutical reform proposals and proposed alternative recommendations to increase the role of generics in Europe.*

Consumers' access to generic drugs is important in a number of ways. Their presence in a national market reduces prices as generics cost usually 20-80% of the original price. They also stimulate competition and create an incentive to develop new innovative medicines. The use of generics also provides "headroom" for innovation. That is,

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IN TOTAL, EUROPE HAS 26% OF THE GLOBAL GENERICS MARKET WHILE THE US CARRIES 40% OF IT.

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their lower cost allows health budgets to afford new, expensive products. In the same way, it assists doctors in meeting budgetary targets. Generics also provide real choice to consumers in situations where they must pay (or co-pay) directly for medicines.

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### GENERICS IN THE EU

Currently generics represent 15% of the value of the EU pharmaceuticals market and approximately 25% of the volume. There are significant price differences between brands and generics depending on the market penetration within each Member State. For this reason, the savings they offer can differ. However, some examples show that these savings can be significant: US\$2.5 billion in Germany, US\$3.5 billion in the UK and a whopping US\$10 billion in the US. In total, Europe has 26% of the global generics market while the US carries 40% of it.

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### THE POTENTIAL

In 2004, one-third of the top molecules on the market will reach patent expiry. Certain bio-tech products will reach patent expiry too. The question remains: When these drugs go off patent will doctors then prescribe and pharmacists dispense generics? There is huge potential for health services and consumers to book major savings worth billions of Euros. The extent of the benefit will depend on their supply and demand. That is, will generic drugs be made available quickly after the patent expires (supply) and will health professionals choose them (demand)?

The EU has called for greater access to generics. The Commission Communication on a Single Market for Pharmaceuticals published in November 1998 described a multi-prong approach to achieve this aim. It wanted to increase consumers' awareness of generics. The document went on to encourage doctors to prescribe generics. Importantly, it wanted to ensure that the regulatory system enables generics to enter the market immediately after patent expiry. And it called for means to stimulate price competition between generics and off-patent branded products. The Commission's pharmaceutical review proposals released in July 2001 are the first time there is a real opportu-

nity to put these objectives into practice. To date the Council of Ministers, the European Parliament, and the European Commission have called for increased access to generic

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**ENSURING ACCESS TO GENERIC MEDICINES CANNOT BE LEFT TO MARKET FORCES ALONE. INSTEAD, IT REQUIRES ACTIVE GOVERNMENT SUPPORT AND MEASURES.**

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medicines for consumers. EGA sees the UK, Germany, Denmark, and The Netherlands as having established generics markets. A lot of work still needs to be done to increase their use in countries such as Spain, Belgium, Portugal, France and Italy.

The EU is not the only international body promoting the use of generics. In fact, the World Health Organization has been advising their use for many years as a way to control drug prices, ensure quality and encourage rational use and prescribing. To promote their use, the WHO has also said that consumers need to be made more aware of generics and to be assured about their quality. Health professionals also have to be motivated to prescribe them. It also urged governments to allow generics onto the market directly after patent expiry.

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## THE NEED FOR POLITICAL WILL

Ensuring access to generic medicines cannot be left to market forces alone. Instead, it requires active government support and measures for two main reasons. To begin, their demand is stimulated not by purchasers but by health professionals' prescribing and dispensing habits. Secondly, their supply is dependent on regulatory practices and efficiency.

A number of obstacles block the use (or increased use) of generics within the Community. The current regulatory system fails generics due to the lack of harmonised originator products. Rules prohibit generic firms from carrying out much of the

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**ALTHOUGH THE EU IS TRYING TO STOP THIS PRACTICE COMPANIES CONTINUE TO REMOVE ORIGINAL FORMULATIONS AND THEN REPLACE THEM WITH NEW ONES TO AVOID GENERIC COPYING.**

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preparatory work needed to bring drugs to market while they are still under patent. Brand name manufacturers also use data exclusivity rules to supplement existing patents and keep drugs off the generic market for longer periods of time.

In addition, some anti-competitive practices keep patents in effect longer. This includes companies' withdrawing original formulations from the market to prevent generic competition. Although the EU is trying to stop this practice companies continue to remove original formulations and then replace them with new ones to avoid generic

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**A ONE YEAR DELAYED INTRODUCTION FOR ONE GENERIC PRODUCT IN ONE COUNTRY EQUALS EURO 100 MILLION.**

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copying. Companies' massive marketing efforts encouraging brand-name loyalty from prescribers also remains a problem. Finally, the EU currently has no compulsory license provisions.

The EGA views the European Commission's proposal on data exclusivity as a major threat to generics use. This proposal included within the Pharmaceutical Review legislation would prohibit generic applications during the term of data exclusivity. The suggested text would increase the present 6 or 10 year prohibition period to one that is 10-11 years in length. This takes no account of the patent status which means that real market protection for brands could move beyond the patent period. Although this seems like an abstract problem, one should remember that it has huge practical implications on drug costs. A one year delayed introduction for one generic product in one country equals Euro 100 million.

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#### EU PRESSURE ON EASTERN AND CENTRAL EUROPE

Many countries seeking to join the EU, the so-called "accession countries" are highly dependent on generics. This is due to their population's low income and relatively speaking high health costs. Despite this fact, the EU is seeking to introduce patent extensions retroactively and to adopt data exclusivity in EU candidate countries before they even join the EU. The consequences of allowing 10 years of data exclusivity in these countries would create a major health care problem.

## PAYING THE BILL: THE DILEMMAS FACING EUROPE'S NOT-FOR-PROFIT HEALTH INSURERS

by Angelika Kiewel, German Federal Association of Craft Guild Health Insurers on behalf of the Association Internationale de la Mutualité (AIM).

*AIM comprises 45 national federations of statutory health insurers and companies located in 27 countries. They provide social coverage against sickness and other risks to more than 120 million people, either by participating directly in the management of a compulsory health insurance or by offering supplementary or alternative coverage. In her presentation, Angelika Kiewel emphasised that European insurers are concerned about the growing costs of medicines and health care in the region. To keep care accessible, she highlighted some of the ways that insurers want governments to limit spending on drugs and ensure that the money spent goes towards the best possible products to achieve health gains.*

Spending on health care is increasing in nearly all European countries, especially for pharmaceuticals. All health care systems are concerned with controlling costs. To achieve this goal, a set of measures is necessary. Measures targeting pharmaceutical prices (both the manufacturer's delivery price and the sale price), improvements in the quality of licensed medicines and particularly the quality of pharmaceutical use (compliance and pharmaceutical safety). These measures must take into account patients' growing autonomy and give fuller consideration (than was done in the past) to the needs of insured persons and patients in relation to the provision of services.

### THE RELATIONSHIP BETWEEN INNOVATION AND PRICE OF MEDICINES

In all European countries, only real innovations should serve as the basis for demands for advantageous prices in the future. In Germany, when assessing new active ingredients, we use a system of classification that distinguishes among so-called "A" preparations, which are pharmaceuticals containing innovative active substances or active principles; "B" preparations, which contain active ingredients that improve upon known active principles; "C" preparations, which are preparations with marginal differences in terms of active principles; and "D" or "analogue" preparations, which are newly introduced products without adequately demonstrated therapeutic effects. During 2000, for example, only 42% of newly licensed pharmaceuticals were actually innovative. More than 50% came under the heading of "analogue" products. The value of these products is mainly commercial: they can promote price competition on the condition that they do not benefit from price protection.

New medicines are much more expensive than those already on the market. Figures furnished by pharmaceutical companies indicate that the development of a new medicine involves some US\$ 500 million worth of research and development costs. A large share of these costs may certainly be ascribed to marketing efforts, which must necessarily be higher, the more superfluous the product is. According to figures recently published in the US, only a fifth of costs are actually attributable to research and development in the strict sense of the words.

The effect/risk relationship comes into play concerning the authorisation of a new drug. How many undesirable effects—at least those known about at the time of product launch—will I have to accept to achieve the desired effect? Systematic and comparative analyses with known products used for the same indication are necessary in assessing the therapeutic value of a new medicine. AIM promotes assessment at European level. A Medicines Information Network for Europe (MINE) located at the EMEA has already

encountered opposition from the pharmaceutical industry. The distinction between real innovations and analogue preparations is, however, not only in the interest of social insurers; it also makes a long-term contribution to the pharmaceutical industry's ability to compete.

To achieve "for money", beyond the assessment of the therapeutic value of a product, its cost-effectiveness must also be determined. Manufacturers argue that health care economics studies can be presented only after an extended period of use. This is not necessarily the case. In British Columbia, for example, the inclusion of new active substances in the list of reimbursable medicines is linked to documentation on the effectiveness and cost-effectiveness of the substances. The objective of this policy is "to maximise public health benefits against a backdrop of a limited overall pharmaceutical budget".<sup>3</sup>

## DEVELOPING A EUROPEAN STRATEGY ON MEDICINES

European integration requires social insurers to develop European strategies. Suppliers, and by this we obviously mean the pharmaceutical industry, have been operating worldwide for decades. Health care systems must also form networks, agree on their strategies and learn from one another. A good example is constituted by fixed reimbursement amounts, a measure that has been determining pharmaceutical prices in the German health system since 1989. Health insurers, after a detailed analysis of market conditions, establish a fixed amount that they will reimburse for the cost of a medicine. Manufacturers in principle remain free to set their price, but in practice, the price of about 95% of all medicines has fallen. Fixed amounts instituted competition among manufacturers on the fixed-amount market, which accounts for some 50% of the overall market for pharmaceuticals. In the meantime, Denmark, The Netherlands, Sweden, Spain and the United Kingdom have followed Germany's example and introduced a fixed amount, followed by Belgium and Italy on 1 July 2001.

In addition to appropriate instruments for the regulation of manufacturers' prices, a critical look at marketing costs in Europe is also needed. This overview reveals that distribution costs are very high, particularly in Austria, Switzerland, Germany, Luxembourg and the Scandinavian countries.

In Germany, for example, the chemist adds a mark-up of 30% to the wholesale price of DM 1,064. In Belgium, on the other hand, the margin is similar, but cannot exceed DM 15. The pharmacist provides the same service whether he or she is selling an inexpensive preparation or an expensive one.

## PATIENTS NEED NOT MORE, BUT BETTER HEALTH CARE.

The advantages of innovation should benefit manufacturers and patients exclusively. In countries with high surcharges, however, a reduction in distribution costs is essential. Price-dependent margins are in conflict with the goal of independent, professional consultation of pharmacists; a fixed mark-up would be justified in the interests of this duty of advice, and as quickly as possible. In The Netherlands, for example, the pharmacist receives a fixed amount of about Euro 5 for provision of a medicine. Switzerland has also taken action and introduced a new system on 1 July 2001. It is one that provides incentives for the delivery of less expensive preparations of the same quality and links reimbursement to turnover.

<sup>3</sup> J. Klauber, H. Schröder, G. W. Selke (Hrsg.): *Innovationen im Arzneimittelmarkt*. Berlin, Heidelberg 2000.

## WHAT DO PATIENTS NEED AND WANT?

Patients need not more, but better health care. An international comparison of citizens' satisfaction with their health care system conducted by Swiss researchers Domenighetti and Quaglia<sup>4</sup> revealed only a limited correlation between satisfaction and a particular level of spending on health care. Sweden seems to have achieved optimal efficiency while spending only US\$1.701 per capita and enjoying a very high level of satisfaction. The results for Greece, however, are very problematic, as spending and satisfaction are both extremely low. Wastefulness is an obvious problem in Switzerland and Germany. Higher levels of spending do not necessarily lead to greater satisfaction. In fact, in Switzerland the opposite is true.

For patients in Europe, pharmaceuticals are currently accessible regardless of their individual effectiveness. Flagrant shortcomings are, however, obvious as concerns the quality of the therapeutic process.

A new scientific study in Germany relative to the quality of continuing education for doctors came to the conclusion, that two-thirds of the training programmes studied were sponsored by the industry, something about which doctors were not particularly aware.<sup>5</sup> Another study, concerning medical treatment in compliance with guidelines demonstrated that one-fourth of all doctors were completely unfamiliar with the guidelines for treatment of symptoms of hypertonia, a common condition.<sup>6</sup>

Patients expect their doctors to have a high degree of social and emotional competence. These expectations are not justified in everyday practice. Studies in Germany have shown that doctors have an unsatisfactory understanding of patients' expectations. Patients who do not expect to receive a prescription leave the doctor's office with one anyway.<sup>7</sup>

We must ask ourselves whether giving more explanations to patients can result in a more economical, less resource-intensive use of health care assets. Or is the converse true, that knowledge about costs and new therapies would make patients more demanding? Will the "rationalisation trap" lead to a situation where the individual would seek

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### WE MUST ASK OURSELVES WHETHER GIVING MORE EXPLANATIONS TO PATIENTS CAN RESULT IN A MORE ECONOMICAL, LESS RESOURCE-INTENSIVE USE OF HEALTH CARE ASSETS. OR IS THE CONVERSE TRUE, THAT KNOWLEDGE ABOUT COSTS AND NEW THERAPIES WOULD MAKE PATIENTS MORE DEMANDING?

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personal advantage and attempt to maximise his or her individual benefit instead of that of the collectivity, by means of the lowest possible membership contribution? This issue has been the subject of very little research. Empirical proof of the fact that health care costs can be significantly reduced through explanation and better knowledge of the uses and limits of medical intervention nonetheless exists. For example:

<sup>4</sup> G. Domenighetti, J. Quaglia in: *Gesundheitswesen Schweiz 2001/2002*, hrsg. vom G. Kocher und W. Ogger, Basel, S. 70.

<sup>5</sup> Von Reis, O., Bott, U. und Sawicki, P. (1999). *Qualität und Struktur der ärztlichen Fortbildung in der Inneren Medizin am Beispiel des Ärztekammerbezirks Nordrhein*. *Zeitschrift für ärztliche Fortbild. Qualitätssich. (ZaeFQ)*, 93, 569-579.

<sup>6</sup> Schneider, C.A., Hagemester, J., Pfaff, H., Mager, G., Höpp, H.W. (2001). *Leitlinienadäquate Kenntnisse von Internisten und Allgemeinmedizinern am Beispiel der arteriellen hypertonie*, *ZaeFQ*, 95, 339-344.

<sup>7</sup> *Deutsche Apotheker Zeitung*, 138 (15), 1344.

- A meta-analysis of the available studies on the cost-utility effects of patient education in managed care organisations indicates that for every dollar invested in these measures, an average of US\$ 3-5 in health care costs is saved.<sup>8</sup>
- A randomised US study on the effects of joint decision-making among men and women with arterial blockages revealed that 22% fewer patients opted for a bypass operation than patients who were not included in the programme.

Patients therefore need better health care in the sense of more attention instead of medication, and they need more information and counselling.

## CONCLUSIONS

Service providers in the health care policy debate argue that health insurers would not provide innovative products to a sufficient extent due to financial bottlenecks and would apply rationing of services. We as health insurers say that at present, the need for services is unilaterally defined by service providers, which in the pharmaceutical field, for example, use marketing campaigns to urge doctors to use new medicines. At present, health goals for setting priorities for the appropriate measures are lacking. This affects the status of prevention in relation to cure. A completely new orientation in this area is necessary. There is a strong tendency to favour medication, and prevention is also to some extent limited to pharmaceutical prevention. The issue here is therefore not rationing, but prioritising.

What then are the key elements in ensuring access to medicines from the point of view of health insurers?

- Strong social insurers, who take action to regulate costs on patients' behalf.
- Quality criteria for the assessment of innovations at European level.
- Improved pharmacovigilance. The accelerated market access promoted by manufacturers must be associated with certain conditions and restrictions and results in an urgent need for improved pharmacovigilance.
- The patient plays an ever more important role in the process of decision-making. Independent and comparative information is extremely important in this connection. It can, as the examples have shown, reduce unnecessary consumption. The relaxation of advertising regulations and the increase in direct marketing are detrimental to pharmaceutical safety and exercise irrational pressure on health care costs.

In the EU countries with high levels of health spending, many ways of creating economic reserves and ensuring patient access to high-quality pharmaceutical care by means of prioritisation are nonetheless available. This is done, for example, by avoiding superfluous products whose effectiveness is contested; by reducing the rate of prescription of expensive preparations, where comparable and less expensive products are available; and by using new preparations as directed. When these economic reserves are exhausted, health policy objectives naturally take precedence from the social insurer's viewpoint over the reduction of additional wage costs and spending on pharmaceuticals will have to increase, if necessary, at the price of higher contributions.

<sup>8</sup> Bartlett, E. E. (1995). *Cost-benefit analysis of patient education*. *Patient Educ Couns* 26 (1-3), 87-91.

<sup>9</sup> Vienonen, 1999. *Beitrag im Rahmen der Tagung "Citizen Participation" der Gesundheitswissenschaftlichen Fakultät der Universität Bielefeld, 4./5. Februar 1999, Bonn.*

## CONSUMERS' PRIORITIES AND CONCERNS: HOW TO ENSURE CONSUMERS' RIGHT TO THE BEST POSSIBLE HEALTH IN LIGHT OF RATIONAL TREATMENT AND LIMITED BUDGETS

*Speaker: Clara MacKay, Principal Policy Adviser and Editor of Consumer Policy Review, Consumers' Association, UK*

*As part of the day's debate, Clara MacKay described how access to medicines and healthcare has become a central concern for consumers, healthcare providers and government officials in the UK, one of the wealthiest countries in the world.*

How can governments ensure the consumer's right to the best possible treatment in light of rational treatment guidelines, growing drug promotion and limited budgets? In

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WHEN YOU ASK UK CONSUMERS WHAT THEY WANT FROM THE HEALTH SERVICE AND WHAT THEIR CONCERNS ARE, THEY ANSWER: INFORMATION AND ANXIETY ABOUT ACCESS.

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many ways this is a loaded question with too many dimensions to answer in a short article. To begin, there is a question about how treatments get developed and made available; let alone how people gain access to them.

It is somewhat embarrassing to address the issue of access in relation to such a wealthy country as the UK. Its problems do seem trivial in comparison to those faced by other countries. However, there are interesting points to be made and lessons to be learned from the UK's experience. For example, when you ask UK consumers what they want from the health service and what their concerns are, they answer: information and anxiety about access.

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### GENERAL DYNAMICS OF ACCESS IN THE UK

How does the UK's healthcare system work? The centre of the system is the National Health Service, better known as the NHS, which has been around for more than 50 years. Everyone loves it, 90% of the population supports it, but there is anxiety about its capacity to deliver treatments and medicines.

The NHS is a national institution. It is state-funded and state-provided. This means that the service itself is a public service. However, this is something that is starting to change. In the past few years a much closer working relationship has developed between the NHS and the private healthcare sector on a number of fronts--including the direct purchase or leasing of health care from the private sector. And as you all know, the drug

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AT PRESENT, THERE IS A SHOCKINGLY SMALL AMOUNT OF INFORMATION AVAILABLE DESCRIBING HOW WELL TREATMENTS WORK.

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industry is a key UK industry and therefore there is an inclination on the part of the government to keep the sector prosperous and happy.

Health services in the UK are mainly free at the point of delivery. There are some areas including dentistry and prescription drugs that use set charges (fairly reasonable ones) that patients pay. Interestingly enough, the government introduced prescription charges only one year after the introduction of the NHS to combat concerns about rising patient demand and the increasing drugs bill.

### SHIFT IN POLICIES

It is important to describe a number of things happening in the health sector which affect access. Some of the more obvious factors are related to the structure of the health care system and its policies. In the UK, there is a national system--but in reality, decisions about resources and how they are spent are being pushed out to regions and local areas and now to individual doctors in groupings called Primary Care (PC) Trusts. For this reason, access can vary from place to place and from PC Trust to PC Trust.

### INFORMATION PROVISION

Information provision is at the heart of the access debate. There needs to be access to information about medicines and other treatments related to outcomes, quality, and existing alternatives. At present, there is a shockingly small amount of information available describing how well treatments work.

### PATIENT RIGHTS

The UK is not leading the world on patient rights. In fact, the current government abolished the Patients Charter, the nation's only thin statement of rights a few years ago. This document had set out things such as a patient's right to a second opinion; the right

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COMPLAINTS ABOUT CARE USUALLY COME FROM MIDDLE CLASS, EDUCATED CONSUMERS. LESS THAN 10% OF THE COMPLAINTS MADE EACH YEAR COME FROM OR ON BEHALF OF THE MOST VULNERABLE GROUPS.

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to admission to hospital within a certain amount of time, etc. The emphasis has now moved from patients' rights to patients' responsibilities. Today, there is a document called "The Patient's Guide to the NHS" which tells patients very little about not much – but it does remind us not to bother doctors unnecessarily or to skip appointments without cancelling them formally.

In fact, while few people could tell you what was in the Patients Charter, almost everyone in the UK knew it existed. So it did serve a purpose which was to make people aware of "health" as a right.

### REDRESS AND INDEPENDENT ADVOCACY

This is a critical issue for access. Redress and advocacy are important for all patients especially vulnerable patients such as the elderly and people with learning difficulties who currently receive the worst health care in the UK. Consumers in these groups are neither profitable nor especially "sexy" for health care providers or the industry from a commercial sense - their care often does not involve drug therapy. When one looks at redress issues and patterns - it is potently clear that these groups are poorly spoken for. Complaints about care usually come from middle class, educated consumers. Less than 10% of the complaints made each year come from or on behalf of the most vulnerable groups.

### PATIENT GROUPS

Interestingly patient groups are big business in the UK. There are currently about 2,500 of them and it is a growing sector. Patient groups can be extremely powerful advocates on behalf of patients but at the same time they need to be extremely careful about their position of trust.

CA's work on advertising has found that consumers are becoming less and less confident in the information they receive from the government because of their fears about

rationing. Consumers increasingly view patient organisations as “independent” and credible sources of information. So there is a real need for patient groups to take care of how they work. Although CA has not done a full analysis, our assessment is that there are a number of factors involving patient groups and access at work here:

- are increasingly turning to patient groups as an independent source of information
- as funds get tight, organisations need to maintain their public profile and standing and drug treatments often offer a focus for a lobby
- patient groups are getting closer and closer to industry

Some manage this kind of alliance very well. Others are very cavalier or unaware of the implications of these relationships.

### PATIENT / PROFESSIONAL RELATIONSHIP AND SOCIAL JUDGEMENTS

Too little attention is paid to the impact of the patient/professional relationship when it comes to access issues. On a basic level, patients have values and views that they apply when they are discussing different types of treatments, interventions or risk, for example. However, clinicians also have their own set of values and principles and views that they apply in taking decisions. Prescribers’ values can certainly influence the kind of care a patient receives. In the worst case scenarios, value judgements are made about who is a more worthy patient and what conditions are more worthy. Sometimes it shows itself as discrimination based on age or on the fact that someone has Down’s syndrome or is a drug addict. Often these value judgements are justified and legitimised in formal policy.

## CA RESEARCH ON ACCESS

### EXAMINING NICE

Consumers’ Association had done recent work involving the National Institute for Clinical Effectiveness (NICE) which is the UK’s 4<sup>th</sup> hurdle agency with responsibility for assessing the clinical and cost-effectiveness of treatments and for making recommendations about whether or not these treatments should be provided by the health service. While carrying out separate research on DTCA, CA discovered that the UK government was planning a review of NICE, two years or so after it had been set up. We also found that the whole agenda for this review was being shaped by the concerns and issues of the industry and government - with no consideration of the patient perspective or outcome for patients. In response, CA organised a one-day public hearing requesting patient organisations to come and give their views about how well they think NICE works. The results were extremely interesting. A number of key themes and issues emerged, including:

- NICE contributes to the tendency for patient groups to position themselves as lobbies for “access” to drugs – even if they don’t often have any evidence themselves to support this position. The idea behind this seems to be that it is better to get something on the market on the chance that it might be effective, rather than nothing at all. Some question whether other non-drug issues such as rehabilitative care are being overlooked now that the debate is so drug-oriented.
- The existence of NICE in itself promotes a focus on drugs and within that gives a high, public profile to drugs with large, single disease type applications (usually costly) such as drugs for multiple sclerosis (MS), Alzheimer’s disease, and cancer. This fact attracts and encourages a combination of single disease patient groups and drugs. In practise there is much less emphasis on other drugs and other treatments. If drugs are approved, local areas try to provide them and therefore lack money to promote other rational treatments and less high-profile services.

- Leading on from that, the process of a NICE review may actually forge even greater alliances between drug companies and patient groups, to the extent that a number of patient groups are concerned about the level of industry infiltration in such groups. As a case in point, when CA announced its NICE inquiry as a means to find out patients' views, one drug company sent a letter to patient groups offering its support and help in preparing their contribution to the inquiry.

The public hearing on NICE revealed complete confusion about what NICE is trying to measure – Is it effective or is the evidence already there robust? It also showed limited attention is paid to how drugs work in daily practice, that is, outside of clinical trials. The inquiry highlighted the fact that little attention goes to what patients view as an important measure of effectiveness. For example, a MS patient may feel that improve-

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**RATIONING IS OFTEN DRESSED UP AS PRIORITY SETTING. IN REALITY IT IS ABOUT TAKING DECISIONS ABOUT WHO YOU CAN EXCLUDE FROM HEALTH CARE WITH THE LEAST AMOUNT OF EXPOSURE OR PUBLIC OUTCRY.**

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ment in cognitive function is more important than mobility. Almost always “measures” are based on clinical trials. When patient groups try to answer this question, the evidence they provide is often regarded as soft and not valid.

Other results from the inquiry suggest a number of areas that need improvement. CA found a complete lack of transparency about how effectiveness, especially cost effectiveness, is decided. There was also a lack of proper information about the medicines under review. It seems that officials are looking at the information available instead of what is actually needed.

#### OTHER RESEARCH ON ACCESS ISSUES

In addition to its work on NICE, CA has done research on other areas that are interesting for this discussion on access. For example, the organisation has looked at access to dentistry and on how rationing in the UK is done. Rationing is often dressed up as priority setting. In reality it is about taking decisions about who you can exclude from health care with the least amount of exposure or public outcry.

Dentistry is less high profile than the drugs debate. The current government policy states that everyone should have access to dentistry as part of the health service. This is a key public health issue and one where access clearly divides the poor from those better off. When CA conducted its research on dentistry it found a crisis in the availability of state dentistry. Provision is limited and in some cases non-existent. The outcome of the dentistry research strongly confirms that access is random, not substantiated by issues of effectiveness. However, the fact remains that dental health will never receive the same attention as medicines.

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#### LOOKING AHEAD

How can governments possibly eliminate the negative impact of factors or dynamics that create what we call in the UK “the lottery” of care. And by that I mean the situation whereby the reality is that assessing good quality, appropriate care and treatment is a bit of a gamble – you may get lucky – but there is no guarantee. CA has learned a lot from watching EU member states, including the UK, move towards allowing DTCA. While there is increasing emphasis on drugs, one has to look at the cost and determine if it is really a rational treatment. As mentioned, patients in the UK are less and less confident in information provided by government agencies and health professionals are increas-

ingly anxious about access issues. At the same time, research has shown that people do not believe that drug companies will provide reliable information. As a result, patient organisations will become more heavily relied upon to provide information. For that reason, it is worrisome that more and more patient organisations are becoming so closely linked with the drug industry – in different ways and for different reasons.

There is a growing need to ensure access to healthcare. Lessons can be learned from the struggles taking place in a developed country like the UK faced with limited budgets, a strong pharmaceutical industry and various treatments. The current answer seems to be that ensured care remains rather basic. To improve access to quality and essential healthcare, a few areas must be strengthened:

- **MORE INDEPENDENT INFORMATION** must be made available on drugs and other treatments, outcomes, standards etc.
- **PATIENT RIGHTS MUST BECOME A RENEWED TOPIC.** Consumers need access to independent advocacy and patient groups must understand the importance of independence from the industry. There is now a growing lobby within the UK for an independent National Patient Body with remit to ensure equitable distribution of healthcare, among other things. This type of action needs to be supported by statutory patient rights.
- For the system to improve, there must be **GREATER TRANSPARENCY** about its processes and decision-making. What is cost effectiveness? Who decides what is clinically effective?
- The government/NHS relationship must be reviewed. While it is clear that the government supports the NHS's goals, there are growing tensions about **HOW TO MANAGE PUBLIC AND PRIVATE SECTOR INTERACTION AND POSSIBLE CONFLICTS OF INTEREST.**
- The system needs to broaden its focus to include important, non-drug treatments.

## DISCUSSION

*During the day's debate a number of issues were viewed by participants as crucial aspects of the European access situation. Below is a summary of the main points made during the seminar's discussion periods.*

### THE NEED FOR GREATER TRANSPARENCY IN THE EU

One participant mentioned that EU countries are now sharing information with each other about drug approvals. However, this information is usually not shared with nations outside of the region. Currently there is a discussion to see if such information-sharing can be done with all of the International Conference on Harmonization (ICH) countries. There is talk of drafting a technical document that could be shared by all countries. The participant raising this point emphasised that the industry wants a fee-based system and wants regulators to harmonise their operations. At present, there is some pressure in the US to farm out drug reviews to consultants to move applications along more quickly. Interestingly, this could raise questions about conflict of interest as US Food and Drug Administration (FDA) employees cannot have outside consultancies or own company shares while people on its committees can.

A speaker suggested that the government could remove control of needed trials from drug companies. He said this would eliminate secrecy and address the need to make the data available to the wider scientific community. It would result in a sharing of the knowledge base. He said the ICH is proving that you can get globalised regulatory data and can pass it on to the next regulatory agency looking at the drug.

The remark was made that the EU could also decide to give licenses at first for a short period to make sure that the newly approved drugs were working well. This would work in the same way as some countries' practice to issue a first driver's license for a limited period. The speaker said there is a need to control new drugs in a better way and this could improve adverse drug reaction controls.

Numerous participants brought up the fact that the Commission's DG Enterprise, not Sanco (health) held the lead on drugs. They called for decisions about pharmaceutical policy to move to DG Sanco to ensure that public health remained the priority.

### NEW TRENDS IN DRUG PROMOTION

A participant from Canada remarked that when new drugs come onto the national market it is impossible to access trial information and company data because of secrecy rules. At the same time, companies trumpet drug introductions which are then picked up by the media. Some patient organisations (often allied with industry) also show support for the new medicines. Doctors have little information about these new drugs, but patients quickly go to their doctors to get them. Health care providers and prescribers don't know what to do. They lack objective information about the product so quickly after its launch.

A number of participants also expressed concern about the Commission's current proposal to allow drug companies to inform consumers directly about some prescription-only medicines. They saw this as a way to open the door to direct-to-consumer advertising and feared the consequences for access to needed medicines.

### IMPROVING ACCESS TO OBJECTIVE DRUG INFORMATION

Another participant said the process of judging new medicines is getting worse. He thought it was impossible for the average general practitioner to judge new drugs. The need for independent drug information will increase with the speed of the regulatory procedure.

One audience member pointed out that it is currently impossible to compare post-marketing data with pre-approval data. It is simply not available. He said adverse drug reactions could be picked up earlier if one could do such a comparison.

## BALANCING PRIORITIES

A participant pointed out that access is not just about drugs. He said that in his country, Germany, patients can now get needed prescriptions and medical tests, but there is not enough nursing and social care available. There is a need to consider real needs and decide where the available funding should go.

## THE GROWING POWER OF THE INDUSTRY

Participants discussed the growing power of the pharmaceutical industry and wondered if the EU and national authorities could actually regulate these companies. The point was made that some companies have more money than countries. How can they then be controlled and how can they work for social good? many participants wondered.

One presenter said it is not possible to put companies under public control. What is possible is to contest their actions through litigation. This is happening more and more often. However, it is slow and expensive. He said that litigation pressure is only partial pressure but it does play a role. He believed there is so much about companies' actions that is out of control, such as price-setting, product quality and tax structures, that this is one way to address their behaviour.

A speaker mentioned that while the legal structure is good, laws are not always executed or they are purposefully undermined. He said there is a need to fight industry influences. This must be done to accomplish more than improving the legal basis. It should make undue influence a punishable crime. Such influence can result in reduced quality.

Another speaker agreed that nationalisation of companies is difficult. However, he said there is potential to remove key aspects of safety and quality testing away from the companies. The ICH has shown that international standards can be made. At present there is just a lack of political will to do so. There is a need to ask questions about health and safety standards and translate that information into institutional references. Today regulators say that they are not conducting testing because of a lack of money. However, companies could be forced to pay for it.

At present, companies submit data to regulators when they request approval for a drug. Government agencies are often reliant on the information submitted by companies. People questioned: should that be the situation? Regulators running behind companies asking for better data when it is needed?

A member of the audience compared the pharmaceutical industry with that of the multinationals involved in the promotion of baby food. She stressed that harmonisation efforts in both areas are streamlining liberalisation. The industry often calls for regulation of the things it does not like. She said there is a need to look at regulation at the national level, the myth of deregulation, and re-regulation in the interest of industry. She stated that industry should not be part of drafting codes, they should be regulated. She said there is no talk about sanctions anymore. Instead there is a move towards policies based on industry promises to work better. She wondered about the long-term consequences of this.

Another mentioned the changing regulatory environment. The situation has developed into one in which the industry pushes for regulations that benefit itself. Are public health advocates the only ones that are critical of this? He wondered what professional

associations thought about this trend. A presenter responded to this saying that professional associations differ in their reactions to this trend. For example, some professional groups are heavily dependent upon drug manufacturers for funding. At the same time, a few major journals are waking up to the problem. Another participant emphasised that the American Medical Association has recently released guidelines outlining how doctors should deal with the industry. Ironically, however, drug companies are financing the distribution of this material. One member of the audience pointed out that guidelines can be written by industry and then countersigned by an association.

Under the new EU Commission's proposal company information about drugs will have to be approved by the European Medicines Evaluation Agency (EMA) said one participant. There will be a special board to review this material which at present includes seats for two industry representatives and two places for patient groups. He questioned if the industry should be represented there.

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### THE IMPORTANCE OF THE PUBLIC SECTOR

One member of the audience emphasised the importance of the public sector and innovation within it to bring about sustainable health rights. She said there is also a need to look at the role of health and the public sector from a development perspective in order to strengthen them.

Another said that public sector innovation is usually bought up by the industry, as Taxol was after being developed by the US National Institutes of Health. In this way, they forego some basic research, gain a monopoly and reap huge profits.

A representative from a Southern country said that during the 1970s the public sector played a leading role in increasing access in poor countries. However, when it was time to move a new chemical entity onto the market, it had to go to the private sector. A number of public sector agencies exist today, such as the Indian Central Drug Research Authority (CDRA) that still carry out important work in drug research and development. These agencies could provide a model for other countries. He emphasised that the public sector must be brought back into the picture.

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### GENERICS AND ACCESS

One participant wanted to challenge the role of the generics industry and asked how much it wanted to be an ally of public health groups in the access debate. She called on the representative from EGA to have generic companies make essential drugs instead of generic drugs that are of little therapeutic value. The EGA representative said the generics industry seeks to make a profit, and is not a charity or a nationally led industry. Therefore it needs to produce as wide a variety of drug as it can at high volume. He said the industry could never agree to only produce "rational, effective drugs" but would continue to produce the drugs that were demanded.

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### THE ROLE OF PATIENTS AND PATIENT GROUPS

There is a growing patient-centred feeling and increased shared decision-making, said one speaker. Some research shows involved patients make better decisions and need fewer resources. The situation has become somewhat unclear with the huge growth of patient groups. One has to ask: which groups are actually legitimate and representative of people? He said he was starting to favour consumer unions as he thought many patient support groups acted in self interest and did not think about solidarity. The next speaker mentioned that patient groups followed different paths. Many understand the value of disseminating objective consumer information and see the importance of staying independent. They know that their reputation is at stake. One asked if any attempt had been made to publish a list of patient groups receiving industry funding.



## HAI EUROPE/MEDICO INTERNATIONAL

SUSTAINING ACCESS TO MEDICINES IN EUROPE: THE COMING CRISIS  
2 November 2001 Steinbach, Germany

## PROGRAMME

*Chair: Dr. Joel Lexchin, Associate Professor in the School of Health Policy and Management, York University in Toronto, Canada and member of the HAI Europe Association Board*

8:45-9:15

REGISTRATION

9:30

## MORNING SESSION

WELCOME BY HAI EUROPE

*Speaker: Lisa Hayes (seminar co-organiser)*

9:40

PEOPLE'S HEALTH NEEDS VERSUS COMPANIES' MARKETING RIGHTS

*Speaker: Andreas Wulf, Medico International, Germany (seminar co-organiser)*

10:00

PROMOTING PRODUCTS OR HEALTH?

*Speaker: Charles Medawar, Director, Social Audit, UK*

10:25

COFFEE BREAK

10:40

FAST TRACKING OF MEDICINES: IMPROVING ACCESS WHILE ENDANGERING PUBLIC HEALTH?

*Speaker: John Abraham, Professor of Sociology, University of Sussex, UK*

11:00

RISING HEALTH CARE EXPENDITURES AND DECLINING REGULATORY QUALITY IN THE EUROPEAN DRUG MARKET: WHAT DO WE OWE THE PHARMACEUTICAL INDUSTRY? UNSAFE LICENSING PROCEDURES, USELESS PSEUDO-INNOVATIONS, FALSIFIED STUDIES, MANIPULATED DRUG INFORMATION, CORRUPT OPINION LEADERS

*Speaker: Peter Schönhöfer, co-editor, Arznei-telegramm, (independent German drug bulletin) and Professor em. of Clinical Pharmacology at Bremen's Central Hospitals*

11:30

IMPACT OF EU POLICIES FOR EASTERN AND CENTRAL EUROPE AND OTHER REGIONS

*Speaker: Graham Dukes, Professor of Drug Policy Studies, University of Oslo, Norway*

12:00

DISCUSSION ON MORNING PRESENTATIONS

12:30-1:30

LUNCH

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**AFTERNOON SESSION****1:30-1:50****THE PRESSURES FACING NATIONAL GOVERNMENTS: BALANCING THE NEED TO CONTAIN COSTS WITH STAKEHOLDERS' DEMANDS: A PERSPECTIVE FROM GERMANY***Speaker: Hermann Schulte-Sasse, Former Head of the Department for Health Care and Health Insurances in the German Ministry of Health*

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**2:00-2:20****THE ROLE OF GENERICS: HOW THEY CAN HELP AND THE THREAT FROM NEW EU PROPOSALS***Speaker: Greg Perry, Director General, European Generic medicines Association (EGA), Belgium*

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**2:30-2:50****PAYING THE BILL: THE DILEMMAS FACING EUROPE'S NOT-FOR-PROFIT HEALTH INSURERS***Speaker: Angelika Kiewel, German Federal Association of Craft Guild Health Insurers on behalf of the Association Internationale de la Mutualité (AIM)*

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**3:00-3:20****TEA BREAK**

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**3:30-3:50****CONSUMERS' PRIORITIES AND CONCERNS: HOW TO ENSURE CONSUMERS' RIGHT TO THE BEST POSSIBLE HEALTH IN LIGHT OF RATIONAL TREATMENT AND LIMITED BUDGETS***Speaker: Clara MacKay, Principal Policy Adviser and Editor of Consumer Policy Review, Consumers' Association, UK*

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**3:50-4:45****DISCUSSION ON AFTERNOON PRESENTATIONS**

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**4:45****CLOSING BY CHAIR**

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**5:00****REFRESHMENTS**



HAI EUROPE/MEDICO INTERNATIONAL

SUSTAINING ACCESS TO MEDICINES IN EUROPE: THE COMING CRISIS  
2 November 2001

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