

eurohealth

**Tripping on drugs policy?
Approaches to illicit drugs**

The new EU health strategy: Too much power for Brussels?

Anatomy of a single market: Cross border care in the EU

A review of Health Technology Assessment

preface

Thank you...

I am pleased to say that we have another top-notch series of articles for our spring issue of *Eurohealth*, including a first look at policies to deal with illicit drugs and their effects on public health across the EU. My thanks are due to all contributors to this issue for the excellent quality of their contributions. My particular thanks to Alan Maynard at York University's Health Policy Group for his efforts in coordinating the lead section on drug policies.

Welcome...

On behalf of the editorial team I would like to welcome Anna Maresso as the new Deputy Editor of *Eurohealth*. Anna is the Editorial Officer at the European Observatory on Health Care Systems and will therefore be adding a *Eurohealth* string to her editorial bow. I look forward to working with her on the exciting issues of *Eurohealth* that we have planned.

Coming soon...

The next issue will lead with an extensive analysis of the pharmaceuticals market in Europe and the interplay between national healthcare systems and the free movement of goods. A wide range of articles should stimulate debate about how Europe can create a virtuous circle that satisfies the needs of national healthcare systems, European public health goals, and its pharmaceutical industry, all within the framework of a single market.

Right of reply...

We also now have a new email address for your comments on any articles in *Eurohealth*. If you wish to respond to issues raised or take up a particular point with any of the authors, you can write to us at: eurohealth@lse.ac.uk

Comments on particular points can be forwarded to authors, and short letters to the editor, sent by email to the above address, may be published in the back of the journal. We will also continue to run notices in the news section. Please contact the editor if you wish to notify readers of an event or conference.

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eurohealth

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The new EU health strategy: *Too much power for Brussels?*

The proposal for a new health action programme that the Commission published on 16 May 2000, together with a communication on the future strategy of the Union in the field of health, was heralded by many as the beginning of a genuine European health policy.¹ At the same time the ambitious new programme is also likely to raise fears of a Brussels-dominated harmonisation of healthcare systems. But the critics of Brussels interference in health policy tend to overlook the ongoing integration of markets relevant to health, and growing mobility throughout the European Union. If Member States want to achieve common aims such as keeping healthcare costs down and preserving solidarity structures in healthcare systems, they will need to allow a stronger role for the European Union.



Génon Jensen



Robert Nitsche

The new approach proposed by the European Commission has been welcomed by EU institutions and many observers. It is generally regarded as ambitious in that it gives up the current sector-orientated approach in favour of a comprehensive framework programme. Structured along horizontal strands rather than specific diseases, it provides for more flexibility in the choice of issues to be dealt with and for greater coherence.

But while this integrated approach clearly represents an important advantage of the new programme over the current programme generation, it primarily represents a change in the structure rather than in the content and scope of EU health policy.

A cautious Commission

Looking at the actions that the Commission proposes under the three horizontal strands: information gathering and dissemination, communicable diseases, and health determinants, it appears clear that the Commission has not gone very far in redefining the role of the European Union in health policy. It has rather chosen to cautiously overhaul its current interpretation of the mandate given to it by the EU Treaty, mainly seeking to consolidate it in areas that have proved successful in the past.

This cautiousness, which some might criti-

cise as a lack of strategic vision, and others might regard as the only viable option in the face of Member States' eagerness to keep health policy a national responsibility, has resulted in a striking imbalance between the three strands of the programme:

Under the first strand (information), the Commission proposes to set up a comprehensive network for the collection and dissemination of information, partly building upon existing EU-sponsored networks and information resources. As for the second and third strands (diseases and health determinants), the programme offers a peculiar picture. On the one hand, a considerable part of the actions under these strands consist of information collection and communication and could just as well have been located under the first strand. On the other hand, most of the remaining action proposals are actually preparatory measures that might or might not lead to Community action at a later time. This is apparently motivated by the wish to anticipate resistance from Member States. Among the concrete actions named, non-binding European guidelines are the most far reaching and, mostly, the term 'if appropriate' indicates that their implementation is far from certain. Only in the area of blood products, where the EU Treaty provides an explicit mandate for the Commission, the programme contains a clear commitment to elaborating EU quality standards.

Critics fearing that the EU might try to impose a harmonised healthcare system on Member States will therefore not find many arguments for their case in the Commission's new strategy. It is neverthe-

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less likely that conflicts over the role of the EU in health policy will grow in the coming years.

A number of factors in the long term development of the European Union point towards greater integration and justify a much more ambitious European health policy:

EU citizenship and socioeconomic cohesion

The improvement of living and working conditions and their convergence throughout the European Union are part of the core objectives of the Union. Health is obviously a central dimension of this objective and has indeed been subject to extensive European legislation in those areas that are directly related to production and trade, such as health at the workplace and road safety. However, the European Union is no longer only an economic entity. More and more it develops a social and a civic dimension. The most recent sign of this development is the new EU Charter of Fundamental Rights, which is due to be adopted before the end of this year. Based on the notion of EU citizenship which is part of the EU Treaty since 1992, it reaches much further than the 1989 Charter which only dealt with the social rights of workers.

One of the most important implications of a meaningful EU citizenship in the area of health is the development of EU minimum quality standards for healthcare, including training of medical professionals. The existing standards cover some medical goods, but leave out services. EU citizens, however, have the right to expect certain quality standards in treatment wherever they are in the Union. The same argument holds true for minimum standards concerning patient rights and related rights such as data protection and non-discrimination (for example of AIDS patients, the mentally ill, and so on).

A second important aspect of EU citizenship with regard to health is information. Direct information from EU sources to the citizen is important not only because some EU policies have a huge impact on citizens' health (agriculture, environment, consumer safety, pharmaceuticals) and because of growing cross border cooperation between healthcare institutions in some border regions, but simply and more fundamentally because creating equal access to relevant information is a vital condition for developing European civil society. In the field of health, this should cover both public health issues ranging from nutrition to drug abuse

and information relating to healthcare. The new possibilities offered by the internet will even amplify the need for both quality standards and reliable information.

Another related aspect is the need to make it easier for EU citizens to move between Member States by coordinating national insurance regimes much better. Today, this is still a major hurdle for trans-European mobility, even though the free movement of labour is one of the core principles of the common market. This list could be extended; more aspects are likely to gain importance in the course of the ongoing process of spelling out EU citizenship in all areas.

The consequences of the EU Common Market

EU common market rules apply to sectors highly relevant to health, like pharmaceuticals and medicinal products. To date, the Council only seems to realise the need for a European economic policy for these sectors, but not yet the need for a comprehensive regulatory approach with a view to their role for a sustainable health policy. However they are inseparable, as the example of Norway shows: Until 1992, the country required new pharmaceuticals to have a therapeutic advantage over existing products. It had to change legislation when it joined the European Free Trade Association, as criteria going beyond the effect and safety of pharmaceuticals are not compatible with EU common market law. As a consequence, the number of pharmaceuticals with equal effect on the market soared, and Norwegian doctors who were known for their rational prescribing practice nowadays prescribe many more pharmaceuticals than before. The EU's approach is clearly unbalanced. On the one hand marketing authorisation for new pharmaceuticals is centrally granted for the whole of the EU but on the other hand nobody talks about an EU-wide 'minimum' positive list or other measures to enhance cost effectiveness of pharmaceuticals and to influence innovation (the recent EU orphan drugs Directive is the only notable exception). The Commission has proposed more collaboration between Member States in assessing cost effectiveness, but even this seems to be going too far for some Member States.

In addition, the common market with its free movement of goods, services and labour has an impact on many aspects of health policy that Member State governments like to regard as a national issue. Can rational prescribing practice (or even the

"The Commission has chosen to cautiously overhaul its current interpretation of the mandate given to it by the EU Treaty."

“Member States appear very anxious to keep healthcare policy out of the European Union’s reach.”

simple aim of prescribing fewer antibiotics in order to fight antibiotic resistance) be effectively achieved at national level when doctors and nurses are supposed to move freely between Member States and the content of training programmes varies substantially? Can Member States effectively act against smoking if EU law prevents them from restricting tobacco advertising for health reasons? Clearly, the EU lacks a legal base for acting on such European health threats.

Common problems

Many public health problems are common to all Member States. Some lend themselves to common action simply because of their size (such as research and research related legislation), others have important trans-border aspects. While it is true that the public attitude towards some of these issues (e.g. illicit drugs, alcohol, sexually transmitted diseases) differs between Member States and that it would therefore be wrong to propose detailed common regulation, there needs to be a systematic attempt at discussion and cooperation (in addition to the information needs discussed above). Furthermore, many of the current problems with regard to healthcare systems appear in similar ways in all Member States, regardless of the differences between insurance based systems and systems run directly by the state.

But how great are the chances that Member States will agree to a genuine, comprehensive European health policy that includes the above elements and comprises both public health and certain aspects of healthcare policy?

Some Member States have come forward with progressive ideas. France, for example, favours a systematic approach to health monitoring and calls for a specific EU health monitoring centre. But generally, Member States appear very anxious to keep healthcare policy out of the European Union’s reach.

Would a genuine European health policy really endanger the Member States’ ability to keep up healthcare that guarantees solidarity between rich and poor, ill and healthy and young and old? Most of the above mentioned elements would certainly not. Even if one goes as far as to deliberately organise more of a European division of labour in healthcare delivery structures, e.g. by defining EU-acknowledged centres of excellence where highly specialised treatment would be given to patients from all

Member States, this would not call into question the fundamentals of national health systems. Experience shows that sizeable ‘health tourism’ – which indeed would undermine state control in some ways – only emerges where patients have to pay at the point of use. But anyway state controlled healthcare and compulsory insurance schemes can only claim legitimacy as long as they fully cover necessary healthcare measures. They should be maintained because solidarity in financing healthcare is a worthwhile aim. But the signs of erosion of solidarity structures in healthcare, which are visible in many Member States, are not due to the European Union. On the contrary, European cooperation can help control costs and keep up quality of services. There is a danger that traditional systems will one day appear as old fashioned and ineffective in comparison to private insurance schemes that offer full mobility across Europe.

In this perspective, the attitude of Member States appears as a somewhat simplistic defensive reflex, rather than as a differentiated strategy. It is thus to be welcomed that the Commission intends to consult with NGOs and other stakeholders much more in the future, not only because participation of civil society is an important part of European democracy, but also because this will widen the scope of topics and bring in new arguments. It is however important that EU-wide organisation of citizens’ NGOs is financially supported by the Commission, because they have, by their very nature, a weaker position than industry and other well funded stakeholders.

While the Commission’s communication on the future EU health strategy has the merit to bring some new topics into the policy arena, its action programme is more of a flexible framework than an operative work plan. The Council of Ministers and the European Parliament should regard the discussion on the programme – and the subsequent elaboration of annual work plans – as an opportunity to develop a new definition of Europe’s role in health that corresponds to the reality of European integration.

NOTE

This article is a personal view and does not necessarily reflect the opinion of all EPHA members. To view EPHA’s policy paper on the new health programme and advocacy efforts, visit EPHA’s website, www.eph.org.

REFERENCES

1. The draft programme is currently being debated by the European Parliament and Council. It is expected that the Parliament and Council will adopt their first reading position in May 2001.

Drugs and drug policy

Trends and challenges from a European perspective



Richard Hartnoll

“50–80 per cent of drug injectors are already infected with hepatitis C.”

Over the past two decades, ‘drugs’ have moved up the political agenda in Europe. This has occurred not only within individual countries but also at European level where successive European Councils and treaties have given growing competencies to EU bodies, especially in the field of public health. The creation of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) in the 1990s was one example of this development. The allocation of specific budgets to drugs and public health in European Community Programmes (Prevention, AIDS, Research) are others.

The reasons for this were various. In part they reflected concern about changing patterns of drug use within Europe, for example increases in heroin use, drug injecting and AIDS in the 1980s or the emergence of ‘ecstasy’ in the 1990s. In part they reflected growing anxiety about drug related crime and issues of public order linked to drug use and supply. At international level law enforcement agencies stressed the increasing scale of illegal production and trafficking, and some governments, notably the USA, promoted a high profile policy of war on drugs. The past two decades have also seen substantial changes not only in the patterns of drug use, but also in social and public health policies and responses to drugs. Controversies over issues such as harm reduction or decriminalisation have further contributed to the visibility of this issue.

Trends in drug use

An overview of the drug phenomenon in Europe can be found in the EMCDDA’s Annual Reports, which can be downloaded at www.emcdda.org. More detailed figures are available in an online Statistical Bulletin at the same address. The latest report was published in October 2000.¹ There are notable trends in illegal drug use across different types of drug.

Not surprisingly, the most widely available and used illegal drug is cannabis. Prevalence increased substantially in many countries over the 1990s, and continues to rise in countries with previously lower levels, whilst stabilising in high prevalence countries. By age 18, at least 40 per cent have tried cannabis, and among young adults the figure is probably over 50 per cent, though most use is experimental or intermittent – frequent or heavy use is much less common. Few health problems are observed, though there has been some rise in the (relatively small) numbers seeking treatment.

Amphetamines and ‘ecstasy’ (MDMA) are the second most commonly used illegal drugs. Following increases in the 1990s, ecstasy use is now stabilising or falling, while use of amphetamines in European countries is stable or rising. Lifetime experience of either drug rarely exceeds 10 per cent amongst young populations (the UK is one exception). Although some deaths related to ecstasy have received extensive media coverage, the number of such deaths is very low compared to the level of exposure, and the risk of fatality per consumption is in the order of one in a few million. The possibility of neural damage and cognitive impairment linked to heavy, chronic use of ecstasy is of growing concern, but evidence regarding the longer term risks to health, especially of less intensive exposure, is incomplete and inconsistent. Although relatively few serious health problems are reported regarding amphetamines, in some northern European countries, the use of amphetamines by injection constitutes a significant component of heavier, problematic drug use. A variety of other synthetic drugs, often chemically related to amphetamines and ecstasy, have also appeared on the market, though none show signs of achieving the level of popularity observed for ecstasy in the 1990s.

While cocaine use prevalence is generally lower than for amphetamines or ecstasy, the use of cocaine is clearly rising, especially amongst socially outgoing, employed young (and sometimes not so young) adults. It is often used in recreational contexts on an intermittent basis and usually sniffed in powder form. In most cases this pattern of use does not lead to serious health consequences, but a minority do escalate their level of use and experience significant problems, though they may often not seek treatment. The other setting in which cocaine is increasingly found is amongst heroin users – in a few areas it has

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replaced heroin as the primary drug reported by clients entering treatment. 'Crack' cocaine, which is smoked and which was seen as the major problem drug in the USA in the 1980s and 1990s, has also emerged in parts of Europe, primarily amongst severely marginalised groups such as street addicts and female sex workers in deprived urban settings.

Heroin use and dependence rose substantially during the 1980s, followed in some countries by further rises in the 1990s. Overall, however, experience with heroin is uncommon – typically around two per cent of young people have tried it – and the number of heroin dependants, estimated to lie between one and 1.5 million across the EU, appears to be stable. Known users are a predominantly ageing population with serious health, social and psychiatric problems, though heroin use is also reported among younger groups, for example heavy 'recreational' multiple drug users, marginalised minorities, homeless young people, young offenders, prisoners (especially women) and sex workers. Despite its relatively low prevalence, the health and social consequences of heroin are disproportionately high. Thus heroin is the illegal drug most commonly involved in drug related deaths, drug related infectious diseases such as HIV and hepatitis, clients entering treatment for drug problems, and drug related crime.

Challenges for public health policy

The challenges facing public health policy in the coming years arise from several directions. Of greater significance perhaps than trends in any one particular drug is an increasing awareness of patterns of multiple use involving not only illegal drugs but also alcohol, solvents, benzodiazepines and other psychoactive medicines. Alongside this, there is increasing attention to the overlap between drug using populations and other populations – psychiatric patients, alcoholics, youth in trouble, prisoners, the homeless – and to the interactions between what have often been treated as separate social issues – dependence, mental health,

education, criminal justice, housing, social exclusion. The range of health related problems linked to drugs thus cuts across pharmacological categories, across the legal-illegal divide, and across traditional sectoral and departmental responsibilities.

Over the 1980s and 1990s, health services developed to cater for the needs of heroin addicts by providing specialised treatment including detoxification, psycho-social interventions and, increasingly, methadone maintenance and other interventions in response to HIV and AIDS. In contrast to the USA, the ideological battle between abstinence orientated and harm reduction approaches has now largely been resolved in Europe and a range of harm reduction measures – not only methadone maintenance but needle exchanges, safer drug use messages, even heroin prescription and 'fixing rooms' in some countries, are now accepted as part of mainstream public policy. The challenge is now to develop responses to the changing and expanding concept of 'problem drug use', since the stereotype of the injecting heroin addict no longer offers an adequate basis for this policy.

Responding to problem drug use

Broadening the concept of 'problem drug use' across pharmacological categories raises many new challenges, for example for definition and diagnosis, for assessing the long term risks of drug use patterns such as chronic use of amphetamines and ecstasy, for creating and developing appropriate treatment and harm reduction responses to heavy cocaine and alcohol use.

Developing a coherent health policy across the legal-illegal divide also brings its own challenges, especially since this divide bears little scientific relationship to the relative health risks of the various substances involved. An interesting case to observe over the coming years will be France, which is now attempting to develop one umbrella policy covering illegal drugs, tobacco, alcohol and medicines. In other countries there are clear moves to depenalise and perhaps decriminalise drug use and possession as part of a move

towards dealing with drug use as a public health and regulatory issue rather than a criminal one.

Crossing sectoral and departmental boundaries is yet a further major challenge. Many countries in Europe are already moving towards the establishment of inter-sectoral co-operation, for example in terms of inter-ministerial coordination units at national level, or multi-sectoral cooperation, such as between health, police, social and education services, at local level.

Trying to meet these challenges brings the risk that old themes will be ignored. Broadening the concept of 'problem drug use' does not mean that the problems linked to heroin will disappear – serious social and public health risks will remain strongly linked to chronic heroin use, disproportionately concentrated in socially excluded groups and communities. The emergence of crack cocaine will only make these problems more intractable. Seeking to extend harm reduction beyond injecting drug use does not mean that preventing transmission of infectious diseases is no longer a priority – indeed, there are already some pointers that the incidence of HIV infection could increase again, and 50–80 per cent of drug injectors are already infected with hepatitis C.

Beyond these issues is the wider and changing political, social and economic context. Enlargement of the European Union, political and economic migration, globalisation of drug markets – all these factors will increasingly complicate the task of developing and applying a coherent public health policy that also takes account of the complex and dynamic processes taking place with the existing Union.

REFERENCES

1. European Monitoring Centre for Drugs and Drug Addiction. *Annual Report on the state of the drugs problem in the European Union 2000*. Luxembourg: Office for Official Publications of the European Communities, ISBN 92-9168-097-4, 2000.

Sense and nonsense in British drug policy

For decades, as illicit drug consumption has increased, there has been controversy about policy. Successful governments have mobilised more resources and more rhetoric, depicting drug use as an 'evil', which it is essential to counter.



Alan Maynard

"Public policy choices do not reflect public opinion."

In fact illicit drug use kills far fewer people – some hundreds – than alcohol, which kills thousands, and tobacco, which is associated with the deaths of over 120,000 each year in Britain. Of course these addictive substances are provided by legitimate companies trading for a profit, whilst illicit drugs are part of a vast hidden economy that provides 'social security' for the criminal classes! This facilitates the continuing perpetration of myths about the illicit drug market and how it is and could be regulated.

In 1997 the UK Police Foundation, with the assistance of the Prince's Trust, set up an Inquiry to review the effectiveness of the 1971 Misuse of Drugs Act. The Inquiry team, made up of academics, serving police officers, a lawyer, a journalist and people associated with policy and the provision of care for users, and chaired by Viscountess Ruth Runciman, took written and verbal evidence for two years and reported in 2000.¹ The group offered radical yet pragmatic changes in policy.

They worked against a background of much uncertainty about the actual nature of the drugs problem. Many Britons do not recognise that 25 per cent of 16 to 59 year olds say they have tried cannabis, 10 per cent have tried amphetamines and four per cent have tried ecstasy. The number of drug offenders dealt with by the criminal justice system annually rose from 12,532 in 1974 to 113,154 in 1997. Most of these cases concerned cannabis possession, 55 per cent of which were dealt with by a caution, consuming scarce police time. In 1997–98, 75 per cent of the £1.4 billion allocated to the drug problem was spent on law enforcement. Of the rest, 13 per cent was spent on rehabilitation programmes and 12

per cent funded education and prevention interventions.²

What is known about the effects of imprisonment indicates that it does not alter drug usage. Tens of thousands of young lives are blighted each year by a criminal sentence for the possession of cannabis. Government condemns drug use, spends many millions on anti-drug policies but fails completely to evaluate its policies. As in other areas of social policy, public decision makers refuse to experiment and evaluate, preferring not to be confused by facts! Obviously proper evaluation of policy is expensive but the price of ignorance about policy is even greater. Governments blunder into expensive policies worldwide, asserting rather than evaluating their cost effectiveness.

The Police Foundation report demonstrated that public policy choices do not reflect public opinion. They commissioned a public opinion survey from MORI. This demonstrated that the public can distinguish between the risks of different drugs. The majority of respondents favoured tougher drug laws for the very harmful substances (e.g. heroin and cocaine), whilst about 50 per cent of adults argued for the legalisation of cannabis.

When asked about the allocation of police resources, most prioritised sexual assaults and heroin dealers whilst heroin users and cannabis users were prioritised only by eight per cent and 0.5 per cent respectively.³ Finally this survey showed no evidence of a generation gap in attitudes to illegal drugs: all age groups had similar knowledge of the very different drugs and similar preferences about public policy.

The failure of the political system to respond to such social preferences is a product of the public debate about illicit drugs which firstly aggregates them all as 'evil' and secondly does not encourage a comparative view in relation to the much more damaging but legal products such as alcohol and tobacco. The MORI survey showed 44 times more people in favour of

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“The media gave the Inquiry report a sympathetic response with supportive advocacy of changes in policy and in the law.”

targeting police activity at drunken drivers than cannabis users but the British continue to have relatively liberal drink-drive laws that could be applied much more rigorously.

In order to rank alternative addictive substances, Professor David Nutt, a member of the Inquiry, formulated and tested in a limited fashion a device to obtain the rankings of the risks of substances from some experts in terms of their harm. Risk was estimated in terms of the drug itself, the route of use, the effect on behaviour and the ease of stopping. As a consequence of this assessment and debate in the Inquiry group, heroin and cocaine continued to be classed as A (most risky) but ecstasy was reclassified as B and cannabis was placed in group C (least risky). Alcohol was classed as A and tobacco as B. The Police Foundation Inquiry argued strongly for future classifications of risk to be explicit and evidence based in terms of this or some other ‘hierarchy of harm’.

The Inquiry group proposed that prison no longer be used for the personal use of class B and class C drugs. Furthermore they proposed that the normal sanction for the possession and cultivation of cannabis should be an out-of court disposal. Police should retain the power to arrest suspects for the possession of class A and B drugs, but not for class C (e.g. cannabis).

There are some who continue to favour legalisation of some or all substances. This is impossible given the current set of international Treaties to which the UK is a signatory. Unilateral withdrawal from these Treaties would be a very difficult task because like most international treaties they are dominated by political groupings (in particular the USA) which will not, as yet, sanction rational, evidence based changes in the ways in which the international illicit drug market is regulated. Such constraints make innovation difficult (as experienced by the Dutch) and rational debate elusive.

The Police Foundation put forward 81 recommendations for changes in the law. The

initial government response was of considerable hostility and negativity. However the media gave the Inquiry report a sympathetic response with supportive advocacy of changes in policy and in the law. The government’s eventual response to the detailed recommendations was to support some but generally to continue to be negative about changes which reflect public opinion.

Wendall Holmes, a member of the US Supreme Court at the beginning of the last century, argued that the law should reflect “the felt necessity of the time”. The Police Foundation Inquiry concluded that the demand for illicit substances would best be dealt with by education and rehabilitation rather than the legal system. Current government policy in the UK continues to emphasise the roles of the police, the courts and prison, even though police generally favour radical change to reduce wasting their time on minor cannabis offences. Whilst the evidence base for education and treatment investments is poor, there are hints of greater cost effectiveness compared to the use of the legal system. It is imperative that these ‘hints’ are substantiated by detailed evaluation which both reviews what is known and prioritises investment in trials and piloting of the many interventions for which there is no evidence base. Whilst there is significant academic enthusiasm for such work, which could extend the drive for evidence based medicine – the Cochrane Collaboration⁴ – to all other areas of social policy – the Campbell Collaboration⁵ – government shows little inclination to invest appropriately.

All changes in policy about illicit drugs are social experimentation which affects the welfare of individuals in society. Such experimentation should not be done blindly but with care in terms of the formulation of intervention and its evaluation. The great variations in arrest rates, sentencing, imprisonment regimes and treatment provision are natural experiments awaiting evaluation. Until such evaluation takes place, it will be difficult to distinguish well between sense and nonsense in the regulation of the illicit drug market. As a consequence resources will be wasted, profits made and lives blighted by addiction and legal stigma. Hopefully in time even politicians will come to their senses!

Note: This article is a personal statement by one member of the Police Foundation Inquiry team.

REFERENCES

1. *Drugs and the Law: Report of the Independent Inquiry into the Misuse of Drugs Act 1971*. Police Foundation, London, 2000.
2. *Drugs: Dilemma, Choices and the Law*. York: Joseph Rowntree Foundation, 2000.
3. *Ibid.* Table 2.4, page 35.
4. Maynard A, Chalmers I. *Non Random Reflections on Health Services Research*. BMJ Publishing 1997.
5. See website www.campbell.gse.upenn.edu

Going Dutch?

Successes and problems of drugs policies in the Netherlands



Henk Garretsen

Dutch drugs policy is the continual subject of international attention and debate. Many see the Netherlands as 'the place to be' for drug users. However, Dutch drugs policy cannot be seen as particularly permissive with regard to legislation and control. This article describes current Dutch drugs policy, showing its successes and problems and discussing present debates.

The facts

Balancing public health and public order

What are the facts about drugs policy in the Netherlands? The main aim of the drugs policy in the Netherlands is "to protect the health of individual users, the people around them and society as a whole".¹ Important goals are to minimise health risks for users and to minimise drug related nuisance and criminal behaviour.

"The view that it is not possible to win a war on drugs is a prevailing one."

Normalisation is a key principle; the view that it is not possible to win a war on drugs is a prevailing one. 'Drugs are here to stay' and drug use and drug users are approached in a pragmatic, businesslike way. Users are responsible for their own behaviour and when receiving help (quite often methadone treatment) users have to meet arrangements made.

Users are not forced to try to abstain from drugs; if they are unwilling/unable to do so the care is not directed towards the use itself but towards reducing health risks related to this use. This approach is called harm reduction. In order to reach as many addicts as possible harm reduction activities are usually incorporated in low-threshold programmes.² Important activities are among others methadone programmes, condom distribution, needle exchange and street corner medical care.

It can be concluded that the (public) health approach is very important in Dutch drugs policy. However, so is the public order point of view. Important issues are tackling organised crime, tackling drug related nu-

sance and maintaining public order. Regulations on drugs are laid down in the Opium Act. Importing and exporting drugs are the most serious offences under the provisions of this act, with a maximum penalty 12 years imprisonment and a fine of 100,000 guilders. Manufacturing and selling are offences too, as is the possession of drugs. The use of drugs in itself is not an offence.¹ Whilst the highest priority in the prosecutions policy given to the international trafficking of drugs, a very low priority is given to the possession of small quantities of drugs for personal use.

Both at the level of the society as a whole and at city level drug policies attempt to develop an integrated approach and try to balance public health and public order. As a consequence of this integrated approach at the national level the responsibility for drugs policy is borne by a number of ministries: the Ministry of Justice (responsible for criminal law matters), the Ministry of Health, Welfare and Sport (responsible for prevention, care and for the coordination of the policy as a whole) and the Ministry of Interior (local government and police). Big cities and cities close to the borders of Germany and Belgium develop their own policies and many harm reduction activities. In general activities are developed as much as possible in cooperation with politicians, treatment workers/health representatives, police and home office on the one hand and among others users organisations, neighbourhood resident organisations and shop owners, on the other.

Distinction between soft drugs and hard drugs

One of the most important issues in Dutch drugs policy is the distinction which has been made between soft drugs and hard

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“It is possible to obtain soft drugs without coming into contact with the black market for hard drugs.”

drugs. In 1976 the Opium Act was amended in this respect. At that time a distinction was made between cannabis products (hashish and marijuana) which were seen as ‘soft drugs’ with an acceptable health risk, and ‘hard drugs’, drugs with an unacceptable hazard to health. The possession of small quantities of soft drugs is seen as a minor offence and has no priority in the prosecutions policy. However, in principle both the possession and the sales of soft drugs are prohibited. But, one tries to keep the markets for soft drugs and hard drugs separated by being more tolerant to the use and trade of soft drugs. In doing so, for users it is possible to obtain soft drugs without coming into contact with the black market for hard drugs. In this way there is a reduced chance that cannabis users will switch to hard drugs.

The sale of small quantities of soft drugs is tolerated, even regulated, in coffee shops which are not allowed to sell alcohol. Technically this sale is an offence, but prosecution proceedings are only instituted if the operator or owner of the shop does not meet the following criteria:¹

- no more than 5 grams per person may be sold in any one transaction
- no hard drugs may be sold
- drugs may not be advertised
- the coffee shop must not cause any nuisance
- no drugs may be sold to minors (under 18), nor may minors be admitted to the premises
- the mayor may order a coffee shop to be closed.

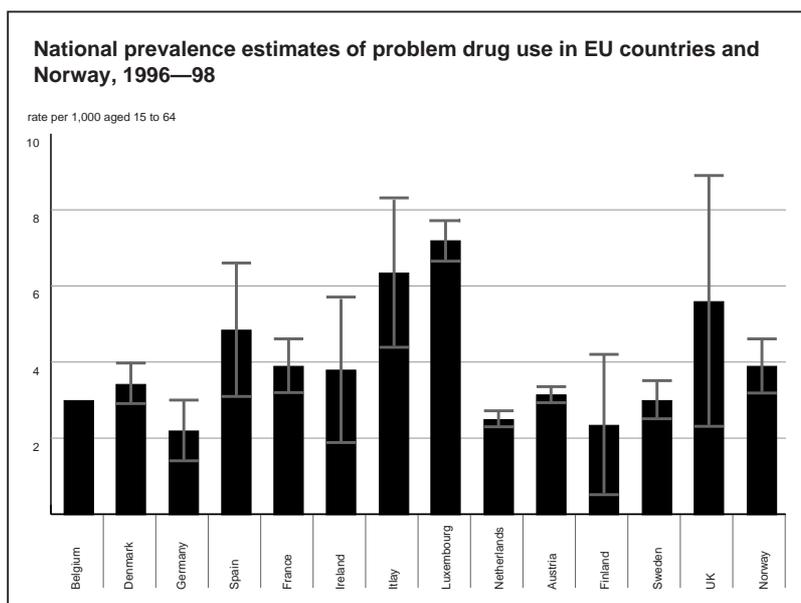
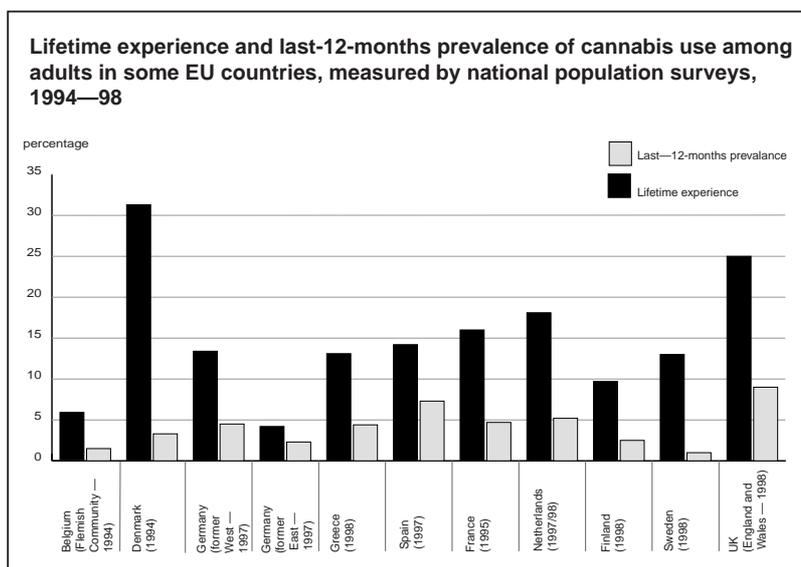
These criteria are strictly adhered to. When criteria are not met the coffee shop will be closed down.

Successes?

To a certain extent the Dutch drugs policy probably has positive results. According to the ‘nationwide drug monitor’, in which the results of many statistics and the views of many experts are incorporated, the number of problematic users of hard drugs (estimated number 25,000 – 29,000) is stable, the population of hard drug users gets older, the mortality and the number of overdoses decreases as does the number of HIV infections.³ Compared to other European countries the number of problematic users is low.

Because of the Dutch coffee shop policy one could expect that the use of cannabis in the Netherlands is relatively high but this is not the case. Compared to other countries the position of the Netherlands is somewhere in the middle. However, despite the positive overall picture, there are some negative aspects too. The number of cannabis users is growing, particularly amongst youngsters. The number of cocaine users is also increasing.

With regard to public opinion it is important to realise that all over Europe citizens are not very well informed about drugs and drug use. In general however, citizens in the Netherlands seem to be better informed than in other European countries.⁶ Another positive development is that, especially in some big cities, it appears to be more and more possible to develop new, promising, preventative policies in cooperation with users organisations and citizens.



Source: European Monitoring Centre for Drugs and Drug Addiction. Lisbon, Annual Report 2000.

Problems and debates

The Netherlands is confronted with a number of problems that are very difficult to influence. For instance, because of its geo-economical position as the transit 'port of Europe' it attracts much international trade, part of which is illegal drugs trade.⁴

Other problems however are related to the developed policy in itself. The pragmatic nature of this policy cause some problems. For instance, a number of things are officially forbidden but in practice tolerated. It is difficult to deal with so called 'pseudo legal' situations. A hot issue at the moment is the situation with regard to the coffee shop policy: It is tolerated that users buy small quantities of soft drugs in coffee shops but the supply of these shops is not regulated at all. Pleas to regulate/legalise this supply have relatively high support in parliament but are not successful because of the international pressure; the Netherlands is too far out of tune already.

Debates about possible legislation have been taking place in the Netherlands for many years with regard to all drugs, and exclusively about cannabis and marijuana. Arguments that drugs should be available have to do with fairness ('why is alcohol freely available and heroin not?') but also with other factors. The criminality of drugs leads to the creation and operation of international illegal criminal organisations, to drug related crimes against property, to drug related nuisance and to health problems. Users have unstable patterns of daily activities that are drug related. Next to that there is no quality control with regard to the drugs used, as is the case with legally available substances like alcohol. Impurities may be added to the drugs and there is a genuine risk of inadvertent overdose. On the other hand it is argued that a free availability of drugs has significant drawbacks too. Crimes against property will only partly disappear because some users were criminals prior to becoming addicted to drugs. Furthermore, of course, legalisation in the Netherlands alone would likely cause a significant increase in drug tourism, and, a 'go it alone' policy in the Netherlands will harm international relations.⁵

Major problems have occurred in the investigation and prosecution policy. Uncertainty around the legality of some methods of investigation (the so called controlled trafficking/deliveries of huge amounts of both soft and hard drugs) forced the government to dismantle all

regional criminal investigation squads that had been specially formed to fight organised drug crime.⁴

Safety and drug-related nuisance issues such as street pollution, street prostitution and crimes against property are still cause for concern.² Perhaps these issues are not increasing to a large extent but they remain a problem and public acceptance seems to be declining. Every now and then public opinion calls for the closure of coffee shops and/or 'tolerance premises' – areas or houses where the use and selling of drugs is tolerated by the authorities. The closing of these known premises which quite often follow a number of official regulations can mean that there will be less control over drug related activities and that fewer harm reduction activities will be possible.

Current debate focuses on the quality of treatment, care and prevention and on priority setting and target groups. Interventions should be more evidence-based and more social care should be developed for those categories of addicts who need basic help with their living conditions. Developments in recent years that are still a subject for discussion include forms of compulsory treatment and the supply of heroin to users, which is on trial in six Dutch cities.

Epilogue

Dutch drugs policy has been praised and criticised. The policy is continuously under discussion in the Netherlands itself and internationally. The Dutch approach is pragmatic and seems to be rather successful in a number of respects. However, many problems occur and debates are ongoing. But, perhaps one of the biggest problems experienced is the ongoing international pressure which makes it difficult (for the government and for others) to have rational debates and to make rational decisions.

"A 'go it alone' policy of the Netherlands will harm international relations."

REFERENCES

- 1 Ministry of Health, Welfare and Sport. Factsheet: *Drugs Policy in the Netherlands*, 1997.
2. Trimbos Institute. Factsheet: *Hard Drugs Policy*. Utrecht, 2000.
3. Trimbos Institute. *Nationale Drugmonitor, Jaarbericht 1999*. Utrecht, 1999.
4. Lemmens P, Garretsen H. Unstable pragmatism: Dutch drug policy under national and international pressure. Editorial, *Addiction* 1998;93:157-62.
5. Garretsen H, Sturmans F. The War on Drugs: An international discussion is desirable. Letter to the editor. *British Medical Journal* 1996;312:635-6.
6. Stichting Toekomstscenario's Gezondheidszorg (STG). Verkenning drugsbeleid in Nederland (Exploring Drugs Policies in the Netherlands). STG. Zoetermeer, 1998.

Dynamic modelling of drug use

Drug misuse and associated problems vary across different European countries and across time. In response to drug problems considerable efforts have been made to gather information.

Given the illegal nature of the drug trade it is not surprising that data remain limited.



Christine Godfrey

Researchers attempt to explore social problems by employing a variety of different techniques both to understand these phenomena and to attempt to predict future trends and simulate the impact of different policies. Where data are scarce or there are gaps in information, statistical and mathematical models also provide a means of estimating the size and nature of the social issue. There are many different modelling techniques from a range of disciplines. Not all the techniques available have as yet been applied to the drug field. The different techniques have varying characteristics. Some modelling techniques are easy to understand but can they explain such a complex area? In contrast, other models are so technical as to seem to be a 'black box' and it is difficult to assess the assumptions that have been made. What is the role of such models in understanding all the social processes involved in illicit drug use?

The project

The European Monitoring Centre for Drugs and Drugs of Addiction (EMCDDA) funded a group of experts drawn from across Europe to consider the feasibility of developing dynamic models of drug use and related problems in a series of meetings during 1997 and 1998. Some models start with data, others with mathematical models. Disease modelling has used a number of these different techniques and many of the examples considered in the project had been applied to estimating the spread of HIV/AIDS. However, modelling is often driven by the questions that need to be addressed. The purpose of the first meeting of the project was to identify all the different techniques that could be used to model drug use and problems. Reviews of techniques were then undertaken. Finally a larger seminar was held to consider the use of modelling and construct some priorities for future research. The EMCDDA

Monograph No. 6, *Modelling Drug Use*, to be published shortly, contains the results of this project.

Modelling techniques

The modelling techniques identified can be divided into four main groups:

- Models using available data.
- Specific statistical and mathematical techniques.
- Models of health consequences of drug use.
- Economic models.

Starting with available data and exploring how different techniques can be used is an attractive strategy. Three areas are outlined in the monograph. Geographical information systems (GIS) provide a means of identifying how socially related behaviour of drug use may spread across an area. The models are demanding of data but can be developed beyond a simple display of use and spread of drug use. These systems can be augmented by linking the spatial framework with relational databases and epidemiological functions and therefore could be used for more complex modelling and predictions.

Another approach is to use a range of modelling and statistical techniques with available data. Models can provide a range of estimates and combining different techniques to address the same questions allows some triangulation of the estimates. Finally, readily available indicators can be used with time series statistical techniques to investigate the relationships across time and potential to predict future trends.

Four different reviews of specific modelling techniques were considered. One starting point to estimate a 'hidden' population is the back calculation method. This is a technique that has been applied extensively across Europe to estimate the numbers with HIV infection. The potential use in the drugs field may be to use data on known populations such as those attending treatment with data on the time delay between attending for treatment and drug initiation to estimate the total number of drug users. A second but linked technique is compartmental modelling. In these models the population is divided into two or more groups. The models then explore how individuals move from one compartment to

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another. For example, a drug model may explore how people move from non-injecting to injecting drug use.

Obviously in social processes such as drug use and associated problems there may be more complex links including feedback mechanisms from different parts of the system. These 'system dynamic' models have been used to simulate policy changes such as switches of expenditure between enforcement and treatment. Such models have the potential to address very important policy questions but they can also lose their transparency. Finally, structural equations and path analysis, techniques that examine the relationships between known data to examine the underlying concepts were considered.

One of the major concerns about drug misuse is the associated health consequences, especially infectious diseases such as HIV, and hepatitis B and C. There is considerable scope to use a number of the modelling techniques to address specific questions such as how drug related infectious diseases may spread across the population. Similarly, scenario analysis also involves using different mathematical and statistical techniques within a conceptual model which links different policy developments and consequences.

Economic models start with a different focus. Market models attempt to predict the behaviour of consumers and suppliers in varying circumstances. There have been a limited number of studies for example that have considered how price and income affect the demand for drugs. The second type of economic models are those which specifically consider the cost effectiveness of different policy options.

What relationships need to be modelled?

The next step in the project was to consider which of these techniques could be used to understand drug use and problems in Europe. Drug use is a dynamic process and to understand how drug use changes it is necessary to understand the whole process of 'drug use careers' and the risk factors and social problems that influence these careers. The different patterns of use and such careers feed into the levels of use and obviously the problems and social costs associated with drug misuse. However, the levels of drug use and problems are also influenced by the supply and supply systems and policy interventions. This schema is illustrated in Figure 1. This framework was

used with the review of available modelling techniques and data availability to suggest some projects that could be undertaken.

The priority questions identified were:

- What are the levels of drug use and problems and how do these vary across time and geographical areas?
- How can the spread of new drugs be predicted?
- What is the current drug using career and how does this interact with treatment?
- How can the social processes that help determine demand for drugs be modelled?
- How can the impact of interventions be modelled?
- Are the current costs of drug-related problems and the cost-effectiveness of the different policy options to reduce these cost-related?

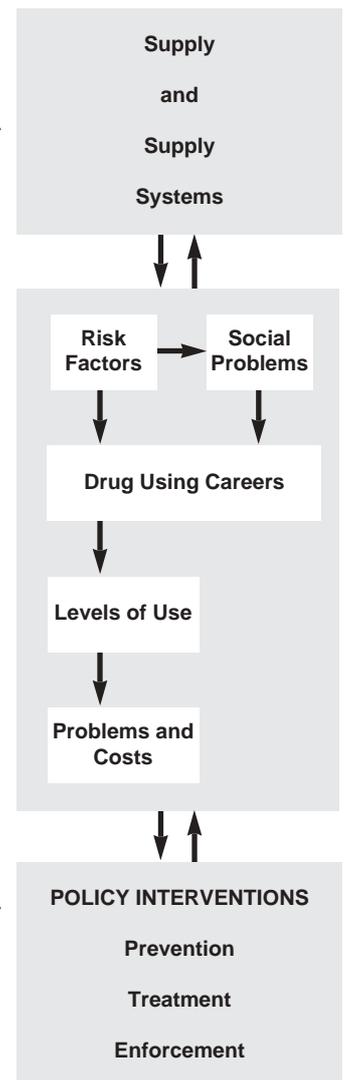
Several practical projects were identified. First, modelling the health consequences of drug use particularly hepatitis B and C and their costs. The use of GIS models, and the production of spatial-temporal maps, was the second area identified. A third was investigation of the social processes and how these may impact on the initiation of drug use. The use of back calculation methods to investigate time trends and incidence was another area where research could be initiated. The fifth area was to consider whether drug markets across Europe could be modelled. This work would be more developmental than the other two areas, building on qualitative studies of the individuals and organisations involved in drug markets and examining the potential to build statistical models of the demand and supply of illicit drugs. Finally, estimating the cost-effectiveness of different policies was another area that was seen as a priority for modelling studies.

Where next?

Policy makers need research in order to inform their policy decisions. Modelling studies have a to illustrate the potential consequences that could arise from different policy mixes. It is clear from the monograph that there is considerable potential for future research even if many techniques remain of unproven worth. As a number of projects are now underway, the next important task is to consider how, when the results become available, they feed into the policy making process, a potential subject for a future monograph.

“Many of the examples considered in the project had been applied to estimating the spread of HIV/AIDS.”

Figure 1 Modelling drug use, problems and policies



Access to healthcare in the European Union

The consequences of the Kohll and Decker judgements

The 'Kohll and Decker' judgements of the European Court of Justice (ECJ) have heralded a new era in which Europe is likely to become more important in the field of healthcare and social protection. The rulings substantially increased a patient's options of receiving non-emergency healthcare in another Member State at the expense of his or her social protection system. However, as they left many questions unresolved, a lot of confusion and uncertainty exists as to the real impact of the Court's decisions on health and social protection systems. A recent study by AIM (the Association Internationale de la Mutualité), commissioned by the European Commission, attempts to sound the positions of various actors and to measure possible implications for the future.¹



Willy Palm



Jason Nickless

The rulings and the reactions they produced

In the *Kohll*² and *Decker*³ decisions the ECJ considered that by demanding prior authorisation for the reimbursement of orthodontic treatment and the purchase of spectacles outside the territory the Luxembourg health insurance rules had created an unjustified impediment to the free movement of goods and services within the European Union.

Although the substance of the political reactions that followed these decisions varied from source to source they were largely fierce and defensive. Many of the Member States rejected any possible implications for their health systems, arguing that the decisions only applied to systems that operated through a reimbursement mechanism and that medical services in their country are not reimbursed but provided in-kind through contracted providers, via social insurance or a national health system. They therefore maintained their traditional restrictive policy of authorising non-emergency healthcare abroad only if it is medically required. Only Luxembourg, Belgium and Denmark amended their legislation and established administrative procedures for the unconditional reimbursement of certain out-patient services and healthcare products purchased in another Member State. In Austria, even before the rulings in *Kohll* and *Decker*, socially insured persons were entitled to reimburse-

ment of care from a non-contracted provider in Austria or abroad, at a rate of 80% of the amount paid for the same treatment from a contracted provider. The diagram below indicates which Member States rely on a reimbursement mechanism and which provide healthcare benefits in-kind.

The prospect of an open, European-wide, healthcare market is welcomed by public opinion, especially in countries where resource problems entail waiting lists and other access restrictions.

Dual system of access to care abroad

Even though the Luxembourg rules requiring prior authorisation were an exact implementation of the EC Regulation on the coordination of social security for migrant workers, the ECJ did not invalidate the current E112 procedure based upon article 22(1)c of that Regulation.

Through its decision, the ECJ created a dual system of social cover for healthcare received abroad.

- On the one hand, there is the E112 procedure governed by the EC social security coordination Regulation, that integrates the patient who has received authorisation from his or her social security institution, into the social protection system of the country where s/he receives the medical treatment, "as though he were insured with it". This mainly implies that the patient is subject to the same cost-sharing and the same regulations (e.g. referral for specialist care), and that costs are settled between both social protection systems according to the tariffs of the state where treatment was delivered.
- On the other hand, patients using the procedure created by *Kohll* and *Decker*

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are not integrated into the social protection system of another Member State but when returning to their country of residence, they claim the coverage of their social protection system “as if they received the treatment there”. This would mean that reimbursement in the state of residence is subject to the conditions and according to the tariffs applicable there.

This situation of duality not only increases the administrative burden for access to cross-border care, it also risks creating confusion among patients, healthcare professionals and payers.

Unresolved questions and new cases

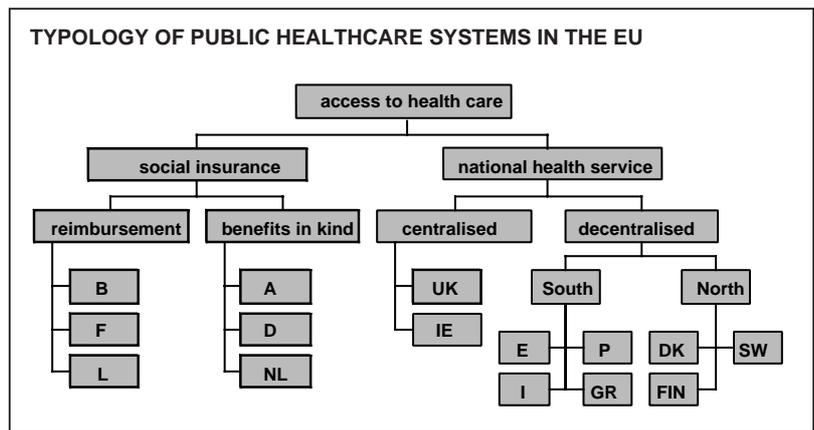
Since the ECJ did not define the scope of its decision, further clarification is needed for restoring a minimum of coherence in administrative practice, on a national level as well as between Member States. Taking into account both the divergence and firmness of the positions taken by the Member States and the complete silence of the European Commission, only the European Court of Justice could fill this need.

At the moment, five requests for a preliminary ruling are pending before the ECJ,⁴ all referring to the *Kohll* and *Decker* decisions and the unresolved issues left in their wake. These new cases could contribute to more clarity as to the real ambit of the principles of free movement of medical goods and services in relation to social protection.

- Are all socially insured persons in the EC completely free to choose between the procedures of the EC Regulation and that created by *Kohll* and *Decker*?
- What powers do Member States now have to make access to healthcare subject to certain conditions (e.g. age) or procedures (e.g. waiting periods) and, more generally, to what extent can they define the scope of their own health protection system?
- Would the principle of free movement of services also apply to in-patient care, which is subject to national planning and involves considerable investment and functioning costs?
- How does the principle of free movement of services effect benefit in-kind systems, where healthcare is given by contracted or employed providers?

Is healthcare a service?

In their opinion relating to some of these pending cases, the Advocate Generals suggested to the ECJ that medical services that



form an integral part of a public healthcare system and are financed from public means are not ‘remunerated services’. Remuneration is an essential element in the definition of services falling under the scope of free movement of services (Article 50 of the EC Treaty). The Advocate Generals therefore advance that this principle of free movement of services should not apply and certain Member States would retain the right to submit social coverage for healthcare services delivered in another Member State to the condition of prior authorisation.⁵

If the ECJ were to follow this opinion, then the implications of the *Kohll* and *Decker* decision would limit itself to mainly outpatient medical services in the reimbursement systems of Luxembourg, Belgium and France. The ECJ does not have to follow the advice of the Advocate Generals but if it did it may lead to an undesirable split between the so-called reimbursement systems and in-kind benefit systems. Would such a move represent an unfair persecution of certain states because of the way they choose to operate their social security system? Would the ECJ be placing pressure on certain Member States to adopt a particular type of healthcare system?

ASSOCIATION INTERNATIONALE DE LA MUTUALIT (AIM)

AIM, the international association of mutual health funds, groups some 44 national federations of mutual health funds in 28 countries, mainly in Europe. Mutual health funds provide social cover against sickness and other social risks to more than 120 million people in Europe alone, either by taking part in the administration of compulsory health insurance or by providing complementary, alternative or substitutive health insurance.

AIM's goal is to defend and promote, at international level, the social values and basic principles shared by its members: health and wellbeing as a fundamental right, solidarity and non exclusion as essential guarantees for access to healthcare for all, autonomous management and non profit orientation as guiding principles for health insurance based upon the needs of citizens.

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“This situation risks producing confusion among patients, healthcare professionals and payers.”

The key point to note in the *Kohll* and *Decker* cases is that the ECJ merely sanctioned the unjustified discrimination between healthcare providers established in different Member States. Indeed, in Luxembourg, treatment from any doctor in its territory is reimbursed by Luxembourg social security. Translated into Euro-speak this should mean any doctor in the EU. Otherwise the Luxembourg compulsory health insurance would implicitly discriminate against providers established in another Member State who cannot benefit from this privilege.

Under the *Kohll* and *Decker* procedure treatment received in another Member State is treated as if it were provided in that patient's own Member State. Therefore if the treatment is not covered by the social protection system in the patient's home country – because that particular service does not fall within its material scope (e.g. dental care or cosmetic surgery) or because treatment under the public system is only made available through designated, contracted providers – it will no more be covered by the *Kohll* and *Decker* procedure.

This hypothesis is firmly based on the principles of sovereignty, subsidiarity and non-discrimination and will affect both benefits in-kind and reimbursement systems. It is the way in which medical services are purchased in the context of social security that appears to be the key factor, rather than the way of remunerating the service. Indeed, the procurement system represents the link between social protection, falling within the national public sphere, and the healthcare sector, integrating within the European internal market. Even if it belongs to the national competence to determine the way of contracting with medical providers, it is not allowed to discriminate against foreign medical providers without justifiable cause.

In this sense, the *Kohll* and *Decker* rulings also contain a message for the benefit in-kind systems. Even if a Member State has decided to reserve medical services in the context of social protection to contracted providers, it should guarantee that foreign providers are given equal opportunities to compete for these contracts. It should also be remembered that the ECJ in a former case declared European public procurement rules applicable to social security institutions contracting with service providers.⁶

Future perspectives

From this perspective, *Kohll* and *Decker*

would concern discrimination between providers rather than free movement of patients. It could force national contracting mechanisms to open up to all healthcare providers in the European Union.

Instead of the announced and dreaded worst case scenario of unregulated free movement of patients, European cross-border contracting could at the same time become an attractive option for improving access to healthcare while maintaining control of the cost and the quality of care. It should encourage Member States to ease their position with regard to covering treatment abroad, notably where it meets real needs. This could be achieved in several contexts:

- in border regions where providers across the border could complement a limited regional supply of medical services;
- for highly specialised treatments provided in certain qualified centres of excellence with an international radiation;
- in foreign tourist centres where temporary concentration of nationals might justify contracting with a local provider offering certain facilities, e.g. linguistic qualifications;
- for certain treatments that cannot be provided in time (and are subject to waiting lists) due to shortage of staff or other resources.

It is clear that the further development of cross-border patient mobility is not a matter of individual motives linked to the specific situation of the patient. Other actors – physicians, hospitals, health authorities, insurance carriers, employers – are becoming more conscious of the existence of a European healthcare market, and they are influencing the patient in his choice and are promoting an increase of cross-border care.

However the creation of an internal healthcare market and the further development of cross-border purchasing of care, will undoubtedly cause the need for a kind of European reference framework providing benchmarks as to quality standards, equivalence of medical practice, licensing and accreditation, etc. If further economic integration in healthcare is to avoid increasing social inequalities in access to care, it will also be necessary to democratically define the prerequisites and the limits of this process. It seems that only the European level is able to deal with this efficiently. In this context, the latest Community strategies on concerted action in the fields of social protection and public health could provide the necessary instruments.

REFERENCES

1. Palm W, Nickless J, Lewalle H, Coheur A. *Implications of Recent Jurisprudence on the Coordination of Healthcare Protection Systems*. Report produced for the European Commission Directorate General for Employment and Social Affairs, May 2000. Available in several languages on AIM's website.
2. ECJ, *Kohll*, C-158/96, (1998) ECR I-1931.
3. ECJ, *Decker*, C-120/95, (1998) ECR I-1831.
4. C-368/98, *Vanbraekel/Alliance Nationale des Mutualités Chrétiennes*; C-157/99, (*Geraerts-Smits/Stichting Ziekenfonds VGZ and Peerbooms/Stichting CZ Groep Zorgverzekeringen*); C-385/99 *Van Riet/ZAO Zorgverzekeringen and Müller-Fauré/OZ Zorgverzekeringen*.
5. ECJ, 27 September 1988, *Humbel*, 263/86.
6. ECJ, 24 September 1998, *Tögel*, C-76/97.

A guarantee of similar standards of medical treatment across the EU:

Were the European Court of Justice decisions in *Kohll* and *Decker* right?



Jason Nickless

“The mutual recognition rules were the wrong legal basis upon which to reject the Luxembourg government’s suggestion that total freedom of movement might pose a threat to human health.”

The Luxembourg government and health insurers attempted to justify their restriction to the free movement of services in the *Kohll* case on the basis of the protection of human health by advancing that the “quality (of healthcare) can only be ascertained at the time of the request for authorisation”.¹ The European Court of Justice dismissed this assertion by referring to the substantial

secondary legislation concerning the mutual recognition of diplomas. It concluded, “It follows that doctors and dentists established in other Member States must be afforded all guarantees equivalent to those accorded to doctors and dentists established on national territory, for the purposes of freedom to provide services”.¹ Closer research into the legislation on the mutual recognition of diplomas indicates that the European Court of Justice may have been a little hasty in concluding that medical standards are roughly the same in every Member State.

This article will introduce the EC rules on the mutual recognition of diplomas before considering the gaps in the European Court of Justice’s conclusion that these rules imply a similar standard of healthcare right across Europe. It then concludes that these rules are clearly the wrong legal basis upon which to make such an assertion and

that the resulting uninformed free movement of patients may increase risks to human health.

The mutual recognition of diplomas

The EC legislation on the mutual recognition of diplomas aims to allow EC nationals to pursue employed and self employed activities in another Member State. The legislation in this field is divided into ‘sectoral’ directives and ‘general’ directives.

The sectoral directives

The sectoral directives deal with specific occupations and have been adopted for the following medical professions:

- doctors
- general practitioners
- specialised doctors²
- nurses responsible for general care³
- dentists⁴
- midwives⁵
- pharmacists⁶

Two Directives were passed for each profession, one provides a list of equivalent diplomas and professional titles whilst the other harmonises the minimum training requirements for the award of those diplomas by national institutions. The first Directive applies to professionals who wish to practice in the territory of another Member State. For example the Directive on doctors declares that a “*Wettelijk diploma van doctor in de genees-, heel- en verloskunde*” (diploma of doctor of medicine, surgery and obstetrics required by law) in Belgium is equivalent to a “*Ptychio Iatrikis*” (degree in medicine) in Greece.

The other Directive lists minimum training requirements which set minimum standards for everyone, whether they intend to provide services in another Member State or not. They represent a minimum harmonisation and relate to both the duration

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of training and the substantive content of that training. For example the Directive on doctors states that the diplomas listed as equivalent may not be awarded unless the person concerned has undergone a six year course, or 5,500 hours of theoretical and practical instruction, at a university, which gives them *inter alia*:

- (a) "adequate knowledge of the sciences on which medicine is based and a good understanding of the scientific methods including the principles of measuring biological functions, the evaluation of scientifically established facts and the analysis of data"
- (b) "sufficient understanding of the structure, functions and behaviour of healthy and sick persons, as well as relations between the state of health and physical and social surroundings of human beings"

"Not all healthcare professions have been subject to sectoral directives that ensure minimum levels of education and training."

The Member States are obliged to give automatic recognition to diplomas obtained in other Member States that comply with these minimum requirements. This recognition must be given without imposing any further requirements relating to probationary periods or aptitude tests. However, those holding a diploma obtained in an EC State other than the one in which they wish to practice will still have to register with the appropriate authorities in the state of practice.

The general directives

All those who are not covered by the sectoral directives may rely upon the general system of recognition developed in Directive 89/48⁷ and Directive 92/51.⁸ Unlike the sectoral directives, the general directives do not lay down any minimum standards for training and only affect people who wish to provide services in the territory of another Member State. This general approach was adopted because of the time and complexity required for the production of the sectoral directives.

The system works on the basis of 'mutual trust' but recognition is not automatic. It applies to regulated professions – professions where laws or regulations set down minimum qualifications for the pursuit of a

particular job. The basic premise is that if someone has fulfilled the education and the training period required to practice a regulated profession in one Member State, another Member State cannot refuse access to that profession in its territory solely on the basis of inadequate qualifications. There are no rules specifying which professions have to be regulated, that is left to the discretion of the Member States.

Directive 89/48 applies to regulated professions that require a diploma obtained after at least three years of higher education. It basically states that if a regulated profession in State A requires a four year university diploma, this requirement could be fulfilled by a three year diploma awarded in State B. The two qualifications will be treated as equals. Directive 92/51 introduced a similar approach for professions requiring at last one year of post secondary education.

However, recognition under the general system is not automatic, this is because there are no harmonising measures regarding course content. This means that EC States are sometimes permitted to demand extra proof of competence before they allow someone who has obtained qualifications in another Member State to practice a regulated profession in their territory. The additional requirements of an aptitude test or probationary period can be imposed where:

- the period of education and training in the host state is at least one year more than the state where the applicant has obtained his qualification;
- the host state can prove that the contents of the other state's training programme differs considerably from that provided within its territory.

An equal standard of medical treatment across the EU?

This brief description of the EC rules on the mutual recognition of diplomas exposes a few gaps in the reasoning of the European Court of Justice concerning standards of medical care across the EU.

The first point to make is that not all healthcare professions have been subject to sectoral directives that ensure minimum levels of education and training. Important medical services have been left to the general system. These include specialised nursing, physiotherapy and other paramedical services such as dental assistants.

The Member States are therefore free to set very low standards of training for health-

care providers who are not covered by the sectoral directives. Thus Member State A may decide that people can pursue the profession of physiotherapist after six months of night classes as there is nothing in the general mutual recognition provisions to prevent this. It simply means that physiotherapists registered in Member State A will not have their qualifications recognised in other Member States.

Even where minimum standards have been laid down by sectoral directives on mutual recognition there are still convincing arguments to indicate disparities in the quality of healthcare services from one Member State to another.

First, the substantive requirements for training are rather subjective and lacking in clearly defined substance, for example, “*an adequate knowledge*” or “*sufficient understanding*”.

Second, the Member States are free to develop higher standards if they so wish. If patients are used to higher standards it is arguable that by independently obtaining medical care in another state (as they would under the procedure envisaged in Kohll and Decker) they are endangering their health by making an uninformed decision.

Third, the activities of those covered by the sectoral directives (e.g. specialised doctors and dentists) are dependent to some extent on other professionals who are not covered by the sectoral directives, for example dental assistants, specialised nurses etc. Receiving healthcare treatment is a complex process, typically relying upon more than one actor (especially if it involves after care) and the present state of EC law does not guarantee that the qualifications of the support staff in one state are the same as those in another state.

Fourth, the sectoral directives only apply to degrees obtained within the European Union and held by nationals of its Member States. However, the Member States are allowed to freely recognise medical diplomas from non Member States as long as the holders of these qualifications do not provide services elsewhere in the EU.⁹

This means that a country is free to engage a doctor who obtained his degree outside the EC and so was not subject to the minimum training requirements imposed upon EC doctors. This article is by no means arguing that third country degrees are in any way inferior to those obtained within the EC. It is merely pointing out that the rules on the mutual recognition of diplo-

mas cannot be used to say that there is a single unified standard of healthcare provision throughout the EU.

Fifth, the sectoral directives generally make no mention of the field of competence of each profession, the only exceptions being those relating to midwifery and dentistry. Thus, the range of treatments professionals are allowed to provide remains an issue for national law. For example general nurses in some states may be allowed to administer epidural injections, whereas in others this is not the case. Similarly the competence to perform certain tasks maybe exclusively reserved to one profession in certain Member States but not in others.

Finally, and most importantly, it should be remembered that the minimum standards provided for in the sectoral directives only apply to periods of training and not the continuing standards of healthcare ensured by periodic registration or continuous training obligations. The extent and supervision of medical standards is left to the competence of the Member States and therefore varies from one country to another.

Conclusion

It is clear from the above that the European Court of Justice cannot rely upon the legislation on the mutual recognition of diplomas to state that a similar standard of healthcare is available right across the EU. The mutual recognition rules were the wrong legal basis upon which to reject the Luxembourg government’s suggestion that total freedom of movement might pose a threat to human health.

By bypassing the consent procedure provided in Regulation 1408/71 the Kohll and Decker decisions have enabled patients to make uninformed decisions about medical treatment in other Member States. Patients are unable to ascertain the quality of the medical care they receive and should therefore be warned about any possible variations in standards before they agree to undergo treatment abroad. By making an uninformed decision to receive lower quality care, patients could be putting their health at risk without knowing it. The European Court of Justice should bear this in mind when deciding future Kohll and Decker type cases, especially in view of its recent duty to ensure a high level of human health protection which was imposed after the decisions in Kohll and Decker by the new article 152 EC Treaty.

“The sectoral directives generally make no mention of the field of competence of each profession.”

REFERENCES

1. Raymond Kohll v Union des Caisses de Maladie Case C-158/96, paragraphs 43/8
2. All the Directives concerned with doctors, general practitioners and specialised doctors have been consolidated in Directive 93/16/EEC OJ 1993 L165 p.1
3. Directive 77/452/EEC OJ 1977 L176 p.1 (since amended) and Directive 77/453/EEC OJ 1977 L176 p.8 (since amended).
4. Directive 78/686/EEC OJ 1978 L233 p.1 (since amended) and Directive 78/687/EEC OJ 1978 L233 p.10 (since amended).
5. Directive 80/154/EEC OJ 1980 L033 p.1 (since amended) and Directive 80/155/EEC OJ L033 p.8 (since amended).
6. Directive 85/432/EEC OJ 1985 L253 p.34 and Directive 85/433/EEC OJ 1985 L253 p.37 (since amended).
7. OJ 1989 L19 p.16
8. OJ 1992 L209 p.25
9. See for example Article 23(5) Directive 93/16 intended to facilitate the free movement of doctors.

The impact of Europe on healthcare: The Dutch case

The question of the possible impact of European regulations on the principles of national healthcare systems became urgent after the European Court of Justice ruling in the Kohll and Decker cases. In the Netherlands the debate was fuelled by a report to the Minister of Health by the Council for Public Health and Health Care.¹ In this report the Council investigated the possible impact of these developments, the opportunities and threats they presented and the strategies for coping with that impact. This article addresses that report and includes some analysis of developments since, in particular the Smits/Peerbooms case.



Tom van der Grinten



Marina de Lint

Possible impact of Europe on national healthcare systems

One of the main goals of the European Union is the creation of an internal market, an area without internal frontiers, where the free movement of goods, services, people and capital is guaranteed. In order to achieve this goal the European Treaty offers the European Union separate powers with respect to the internal market, in addition to the powers developed in the fields of employment, research and public health.

The European Union does not have separate powers regarding the organisation, financing and functioning of the national healthcare systems. Healthcare, as part of the social security system, is taken as the exclusive policy domain of the national authorities.² This is the formal, legal position. The reality, however, is different. All these four fields have an impact on healthcare, especially the European activities regarding the internal market, not in a formal sense – as a result of deliberate policy – but as a side effect. In a sense ‘Europe’ stands for the ongoing economic regulation of social life and the processes of individualisation, free choice and consumerism, which do not come to a stop outside the healthcare gate. The mechanisms of the internal market penetrate the national healthcare systems in an ‘enveloping move-

ment’, in so far as of course as these systems are open, or vulnerable, to such influence. It is likely that Dutch healthcare is one such vulnerable system.

Internal market

Before we go into the mechanisms of the internal market we need to clarify why the competencies of the European Union in safeguarding the two domains within this field – free movement and proper competitive relations – may extend to the field of healthcare. This depends on the extent to which healthcare providers and insurers can be seen as part of the economy, that is ‘as entities that perform an economic activity on own authority’.³ Or to put in another way: it depends on whether or not the activities of providers and insurers are ‘services’ according to the definition of the Treaty. This question now turns out to be one of the major issues in the debate about the possible impact of Europe on healthcare; we shall address this point later.

Free movement

The Treaty offers the European Union far-reaching powers to stimulate the free movement of goods, services, people and capital between the Member States and to eliminate all possible barriers in this respect. The actual crossing of borders by healthcare services, healthcare professionals and patients is, however, strikingly limited. For example, fewer than one per cent of Dutch patients go abroad for healthcare. There appears to be a regional orientation of patients either within the country or in the border areas (Netherlands – Germany; Netherlands – Belgium). However, the pressure is heavy and growing in view of the waiting lists that are occurring in ever more areas of the healthcare sector. At the moment these waiting lists are a big – if not the biggest – problem in Dutch healthcare. For the time being, however, the international movements of patients are mainly characterised by obstacles, including legal ones.

European Court judgements concerning the free movement of patients

These legal obstacles were first challenged by the European Court judgement in the

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Decker/Kohl cases. These revolved around the buying of medical services in another Member State while the reimbursement took place by the insurer of the home country in a system based on restitution. In both cases reimbursement was refused because the patient did not have the insurer's prior consent, but the Court decided that the requirement of prior consent was an unnecessary obstacle towards the free movement of patients.⁴

This judgement was unexpected and, what is more important, it inserted a crowbar into the apparently well protected national healthcare systems. The judgement made it clear that the healthcare systems are more open to the general forces of the free movement of patients than the formal exclusion by means of the subsidiarity principle suggested. However, it is not yet clear to what extent these cases are relevant to other healthcare systems, such as the Dutch service-in-kind insurance, and for other healthcare services, such as hospital care. At the moment there is a Court ruling under way in two joined cases which challenge these questions: the Smits/Peerbooms cases.

Smits/Peerbooms cases: the Advocate General's report to the Court

In short, the Smits/Peerbooms cases⁵ deal with the question of the reimbursement of costs of treatment in a hospital outside the Netherlands that was not contracted by the Dutch health insurance funds. The insured party asked for reimbursement of the costs without the prior consent of the insurer to obtain such treatment. Reimbursement was therefore refused, on the grounds that sufficient and adequate treatment was available in the Netherlands.

In contrast to an insurance system based on restitution the Dutch system of *services-in-kind* is characterised by the following:

- (a) the insured pay premiums to the insurance bodies;
- (b) insurers – that is to say: health insurance funds – negotiate with and purchase healthcare services for their insured from healthcare providers that are formally permitted to offer healthcare services;
- (c) the insured address themselves to these contracted providers and get their help 'free', without payment;
- (d) the healthcare providers are directly paid by the health insurance funds.

An essential element in this system is the mechanism whereby patients are only allowed to use contracted doctors and service organisations, unless they have the prior consent of the health insurance fund to resort to non-contracted care providers within or outside the country.

The Advocate General uses two different lines of argument to come to the conclusion that the obstruction of the free movement of patients in these cases is justified:

1. In a system of *services-in-kind* provided by compulsory health insurance, the services can not be defined as services under the Treaty.
2. The financial equilibrium of such a system can be seriously harmed if patients turn to non-contracted healthcare providers without the prior consent of the insurer.

The Advocate General's arguments in support of his opinion are summarised below, together with our comments.

“The European Union does not have separate powers regarding the organisation, financing and functioning of the national healthcare systems.”

Re 1. Healthcare services cannot be defined as services in terms of the Treaty

The insured does not pay for the treatment.

This argument does not seem relevant as the Court has already decided that payment does not have to be made by the party consuming the service.⁶ Moreover, the insured does pay, although indirectly, in the form of premiums.

Prices are not realistic.

This argument is also not relevant as a service is seen as an activity that usually (if not always) is performed in return for payment.⁷ In other words realistic prices are not required under the definition of a service.

Health insurance funds perform government tasks and are therefore comparable to national education institutions.

The Court determined in an earlier case⁸ that such institutions do not perform services in terms of the Treaty. However, in this case a major (decisive?) factor was the fact that national education institutions are funded by the state, whereas health insurance funds receive little if any such support since they are funded by premiums, either income-related or flat-rate.

In the Poucet and Pistre judgements⁹ the Court declared that health insurance funds cannot be seen as enterprises.

The question is whether this also, or still, applies to the Dutch health insurance funds. The Dutch Competition Authority (NMA) has for example decided that health insurance funds are enterprises, primarily as a result of the introduction of market elements under the Compulsory Health Insurance Act.¹⁰ Furthermore, even if health insurance funds are not defined as enterprises, this does not mean to say that medical care is not a service: health insurance funds do not (yet) provide medical care themselves.

In short, serious arguments can be advanced against the first claim of the Advocate General. It appears that the Advocate General may have foreseen this, as he offers a second line of defence:

Re 2. Harm to financial equilibrium if patients turn to non-contracted providers without prior consent

Resort to non-contracted care providers means an extra financial charge for the health insurance funds as they have reached agreement in advance with contracted care providers for all the medical care that their insurance policy holders will need in any one year. The consent requirement is therefore the only means health insurance funds have to control this extra financial charge and to maintain financial equilibrium.

This is a strong argument, especially in the current situation in Dutch healthcare where we are faced with scarcity and waiting lists as the main mechanisms for rationing healthcare. Nevertheless, resort to non-contracted care providers does not necessarily generate an extra financial charge for the health insurance funds. In situations where the use of non-contracted care can be seen as a substitute for contracted care, health insurance funds have the opportunity to steer by the use of budgets. Insured patients who obtain medical care from non-contracted care providers do not obtain that care from contracted care providers. If contracted care providers fail to attain the agreed production, their budgets are cut in the next year. Health insurance funds are therefore able to compensate for the 'extra financial charge' created by the resort to non-contracted care providers.

It is clear that in the current situation of scarcity of resources and the existence of waiting lists for a growing number of services, this principle of substitution and the resulting budget cuts is purely hypothetical. Nevertheless, the point here would appear to be whether the scarcity of resources and the resulting waiting lists should be defined in terms of a non-disputable financial equilibrium of the system that justifies obstruction of the free movement of patients.

At the moment governments – not only the Dutch – appear to be lobbying the Court heavily, mostly in line with the opinion of the Advocate General. On the other hand European Commission officials have indicated that it does not share the Advocate General's view, as patients must always be able to choose freely from whom they obtain medical care. The consent requirement impedes patients' freedom of choice. The European Court now has the final say.

Regulation of competition

There are European rules for both enterprises as well as Member States. Enterprises are subject to a cartel ban: all agreements or forms of conduct between enterprises that may hinder competition are prohibited. Furthermore enterprises may not abuse commercial power. Member States may not give (disguised) state aid or circumvent cartel regulations.

An impact assessment of European competition rules and policies on the Dutch healthcare system shows that there is a serious possibility that several features of the Dutch healthcare system contain unnecessary obstacles for the entry and proper functioning of for-profit foreign insurers and service organisations. These features are the public - private mix of the Dutch insurance system, supply side regulations, cost containment policies and centralised bargaining and contracting machinery. As court rulings with regard to these features are not yet at hand this assessment is based on an expert interpretation of the European competition regulations.¹¹

This assumed vulnerability is mainly due to the typical public-private mix in the structure and culture of Dutch healthcare. Both these characteristics appear critical in relation to Europe:

- The intermingling of roles and responsibilities in the system between the key stakeholders: government, private not-for-profit service organisations and insurers (health insurance funds) and market players (such as private for-profit insurers, nursing homes, etc.)
- The behaviour and steering mechanisms which are used in this system, namely competition and regulation, whereas the internal market (and the continued effect in for example the Dutch Competition Act) primarily presupposes a dichotomy.

The Dutch Competition Act is equally relevant for the relations and behaviour in Dutch healthcare as the European rules and legislation are for competition. Here we come across a remarkable link between the internal market and national legislation. Because the Dutch were rather late (compared to other Member States) in reassessing the Competition Act, the government was able to use the most advanced ideas and experiences. That is to say, the European way of stimulating competition. In the parliamentary debate there was a lobby to keep healthcare explicitly outside the jurisdiction of the Act. This was however rejected, resulting in a rather explicit choice for using the rules and legislation for competition for governing healthcare as well, at least after a transitional period of five years. So it is on the waves of the Dutch Competition Act that Europe penetrates Dutch society and the Dutch system of healthcare, with two striking differences:

- The Dutch Competition Authority has now defined provider organisations and insurance companies, including health insurance funds, as enterprises that have to obey the competition rules. The European Court has not yet decided whether (Dutch) health insurance funds are enterprises or not.
- The Dutch Competition Authority assesses the compliance of the activities of these enterprises with the Competition Act and the national healthcare legislation concerning the financing of care, the planning of services and professionals and price regulation. The European Court assesses compliance with the European Treaty; it can overrule national legislation.

The consequences of these differences are remarkable. For example, a merger of hospitals, leading to a (regional) monopoly, was accepted by the Dutch Competition Authority because the Authority considered that the healthcare planning laws impede hospitals from competing. The same line of argument ended for the general practitioners in a rejection of mutual price-agreements and the closed shops of the establishment of new practices, leading to entry barriers. The argument in favour of a difference in policy between hospitals and GPs is that the latter are formally put in a position to compete for a contract with the insurer; competition therefore already exists in practice in the domain of the GPs, whilst in the hospital world that is not (yet) the case.

Coping strategies

In view of the possible impact of Europe on Dutch healthcare and the associated opportunities and threats, the government is increasingly obliged to act.

At national level action has already been taken to liberalise supply side regulation, especially regarding capacity, and to decentralise the bargaining and contracting system. And there are serious preparations for a fundamental political choice with respect to the insurance system. In theory the choice is between (a) a retention of the mixed system, although this would mean that the system remained vulnerable to Europe; and (b) introducing a public-private distinction in the system, so that as a consequence the exceptional position of the Netherlands would disappear.

Advisory reports submitted by the Dutch Council for Public Health and the Social

and Economic Council^{12,13} define the second option as the preferred one, although there is now a debate on the direction of this choice: should, and could, it be the publicly based or the privately based system? This discussion, and its possible outcome, is primarily evoked by the uncertainty about the actual impact of Europe on national healthcare systems. For a more proper policymaking process it is therefore essential that national governments also take action at European level. The most important action in this respect would appear to be the development of a European perspective for healthcare policy and organisation – not as a single policy statement, as that would be too global, but differentiated according to the relative urgency of individual topics. The fact that this policy development does not seem to be the most popular at the moment is not an argument for turning away from it.

“There are serious preparations for a fundamental political choice with respect to the insurance system.”

REFERENCES

1. Dutch Council for Public Health and Health Care (RVZ). *Europe and Health Care*. Zoetermeer, December 1999.
2. On the basis of cases 238–82, Duphar, 7 February 1984 and C-70/95, Sodemare, 17 June 1997.
3. Case C-41/90, Höffner v Macrotron, 1991
4. Case C-120/95, Decker, 1998 and C-158/96, Kohll, 1998.
5. Joined cases C-157/99.
6. Case 352/85, Bond van Adverteerders, 26 April 1988.
7. article 60 of the Treaty.
8. Case 263/86, Humbel, 27 September 1988.
9. Joined cases C-159-160/91, 1993.
10. Decision d-g 16 December 1998, No. 1165, ANOZ.
11. Pieters, D. *De Nederlandse Zorgverzekering in het Licht van het Recht van de EG (The Dutch Health Insurance System in European Perspective)*. Zoetermeer, December 1999.
12. Dutch Council for Public Health and Health Care (RVZ). *De Rollen Verdeeld. Burger, Ondernemer en Overheid in de Gezondheidszorg (Division of Roles. Citizen, Entrepreneur and Government in Healthcare)*. Zoetermeer, December 2000.
13. Social Economic Council (SER). *Naar een Gezond Stelsel van Ziekteostenverzekeringen (Towards a Healthy System of Healthcare Insurance)*. The Hague, December 2000.

Delivery of non-national prescriptions within the EU:

How flexible is the common market for pharmaceuticals?



Mia Mäkinen



Jari Forsström



Päivi Rautava

The purpose of this study was to test the functioning of the European single market in the pharmaceutical field by testing the acceptance of non-national European prescriptions in the pharmacies of the Member States. As a result almost all the prescriptions were delivered. Some differences were seen between the countries.

The establishment of a single market for pharmaceuticals has not occurred at the same speed as in other areas of trade in consumable goods. This is due to its special nature. According to the European Commission¹ the pharmaceutical industry must supply citizens and the healthcare sector with high quality, effective and safe products at a reasonable price, whilst at the same time yielding profit for the innovative European industry.

The Pharmaceuticals Unit of DG Enterprise is responsible for harmonisation of the pharmaceuticals market. Harmonisation is carried out through cooperation between regulators and the pharmaceutical industry, but also with third countries.² Product authorisation procedures have been harmonised in Europe so that both the centralised and mutual recognition procedures should accept equally safe and qualified products to the European markets.³ User directions, classification and the sale of pharmaceuticals have become more unified.^{2,4}

As there is no specific EU legislation regulating and facilitating delivery of pharmaceuticals to patients, pharmacies act according to their respective national legislation. Patients would benefit greatly from a single,

EU-wide system of prescription delivery.

The study

This study was carried out to examine briefly the European pharmaceuticals market from the consumers' viewpoint. Within the EU, the supply of pharmaceuticals in fulfillment of prescriptions written in another Member State is a minor part of the overall pharmaceuticals market. European integration has brought European countries closer together. Europeans are more transient today, and would benefit from the uninterrupted, continuing care wherever they go.

Within the Nordic countries, the delivery of a prescription from another Nordic country is permitted in law.⁴ It excludes drugs affecting the central nervous system and narcotics.

Competition Commissioner Mario Monti's has outlined a similar idea for Europe: "The Commission therefore takes the view that individual refusals by chemists to honour prescriptions are not contrary to Community law, but that a general rule prohibiting chemists from honouring prescriptions is contrary to that law. The fact that the doctor issuing a medical prescription is established in another Member State cannot be an automatic criterion for refusing to honour it."⁵ During the Spanish Presidency, the Council commented on the delivery of non-national European prescriptions based on Council Directive 93/16/EEC on the mutual recognition of professions of physicians.⁶ Thus the equality of medical doctors' documents including prescriptions is a logical consequence and would ensure the continuity of care.

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Methods

Phenoximethylpenicillin was chosen as the drug to be tested. Its ostensible use was for the cure of tonsillitis. Phenoximethylpenicillin is a basic pharmaceutical and widely acknowledged. For a healthy person, without a penicillin allergy, it is relatively harmless.

The prescriptions were issued by two of the researchers with the right to exercise their medical specialities in Finland and in Luxembourg. The prescriptions were formulated in Finnish and Luxembourgian forms respectively. The drug was described by both its national trade name and its generic name, to avoid misunderstandings. A typewriter was used. Official stamps and numeral codes for the identification of the doctors were used according to the respective national rules.

The hypothetical patients were the three researchers and a few other healthy individuals. The presentation of the prescriptions was solely for the purpose of the study. The pharmaceuticals obtained were not used and therefore no ethical problem could have arisen. The cities and the targeted pharmacies were chosen randomly. We did not use pharmacies belonging to the same store chain more than once. The study was carried out during 1999, in larger cities of the European Union.

Results

The prescriptions, both Finnish and Luxembourgian, were accepted in most of the pharmacies tested, without any difficulties associated with their foreign origin. A common problem seemed to be a lack of stock of the pharmaceutical being sought.

Pharmacies in the UK and Sweden did not accept the foreign prescriptions, although the Finnish prescription was accepted in Sweden under the Nordic arrangement. The British pharmacies refused to fulfil the Finnish prescriptions, in accordance with their national law. One London pharmacy investigated whether the doctor who prescribed the Finnish prescription was recognised in Britain, in which case they could have supplied the pharmaceutical. In Belfast there were difficulties with both prescriptions: the pharmacists even called different authorities to check the legality of fulfilling a foreign prescription, and each gave a different answer. The pharmaceuticals were not supplied.

In Portugal, the Finnish prescription for penicillin was fulfilled. One pharmacy would have fulfilled the Luxembourgian

prescription for amoxicillin; another did not accept it (see table). The Finnish prescription was naturally accepted in Denmark, as were the Luxembourgian prescriptions. In Belgium, the tested prescriptions were Finnish, and accepted. The pharmacies did not have phenoximethylpenicillin because of problems with resistance issues. One pharmacy offered to order the medicine within a day, another would have supplied amoxicillin instead. The Finnish pharmacy accepted the Luxembourgian prescription as the physician was one recognised in Finland.

“Patients would benefit greatly from a single, EU-wide system of prescription delivery.”

OUTCOME OF THE STUDY: MOST OF THE PRESCRIPTIONS WERE FULFILLED

Country City	prescription tested	Prescription presented	Prescription fulfilled
Austria Graz	penicillin	1 Lux	yes
Belgium Brussels	amoxicillin	3 Fin	yes
Denmark Copenhagen	penicillin penicillin	1 Fin 1 Lux	yes yes
Finland Helsinki	penicillin	1 Lux	yes
France Nice	penicillin	1 Lux	yes
Germany Frankfurt	penicillin	2 Fin	yes
Greece Athens	penicillin penicillin	1 Fin 1 Lux	yes yes
Italy Rome	cephalexin	1 Fin 1 Lux	yes yes
Luxembourg Luxembourg	penicillin	1 Fin	yes
Netherlands Utrecht	penicillin	1 Lux	yes
Portugal Villa Real de San Antonio Costa Marin	penicillin amoxicillin	1 Fin 2 Lux	yes yes no
Spain Barcelona	penicillin penicillin	1 Fin 1 Lux	yes yes
Sweden Stockholm	n/a	2 Lux	no
United Kingdom London Belfast	n/a n/a n/a n/a	2 Fin 1 Lux 1 Lux 1 Fin	no no no no

Finnish prescriptions were tested and fulfilled in Germany and Luxembourg, while Luxembourgian prescriptions were tested and fulfilled Austria, France and the Netherlands. In Greece and Spain both types of prescription were tested and fulfilled. In Italy the pharmacies accepted both prescriptions, but didn't have penicillin. The first pharmacy offered to order it and the second would have supplied cephalor instead.

"There is no European legislation on this issue ... pharmacies follow national regulations."

Discussion

There were limitations to the validity of this study: the small sample; the fact that clearly written prescriptions are not the norm; the choice of a rather harmless drug and the use of pharmacies in larger cities, where tourists are common. Thus, it could be considered as a direction-giving survey. The trend was that prescriptions issued in another Member State were delivered; only a few countries made exceptions. Pharmacies refusing to accept foreign prescriptions referred to their national legislation. In the absence of exact EU legislation, these pharmacies acted correctly. Indeed some of the pharmacies that fulfilled prescriptions acted against their national law.

The Nordic custom in the fulfilment of prescriptions could be a model for practice in the whole Union. This model does not require recognition of doctors in databases as narcotics and other pharmaceuticals affecting the central nervous system are excluded. Information technology solutions could help to recognise the trade names, as differences exist.

Varying pharmaceutical selections, including different dosages and product forms, are perhaps the most difficult problem for the fulfilment of foreign prescriptions. The pharmaceutical harmonisation processes, especially central recognition, though viable for only some kinds of pharmaceuticals, may unify the pharmaceutical selections to a certain extent. However, because of differences in treatment protocols and in our case differences in microbial resistance, not all pharmaceuticals will be obtainable in every country. It could be harmful if the pharmacist were to change the prescribed medicine to another, therapeutically gener-

ic product. Who would then be responsible for the possible problems arising from the medication? It would not be practical for the pharmacist to contact the prescribing doctor in another country, or even another doctor in their own country, to ask advice on changing the pharmaceutical. Nor is neglecting to deliver the requested pharmaceutical in the interest of the patient.

Problems arising in the presentation of a prescription written in a foreign language are not easy to resolve. Firstly, at the site where care is given, there should be an understanding between the doctor and the patient about the usage of the medicine, including dosages, application, side effects and interactions of the medicine. The pharmacist can then reassure the patient about the pharmaceutical. Information is also included in a leaflet inside the medicine pack, but it is given in the national language. Information technology solutions and educated, language skilled personnel could offer a solution.

In short, European-wide harmonisation of the fulfilment of foreign prescriptions would clarify the situation. However, this does not actually fall within the competence of the Union. One possibility for unified practice may be a preliminary ruling of the European Court of Justice on the interpretation of European law. If that happens, problems arising could be discussed and solved. There would, in particular, be complications arising from the varied reimbursement systems operating across the EU.

REFERENCES

1. See, for example, the Commission Communication on the Single Market on Pharmaceuticals, COM 98 (588)final. Website <http://pharmacos.eudra.org/smarket/pdf/Com1198.pdf>
2. European Commission. EudraNet service to the European pharmaceutical regulatory sector. <http://eudraportal.eudra.org/>
3. The European Agency for the Evaluation of Medicinal Products (EMA). www.eudra.org/
4. For Finland see National Agency for Medicines, website www.nam.fi/
5. Written Question E-2306/96 by Mr Robles Piquer. *Official Journal of the European Communities* C 72, 7.3.97, p.27-28.
6. Council Resolution, Document 395Y1230(04).

Health technology assessment in Europe

An introduction

David McDaid

“The rise in the costs of medical care has increased the interest from policy makers in methods for identifying cost effective interventions.”

Health technology assessment (HTA) has been defined as “the structured analysis of a health care technology, a set of related technologies, or a technology related issue that is performed for the purpose of providing input to a policy decision”.¹ The analysis may take many forms, and may consider clinical effectiveness only, or also other dimensions such as the socioeconomic impact. Technology itself is a broad term encompassing all types of intervention including pharmaceuticals, medical devices, diagnostic procedures and delivery mechanisms. What distinguishes HTA from other health service evaluation is the key emphasis on facilitating the use of such information in the decision making process.

HTA can trace its origins back to the early 1970s, with the US Office of Technology Assessment being the first agency to explicitly explore the policy consequences of different health care interventions. In the subsequent 25 years the HTA movement has expanded tremendously, in part benefiting from the raised profile of evidence based medicine notably through the creation of the Cochrane Collaboration. The rise in the costs of medical care has also increased the interest from policy makers in methods for identifying not only clinically effective, but also cost-effective interventions. There are now more than 20 European members of the International Network for Health Technology Assessment, who publish in excess of 150 reports annually, and the interest in HTA in eastern Europe and Russia is also increasing.

Access to HTA resources across Europe remains uneven, and linking the production of HTA reports to subsequent changes in policy are difficult to identify (for both practical and methodological reasons). Articles in this issue cite examples where HTA reports have, however, been instrumental in decision making, such as the work of the Swedish Council on Health Technology Assessment (SBU) on pre-operative testing in elective surgery. In England and Wales the new National Institute for Clinical Excellence (NICE) provides guidance to national and local decision makers on the appropriateness of new and existing technologies, based on an appraisal of clinical effectiveness, economic, equity and ethical considerations. The use of such guidelines in practice will be monitored by another new standards body, the Commission for Health Improvement (CHI). Andrew Dillon of NICE and Julia Chamova of SBU both present articles in this section about their respective institutions' work.

With sound structures for HTA production in place, the challenge now is to make the best use of existing resources in Europe, whilst continuing to foster the development of HTA in those regions where its use has been less prominent. Voluntary European collaborative ventures are already well established and an important issue for policy makers and researchers now is how to build upon these initiatives and further the development of cooperation and coordination of activities. Given political sensitivities between Member States which may make a single European HTA Agency a difficult proposition, and mindful of differences in methods used in HTA production across Europe, one plausible future direction to examine may be to develop a clearing house for HTA reports, which would report objectively on methods, findings and the ‘universality’ of results. The European Collaboration for the Assessment of Health Interventions involving individuals from all EU countries is currently evaluating potential model systems and methods to promote cooperation and will report its initial findings in Stockholm in May. These should make interesting reading.

REFERENCES

1. US Congress, Office of Technology Assessment. *Identifying Health Technologies That Work. Searching for the Evidence.* OTA-H-608 (Washington DC US Government Printing Office, September 1994.)

European health technology assessment

Quo vadis?

Across Europe, decision makers are faced with difficult choices about how to allocate increasingly scarce resources both within healthcare budgets and between health and other competing policy claims, such as education and housing. Pressures to contain the rising costs of healthcare in particular have grown, as populations age and as medical advances continue to inflate both costs and expectations.



David McDaid

“A cadre of knowledge brokers could act as a conduit between the worlds of research and policy making.”

One common response to these problems has been the growth of the ‘evidence based medicine’ (EBM), as a way of identifying effective forms of care. Another has been the rise of ‘health technology assessment’ (HTA) as a way of informing the decision making process, particularly when the adoption of new technologies is being considered. It should be noted, however, that HTA can but does not necessarily have to include some form of economic appraisal.

European EBM and HTA activities have come a long way during the last decade, with substantial, albeit uneven, growth in awareness and production of such knowledge. Initiatives are being taken to make use of evaluative information not only on the efficacy and safety of an intervention but also considering broader dimensions such as socioeconomic impact. Nevertheless there is still much to do and many barriers have yet to be overcome to increase the use of economic and clinical evaluation.

Overview of HTA in Europe

Recent surveys of healthcare evaluation in Europe such as these reported by the ASTEC group (Analysis of Scientific and Technical Evaluation in the European Union)¹ and HTA Europe² highlight the current degree of variation in the development and use of evidence based research within and between EU Member States. Whilst there is much knowledge production in a number of Member States, most notably the UK, Sweden and the Netherlands, in others HTA has yet to achieve a critical mass. Furthermore, there

is a need to improve mechanisms linking the production of HTA knowledge to the decision making process throughout Europe and also to collate evidence from existing research. These latter objectives may particularly benefit from a pan-national coordinated approach between national and regional players.

The existing variation in the production and use of HTA should be viewed in its historical and cultural context. Traditional bio-medical and clinical research has dominated research in some systems such as Italy and Germany, with much less status being conferred to health services research and economic evaluation. Decentralisation has led to the development of several HTA agencies in Spain, whilst hampering the development of a national HTA agency in Italy. In some countries, historically there has been a reliance on evidence obtained through consensus and expert opinion, e.g. Austria and Germany. Economic evaluation has been most closely associated with countries where health economics training has the longest tradition, France, the Netherlands, the Nordic countries, and the United Kingdom.

Despite these variations in the use of HTA, overall the picture is encouraging. HTA groups have been established in most EU countries, as well as elsewhere in Europe and seven Cochrane Centres are also in operation. Awareness of the potential contribution of economic evaluation has increased. So called fourth hurdle systems explicitly linking economic evaluation to the health policy decision making process have gained a foothold in several countries. By introducing such mechanisms a technology is considered not only in terms of its safety, efficacy and effectiveness but also by its relative cost effectiveness. Since 1997, England and Wales, Scotland, Finland, the Netherlands and Portugal have all introduced such mechanisms, although in most instances these so far provide guidance rather than mandatory rulings on the availability of technologies.

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The road ahead: facilitating the use of HTA evidence in decision making

Although HTA in Europe has come a long way in recent years, there remain numerous challenges to overcome in order to facilitate greater use of HTA in the decision making process. Which direction do we take now? Although dismantling these barriers is complex, fundamentally there are two key issues. Firstly there are shortages in the available research capacity in several disciplines and/or regions of Europe. Careers for academic health service researchers need to become more stable and attractive compared with private sector alternatives and more locally available training courses in several disciplines such as systematic review and health economics are required. More efficient use must also be made of the existing research capacity by building on the voluntary collaboration that has been fostered by networks built through previous European research projects.

Notably, the European Commission sponsored European Collaboration for Assessment of Health Interventions and Technology (ECHTA/ECAHI) is aiming to develop such collaborative links and furnish a common European evidence base. The Cochrane Collaboration and the International Network of Health Technology Assessment Agencies can also make important contributions.

Secondly more emphasis needs to be placed on facilitating the use of existing HTA information in the decision making process. Linkages between the production of HTA and the policy making process are weak. Dissemination activity is still largely limited to passive dissemination through academic journals, reports and conferences, with the majority of HTA resources focusing on production rather than dissemination and implementation.

Of course there are many examples of initiatives to tackle these issues. In Sweden SBU, the Swedish Council on Health Technology Assessment, has a network of roving ambassadors, local informants who disseminate results throughout the country, while in England a new NHS special authority Service Delivery and Organisation (SDO), building on experience of other agencies, notably the Canadian Health Services Research Foundation and the US Agency for Health Research and Quality, funds research into mechanisms to improve the use and delivery of effective interventions. A broad ranging initiative, SDO will consider the

context into which interventions are to be provided, and aims to learn from a wide range of disciplines including organisational science, ergonomics, historical and political analysis, economics and behavioural science.

Receptor capacity also requires development, that is, research on mechanisms and training programmes that can improve understanding and use of HTA information by decision makers. One possible solution to this deficit might be through the creation of a cadre of *knowledge brokers*, trained in a mixture of research and policy skills, who could act as a conduit between the worlds of research and policy making. Furthermore linkages and exchanges between policy makers and researchers can be fostered before HTA research is funded to ensure its policy relevance and increase all participants' sense of ownership over the HTA process.³

Crucially, the success of HTA will ultimately be dependent on the impact it is perceived to have in improving access to effective healthcare and controlling healthcare costs. As yet the emphasis has been firmly on increasing the production of HTA outputs, but it is only a matter of time before research funders demand evidence of a return on their investment. Without positive indications, the climate for continued HTA work may deteriorate. No systematic attempt has yet been made to ascertain the impact of HTA in Europe, although the early signs would suggest that overall HTA reports have had little impact and there are difficulties in measuring any impact. Generating a greater awareness of HTA has been the most significant impact thus far, but more disappointingly economic evaluation does not appear to have had a major policy impact.⁴

Conclusion

Structures are now in place for the production of high quality HTA in Europe, with the caveat that research capacity requires some targeted investment. The key objective is to facilitate the use of HTA evidence in policy and decision making. The first steps on the road ahead should involve investment in research into HTA impact assessment, improving communication between researchers and policy makers within regions and countries, and promoting voluntary cooperation and communication across Europe, perhaps through a HTA clearing house.

"Linkages between the production of HTA and the policy making process are weak."

REFERENCES

1. Cookson R, Maynard A, McDaid D, Sassi F, Sheldon T. *Analysis of the Scientific and Technical Evaluation of Health Care Interventions in the EU*. Report prepared for the European Commission, 2000. See www.lse_health@lse.ac.uk
2. Banta D, Oortwijn W (eds). Special section. Health Technology Assessment in the European Union. *International Journal of Technology Assessment in Health Care* 2000;16(2):299-638.
3. Lomas J. Using 'linkage and exchange' to move research into policy at a Canadian foundation. *Health Affairs* 2000;19(3):236-40.
4. Hoffman C, Graf von der Schulenberg M. The influence of economic evaluation on decision making. A European survey. The EUROMET group. *Health Policy* 2000;52(3):179-92.

Health technology assessment

The Swedish experience



Lars Werkö

Sweden was one of the first countries to begin assessing health technology. One of the first health technology assessments was a study of computed tomography (CT) scanning carried out in the early 1970s.¹ Even before this study, the National Swedish Board of Health and Welfare had asked selected physicians prominent in their specialties to evaluate healthcare technologies to determine whether they were consistent with proven scientific knowledge and good clinical experience. This informal approach based on expert judgement has been superseded over the past 15 years by rigorous health technology assessment (HTA).



Julia Chamova

The Swedish Council on Technology Assessment in Health Care (SBU)

Numerous HTA initiatives have taken place in Sweden² and several well-established institutions are engaged in HTA activities, including the Swedish Council on Technology Assessment in Health Care (SBU) at the national level.

Establishment of a national HTA agency

SBU was created in 1987 as a project unit within Spru, the Swedish Rationalisation and Planning Institute. Its main purpose is to supply decision makers and healthcare providers with continuous, up-to-date scientific evidence on the overall benefits, risks and costs of both established and new healthcare technologies. Effective use of available resources for healthcare is the overall aim.

The first SBU technology assessment addressed preoperative testing in elective surgery.³ The study team reviewed the literature and found little justification for routine use of preoperative x-rays, electrocardiograms and laboratory tests. A survey

of practice revealed considerable variations: some hospital departments always performed such tests, while others never did. An economic analysis showed that the cost of preoperative investigations in Sweden totalled SKr 726 million (US \$91 million), in 1989. SBU recommended that preoperative routines should not be used in the absence of specific indications. Follow-up surveys in 1990 and 1991 to evaluate the impact of the report showed a significant decrease in routine preoperative testing. The savings in economic terms, apart from the increase in quality of care, were calculated at SKr 50 million (US \$6.25 million) per year, or five times the annual budget of SBU at the time.²

A special independent evaluation of SBU's activities, required by the central government after the initial years of operation, concluded that SBU's approach had been successful and suggested that it would be beneficial to formally establish SBU as a public authority, reporting to the Ministry of Health. The government accepted this recommendation, and since 1992 the Council has served as an independent agency being a focal point and coordinating body for HTA activities in Sweden.

What fields are evaluated?

Initially, SBU conducted a survey addressing the need for assessment of health interventions in Swedish healthcare. The respondents identified several hundred methods that were thought to need



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scientific evaluation. Using the survey results as a base, criteria for prioritising evaluation topics were established:

- scientific information must be available in the international literature;
- the technology must have an extensive potential importance for health and quality of life of the population;
- the technology should have a major economic significance;
- there should be uncertainty concerning the value of the technology, especially in relation to the demand for financial resources.

Assessment process

Subjects for assessment are proposed by the Scientific Advisory Board and decided upon by the SBU Board of Directors. A project group of 5 to 15 people is formed at the start of the project and consists of healthcare professionals with special knowledge in the subject of evaluation, experts in health economics and, when required, ethicists, social scientists and lay persons. At the beginning of the project the group participates in an intensive educational programme on critical analysis of medical literature. After deciding on the criteria for selecting scientific studies for critical appraisal, the group conducts systematic searches of scientific databases, and goes on to systematically review the entire body of the scientific literature in the field. Since the subjects for most SBU projects are broadly defined, for example, treatment of back and neck pain, and most people in the groups are participating in this project in parallel to their regular work, the assessment takes up to three or four years to complete. Upon completion, the assessment manuscript is sent to the external reviewers and then to the Board of Directors and Scientific Advisory Committee for approval.

Before the final manuscript is published as an SBU report, special attention is given to its language which is simplified as much as possible so it can be read and understood by a wide audience. SBU reports serve as policy recommendations to the Swedish Government and decision makers throughout the healthcare system.

SBU's efforts to change policy or practice in Swedish healthcare

Since its inception, SBU has published more than 50 reports. In 2000, about 20 projects were in progress. Although it is a governmental agency, SBU does not have a

formal mandate to direct clinical practice, for example, through clinical guidelines. Its only means to promote change has been through education and dissemination of information. One important mechanism in this regard is the project groups themselves, and today approximately 400 health professionals throughout Sweden are involved in SBU work. Most of them are key people in Swedish healthcare.

SBU in collaboration with the Medical Products Agency and National Board of Health and Welfare has established an internet-based, early warning system – SBU Alert – to inform users about emerging health technologies.⁴ Primary target groups for SBU Alert reports include politicians, leading officials and chief medical officers. SBU Alert, with support from other national organisations, aims to appraise current knowledge and point to possible gaps in knowledge regarding new technologies that may require further study. The main principle is that assessments should be based on existing data, documented experience and general considerations. The goal is to cover 100 to 150 technologies in the Alert database during its first five years. The agency is actively collaborating with EuroScan, the European Information Network on New and Changing Technologies.

Regarding the impact of assessments, SBU has come to realise that disseminating and implementing the results takes nearly as much effort as carrying out the assessment itself. Assessment results need to be actively communicated to professionals and the public. Therefore, SBU disseminates the results of its assessment not only through publication of the reports and articles in scientific journals, but also through conferences, lectures and special educational activities. A newsletter, *Science and Practice*, has a circulation of 110,000 copies and is distributed free of charge. It contains summaries of SBU reports and other international studies plus interviews with project leaders, SBU Board members and other key actors in the field. The international scope of HTA is continuously emphasised.

In collaboration with all Swedish county councils, SBU has developed a network of special 'ambassadors' who have the task of promoting more effective dissemination of project findings. Most of the ambassadors are clinicians who work part time as SBU representatives. They are supplied with material from SBU and take part in special educational programmes for clinicians and

“HTA has achieved strong recognition in the clinical community.”

health administrators. Currently, approximately 30 SBU ambassadors serve in different regions of the country.

Attitudes toward HTA in Sweden

The Swedish system of HTA is still developing and has achieved some significant success. The main achievements include the development of a well organised, respected governmental body for assessment, thereby establishing HTA and evidence based medicine (EBM) as key concepts throughout the medical community.

HTA was introduced in Sweden with two objectives in mind:

“A general problem for HTA internationally is the large number of unevaluated technologies.”

- To speed the diffusion and use of healthcare technologies with proven safety, efficacy and effectiveness to ensure broad and equitable access to the technology.
- To monitor healthcare technologies that have not yet been scientifically assessed and/or whose policy implications are not yet fully understood so that potentially harmful, useless or less effective technologies can be retired and replaced.

Since its inception, HTA has achieved strong recognition in the clinical community, mainly because of the high scientific quality of SBU reports and its independent position free from conflicts of interest. HTA and EBM are now being introduced into the programmes of medical universities and the continuing medical education programmes of healthcare personnel. Survey data indicate that most physicians in Sweden are well aware of SBU activities.

International collaboration – the way to the future

A general problem for HTA internationally is the large number of unevaluated technologies. Even if more funds were available, resources such as research centres and well trained researchers are limited. Active networking prevents duplication of activities and promotes information sharing and comparison. A natural solution for Sweden is international collaboration and openness to HTA activities in other countries. While Sweden is ready to carry out its share of the

work, it must cooperate with others in this task. For this reason, HTA in Sweden has adopted an increasingly international focus.

Thus, SBU has developed close ties with similar organisations around the globe. Since 1996, the secretariat of the International Network of Agencies for Health Technology Assessment (INAHTA) has been hosted by SBU. The membership in INAHTA is open to any non-profit, governmental organisation that assesses healthcare technology and receives at least 50 per cent of its funds from public sources. At present, the Network unites 35 institutions from 18 countries.⁵ The main purpose of the Network is to share information and accelerate exchange and collaboration among HTA institutions. INAHTA, in collaboration with the University of York, UK, manages the one of the world's few publicly available HTA databases of ongoing projects and published reports.

In the early 1990s, European HTA agencies and programmes joined together to develop a proposal to promote coordination of HTA in Europe. SBU has taken an active part in the EUR-ASSESS and HTA-Europe projects² funded by the European Commission. Currently, SBU coordinates the EU-sponsored project to establish a European Collaboration Network on HTA.

While many practical problems still need to be overcome, and international structures and cooperative networks need to be more effective, international cooperation remains a high priority in Sweden.

REFERENCES

1. Jonsson E, Marke LA. CAT scanners: the Swedish experience. *Health care Management Review* 1977;2:37-3.
2. Carlsson P, et al. Health technology assessment in Sweden. *International Journal of Technology Assessment in Health Care* 2000;16:2.
3. SBU. *Preoperative Routines*. Stockholm: SBU, 1989. www.sbu.se
4. Carlsson P, et al. The early experiences of a national system for the identification and assessment of emerging healthcare technologies in Sweden. *International Journal of Technology Assessment in Health Care* 1998;14:4.
5. See INAHTA website, www.inahta.org, January 2001.

NICE idea

The UK National Institute for Clinical Excellence



Andrew Dillon

“There seems to be no reason why the systematic review of the evidence in the public domain should not be based on methodologies and techniques adopted by all EU countries.”

Andrew Dillon is Chief Executive of the UK National Institute for Clinical Excellence (NICE), London.

The creation of the National Institute for Clinical Excellence (NICE), in April 1999, marked the beginning of a new approach to producing clinical guidelines and undertaking technology appraisals in the United Kingdom. It is part of a movement to place evidence based practice at the heart of NHS care. The term ‘technology’, as it applies to the Institute’s work, is used to describe pharmaceuticals, medical devices, diagnostics, clinical procedures and certain aspects of health education, although pharmaceuticals have dominated our initial programme. The Institute’s purpose is to offer guidance to the National Health Service in England and Wales on the clinical and cost effectiveness of pathways of care (guidelines) and technologies. The Institute also funds clinical audit at a national level and maintains a number of other programmes.

NICE is a small organisation, employing around 25 staff although it is expected to grow to around 36 over the next 12 months. The intention is to keep the organisation small, relying on partnerships with the NHS Research and Development Directorate and academia, and by using the substantial databases maintained by manufacturers, to provide a source of evidence and expertise. Thirteen staff are dedicated to the technology appraisals programme.

NICE and the NHS

The Institute is part of a process of modernisation of the NHS in England and Wales. There are a number of new and existing bodies, such as the Commission for Health Improvement (a standards and development agency with inspection powers in NHS organisations), the Health Development Agency (a public health standards and development organisation) and the NHS Research and Development Programme, which, together, aim to improve the quality of clinical practice and service delivery. These organisations need to work together effectively to make more for the NHS than just the sum of their parts. They have the ability to work in support of the people who rely on the NHS for their care and for those who provide that care, by setting standards and by helping the service to assess its performance against those standards, and when neces-

sary, to improve that performance. The Institute will work closely with corresponding agencies in Scotland that perform similar functions, including the Scottish Inter-collegiate Guidelines Network (SIGN) and the Health Technology Board for Scotland (HTBS).

Examples of where close working relationships will be important include sharing approaches to audit and implementation advice with the Commission for Health Improvement. Hospitals, primary care groups (collectives of primary care physicians) and health authorities will want to feel secure that where they have followed the Institute’s advice on the management of a clinical condition or in the use of a technology, that the Commission will accept that approach. Similarly, the Audit Commission’s work on best value in the delivery of services needs to dovetail with any guidelines produced by the Institute for related clinical practice (for example, the Audit Commission has produced a report on the care of elderly people with hip fracture¹ which was published in the month prior to the publication of the Institute’s guidance on the selection of hip prostheses for primary hip replacement).

The Institute is also coordinating carefully its programme of work with the NHS Research and Development Programme. The R&D Programme will continue to undertake health technology assessments, but they will be over a much longer timescale than the rapid reviews undertaken by NICE. Some of these assessments will be used by the Institute as the basis of its appraisals, with the Institute effectively providing a ‘front end’ to the work of the R&D Programme.

The UK spends less on healthcare, expressed as a percentage of gross domestic product, than most European countries (about 6.5 per cent). The current Government intends to raise this close to the current EC average over the next few years. The UK is conservative in its use of health technologies. For example, the average number of prescription items per capita dispensed annually in the UK is around 10, whilst in Italy the rate is 26 and France around 52.²

NICE

The National Institute for Clinical Excellence was established in April 1999 to provide the NHS in England and Wales with guidance on the clinical and cost effectiveness of new and existing treatments.

HDA

The Health Development Agency is a special health authority, established in April 2000, that aims to improve the health of people in England and in particular, to reduce inequalities in health between those who are well off and those on low incomes or reliant on state benefits.

CHI

The Commission for Health Improvement was formed in April 2000. It undertakes regular visits to NHS organisations to review and support the development of clinical governance arrangements and to support the development of leadership in NHS organisations. The Commission carries investigations on specific topics and reviews the implementation of NICE guidance and the National Service Frameworks.

PRODIGY

PRODIGY is an interactive programme that sits on a general practitioner's computer, within the current clinical software, and offers authoritative, professional advice during consultations, including treatment options, prescription advice, care planning and patient information leaflets.

NHS Research and Development Directorate (and Programme)

aims to support a knowledge based health service in which clinical, managerial and policy decisions are based on sound information about research findings and scientific developments. The research programmes under this strategy focus on the needs of the health service.

Audit Commission

The Audit Commission appoints auditors to all local authorities and NHS bodies in England and Wales and helps to bring about improvements in economy, efficiency and effectiveness through value for money studies and the audit process.

Pharmaceuticals and other products and procedures are selected for appraisal by the Institute on the basis of the extent to which the technology is likely to result in:

- a significant health benefit, taken across the NHS as a whole (for example, a technology which might help reduce hospital admissions);
- a significant impact on other health related Government policies (for example, a new approach to smoking cessation);
- a significant impact on NHS resources (for example, an expensive new technology or, conversely, an existing intervention with no proven worth or which has been superseded by other, more cost effective technologies).

The extent to which the Institute can 'add value' is also taken into account. This would be the case, for example, where there are significantly divergent views on the use of a longstanding technology.

The Institute's work

By 2001, the Institute will be producing, on average, four sets of technology guidance each month. Clinical guidelines will be commissioned from multi-disciplinary authoring groups. Like the technology appraisals, they will be based on a rigorous review of the evidence, taking into account both clinical and cost effectiveness. These guidelines will take between 12 and 24 months to complete. The Institute plans to commission and publish up to 18 guidelines each year - possibly more, as the programme develops - supplemented by the guidelines delivered through the PRODIGY primary care decision support system. The authoring of guidance in PRODIGY is the Institute's responsibility, although the software architecture remains with the Department of Health. This programme represents a substantial workload for a young organisation, requiring close planning and careful quality control.

The Institute draws together a range of national clinical audit responsibilities. These consist of full national multi-disciplinary audits undertaken by consortia of professional groups and the responsibility we have for the funding and overall direction of the four national Confidential Enquiries.³ The Institute also funds clinical effectiveness publications produced by the Centre for reviews and Dissemination at York University and the National Prescribing Centre in Liverpool. These guidelines and technology appraisals will

be brought together with clinical audits and audit methodologies as integrated packages of guidance.

Our challenge is to bring together these guidance authoring and audit responsibilities in ways which will leverage maximum incremental improvement in the quality of care available through the NHS. In doing so, we will help to populate the evidence landscape on which clinical governance will rely.

HTA in healthcare systems

All health systems should support the rapid introduction of effective technologies. Industry has concerns about cost effectiveness studies being undertaken on technologies (this applies particularly to pharmaceuticals) before they have been released into the market, arguing that there will always be insufficient data to support such studies. However responsible healthcare systems, keen to ensure both rapid and consistent uptake of new drugs and other technologies, will want to issue guidance at the time a technology is made available, rather than leaving the decision as to whether to consider prescribing (as opposed to the appropriateness of actually prescribing in an individual case) to the discretion of a large number of individual clinicians. Busy clinicians do not always have the time to undertake objective appraisal and there is a danger that their individual decisions on access to specific technologies may, as a result, disadvantage patients. However, the need to support innovative products is key here.

There seems to be no reason why the systematic review of the evidence in the public domain, which underpins any judgement about the appropriate use of a technology, should not be based on methodologies and techniques adopted by all EU countries. This would considerably help manufacturers as they face up to the need to prepare the data required to support clinical and cost effectiveness analyses into their research and development. It would also be appropriate (as we have done with the UK Institute's methodologies) to agree the approach with industries involved.

It is likely to be the case that clear statements of long term national healthcare priorities would help manufacturers determine their product development strategies. By bringing together long term healthcare priorities and healthcare product development strategies, all set in the context of an agreed and consistent approach to clinical and cost effectiveness appraisal, we will be

able to maximise industry R&D and national healthcare investment.

Differences in the way in which technologies are actually used by individual national healthcare systems are, however, likely to remain. Driven by differences in approach to clinical practice, resource availability and national priorities, these national characteristics should not prevent the appropriate standardisation of methodological approaches.

REFERENCES

1. Audit Commission. *United They Stand: Coordinating Care for Elderly Patients with Hip Fracture*. (Update) 2000.
2. OHE Compendium of Health Statistics. 12th ed. 2000.
3. The four national confidential enquiries examine: Perioperative Deaths; Suicides and Homicides by People with Mental Illness; Maternal Deaths; Stillbirths and Deaths in Infancy.

Health technology assessment in Central and Eastern Europe



László Gulácsi

The development of HTA 1990–2001

Since 1990 a wind of change has swept through the healthcare systems of Central and Eastern European Countries (CEECs), bringing with it among other things, an increased interest in health benefits and costs of both new and existing technology. Improving clinical practice – i.e. attaining ‘clinical excellence’ and ‘organisational excellence’ – is an issue high on the agenda of CEECs after a decade of transition, with growing attention being paid to the evaluation and improvement of services. This endeavour has relied on the use of a number of internationally recognised instruments, including health technology assessment (HTA).

Prior to 1989, HTA had not been formally present in the healthcare systems in the CEECs, largely due to political factors. With tight political control prevailing in

every sector of society, it was simply not possible to conduct economic analyses. HTA principles were first introduced into the countries of CEE in the 1990s (Hungary and Lithuania in 1993; Russia in 1997; Czech Republic, Latvia and Poland in 1998) with the support of various international and West-European organisations (ISTAHC,* INAHTA,† WHO, Council of Europe and SBU‡). Subsequently, HTA conferences were organised in Lithuania, Russia, Poland and Hungary, and a number of healthcare professionals were trained in various HTA centres in Europe and elsewhere. Between 1993 and 1998, Hungary organised annual conferences focusing on HTA and quality of care as the key topics with the participation of a group of professionals called the ‘Central and Eastern European Study Group’. At their meetings in Poland in 1999 and 2000, Study Group members decided to raise the profile of the ‘HTA Network of Central and Eastern European Professionals’ and to join ISTAHC as a network in order to strengthen the HTA development in the CEECs. As their first concerted action, the Network conducted a questionnaire survey between November 2000 and January 2001 in eight CEE countries (Czech Republic, Hungary, Latvia, Lithuania, Poland, Slovak Republic, Russia and Yugoslavia), in order to evaluate the current stage of HTA development and utilisation. Some of the initial findings are reviewed briefly here.

The importance of HTA and healthcare reforms in CEECs

The emergence of HTA was an important part of the healthcare reform process in all European healthcare systems during the past two decades. Most CEE countries

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This contribution is the first presentation of the findings of the questionnaire survey on ‘Technology Assessment in Health Care in countries of Central and Eastern Europe’ that was conducted by members of the HTA Network of Central and Eastern European Professionals, between November 2000 and January 2001. Members of the Network include: Jan Bielik (Slovak Republic), Andrei Biskop (Russia), Ales Bourek (Czech Republic), Professor Viktorija Cucic (Yugoslavia), Danguole Jankauskiene (Lithuania), Krzysztof Landa (Poland), Egils Lavendelis (Latvia) and Audronė Piestiniėnė (Lithuania) The author also wishes to express his appreciation to Julia Chamova (SBU, Sweden) for her contribution to the survey.

* International Society for Technology Assessment in Health Care

† The International Network of Agencies for Health Technology Assessment

‡ The Swedish Council on Technology Assessment in Health Care

Table 1 Key characteristics of HTA in the countries of CEE in 2000/2001

Countries	Legislation	HTA Professional Society	HTA or related organisation	Annual state budget for HTA	Current HTA project/s	HTA report/s
Czech Republic	in part	No	No	No	No	No
Latvia	in part	No	Yes	Yes	Yes	Yes
Lithuania	in part	No	Yes	Yes	Yes	Yes
Hungary	in part	Yes (1997)	Yes	Yes	Yes	Yes
Poland	in part	No	Yes	Yes	Yes	Yes
Russia	in part	No	Yes	Yes	Yes	Yes
Slovak Republic	in part	No	No	No	No	No
Yugoslavia	in part	No	No	No	No	No

Table 2 HTA and related activities in eight CEE countries in 2000/2001

Czech Republic

Implementation of Standards of Efficient Medical Care for the evaluation of medical services reimbursed

Latvia Assessment of medical technologies in healthcare institutions

Lithuania Economic and health impact of public health programmes on cardiovascular diseases, trauma cases, cancer therapy and screening

Hungary Completed reports (1999 and 2000) on prostate cancer screening, breast cancer screening, bone density measurement, prophylactic antibiotic use in surgical operation, prevention and treatment of pressure ulcer and current studies of ACE inhibitors, medication of rheumatoid arthritis and low molecular weight heparin therapy

Poland Completed reports (2000) on stereotactic mammography, circular mucosectomy in treatment of haemorrhoids and current studies on influenza vaccination, stereotactic mamotomy, and facilitating the creation of the Polish healthcare benefit package, HTA analysis for reimbursement of medical procedures

Russia Systematic literature review on exercise therapy for rehabilitation in cases of heart failure

NOTE: Training, education and conferences on HTA were found to be provided for professionals in all participating countries

experienced severe economic recession with serious consequences and hard pressure on public health expenditures. The concurrent greater exposure to, and availability of, new healthcare technologies stepped up patient and professional expectations of the services that should be offered. Measures to liberate the health sector from centralised state control and introduce unregulated competition rapidly lead to complete market failure. The government budget for healthcare was reduced, and hospitals entered into direct (non-price) competition. Imports of new pharmaceuticals, devices and procedures were liberated but no proper evaluation or training for their use was put in place. Healthcare providers such as general practitioners, pharmacists, diagnostic centres, and surgical departments, came to find themselves entrepreneurs in private practice, while patients acquired increasing awareness as customers of healthcare demanding services in return for their taxes and contributions. This led to extremely irrational patterns of investment in technology, with much obvious waste, while leaving basic needs unmet. Various alternative approaches are being used to resolve the conflict between scarce resources and high demand. By virtue of its multidisciplinary character, HTA has assumed a strong position among the possible ways of addressing complex issues of expenditure control and efficiency of healthcare delivery in balance with assuring equity of access to necessary healthcare services.

Current stage of HTA in CEECs

The questionnaire survey focussed partly on legislation, professionalisation, institutionalisation, financing and projects related to HTA. Some key characteristics related to HTA in Central and Eastern Europe are shown in Table 1.

Legislation on HTA

Health Care Laws in effect in the participating CEE countries were reviewed.

Although no explicit, direct and coherent piece of legislation to establish HTA was identified in CEE countries, it was possible to find HTA related requirements concerning effectiveness and cost-effectiveness of healthcare, patients' rights, and quality and safety of care – hence there is partial legislation in this area. In some countries legislation was found to be more explicit than in others, e.g. in Lithuania pursuant to the Health Care Institutions Law, a medical technology that has not been assessed and approved cannot be used.

Current HTA and related activities

A number of different HTA and related activities were found to be underway in the participating eight CEE countries; the most important ones are shown in Table 2.

Financing of HTA activities

HTA activities are financed by governments, international funds and pharmaceutical companies. In some of the CEE countries, pharmaceutical and other private industry funding is quite substantial.

Change agents

All respondents maintained that government support for the involvement of the ministry of health and insurance fund as agents to facilitate change was essential. The role of medical academies, professional associations and the awareness of HTA were highlighted and there was agreement among respondents that the biggest change could be brought about by training as many medical professionals as possible in HTA.

Barriers

The most frequently mentioned barriers to the development of HTA were identified as:

- incomplete legal regulations;
- lack of institutions responsible for HTA;
- insufficient support from the ministry of health and low funding for HTA;

- short supply of HTA specialists;
- need for more training for professionals;
- paternalistic, authoritative, ‘command-and-control’ based traditions prevailing in healthcare;
- no tradition in using HTA;
- passive consumers of healthcare.

Translating scientific evidence into clinical decision making

No systematic method was in place for translating scientific evidence into health policy, clinical decision making and clinical practice. Information was fragmentary, but systematic reviews had revealed that some commonly used interventions in different areas are either definitely, or probably ineffective. In Hungary, for instance, research findings indicated that a great deal of ineffective technology is in use, and/or effective technologies are frequently overused and/or underused. Regardless of healthcare reforms and political changes, needs and assessment programmes through population screening always attracted large funds and aroused much interest from the public, politicians, the media and professionals alike. These programmes, however, had a very limited effect on health status, if any, as the process used was in many cases inappropriate for screening purposes, or the target population was improperly identified. Even available scientific evidence had often not been translated into practice, owing to inappropriate dissemination or interpretation, or simply because of conflicting interests.

Discussion and recommendations

Some issues have emerged from the survey either as requiring further consideration or lending themselves to recommendations.

Legislation on HTA: Although HTA legislation has not been fully established yet, the existing healthcare legislation provides the necessary minimum framework for HTA development in most CEE countries. A process to be completed in the coming years, adapting EU legislation and regulations is a hot issue in Central and Eastern Europe and is especially high on the agenda in candidate countries.

Financing HTA activities: In many CEE countries HTA and related research and training activities are financed from private industry sources, which very often constitute the sole, or the most significant, support. Yet CEE countries, like their more developed counterparts, seem to have growing, and not totally groundless,

concerns about the possibility that industry sponsorship might bias research outcomes. One can think of two possible avenues to address these concerns. Firstly, guidelines for what constitutes a conflict and how to manage conflicts should be developed and implemented, thereby making this relationship transparent.¹ Secondly, governments should be made more aware that investing in HTA yields good returns. Initial investment in HTA can render professionals in a country capable of joining the mainstream of HTA. Sharing results and using what is already available, rather than reinventing the wheel, are the most cost-efficient ways of conducting HTA. This, however, requires a strong and dedicated HTA agency, a pool of trained professionals and an appropriate infrastructure. Finally, HTA is not likely to receive a higher share of public spending in the foreseeable future and the pharmaceutical industry sponsorship that will remain should, therefore, be regulated. At the same time, plans should be drawn up to prepare for increasing government involvement.

Barriers: The survey identified legislative, organisational and budgetary barriers to HTA implementation. Furthermore, insufficient knowledge of HTA and the need for training of professionals have been stressed by all country representatives, and this is recognised as a crucial next step. However, one of the other barriers to HTA utilisation is cognitive. As shown by experience in more developed countries, changes in professionals’ behaviour are generated not only by their abstract (or technical) knowledge, but also by personal experiences – their ‘tacit knowledge’. Tacit knowledge, however, is hard to transfer to other people. The lack of tacit knowledge would very often be interpreted in CEE as a lack of technical knowledge. Hence, activities aimed at spreading information and increasing awareness on how to utilise HTA are often not effective enough, because they try to convey technical knowledge which might already be known by recipients.

The past ten years have brought about substantial achievements in the HTA field. There has been a considerable accumulation of relevant knowledge and expertise, and a core pool of dedicated professionals has formed. The EU has also launched HTA initiatives, and the eventual involvement of the CEE countries in prospective international projects might provide added value and a different perspective to these efforts.

HTA organisations, and organisations with HTA activities in the countries of CEE

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Lithuania State Health Care Accreditation Service, Ministry of Health (Z. Liauksmino Str.5, Vilnius, Phone: 370 2 615177, Fax: 370 2 227310, Coordinator: Audronė Piestinienė, audre@takas.lt)

Poland National Centre for Quality Assessment in Health Care (ul. Syrokomli10, 31-102 Cracow, Poland, Phone: 48 12 427 81 70, www.cmj.org.pl, Director: Rafal Nizankowski, mmnizank@cyf-kr.edu.pl)

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REFERENCES

1. Boyd EA, Bero LA. Assessing faculty financial relationships with industry. *JAMA* 2000;284(17):2209–14.

NEW LEGISLATION ON TOBACCO PRODUCTS

In November 1999 the Commission proposed new legislation on the manufacture, presentation and sale of tobacco products. The Council did not accept 17 of the 32 amendments that the European Parliament adopted during its second reading of the Proposal in December 2000. On 28 February a Conciliation Committee reached an agreement on these issues and adopted the new Directive.

The new legislation reduces the maximum tar level per cigarette from 12mg to 10mg. It sets a limit of 1mg of nicotine and 10mg of carbon monoxide per cigarette. The three ceilings apply to all products manufactured in the EU and imported into the EU. The same rules are to be applied to EU tobacco product exports after a transitional period. The Directive will also lead to the prohibition of descriptors such as 'light', 'low tar' or 'mild'. In addition, manufacturers must disclose to governments all cigarette ingredients, including any potentially harmful additives. Warning labels are to be bigger and clearer, and all packets of tobacco products will have to bear the phrase *Passive smoking harms you and those around you*. Member States will be able to insist on additional warnings on cigarette packets. Member States may also prohibit the use of ingredi-

ents that increase the addictive properties of tobacco products. The Directive requires the final approval of the Council of Ministers and the Parliament and will then enter into force on 30 September 2002.

Jules Maarten, who represented the Parliament in drafting the legislation, said this would finally close a loophole that allowed cigarette makers far more lax rules than food companies. "We know what is in a jar of marmalade but we do not know what is in a packet of cigarettes," he said. Public Health Commissioner David Byrne said he will now focus on bringing forward new legislative proposals on tobacco advertising for the EU Health Council in May of this year. The Commission will be a participant on behalf of the EU in negotiations on the WHO Framework Convention on Tobacco Control, which will resume on 29 April. The Commission will also further investigate the issue of subsidies received by tobacco farmers in the EU and draw up a report next year on how the market in raw tobacco is organised.

More information on the EU's tobacco policies and the new Directive can be found on the Commission website:
<http://health/ph/programmes/tobacco/publication.htm>

RESEARCH

Commission proposes a New Framework Programme for Research and Innovation in Europe

The European Commission has presented proposals for a new research and innovation framework programme for the EU. The Commission is proposing a budget of 17.5bn euros for the programme – reflecting the increasing priority given to research and innovation. The budget, covering a four year period (2003–2006) represents an increase of 17.5 per cent over the budget of the current research framework programme. The research and innovation programme is part of a wider political initiative that aims at creating a European Research Area, as endorsed by the

Lisbon Summit in March 2000. The new programme aims to strengthen Europe's science base and to help research teams to work more closely together in networks. It also aims to concentrate funding on seven key emerging technologies and research priorities. Amongst these priorities is to build on the recent breakthrough in decoding the genome, to help tackle major diseases and strengthen Europe's biotechnology industry.

The programme can be found on website: <http://europa.eu.int/comm/research/area.html>

PROGRAMME OF ACTION ON AIDS, MALARIA AND TUBERCULOSIS

The European Commission has approved a new Communication setting out a Programme for an accelerated EU response to HIV/AIDS, malaria and tuberculosis.

The Programme for Action further develops the policy framework presented in a September 2000 Communication, *Accelerated action targeted at major communicable diseases within the context of poverty reduction*. The new document defines the EU response, over the period 2001–2006, to the global emergency posed by these diseases, which undermines developing country's efforts to achieve economic growth and to improve public health.

Amongst the Commission's goals are to rapidly increase the impact of existing interventions, to increase the affordability of key pharmaceuticals for the poorest populations, and to stimulate research and development. To this end the Commission is exploring opportunities to increase international resources allocated to health, HIV/AIDS and population programmes.

In the year 2000, the EU allocated 800m euros to these three areas, 8 per cent of the total development cooperation programme. The Commission's Programme is committed to working with the World Health Organisation, the World Intellectual Property Organisation and the World Trade Organisation to address the link between Trade Related Aspects of Intellectual Property Rights (TRIPS) agreements and health issues.

The Communication Programme for Action: accelerated action on HIV/AIDS, Malaria and Tuberculosis in the context of poverty reduction is available on website: http://europa.eu.int/eur-lex/en/com/cnc/2001/com2001_0096en01.pdf

FOOD SAFETY

New Directive on GMOs

In February 1998, the Commission adopted a Proposal to revise Directive 90/220/EEC on the deliberate release of genetically modified organisms into the environment. Following a Conciliation Committee meeting in December 2000, the European Parliament and the Council adopted the new Directive on the 15 February. It promotes the harmonisation of risk assessment procedures and requires an environmental risk assessment to be carried out before the authorisation procedure is initiated. GMOs containing genes resistant to antibiotics must be phased out – by 2004 for commercial products and by 2008 for research products. The public must be informed of GMO releases and any authorisation of release must be re-approved following a ten year period. The Directive introduces clear labelling requirements for all GMOs that are placed on the market. The revised Directive thus introduces mandatory consultation of the public, compulsory labelling, traceability and monitoring.

More measures to tackle BSE

The continued detection of BSE in cows in various regions across Europe is leading to growing public concern

that the necessary measures are not being taken to protect consumers from the risk of BSE. Consumer confidence and beef consumption have fallen sharply. The Commission is therefore taking a range of additional measures that aim to ensure the safety and quality of beef and to restore public confidence. Amongst the new measures that have been agreed are the suspension of the use of meat and bone meal in feeding-stuffs for farm animals and the testing of all animals aged over 30 months that are destined for human consumption. In addition, there is now a ban on mechanically recovered meat from the bones of cattle, sheep and goats and the list of specified risk materials that may not be consumed has been extended to include the entire intestine and the vertebral column.

On 9 March the EU's Economic and Social Committee (ESC) organised a public hearing on BSE – Topical aspects.

A number of documents related to the topic of the hearing, which have details of the proceedings of the hearing are available on website:
http://www.esc.eu.int/en/acs/events/BSE_09_03/docs/hearing_bse_09_03_01_en.htm

Round Table on food quality, safety and production

Public Health and Consumer Protection Commissioner David Byrne and Agriculture and Rural Development Commissioner Franz Fischler have launched a wide ranging public debate on food quality. This was initiated by a high level Round Table held on the 5 March, when leading food producers, retailers and consumer experts met to discuss food production and food policy. Amongst the issues analysed were the drivers of consumer and producer behaviour and the increasing emphasis on ethical values such as environment and animal welfare. The Commissioners suggested similar round tables in the Member States in order to collect more suggestions for common policies.

More information on the Commission's initiatives to improve food quality are available on website:
http://europa.eu.int/comm/dgs/health_consumer/library/debate/index_en.html

This site also contains a link that enables interested parties and stakeholders to submit their contributions to the food quality debate and to present relevant data and ideas.

ENVIRONMENT

Commission White Paper on Chemicals

The Commission has adopted a White Paper that sets out the strategy for a future Community Policy for Chemicals. The White Paper seeks to develop a single efficient and coherent system for dealing with new chemical substances, which were introduced into the market after September 1981, and existing chemical substances marketed before this time. The precautionary principle underlies the new Directive. Amongst the key elements of the new strategy is the reversal of responsibility from authorities to industry for testing and risk assessment of chemicals.

The full text of the White Paper is available on: [www.europa.eu.int/comm.environment.chemicals/whitepaper.htm](http://www.europa.eu.int/comm/environment/chemicals/whitepaper.htm) The responses of a

number of NGOs to the White Paper are available on: www.chemical-awareness.com/news

New action programme for the environment

The European Commission has adopted a proposal for new environmental strategy as the 6th Environment Action Programme. *Environment 2010: Our Future, Our Choice* focuses on four major areas for action: climate change, health and the environment, nature and biodiversity and natural resource management. Implementation of EU law by Member States is a principal focus of the programme. In the priority area of *health and the environment*, the new action programme recognises that a more holistic approach is needed to address links between different environment related health risks.

A summary of the 6th Programme can be found at: www.europa.eu.int/comm/environment/newprg/index.htm

Green Paper on Integrated Product Policy

On the 7 February the Commission adopted a Green Paper on Integrated Product Policy. The objective of the Green Paper is to launch a debate on the role and possible measures that could be taken at the EU level to make products more environmentally friendly and on how to assist the growth of a market for such products.

The Green Paper and a number of studies and consultations on which it is based is available on website: www.europa.eu.int/comm/environment/ipp/home.htm

ALCOHOL POLICY

Alcohol and Youth: Conference in Stockholm on Young people and Alcohol.

According to WHO figures, 55,000 people aged 15–29 died from alcohol-related causes in Europe in 1999. For young men, alcohol is the biggest single killer, accounting for one in four deaths. In Eastern Europe, this figure is as high as one in three. Regular heavy drinking and binge drinking also have serious effects on young people's physical and mental health. Alcohol consumption amongst young people in the EU is on the increase. While some progress has been made in reducing overall alcohol consumption in parts of the Western European region, the situation in parts of Eastern Europe is worsening.

To address these issues, a Conference on Young People and Alcohol was held in Stockholm on 19–21 February. The Conference was a WHO ministerial conference as well as an official meeting within the Swedish programme for the presidency of the European Union. It was organised five years after the European conference on Health, Society and Alcohol, held in Paris in 1995, when the European Charter on Alcohol was endorsed. The Stockholm Conference aimed to generate further action to reduce alcohol-related harm in societies.

All 51 European governments represented there endorsed the Conference Declaration on young people and alcohol. The Declaration contains a number of objectives, including reducing substantially the occurrence and frequency of high risk drinking among young people and/or to expand alternatives to alcohol and drug use and to increase education and training for those who work with young people.

More information can be found on the Conference website: www.youngalcohol.who.dk/home.htm

Reports from a preparatory youth meeting that was organised by the Swedish Government in cooperation with SIDA, WHO, the Council of Europe and UNICEF, which was held in November 2000 are available on: <http://eu2001.se/social/eng/docs/youthmeeting.asp>

The second European School Survey Project on Alcohol and Other Drugs (ESPAD), which is a comparative study on young people's relation to alcohol and other drugs in 30 European countries, which was presented at the Conference, can be found on: http://social.regeringen.se/ansvar/ordf/pdf/espada_summary.pdf

Council Recommendation

In association with the Conference, the European Commission has recently presented a proposal for a

Council Recommendation on the *Drinking of Alcohol by Children and Adolescents*, which focuses on voluntary codes of conduct for industry. The Recommendation calls for local communities and politicians to become more involved in training and information.

The Proposal and an explanatory memorandum can be found on website: http://europa.eu.int/eur-lex/en/com/dat/2000/en_500PC0736.html

Alcohol and Transport: Still too much drinking and driving in the EU

About 10,000 people are killed every year in accidents where at least one driver has consumed too much alcohol. This represents about 25 per cent of all road deaths. In order to step up the fight against drinking and driving, the European Commission recommended limiting the permitted blood alcohol concentration level to 0.5mg/ml. This limit was proposed in 1988 but, in an area subject to subsidiarity, it was not adopted by the Council of Ministers. The Commission has now decided to consult the European Parliament and Council on a draft Recommendation on the issue. The new Recommendation suggests that a legal maximum blood alcohol concentration limit of no higher than 0.5 mg/ml should be adopted by all Member States.

SOCIAL AFFAIRS

Commission Communication: Scoreboard on Implementing the Social Policy Agenda

When EU leaders adopted the Social Policy Agenda at the Nice European Council Summit, the Commission was invited to present an annual scoreboard to monitor the progress made in the implementation of the Agenda. The Social Policy Agenda marks the commitment of all Member States, European institutions and other actors to modernise and improve the 'European social model'. On 22 February, the Commission adopted its first scoreboard, which it will present to the Stockholm summit

on the 22–23 of March, in the form of a Communication. The Scoreboard provides a clear overview of the action that is being taken to reinforce the quality of work, social policy and industrial relations in the EU.

The Communication is available on website: www.europa.eu.int/comm/employment_social/general/news/act_en.pdf

Actions to fight the trafficking of women and children and child sex tourism

Employment and Social Affairs Commissioner Anna Diamantopoulou and Justice and Home Affairs

Commissioner Antonio Vitorino marked International Women's Day on the 8 March by attending an information event hosted by the European Parliament. It has been estimated that as many as 120,000 women and children are trafficked into Western Europe every year. Information sheets and funding sheets have been prepared to raise awareness about this issue and to give an overview of strategies and actions being taken to address this problem.

This information can be found on website: http://europa.eu.int/comm/employment_social/news/2001/mar/61_en.html

NEWS IN BRIEF

European Social Statistics

The EU's statistical service, Eurostat, has issued a publication, *European Social Statistics*, providing easy access to up-to-date comparative information necessary to study social trends in the EU. It includes the principal series of demographic statistics and covers all EU Member States as well as the EFTA and other European countries. According to the report working people will have to support an increasingly economically inactive population in most EU regions from 2010 onwards.

More information about and an electronic version of this publication is available on website:
<http://europa.eu.int/comm/eurostat>

DG Sanco

Mr F. Sauer has become the Director of the Public Health Directorate. He was the former Director of the European Medicines Evaluation Agency.

A new Organisational Chart of the Directorate General Public Health and Consumer Affairs is available on website: http://europa.eu.int/comm/dgs/health_consumer/general/info/organigramme_en

Employment situation of disabled people

The European Foundation for the Improvement of Living and Working Conditions (EIRO) has published a Comparative study on the general employment situation of disabled people in the EU and Norway. The study compares the measures that EU governments are taking to promote the employment of people with disabilities or prevent discrimination against them.

The Comparative study and the national reports on which the study is based are available on website: www.eiro.euofound.ie/2001/02/study/index.html

Mental Health Conference

The annual MHE-SME European Conference on Mental Health, entitled Visibility Improved, Improved Visibility, was held on the 7-9 March. The Conference aimed to generate dialogue amongst key figures in the field of Mental Health. Amongst the Conference themes were the civil and human rights of mental health clients, mental health promotion and care, and policy and legislation influencing care.

More information is available on the Conference website:
www.ecmh2001.org

Occupational health and safety

Canada and the European Union have launched a global portal on occupational safety and health. The Canadian Centre for Occupational Health and Safety (CCOHS) has joined the European Agency for Health and Safety's website, making this new joint website the most extensive global portal on occupational safety and health (OSH). The joint site provides key information on issues such as best practice, research, statistics and legislation/regulation.

The site is available at www.eu-ccohs.org. In addition, the European Agency for Health and Safety at work has launched an Online Forum for Health and Safety Exchange, which can be accessed on website: http://europe.osha.eu.int/good_practice/forums/

Public Health Programme funding

Descriptions and details of the organisations and the health monitoring and health promotion projects that received funding under the Commission's Public Health Programme in 2000 are available on website: www.europa.eu.int/comm/health/ph/programmes/health/proj00index_en.htm

Pollution related diseases

The draft work programme on pollution related diseases in the context of the framework for action programme in the field of public health (1999-2001) is available on website: http://europa.eu.int/comm/health/ph/programmes/call/ojc87/work_en.pdf

NOTICES**FOURTH EUROPEAN HEALTH FORUM GASTEIN (EHFG) 2001**

Taking place from 26 to 29 September the 4th European Health Forum Gastein (EHFG) 2001 will once again be a focus for high-level discussions amongst key decision makers and experts in European health policy. Under the main organising theme of "Integrating Health Across Policies" the Forum, which has developed into one of the most successful European health policy events, will focus on:

- Health in other policies and sectors
- The Single European Market
- Agricultural policy
- International trade policy
- Patient information and eHealth.

Further information is available at www.ehfg.org or by contacting info@ehfg.org Tel: +43 (6432) 711070; Fax: +43 (6432) 711071.

INTERNATIONAL SYMPOSIUM under the Swedish Presidency of the European Union**'EVIDENCE AND ASSESSMENT FOR IMPROVED HEALTH CARE'**

17 May 2001, City Conference Centre, Stockholm

A symposium for policy makers, health professionals, managers and representatives of the healthcare industry

European leaders in Health Technology Assessment (HTA) will present on May 17 2001 current collaborative work in HTA and the results of the ECAHI/ECHTA project.

Final programme details and registration:
<http://www.sbu.se/sbu-site/index.html>

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