COMMENT

Undue delay in cross border healthcare?

The long awaited judgements of the Court of Justice in the Geraets-Smits/Peerbooms and Vanbraekel cases (C-157/99 and C-368/98 respectively) have now been made (12 July). They have far reaching consequences for Europe's patients and its healthcare systems.

The Smits/Peerbooms judgement in particular has significant implications for the delivery of European healthcare. The prior authorisation rule restricting the acquisition of treatment abroad is declared as an obstacle to the freedom to provide services. It appears to resolve the question of the applicability of the right to service in another Member State for patients from tax funded national health systems. It also refers to hospital care, another area left in ambiguity following the earlier Kohll and Decker cases (see *Eurohealth* 7(1) Spring 2001).

Fundamentally, the Smits/Peerbooms judgement refers to 'undue delay' as a legitimate basis for seeking treatment in another Member State. This is to be interpreted on an individual basis, according to personal medical history and condition. In systems with highly rationed supply this could lead to significant use of services abroad.

This development in the right to receive healthcare services has arrived at a time when patients are becoming more proactive and there is growing information about medical conditions and services provided. The opportunities for patients in this context are great as best practice among healthcare systems and their ability to deliver particular services become more transparent. The failings of national systems to deliver will be clearer, perhaps creating the political incentives for governments to improve them.

Nevertheless, national healthcare systems are also defended by the judgements. Smits/Peerbooms accepted the need to ensure the financial balance of social security systems – a point that provides a check against large numbers of people flocking to receive care abroad. Governments and healthcare administrators can also look to potential benefits of increased cross border care. Areas of expertise and efficiency can be exploited to deliver services to patients at lower costs and there are opportunities for localised surges in demand to be met quickly by utilising capacity in other Member States. The dynamics of scale and of comparative advantage can potentially lead to more efficient service delivery.

The judgements will doubtless be the basis of further discussion and debate as many questions remain to be resolved. But the direction, at least, is now clear: there is the potential for the development of greater cross border use of healthcare services. *Eurohealth* will examine the implications of the judgements in greater depth in the next issue.

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EU health research: science v policy?

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In February, the European Commission put forward a new strat-

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Interview by Paul Belcher Senior Editorial Adviser, Eurohealth

Your appointment as Director comes at an interesting time with the EU institutions in the process of approving a new EU health strategy. What are the health policy priorities and changes in approach in this new strategy?

The priorities in the new health programme are often expressed in terms of a 'three strand' approach: health information, health strategy, and health determinants. I think it is right to move away from the 'vertical' approach of having eight separate health programmes to a new single health programme. Over the years the vertical approach has become inflexible, as it was not possible to introduce other diseases into the programmes.

Are Member States more ready to accept the Commission's health role as you move into this second health strategy, based on Article 152?

I see in the new programme an opportunity to manage better the limited resources at our disposal in a way that may encourage Member States to accept more readily our legal mandate in health. The atmosphere of suspicion about our role and the need to respect the 'subsidiarity' principle have become much clearer in the debate on the new health strategy. I feel that those Member States which have been concerned with subsidiarity in public health are now more reassured about what we are going to do – and importantly what we are not going to do.

Interestingly, in recent debates in the European Parliament and Council of Ministers, national representatives have voiced concerns that the Commission would not have sufficient capacity to run the new programme and they have suggested that we should create a special health coordinating centre to assist us.

One thing is clear, each week that I have been in my new post, there has been a public health crisis of one sort of another – uranium in Kosovo, for example – and in most cases we don't even have the competence to do anything about it. But it shows that politicians are now much more conscious of the importance of health in the expectations of European citizens.

"Health is a very important economic driver"

So, you recognise that there was a lot of scepticism about the EU's first, albeit restricted, role in public health following the Treaty of Maastricht.
Yes, even within the Commission itself! And I would suggest that, ironically, it was BSE and other health crises that were very progressive from a political perspective in developing the broader EU competence in public health based in the Amsterdam Treaty.

Unfortunately, public health was a negative element in the European political picture, viewed as an obstacle to other policies, but now people are seeing that it has a very positive purpose. In my opinion, health is a very important economic driver. If you contrast the difference between an aging population that is healthy and an ageing population that is sick, in economic terms, the difference is huge and it is a real economic challenge which has to be brought into the European integration process.

Do you see scope for further developing the EU's role in health?
I believe that if we are successful in launching this new policy with the full participation of stakeholders, then three or four years down the road to the next Intergovernmental Conference it might be time to reinforce the legal basis for health, which is at a halfway house at the moment.

On the one hand, there is an explicit European Community health competence but it is very limited and relates only to public health policy here in DG [Directorate General] Health and Consumer Protection [DG Sanco]. Yet this is only one part of many health related policies of the Commission, such as health and environment, health in the workplace, pharmaceuticals etc. Even in the late 1980s, the health element of the EU pharmaceutical regulations was already very advanced without any formal health basis in the Treaty. So, there are many health related European policies and now is the time to integrate them better in the medium term.

What in your view are the key lessons that the Public Health Directorate has learned over the past decade? Are there still problems to be solved?
My predecessors had to work more in an intergovernmental role, like the WHO or Council of Europe, than in the integrated mode that I was used to. And they did what they could in the circumstances and they did a very good job. They prepared the ground for the change in the Treaty introducing Article 152 on public health. But, as for lessons to be learned, my opinion before leaving EMEA was that there should be a more flexible and open approach to public health in the Commission, although that lesson was learned even before I came here.

One lesson, which all the departments of the Commission have had to learn the hard way, is about financial management. We don't have a huge budget but we do have a complicated one, with eight budget lines and many small contracts with NGOs. This is the biggest challenge because the rules, necessary for accountability, mean that there is greater scrutiny. Ironically, the new programme will be simpler, with one programme and a single management committee. However, when combined with the new financial complexity, it is actually more complex than before.

One third of my colleagues, one way or another, now have to deal with financial matters. The system has become even more rigid because of the need to be more accountable and this should be addressed in the general reforms of the Commission.

Do you think you have the resources in place to deal with this heavy financial administration, programme implementation and policy development for the future?
At the moment people are excessively occupied with the day-to-day financial administration of our work and we don't have enough time to reflect. But the new programme is an occasion for change.

So you will have more resources in future to implement the new programme?
Well, I need more resources, though not so much in terms of big numbers, as in terms of expertise. We have been given a challenge by the European Parliament to set up a European health centre and this means big resources. The only thing I can say is that the Commission generally is limited in its ability to increase staff and so we have to look at the possibilities within which we can work now. This may lead, perhaps in three to four years, to an external resource being created such as an executive agency. This will not be like the European Medicines Evaluation Agency (EMEA), which is independent, but would be 100 per cent owned by the Commission and assigned very specific tasks, limited budgets, and be set up for a specific number of

years to run a programme. In our jargon, this is 'externalisation'. The advantage of working in this way is that it is a general approach that would apply across the Commission, not only to health, which the Commission has proposed to the Council of Ministers. Council has not yet decided to accept this but in the next few months this may change and we would be one of the first candidates. In contrast, if we had to create a new institutional system only for the public health sector it would be complicated and perhaps take four years before it could be set up.

If there were agreement between the institutions on how certain technical, highly specialised tasks could be delegated, with

activities of the programme, but I also see the potential for direct exchanges between providers and users, or Member States and health organisations which could run as an open debate and which might not lead to any European action now but would help us to understand the context of the situation.

So as well as advising you on policy you would see it as a way of bringing together the various parts of the health community who may not normally communicate so readily?

Yes, and these organisations can be rather hostile to each other! Indeed, there will be times when we would just be observers in the debates and in other cases we would generate the debate in order to get some feedback for a policy issue or a response to questions raised by others. There are so many areas where people would like us to intervene now and we can use the Forum to help shape a general understanding of what is possible, feasible, and desirable.

Some patient groups and NGOs are sensitive about involving industry in the discussions. What is your view?

I think the conditions for participation need to be made transparent. Industry should not use the Forum as a privileged partner. Of course when you put industry with NGOs you have to protect the patient organisations. I would not limit involvement just to the pharmaceutical industry but also include other industries as well, such as the IT industry.

Another concern is funding. Will the Forum be financed from the health programme budget, which is already limited, and will there be any funding to address the financial imbalance of stakeholders who participate?

First, it will be funded from the health programme as there is no other source of funding. It could be linked to the information objectives in the first strand of the programme.

Second, I see the need to support patient groups and NGOs in a special way. Unfortunately, when the consumer groups emerged there was a special direct EU subsidy voted through to support them but this did not happen in the health sector as the health sector developed too late in the process. However, while there is no structural support, there is a lot of support for the health sectors and networks within the health programme.

In the future, I would like to do away with the clientelism that sometimes exists whereby NGOs that lobby us have to be supported structurally for this purpose. I don't know if we should them subsidise them to be lobbyists – that is a different function and I think in the future we should distinguish their roles more clearly. I think we have to be careful to see what the legitimate interests are of all parties and how we can balance the influences to achieve an objective picture. We also need to develop the representativeness at EU level of organisations that may be very well developed at national level but have difficulties emerging on the European scene.

So you intend a much closer evaluation of the organisations that you will fund in the future?

Yes, value for money! It will be necessary to look at what the organisations consist of and who they actually represent. I have been used to a situation in previous jobs where some groups simply gave themselves the name of 'European'. The Health Forum itself will help us recognise those who have really something to say and to give them a greater role.

Looking back, what would you like to have achieved within the next five years?

If European citizens have the impression that something has been done at European level that really helps their health status in the next five years, then that would be a big success. At the moment our impact appears limited, as it is mediated through professionals. There is such a demand from citizens for health, as demonstrated by the increasing use of health websites for example. People don't want to have governments telling them what to do but as policy makers the least we can do is to validate the information provided through the internet etc.

I would also like to see that the evidence based healthcare approach, NICE etc, better shared and made more understandable to the general public. One should not underestimate the capacity of the general public to understand the issues.

The euro will be a big change in the next few years and, I would like citizens to be able to see a similar European impact on health – that Europe has improved their health determinants as well as their general health status. I believe this is achievable.

"There is no possibility of the Commission creating a large directorate dealing with public health."

Along with cost-sharing measures and prescription limitations, reference prices and spending caps are two of the main elements in the German strategy to control drug expenditure.[1] While in 1998 patients paid DM 5.5 billion for prescribed drugs in co-payments (equal to 14.1 per cent of total pharmaceutical expenditure), this amount decreased to DM 4.0 billion (10.0 per cent)

suspended until the end of 2003. During this period, the Ministry will issue an ordi-

France has a complex system for controlling the price of pharmaceutical products, developed over a long period of time.

by therapeutic area. One effect of this is that in some therapy areas targeted by the Government for cost savings there is effectively no prospect of achieving a price premium.

Price negotiations can be difficult and prolonged, and France is very definitely within the low priced group of countries in Europe. Moreover, innovative products may become available in France only after significant delay.

In addition to determining the reimbursement price for new products, the CEPS operates a range of other cost control methods focused on price. These operate at the level of the industry, in the form of

Italy: past reforms and future prospects

Claudio Jommi

"public expenditure on drugs is exploding"

The regulation of prices for reimbursable drugs* in Italy changed in 1994,[1,2] passing from an *administrative model*, where prices were set by the regulatory authorities, on the basis of cost information produced by the pharmaceutical companies, to a *surveillance model*, based on the AEP (Average European Price): the pharmaceutical companies became free to set their prices, provided that they did not exceed the AEP. If they did, products would have been delisted. The new model was consistent with the new regulatory environment, favourable to transparency, a cost-containment approach and a strict relationship between pricing and reimbursability.[3] Initially, only four countries – France, Germany, Spain and the United Kingdom – were considered to calculate AEPs. The principle of 'similarity' was adopted to identify the European equivalents of Italian products: same active ingredient, same route of administration, same or therapeutically comparable pharmaceutical form, and similar dosage. Generics were included in the calculations and OECD GDP Purchasing Power Parities (PPPs) were used to convert national prices into liras.

Industry criticisms

The pharmaceutical industry criticised harshly various aspects of the new model – which was regarded as instrumental to reducing prices – including the restriction of the comparison to only four countries, the inclusion of generics in the calculation of the AEPs (whereas the generic market in Italy is negligible) and the use of PPPs to convert national currencies. Pressure from the pharmaceutical industry and the Council of State, appealed to by the pharmaceutical companies, caused a review of the system in 1998. At present the AEP is calculated as a weighted average of all EU countries' prices (excluding Luxembourg and Denmark, due to the lack of data on the consumption of drugs, produced by IMS Health). In addition, PPPs were replaced by nominal exchange rates. The Italian government required that prices above their AEPs be lowered immediately. Prices below their AEPs, on the other hand, were allowed to reach their AEPs in six annual equal steps: in 2000 the third step was applied.

'Same price for the same drug'

In 1996, in order to curb the public pharmaceutical spending, the so called *'same price for the same drug'* principle was temporarily introduced. According to this model, drugs with the same active ingredient and the same or therapeutically comparable pharmaceutical form (but possibly different dosages) had to have the same price per unit of compound. If not, all drugs but the cheapest were delisted and thus excluded from coverage by the national health service (Servizio Sanitario Nazionale, SSN). This rule strengthened the relationship between pricing and reimbursement: as expected, many pharmaceutical companies reduced prices to maintain their products under SSN coverage, whereas some other companies decided not to reduce prices and their drugs were consequently delisted. In 1998 the 'same price for the same drug' was in principle abolished: according to the new regulation, drugs in the same 'therapeutic class' (mostly coincident with the fourth level of the ATC classification) must have the same reimbursability status, provided that they are not priced above their AEP (even if they have different prices).

The contractual model

In 1997 a new *contractual model* was introduced for prices of products licensed through the European procedure.[4] This model was extended to drugs licensed through the mutual recognition procedure in 1998. Cost-effectiveness (using the SSN perspective), the product's price in other countries, sales forecasts (in order to control public expenditure) and industrial implications (effects on investments, employment, exports) were listed as the

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* Prices for non-reimbursable drugs have being set freely by the pharmaceutical companies since 1994, even if the regulatory authorities monitor them. Initially a ceiling to their growth rate was imposed. At present, (i) the pharmaceutical companies are simply obliged to report any price increases to the Ministry of Health and the Interdepartmental Economic Planning Committee; (ii) no more than one increase is allowed per year; (iii) the Ministry of Health may intervene to prevent unwarranted price increases.

parameters to be considered in the negotiation. Negotiations were run by the CUF* on the basis of a preliminary investigation managed by a technical group made up of representatives of the CUF, the Departments of Health, Treasury and Industry. In 2001 the contractual model has been partially reviewed:

i even if the CUF is still accountable for the final decision, the negotiation is now managed by the technical group, where a member of the CUF simply participates as an 'outside observer';

ii the technical group includes experts coming from the permanent Central-Regional Governments conference;

iii an economic evaluation dossier will be required only for important innovations.

The contractual model could in principle have been accepted comfortably by the pharmaceutical industry: economic evaluations should have been run using the SSN perspective; industrial parameters were included for the first time since 1994. However, the pharmaceutical industry criticised the way the CUF managed negotiations, because the Committee focused on therapeutic value (degree of innovation) and costs consideration (sales forecasts), overlooking the industrial issues and the relationships between drugs and other healthcare services.

Reference pricing

Finally, the introduction of a *reference pricing system* is scheduled for July 2001. For active ingredients with a generic available on the market, the SSN will reimburse the average weighted price of drugs with a 20 per cent minimum lower price than the originator (provided that the average is calculated on drugs with the same active ingredient, the same route of administration, the same form and the same dosage). The patient will cover the possible difference between the price of the actual prescription and the reference value. Reference pricing will be applied only to 49 active ingredients, due to (i) the absence of a generic drug for many out of patent active ingredients (a generic drug is available for 50 per cent of the out of patent market) and (ii) the limited dimension of the out of patent market (25 per cent of the drugs covered by the SSN).

Analysis

There are several key facets to price regulation in Italy. Firstly the regulation is quite complex and parameters are heterogeneous. This could be interpreted as the result of the absence of a strategy in the regulation of prices. The regulatory framework looks like the 'sum' of responses to different short term needs:

i to implement a transparent model (based on the AEP), after the 'Tangentopoli' era;

ii to contain public expenditure and respect the global budget for pharmaceutical spending, introduced in 1994 and abolished in 2001 (AEP, contractual model, 'same price for the same drug');

iii to link prices with reimbursability taking into account the therapeutic value of the drug ('same price for the same drug');

iv to pursue static efficiency (price competition among similar drugs) ('same price for the same drug' and reference pricing).

Secondly, dynamic efficiency ('appropriate' incentives should be present to encourage competitive research and development) and industrial goals have been mostly neglected and pricing policy has been mostly driven by short term cost-containment and long term health policy objectives. The principle of pricing on the basis of the therapeutic value prevailed. This approach is consistent with the central role played by the CUF, made up of pharmacologists, pharmacists and clinicians.

The future of pricing policy is difficult to predict. On one hand the regulatory authorities seem to be paying more attention to the changed nature of the policy field: it seems the CUF has abandoned its central role in the negotiation of prices (even if the CUF has the ultimate decision) and the scope for other factors (in addition to therapeutic value) could increase in the near future. On the other hand, public expenditure on drugs in 2001 (+25 per cent; +14 per cent in 2000) is exploding. This is due to:

i the abolition of co-payment;

ii the abolition, or widening, of some of the CUF's Notes (the compulsory guidelines introduced in 1994), which enlarged the public coverage of some drugs (for example SSRIs and lipid lowering drugs);

iii the introduction of new and expensive drugs like the anti-inflammatory Cox-2.

Drug public expenditure increase could foster a policy orientated to:

i a short term general prices cut;*

ii a price negotiation again driven by a cost-containment approach;

iii a gradual extension of reference pricing to therapeutic classes, as in phases two and three of the German model), together with a strengthening of information policy on generics.

Finally, the more Regions are made accountable for their health budget,[5] the more they are putting pressure on the central regulatory authority to intervene – either with a stringent centralised cost-containment approach, or by decentralising some drugs policy, for example local reference prices and formularies.

* Price cuts and freezes have been used extensively in the past. For example, in 1995 the government mandated a general price cut of 2.5 per cent for products covered by the SSN. The price cut was raised to five per cent for companies whose total revenues had increased by more than 10 per cent in 1994 compared to 1993. This was followed by a virtual price freeze in 1996.

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Profit or loss?

Fulfilling dual aims in pharmaceutical price regulation in the UK

The British system of regulating pharmaceutical prices is unique. No other country directly regulates the profits of companies selling products to its publicly funded healthcare service. The British system is an outcome of several special features of healthcare delivery and industrial regulation in the UK. The National Health Service is a highly centralised, tax-funded system that occupies a monopsonistic position in the pharmaceutical market, while the British state is notable for its preference for an arms-length relationship with industry and minimal regulation. These two factors combine to form the organisational context of pharmaceutical price regulation in the UK. The outcome – the Pharmaceutical Price Regulation Scheme (PPRS) – is an attempt at fulfilling simultaneously health and industrial policy goals. It aims to achieve the health policy goal of cost containment and the industrial policy goal of a successful and internationally competitive pharmaceutical industry.

Operation of the PPRS

The PPRS has existed in one form or another since 1957 when the first Voluntary Price Regulation Scheme (VPRS) was signed by government and industry in response to the r-1.2owhen t132 Tw(ctly01T*005 Te)Tjne to form the orgTw(foted s00.0eV,-1.26when *ual priDf regu

not themselves regulated, what it in fact does is effect to some degree the amount, in aggregate, that government pays for NHS medicines. High prices in one part of a company's portfolio must be offset by lower prices elsewhere. It regulates, but does not set, prices directly in so far as they cannot easily be raised once they have been set by companies and so in real terms prices of individual medicines continually fall. Only if company profits fall significantly below the allowable ROC is a rise in price of an individual medicine considered by the Department of Health.

The basic 'dynamic' of the PPRS is therefore that as real prices of products are eroded by inflation, pharmaceutical firms must release new medicines into the marketplace in order to maintain their allowable profit level. Free pricing at launch is a key feature of the system and such releases enable companies to move back up to their allowable rate of return if they have fallen back from it. Through this, the scheme aims to encourage innovation.

The scheme exercises no control over volumes of consumption and therefore cannot determine the overall NHS drugs bill. The release of new medicines into the marketplace could, in theory, have a significant effect on NHS costs if demand for them proved to be very high. The effect of the scheme is therefore quite limited: it helps, where a company is already at its profit ceiling, to ensure that the effect on the NHS's costs of the release of new drugs under patent protection are to some degree compensated for by price reductions on other, older products.2release 2a2un-,oexerc6 Tw[(of the eeregate, ere 6 Tw8tly in so twyic0 -1.27.640.0spnr 2a2)i.9755 143.312 321.047 smeow the allowable ROC is a rise ex

alongside particular circumstances that underpin its uniqueness. The position of the Government as the dominant purchaser in the market place is the key factor. This is important in the European context where the interconnectedness of price regulation with state-dominated healthcare markets means that synergy between national systems is extremely difficult to achieve in the absence of convergence in the funding of healthcare.

Aside from features of the British healthcare system, there are features of the UK market that appear to enable the particular form of the PPRS. The market is small by international standards and this can only in part, it seems, be attributed to NHS rationing. Indeed, as cost sharing mechanisms are extremely limited, direct payments for medicines by British consumers are lower than in most other European countries yet prescriptions per head are 30–80 per cent lower in the UK than in other European countries such as Germany, France and Italy.[5] The smaller volume of consumption inevitably allows greater flexibility over price.

Furthermore, British physicians are extremely conservative in their uptake of new medicines, seemingly waiting for evidence of their effectiveness to be well established.[6] Such therapeutic conservatism allows greater flexibility over the price of new medicines, as a surge in volume at launch is far less likely in the UK than elsewhere. These two factors mean that higher prices and free pricing at launch have less effect on overall costs than they would otherwise, or elsewhere.

Convergence?

The PPRS shows how the regulation of pharmaceutical prices and the structure and operation of publicly funded healthcare services are interlinked. Furthermore it suggests that characteristics of consumption, prescribing and the pharmaceuticals market that are to some degree separate from the structure of healthcare services are important features of the landscape in which any regulatory regime develops. Any attempt to develop greater uniformity in the price regulation of pharmaceuticals across the EU is likely to encounter these quite fundamental obstacles.

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Competitiveness, innovation and new market dynamics

"A successful pharmaceutical industry is a prime example of what is needed in a successful knowledge economy. The UK's pharmaceutical industry has an outstanding tradition and has contributed very substantially to our economy and to the welfare of our citizens".

Vincent Lawton is Managing Director of Merck Sharp & Dohme.

The pharmaceutical industry too often gets a bad press. So it is refreshing to be able to begin this article with the words above – especially so when those words come from no less a source than Britain's Prime Minister, Tony Blair.

The significance of PICTF

To his credit, Mr Blair has shown commitment to the pharmaceutical industry in Britain, by agreeing to establish the Pharmaceutical Industry Competitiveness Task Force (PICTF), to look at what can be done to make the UK even more attractive as a location for the industry. After a year's work programme, in which I was involved as a member of the task force, PICTF published its report at the end of March.[1] I think PICTF achieved three things.

First, it showed that different government departments can work with each other,

number of practical steps that we can take here and now to make Britain an easier place in which a global pharmaceutical company can do business. And third, it established the idea that the Government and the industry need to continue working together, at a very senior level, to ensure that we make further progress. To that end a Ministerial Industry Strategy Group is being set up to take the PICTF relationship and its agreed actions forward.

In short, PICTF is an excellent example of the much-vaunted public-private partnership in practice. However, the welcome I extend to the PICTF report is qualified. The reason for this lies in what I see to be a continuing gap between the British Government's pro-industry sentiments in their speeches and statements, and what is happening on the ground.

Unfortunately, unless we close that gap, the steady loss of pharmaceutical investment to the UK, as to Europe as a whole, will continue.

The competitiveness gap

The UK's competitiveness malaise is not solely a UK problem. The EU as a whole is losing out to the USA as a source of an innovative and competitive drive in pharmaceuticals.

Ten to twenty years ago, the European and the US industries were neck and neck in the rush to get new molecules patented. Today, the US industry is approaching half of all registered patents -– and the EU has fallen back. The dominance is even greater when stated in terms of patents cited, where the US industry accounts for over half of patents cited and the EU under one third.

The stated objectives of NICE are not the issue. Everybody wants to get the best medicines to patients as quickly as possible. We all want to eliminate clinical practice that is either out of date or was never effective in the first place.

Unfortunately, the British experience to date is that NICE has become self-defeating. We have the new phenomenon of

prices. As figure 1 shows, for selected 1990s breakthrough products, the price of subsequent entrants was significantly lower, by an amount up to 75 per cent in real terms.

– In the UK there is large scale competition in the off-patent market. There are over 100 suppliers, distributors and wholesalers of generics. Over 70 per cent of prescriptions today in the UK are written generically.

The evidence is clear: competition exists in the pharmaceutical market and it has a clear and demonstrable effect on both quality and value. Competition works.

Enabling conditions

A greater reliance on market competition and consumer choice is one of a number of 'enabling conditions'[4] for competitiveness that my company, Merck & Co., Inc., has developed based on work by Michael Porter. Those conditions in full are summarised in figure 2. Other important factors which make for a competitive industry include adherence to the rule of law and a strong commitment to basic biomedical research.

American companies have long been champions of deregulation and market reform. In the UK this position has led us to advocate the progressive deregulation of the Pharmaceutical Price Regulation Scheme.

Where next for pharmaceuticals in Europe ?

Erkki Liikanen

European Commissioner for Enterprise

The provision and funding of healthcare is widely seen as one of the key challenges facing modern societies. Every time we open the newspaper we see new questions raised, and new comparisons made between the health systems of different countries and regions – debates around the delivery of specific medicines for specific diseases and the funding of new treatments.

This is a situation that will continue to exist for the foreseeable future. The pressures of ageing populations, new diseases and even the recurrence of old diseases, such as tuberculosis, represent a continuing challenge for post-industrial societies across the world. The medicines to treat disease are of course central to this debate; there is a social imperative, and wide consensus, that citizens should have rapid and open access to the treatments they need.

"there is a social imperative, and wide consensus, that citizens should have rapid and open access to the treatments they need."

Role of the EU

A primary objective of the European Union and its Member States is to improve the length and quality of life of its citizens. This is a responsibility that both the Commission and the Member States take very seriously. The past ten years have seen for example the development of a Community health strategy, as well as a string of major advances in cooperation at Community level and beyond in the ways we develop, assess, market and deliver medicines.

The 'Bangemann Round Tables' in 1996-1998 examined obstacles in the way of achieving a single market in medicines. A clear conclusion was that different sectors of the pharmaceutical industry are facing different challenges, as are patients and Member States; these different actors are now more closely linked than ever, and efforts to influence the environment for one part of the equation will inevitably impact on all the others. Following the Treaty of Amsterdam, which enlarges the European Community's competence in public health, the Commission now has more scope for involvement in such issues.

The High Level Group

We face a range of demands which are all more or less explicitly linked, and it was in order to attempt to balance out as many of these as possible that Health and Consumer Protection Commissioner David Byrne and I invited stakeholders from a wide variety of interests to take part in the 'High level Group on Innovation and the Provision of Medicines'.

This group, which comprises some of the major players from the different industry sectors, plus Member States' Industry and Health ministers as well as specialists in patients interests, and mutual organisations, represents an attempt to focus on an agenda that has so far been approached with considerable caution by both public and private stakeholders.

The medicines agenda for Europe sits broadly on pillars which interact with and depend upon each other. It is worth setting these out, and looking here in some detail at the situation we are faced with, and some of the ways in which we might make progress.

The medicines agenda

Over many years, a variety of cultural, medical and social traditions, mixed with government healthcare policy, have shaped the structure of the demand for medicines. These infrastructures, consisting of different structures and reward systems, result in different approaches to ensuring the best possible patient access to medicines, and different balances between this objective and its counterpart – an effective, internationally competitive and innovative industry that produces a steady stream of new treatments.

As well as their complementary responsibilities in relation to health, both Member States and the Commission have a responsibility to foster the competitiveness of the Community's industry, by encouraging competition to the benefit of consumers, and enhance performance on a world-wide

basis. Europe has over past years seen a relative decline in competitiveness and

The European market in pharmaceuticals is fragmented. This has considerable impact on the competitiveness of the pharmaceutical industry. Member States have different market structures reflecting differences in the way they organise and fund their healthcare services (including 4a9 sl ied. rences in

Price divergences within Europe fuel the process of parallel importation – the re-exportation of branded medicines from low priced markets to high priced markets. Growth in parallel trade from beyond the expanding European borders cannot be excluded.[1] On patent expiry, the lucrative market position enjoyed by leading branded products increasingly comes under

Enterprise, the Commission Directorate for industrial policy. The Commission has been forced to try to reconcile its legal duties to protect the process of parallel importation under the free movement of goods and competition rules with its indus-

Harmonisation

These important findings may provide renewed stimulus for Community action on the very national price regimes that insulate the sector from competitive forces. At the same time, Commission attempts to tackle the issue of price divergence at source by seeking to harmonise national rules on pricing and profit controls have not found much favour from either the Member States, who regard this as a matter of health policy and therefore of national competence, or from the research based industry, who distrust attempts to set average 'European' prices for their product. Previous efforts to reach consensus under the auspices of the three Bangemann round tables failed to deliver.[8]

The adoption of the so called Price Transparency Directive in 1989 was originally intended as a first step, but may be the last step in the direction of Community regulation.[9] The Commission has not established sufficient consensus among the Member States to move towards a stricter Community level regime. The 1989 measure is limited in its aims: it does not harmonise the levels at which national price controls or profit caps are fixed, but merely endeavours to ensure that the national procedures are efficient, transparent and fair.[10] Moreover, if transparency improves, it becomes easier for the Commission and stakeholders to establish whether or not the Treaty rules on free movement and competition are being respected, particularly if these processes favour domestic production over imports. The recent attempt by the UK parallel trade organisation for judicial review of the modulation provision in the UK Pharmaceutical Price Regulation Scheme (PPRS) is a case in point.*

Where to now?

The recent findings that institutional and regulatory factors might serve to protect and insulate the European industry from competition as opposed to forming barriers to the further expansion of what is usually viewed as one of Europe's most competitive sectors may well offer the Commission a new point of departure from which to tackle the vexed issue of price regulation and concomitant divergence throughout the Community. The key policy questions will be whether the Commission can succeed in convincing national governments to accept intervention in sensitive health policy issues. There are a number of possible avenues to explore.

A more vigorous promotion of generic competition is certainly one avenue, but here the Commission will have to reopen the debate on how far the R&D based companies should continue to enjoy intellectual property right protection – still a matter of national law. Another option would be to adopt the current American experiment and seek to move more prescription products into the OTC market. This might well appeal to budget conscious governments. Inevitably both strategies will lead to bargaining for regulatory concessions on the part of the R&D based industry. A certain relaxation of the current Community restrictions on advertising of prescription products to the public may well be a possible candidate for review in the trade-off game. The Commission should also be careful to ensure that it has the right pressure groups lined up on its side. The debate on how to tackle pricing can no longer be safely confined to a privileged dialogue between industry and governments.

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3. *Scrip* 2001;2638(2). The Commission has however supported the research-based industry in its concerns to limit pre-patent expiry development work for commercial purposes.

4. The judgement of the Court of First Instance in the Bayer case illustrates the limits of its powers in this respect Case T-41\96, Bayer v. Commission. Judgement of 26 October 2000.

5. The European Court of Justice had already made it eminently clear that divergent national price regulations in the pharmaceutical sector do not exclude the operation of the Treaty rules on free movement in Merck and Primecrown 1996. Joined Cases C-267\95 and C-268\95.

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* The research based industry has used the Directive to challenge national schemes that use imported product prices as a benchmark, see *Scrip* 2001;2627 (5). See the complaint filed by LIF, the Danish pharmaceutical industry association, *Scrip* 2001;2612(3). The Commission has also invoked the Directive to launch infringement proceedings against the Greek and Finnish governments, see *Scrip* 2000;2589(7) and *Scrip* 2000;2558(6) respectively.

The National Institute for Clinical Excellence (NICE) for England and Wales was created to evaluate new health technologies and offer advice to the National Health Service (NHS) on whether these technologies are clinically and cost effective. The performance of NICE has been less than impressive; for example, it has approved all new pharmaceutical products and failed to articulate a hierarchy, or league table, of relative incremental cost effectiveness. Consequently, NHS expenditure has been inflated and resource allocation has been distorted.[1]

The example of NICE is an imperfect model for the development of a European wide system of health technology appraisal which informs or determines reimburse-

Strategy for action

Commission proposals to combat antimicrobial resistance

The emergence of antimicrobial resistance has become a major public health problem. Overuse and misuse of antimicrobial agents have encouraged the growth of resistant organisms. Infectious diseases that have become resistant to standard antimicrobial treatment present a threat to human and animal health.

Helmut Walerius

The European Commission has adopted a Communication setting out a Community Strategy to combat the threat to human, animal and plant health posed by antimicrobial resistance. It has also adopted a proposal for a Council Recommendation on the prudent use of antimicrobial agents in human medicine.

The Recommendation encourages national governments to take measures to contain the spread of antimicrobial resistance by encouraging a more prudent use of such agents. The proposed Recommendation represents the first attempt at Community level to take action in the field of human medicine and completes the various actions already under way with respect to veterinary and phytosanitary uses of antimicrobial drugs. The Strategy gives a comprehensive overview of the ongoing actions with respect to surveillance, prevention, research and product development and international cooperation. The Göteborg European Council conclusions underlined again the need for action to tackle the issue.

The Community strategy

The Community strategy is multidisciplinary and based on scientific advice. The evaluation by the Scientific Steering Committee (SSC) of the European Commission, in its opinion of 28 May 1999, stated that prompt action was needed to reduce the overall use of antimicrobial agents in all areas: human medicine, veterinary medicine, animal production and plant protection. The strategies most likely to be effective in the control and containment of antimicrobial resistance will be those that can be introduced speedily without undue costs in all Member States, and which can be monitored and enforced across the EU. The SSC pointed to the possible need to introduce effective legislation and regulation to support the achievement of its proposals. The important areas of action identified concern the prudent use of antimicrobial agents, prevention, the development of new methods for prevention and treatment, and monitoring the effects of interventions.

Successive European Health Councils have also asked the Commission to develop an initiative on the use of antibiotics in human medicine. The Community Strategy outlines a series of ongoing and upcoming EU actions at different levels: support for awareness raising amongst doctors, vets, farmers, and patients; 'prescription only' use in all sectors including agriculture; surveillance of resistance against certain antimicrobial agents and the consumption of these agents; monitoring and reporting on residues in food; phasing out of all uses as growth promoters in feed and as markers in genetically modified organisms; review of existing uses as food additives. In addition research and development of new antimicrobials and of alternative treatments and vaccines is being encouraged. International cooperation in efforts to combat antimicrobial resistance in international forums such as the World Health Organisation (WHO), and in particular with candidate countries as well as developing countries, is to be reinforced.

The Commission has identified four key areas of action and a number of specific actions within those areas that form the major elements of the Community strategy to contain antimicrobial resistance:

1. Surveillance Monitoring the evolution and the effects of interventions through the establishment/strengthening of accurate surveillance systems on antimicrobial resistance in the human and veterinary sector and the consumption of antimicrobial agents.

Action 1: Develop coordinated and coherent surveillance networks at the European level. Encourage the participation of non-EU countries and the links between already established surveillance networks in human and veterinary medicines.

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Action 2: Put in place and improve the collection of data on consumption of antimicrobial agents in all sectors.

2. Prevention of communicable diseases, and infection control to reduce the needs for antimicrobial agents. This includes the prudent use of antimicrobial agents which entails the need for improved product information for authorised antibacterial medicinal products and the promotion of educational and behavioural actions towards professionals (clinicians, veterinarians, farmers) and the general public.

Action 3: Increase the importance of antimicrobial resistance information for the market authorisation process in human medicine, veterinary medicine and agriculture.

Action 4:

antimicrobial resistance among the general public.

– Encouraging research on the development of antimicrobial resistance and the development of rapid diagnostics to enable efficient early treatment of communicable diseases.

– Identifying or establishing, for these purposes, national organisations with effective coordination between the Member States and the Commission.

The Commission will establish an advisory group through the Community network on the epidemiological surveillance and control of communicable diseases to support Member States' efforts and ensure a coordinated Community approach in addressing this action plan. The Commission will also ensure close cooperation with EEA/EFTA countries, applicant countries and international organisations such as WHO to increase synergy and avoid duplication of effort in the fight for a prudent use of antimicrobial agents. The Commission proposal also sets a time frame for the accomplishment of the various measures.

Antibiotic Resistance:
A hazard to public health

Few would question that antibiotics have vastly contributed to the improvements in public health that we have witnessed over the past 50 to 75 years. The chance of previously fit people in Europe dying of pneumonia, a skin infection, puerperal fever or tuberculosis has declined dramatically. We are however on the edge of an abyss – antibiotic resistance is now 'a major public health concern', so said the 1998 UK House of Lords Select Committee.[1] Is this problem as severe as some believe, what is its extent and what can be done, if anything, to reverse it?

Richard Wise

Charles Darwin died almost 120 years ago. If he were alive now he would understand perfectly the problems we face. Bacteria display the evolutionary battle most vividly: exert an ecological pressure and a response will be seen – survival of the fittest. For antibiotics, this means that overuse (or possibly any use) will be followed by antibiotic resistant bacteria emerging. No doubt Darwin would say that this was inevitable, and Professor Steve Jones at London's University College, who has updated the *Origin of the Species*, would agree. We should examine why this is the case and what can be done to delay or minimise the impact of resistance.

Bacteria are ideal subjects for the study of evolution. They divide frequently (once every 20 minutes rather than 20 years for humans), they have many and sophisticated ways of exchanging genetic information (unlike us – that is, until 'genetic engineering' becomes more widespread!) and the selection pressure for change is so great, i.e. vast antibiotic use. It is very difficult to estimate how much antibiotic use there is but it is about 100 million kilograms worldwide per year. When bacteria become resistant, therapy is likely to fail. Doctors will then have to prescribe other agents – often more expensive, sometimes less safe.

Use of antibiotics

Before one can attempt to control antibiotic use, there is a need to know where they are used. Figure 1 is a very rough guide.[2] The statistics will differ by country even in a relatively homogeneous region such as the EU. Animal use in particular varies considerably. As shown, total use is equally divided between animals and man. Two points stand out. Firstly, in humans, the community use of antibiotics greatly exceeds that in hospitals. Secondly, in animals, on a worldwide basis growth promotion (that is antibiotics being used for economic and not health needs) greatly exceeds therapeutic use. A recent US report estimates that 70 per cent of all antibiotics are used as growth promoters in livestock.[3] EU legislation has restricted this misuse in recent years. The agricultural aspects are important as many animal bacteria can infect humans directly through farm work-

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ers, or indirectly, such as Salmonella and Campylobacter, which cause food poisoning. Animal use and abuse of antibiotics must be addressed in parallel with that in human medicine.

Community use

The greatest misuse of antibiotics is in the community. Up to two thirds of antibiotics are used here for respiratory tract infections, usually the common cold, sinusitis, bronchitis and sore throats. These simple infections are overwhelmingly caused by viruses and therefore a great source of antibiotic misuse (antibiotics only being effective against bacteria). Why are so many prescriptions given for these self-limiting diseases? Patient expectation of a quick remedy is an important factor. To this must be added diagnostic uncertainty – 'what if I am wrong?' thinks the doctor.

It is not surprising that one of the bacteria which is causing considerable current concern, *Streptococcus pneumoniae* (an organism implicated in many cases of pneumonia and meningitis), has developed resistance to many of the antibiotics which are employed to treat respiratory tract infections. In particular, resistance to the penicillin family of antibiotics is widespread and is often combined with resistance to other agents. The resistance rate to *Streptococcus pneumoniae* can vary greatly, for example from very high rates of penicillin resistance in Spain yet low rates in Italy. Quite why there are such differences is poorly understood. Similarly resistance rates of this bacteria to erythromycin (another commonly used antibiotic) is far higher in France than in the UK. In this case the incidence of resistance does seem to mirror national usage of this drug, which is also lower in the UK than France. There is greater potential for resistant bacteria than a generation ago, as vulnerable groups such as young children and the elderly live in kindergartens and residential homes.

Hospital use

In hospitals the problems are very different. Although the overall use of antibiotics is much less, they are used more intensively, the patients are more severely ill and the possibilities for cross infection are enormously enhanced. It is not surprising that it is in the Intensive Care Units of hospitals that the major antibiotic resistant infections are encountered. Rather than the respiratory tract bacteria, which are the major source of conb1rn in the community, a different group are found in hospitals. The media in many countries have highlighted problems with the so-called methicillin-antiresistant *Staphylococcus aureus* (MRSA, often labelled the 'super bug'). In many European countries this is now a major problem. As infection control or isolation facilities are often over stretched, infections caused by this organism are more difficult to treat (by using more expensive and possibly more toxic antibiotics) and the patient stay in hospital is prolonged and may be associated with increased mortality. The problems are compounded by the general pressures on hospital care with too few nurses and beds leading to pressure to shorten hospital stay. This can cause a breakdown in the infection control procedures which all hospitals attempt to apply. In my own hospital, patients, for the best of motives, are often moved between three or more wards during their in-patient stay – a recipe for cross infection mayhem. Hospital acquired infection, often caused by multi-resistant bacteria, imposes a great economic burden. In a European study of more than 10,000 patients, 45 per cent were found to be infected and one third of these acquired their infection while in hospital.[4]

Assessing the problem

What can be done to improve this accelerating and accumulating problem? Firstly, it is important for both national governments and local institutions to undertake meaningful surveillance of antibiotic resistance. It is self evident that it is necessary to know the extent of any problem in order to measure the effect of meaningful change. Yet so much surveillance is conducted in an unquestioning way. Most commonly laboratories report the numbers of isolates and their antibiotic resistance patterns to local, antiregional or international centres. This has the advantage of being inexpensive but is of dubious value, as there is no denominator data; and often there is poor access to these results by those who would benefit most. There is a need to collect more robust information so that clinicians can change clinical practice to optimise their use of

Rational use

Secondly, there is a need to educate the medical and allied professions on rational antibiotic use. Unnecessary use in viral infections has already been mentioned. Protracted courses for simple infections, such as those of the urinary tract and the over use of valuable agents for the prophylaxis of surgical operations are obvious candidates for change. The medical profession should also integrate the information which is emerging from the recent science of pharmacodynamics which studies the relationship between the drug and the bacteria. Pointers are emerging that suggest ways to use drugs to their maximum effect and reduce the likelihood of the emergence of resistance. Changing doctors' prescribing habits is difficult and will need to be long term beginning in medial school. There are encouraging signs. In the Netherlands a concerted effort to reduce antibiotic prescribing for many of the more trivial diseases has been successful. In the UK a reduction in antibiotic prescribing by general practitioners of about 20 per cent has been observed over the last two years. There is a need to educate the public, to reduce their expectation of antibiotics for the more minor respiratory infections. A coordinated European approach would be a highly worthy ambition.

There is a need for an extended role for the drug licensing authorities. Should less effective agents be withdrawn? Should certain antibiotics only be available under stricter control in hospital? The European Agency for the Evaluation of Medical Products (EMEA) and the national bodies must adopt a more proactive approach.

Controlling infection

Infection control is at the heart of the problem of reducing the impact of antibiotic resistance. There must be adequate infection control teams who should set themselves targets for controlling their local problems. Community infection control is as yet an underdeveloped area. In particular, how to influence infections in day care and elderly care units must command greater priority. A new cadre of 'community infection control' nurses should be developed.

Antibiotic resistance and infection control have been Cinderella subjects for research funding. Scientifically more glamorous areas such as the mechanisms of antibiotic resistance have attracted funding, yet

The use of antimicrobials can result in the unwanted 'side effect' of the development of resistance. Economists conceptualise this 'side effect' as a negative 'externality' resulting from the consumption of antimicrobials.[1–5] A classic example of a negative externality is pollution, where a cost is imposed on others not directly involved in the decision to produce or consume the commodity causing the pollution. Resistance is an externality that has both global and inter-generational impacts.[6] Once resistant micro-organisms have developed, their spread (although dependent on a number of epidemiological factors) will not be halted by national borders. Collective action across countries is therefore needed.[7] Additionally, many of the major effects of resistance are likely to be incurred by future generations, and policy decisions will therefore have to weigh current costs and benefits against those occurring to future generations.[3]

Surely antimicrobial resistance is a biological problem, which will be solved by scientific means? In part this is true, yet there are a number of aspects where the economics of antimicrobial resistance can help in determining the most efficient means of containing resistance. This article emphasises three main aspects, discussed below.

Bases for policy development

What are the criteria for developing policies to deal with resistance? What should the aim of such policies be? Should they aim to eradicate resistance or just reduce its development? If the latter, by how much? Economics can help in thinking through some of these issues. By concentrating upon efficiency – maximising outputs for given inputs– economists seek to determine the optimal rate at which resistance should be allowed to develop, balancing the costs and benefits of antimicrobial usage over time.[1,8]

The issue of this optimal rate of antimicrobial usage can be informed, for example, by assessing the 'time preference rates' of citizens and policy makers. Time preference is the extent to which people prefer to trade current, against future, costs and benefits, and is operationalised through the notion of a 'discount rate' – similar to a real rate of interest. The issue of whose preferences should count in such decisions is one which is dealt with extensively by both economists and philosophers.[9] Time preference rates specific to antimicrobial usage have not been explored to date, but are vital in assisting policy makers in acting on behalf of both current and future generations.

Development of policy responses

Medical literature and research tends to focus on physical methods of reducing the transmission or emergence of resistance, such as through improved hygiene or the cycling of antimicrobial treatments. Within economics the focus tends to be on developing policy responses that 'internalise' the externality of resistance. In relation to antimicrobial resistance this would mean, for example, providing incentives for consumers, prescribers and/or producers to take account of the possible 'externality' costs of consumption of antimicrobials to society. Although work in this area has been limited, there has been some discussion of policy instruments such as taxation and transferable permit markets in relation to use of antimicrobials in primary care in the UK's NHS[3] and a more extensive assessment of how such a permit system might operate.[10] With such policy responses there are, however, important issues to consider. For example, there are difficulties in directly charging for healthcare provision (unacceptable in many cultures, and in many ways inherently undesirable from an efficiency point of view). There is also the paradox that containing the emergence of resistance requires policies that result in lower antimicrobial usage, yet the resultant loss in revenue for pharmaceutical companies reduces their incentive to research and develop new antimicrobial treatments.

Evaluation of alternative policies

Determining optimal policy responses to contain antimicrobial resistance requires consideration of their respective costs and benefits. The development of methods for the economic evaluation of healthcare has increased rapidly over the last twenty years, and the application of these methods to antimicrobial resistance is a way of ensuring that the most cost-effective policies are being followed.[11] There are, however, two sources of concern in relation to economic evaluation and antimicrobial resistance. The

first is that in most, if not all, evaluations of treatments which use antimicrobials no account is taken of the impact upon the development of resistance and its consequent costs.[2] Although, theoretically, economic evaluation should be able to incorporate the costs of this externality, economics can also explain why this does not, in practice, occur. On the one hand, each

Food matters

Why health must be a factor in the reform of the Common Agricultural Policy

The Common Agricultural Policy is under great pressure. We must stop talking about the outcomes of ill health and focus on the determinants. Changing the Common Agricultural Policy is a symbol of whether the political will to act is real or rhetorical.

Tim Lang

I have argued before in these pages that the terrain of EU food policy is witnessing remarkable change.[1] A health dimension to reform of the Common Agricultural Policy (CAP) has to be part of this process. After decades in which agriculture has dominated not just the finances of the European Union but its political attention, suddenly other food matters are getting a look in. This is to be welcomed. The Commission and Council, famous for arcane and complex meetings to negotiate new agricultural financial packages, have woken up to the fact that there is more to food policy than the bizarre architecture of farm support or the joys of calculating the cost of labyrinthine wheat and dairy régimes. Fear of unmanageable consumers stalks the corridors of power.

A changing landscape

It is food safety, as we know, that has grabbed political attention. In 2000, the Food Safety White Paper promised a wide range of new legal initiatives including a consolidating food law and action on issues ranging from labelling to irradiation. The EC Regulation of 8 November 2000 is now delivering on that process. Even nutrition, long the Cinderella of political attention, got a mention in the White Paper. Not enough, but at least something.

The speed of change is symbolised by the creation of a new Directorate General, DG Sanco, in charge of consumer and health protection and most recently the new European Food Authority (EFA). This new body will start work in 2002. At the national level, Member States such as Greece, Ireland, the Netherlands and the UK have either set up food agencies or are doing so.

This rapidly changing landscape demands at least two responses. First, there needs to be an open but tightly monitored system for watching the changes underway. A recent meeting in Dublin, hosted not by the EU but by the WHO's Office for Europe and the Food Safety Authority of Ireland, began looking at what each government was actually doing to reform its food safety and standards institutions and procedures. For some the issue is food safety. For others the issue is wider food and health policy.

Second, there is a need to be clear about the purpose of all this is. Although there is great potential for the EFA, it is essential to keep asking whether it is necessary. Across Europe, we need to clarify what value agencies add to food policy formulation and implementation. How will this plethora of agencies relate to one another? Sceptics argue that the changes are driven more by the need for politicians to be seen to be doing something than by a genuine desire to shake up food standards and wrench back control from big food companies or agribusiness that have so long dominated EU food and agricultural decision making.

Will EFA be able to deliver the changes the Commission seeks? One fault-line is that the need to have a closely integrated system of risk assessment, risk management and risk communication is confused by the current plan. Under this, the Commission remains in charge of risk management while EFA is charged with risk assessment and communication. Yet the classical model of risk analysis posits that all three must be seamlessly connected. This and other issues questions were explored recently by a report for the European Parliament.[2]

The problems of CAP

The Common Agricultural Policy is the biggest illustration of the delicacy at hand. CAP accounts for about half of the total EU budget. CAP expenditure in 1998 was

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38,748 million euros. No wonder it is the most politically divisive EU policy. The good news is that this is now realised. The bad news is that the realisation is more outside the EC than inside. Europe still lacks a commitment to create a food policy rather than an agriculture policy.

The problem with CAP is not that it does things badly but that it is based on an out-of-date model and set of policy goals. CAP was born out of the ashes of the food deficiencies of the Second World War. The hunger of the 1930s framed its designers' approach. The great architects of CAP and the Food and Agriculture Organisation's World Food Programme argued that what was needed was to unleash investment and science to raise productivity. If adequately distributed, they assumed that public health would improve. By the mid 1970s, this model was already inadequate but rather than going back to policy basics and asking: 'What do we want our food system to be and do?', CAP was by then set in motion. The only conceptual change to the model was to add health education – subsequently criticised as too individualistic and tacitly putting responsibility for food supply onto consumers, a task they cannot possibly execute. This old model is represented in Figure 1.

A model for the future

What is now needed is a new model (figure 2) around which CAP should be reformed: a joint commitment to *good nutrition*, *food safety* and *sustainable food supply*. This is the model that the World Health Organisation's Office for Europe (WHO-E) has steered into acceptance by all 51 of its member states last September. All 15 EU Member States signed this new commitment.

The WHO-E Food & Nutrition Action Plan outlined a programme of action and preparation of scientific arguments and data running up to 2005.[3] A background paper is in preparation which is due to go to consultation later this year leading to a Ministerial in 2002. This offers public health organisations an opportunity to rally support and to work with agriculturalists to re-orient CAP.

Happily, this initiative coincided with others that could begin to deliver this new model for Food and Agriculture. The first was the Eurodiet project, a three year process for setting up an EU-wide system of dietary advice and nutrition information gathering. This process was completed at Crete in May 2000 and made proposals for data-gathering, health promotion and food and health policy.[4]

The second was the little acknowledged but potentially powerful French Presidency work culminating in the Brussels Council Resolution of 8 December 2000 with a list of Actions agreed by Health and Social Affairs Ministers.[5] This should lead to actions such as Health and Environmental Impact Assessments of CAP.

Collectively these are great steps forward for public and ecological health. At last another vision for CAP reform is available for policy makers, other than the sterile neo-liberal vision of just sweeping it all away. Besides failing the political 'laugh test', a growing body of opinion sees it as delivering Europe's food system into the hands of powerful agribusiness about whom Europe's consumers are deeply nervous.

The evidence is mounting about CAP's externalised costs. These are direct and indirect health costs such as contribution to cardiovascular disease and treatment for food poisoning. Environmental assessments for pesticide and nitrate pollution are also measurable for issues such as loss of amenity, cultural dislocation, decline of employment, losses of wildlife, hedgerows, stonewalls, soil erosion and carbon losses from soil.

The major nutritional problems related to the food supply in Western Europe are not caused by a lack of protein (our diets are rich in meat and milk products) nor a lack of energy (we consume high levels of fats and sugars) but primarily by an inadequate consumption of vegetables and fruit.

Appropriate policies – for example to encourage greater investment in horticultural production – can help to resolve this imbalance and simultaneously improve prevailing environmental and social conditions. Vegetables and fruit can be made more accessible to the local population, improving food security and nutrition, enhancing the local economy and strengthening social cohesion in rural areas. Thus, food policies can be geared towards socioeconomic and environmental goals as well as improving public health. Health authorities can promote intersectoral collaboration to address the determinants of public health. We look here at the links between agriculture and health, especially nutrition, and describe some opportunities for changing agriculture policy.

Nutrition, food and agriculture

Recent experience in Europe (such as dioxin contamination in Belgium, BSE in Britain, and a decline in wildlife across Europe) has shown how food contamination and environmental pollution are directly linked to agricultural production methods. These links can be given financial costs: for example, an assessment in the UK suggested that the environmental and health costs of agriculture were as high as $6 billion annually.[1]

This assessment excluded any links between nutrition and agriculture, for which documentation is less well established. There are several reasons why the nutrient quality and diversity of our diets are linked to agriculture policy:

- The biodiversity of our diet has declined dramatically. One estimate suggests that just 15 crops supply 90 per cent of the world's human food and livestock feed.
- The selection of species for commercial crops has favoured productivity (high yields, fast growth, response to fertilisers) over nutrient diversity and nutrient density.
- Stocks of wild foods (fish, wild edible plants, game) with high nutrient density and an abundance of protective phytochemicals and polyunsaturated oils are threatened.[2]
- Policies which lead to the mass destruction of vegetables and fruit in the EU reduce access to these foods, in turn reducing the nutritional content of the European diet.

Besides antioxidants (carotenoids, vitamins C & E, selenium), vegetables and fruits contain dietary fibre and other phytonutrients, such as quercetin, which are biologically active compounds in human metabolism. There is now clear evidence of the health benefits of eating more vegetables and fruits. Estimates suggest that 30-40 per cent of certain cancers (colorectal, gastric and lung) are preventable by increasing daily intakes of vegetables, fruit and fibre. A low intake of vegetables and fruit is also associated with micronutrient deficiencies, hypertension, anaemia, premature delivery,

contrast most other EU countries do not have enough vegetables and fruit to ensure nutrition security for the population. Accession countries are in an even worse state. It has been calculated that levelling up the intake to the highest consuming groups could result in tens of thousands of lives saved each year in the EU.

What should be the objectives of food production?

1970s and 1980s led to the consumption of high levels of fats and meat products but low levels of fruits and vegetables. An extension of the present EU agricultural policy would perpetuate these eating patterns and discourage healthier diets.

In many accession countries, the price of foods has increased more rapidly than income levels, and in some countries between 30 per cent and 60 per cent of household income is spent on food, compared with less than 20 per cent in the EU. In response to this household food insecurity, supplementary food production and small-scale farming has increased and appears to be more efficient than larger scale farming methods.[4] A rapid change due to high levels of capital investment may jeopardise the food security being developed in the region.

Opportunities, 3. The general public

In 2000 the total support for agriculture in the EU was some 40.2 billion euros (nearly 50 per cent of the total EU budget) creating a tax burden on EU citizens of some 130 euros per capita. The protective measures also raise the price of food compared with world market prices, adding another 120–150 euros per capita cost to the consumer. The average family is paying some 1000 euros annually as a result of EU agricultural policies.

Consumer expectations will be an important consideration in the CAP discussions. In order to assess public perceptions, two *Eurobarometer* opinion polls were carried out among farmers and the general public in 2000. The surveys were carried out by telephone interview on 16,000 members of the general public and 3,500 farmers and revealed a widespread interest in agricultural issues and a wish for more information.[5]

Whilst 92 per cent of the general public think that agriculture is important, only 50 per cent had heard about the CAP. Both farmers and the general public were asked to rate the importance of a list of 12 policy objectives, including food safety, envCm ,hIn o 2 policyncpT81 ulicq Tc0.0licc1 TDntr.036 Tc00 5t093 rtance ofscG T the price of

Society and the environment:

A new approach to agriculture

Elisabeth Baumhöfer is Managing Director of the Österreichishen Bergbauernvereinigung (BBV, Austrian Mountain Farmers' Organisation).

We have a responsibility for our future and agriculture plays a crucial part in it. Current agricultural policy undermines rural, environmentally sustainable and socially acceptable methods of agriculture. This is why the Coordination Paysanne Européen (European Farmers Coordination, CPE) is convinced that the EU's Common Agricultural Policy (CAP) needs to be reviewed and redesigned. Importantly, such a review has to be undertaken in dialogue with consumers. The current focus on food safety does not necessarily mean that our food is healthy, nor that it has been produced in a sustainable way.

Stories of nitrates and pesticides in ground water, antibiotic residues in meat, dioxins and salmonella in poultry, the risks of genetic engineering, and not least BSE, far too often make sad headlines in the media and have given agriculture a bad name. These problems are, however, the consequences of industrial farming, under which all farmers have to suffer. Small and medium sized farms still constitute the majority of farming enterprises, and they are far more environmentally friendly than industrial agriculture. Furthermore, they are central to maintaining local economies. Under current agricultural policy a 'farmers' agriculture, rather than an industrial agriculture, faces a difficult task if it is to work in an environmentally sustainable manner and still survive. Instead, it runs the risk of being sacrificed in the interests of multinational companies and global trade, as well as being undermined by the logic of short term cost minimisation.

"subsidies serve only to support large and intensive farming enterprises and they undermine genuine competition"

Society's real needs

We want an agriculture that focuses on the real needs of society. This means:

- Protection of the environment and of biodiversity.
- Production of high quality and healthy foods.
- Avoidance of over production.
- A focus on regional markets and a move away from mass production for the global market.
- Fair trade relations.
- Prices that provide adequate pay for farm workers.
- Maintenance of small and medium farm structures.
- Preservation and creation of jobs in rural areas.

Environmentally and socially acceptable agriculture needs to be further developed and given committed political support in Europe and elsewhere. In Europe, as in Austria, there is intensive mass production which leads to:

- Over production and an undermining of competition.
- Undue pressures on the environment and lower food quality.
- The economic degradation of the regions, including a loss of jobs, rural communities and productive land.

This industrial model, which puts great stress on the environment, is the dominant form of agriculture in the EU and swallows the lion's share of agricultural subsidies. As its legitimacy in the eyes of the public diminishes, however, efforts are being made to conceal it. This is done either with the help of dubious terms such as the 'European Model of Agriculture' and 'Ökoland Oesterreich' ('Eco-land Austria'), or through the use of advertising based on idyllic imagery of the traditional countryside.

It is important to highlight these contradictions and to bring them to the awareness of the public. Nevertheless, consumer behaviour is ambiguous and contradictory. According to opinion polls, 90 to 95 per cent of people asked declare themselves in favour of maintaining smaller scale agriculture. Yet other studies show that 60 per cent of the same consumers buy the cheapest foods when doing their shopping.

HEALTH COUNCIL MEETING

On 5 June 2001 the Health Council met in Luxembourg. Mr. Lars Engqvist, Swedish Minister for Health and Social Affairs chaired the meeting. The Council debated the following items:

The Community strategy on public health

The Council reached political agreement on its common position regarding a programme of Community action in the field of public health.

This six year programme focuses on the improvement of health information and knowledge, enhancing the capability to respond rapidly to health threats, and addressing health determinants. This new programme will replace the eight existing Community action programmes.

The action programme will complement national policies and is intended to ensure a high level of health protection in the definition and implementation of all Community policies and activities. The total budget assigned to this programme will be EUR280m. The decision will be adopted and forwarded to the European Parliament for its second reading, in accordance with the co-decision procedure of the Treaty.

Alcohol as a health determinant

The Council adopted a Recommendation on alcohol and young people. Member States should promote research and disseminate evidence based information on the factors that motivate young people to start drinking. Another recommendation is to raise awareness of the effects of alcohol and foster a multi-sectoral approach to educating young people about alcohol.

Tobacco as a health determinant

The Commission reported on the results of negotiations of the WHO Framework Convention on tobacco control. The Council took note of the presentation of the Commission of its proposal for a Directive on tobacco advertising and sponsorship, as well as of the interventions by delegations.

Variant Creutzfeld-Jacob and Transmissible Spongiform Encephalopathy

The state of play of the monitoring activities, as well as the measures to be taken shortly by the Commission, to respond to the challenges of Variant Creutzfeld-Jacob and Transmissible Spongiform Encephalopathy were orally reported to the Council. The Council also discussed briefly the progress of health issues in other policies and took a note about reports on health in the candidate countries and on Northern Dimension Policies.

For the full conclusions see website: www.europa.eu.int/pol/health/index_en.htm

SUSTAINABLE DEVELOPMENT

The European Commission produced a proposal on Sustainable Development in May 2001. This proposal builds on a Commission consultation paper, and was prepared for the Gothenburg European Council. It will also be published in the EU contribution for the 2002 World Summit on Sustainable Development.

'A Sustainable Europe for a Better World: A European Union Strategy for Sustainable Development' presents a long term vision which includes the insight that economic growth, social cohesion and environmental protection must go hand in hand.

The strategy focuses on a number of problems and threats to sustainable development such as the emission of greenhouse gases, antibiotic resistance, hazardous chemicals, food safety, poverty, ageing of the population, loss of biodiversity, waste volumes, soil loss, transport congestion and regional imbalances. To make the strategy a success it needs urgent action, political leadership, a new approach to policymaking, participation and international responsibility.

The Sustainable Development Strategy consists of several objectives with specific actions.

- Improve policy coherence and put sustainable development at the core of all policies.
- Use price incentives in policy proposals to achieve social and environmental objectives in a flexible and cost effective way.
- Invest in science and technology for the future, supporting research into sustainable development.
- Improve communication and mobilise citizens and business, including encouragement of environmental reporting by business.
- Take enlargement and the global dimension into account.

European Council conclusion

The Gothenburg Summit on 16-17 June concluded that Sustainable Development is a fundamental objective under the Treaties. The European Council agreed a strategy for sustainable development that establishes a new approach to policy making. The arrangements for implementing the strategy will be developed by the Council.

The full version of the Commission's strategy on Sustainable Development is available at: www.europa.eu.int/comm/environment/eussd/index.htm

The complete version of the European Council conclusion from the Gothenburg Council is available at: www.europa.eu.int/comm/gothenburg_council/index_en.htm

TOBACCO

New legislation on tobacco marketing

On 15 May new legislation on the manufacture, presentation and sale of tobacco products was reached in the Conciliation Committee between the European Parliament and the Council. Health warnings will now cover at least 30 per cent of the front and 40 per cent of the back of packets (current warnings cover only four per cent). Cigarettes sold from 1 January 2004 in the EU need to have a reduced level of tar, nicotine and carbon monoxide. The same will be required for cigarettes exported after 2007. The new legislation gives Member States the option of forcing manufacturers to include shocking colour pictures of the health effects of smoking from 2003.

From 30 September 2003, terms such as 'mild', 'ultra light' and 'low tar', which can mislead consumers into thinking cigarettes are safe, will be forbidden.

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

New Directive on tobacco advertising

In 1998 the Directive 98/43/EC on banning tobacco advertising was challenged by the German Government and the tobacco industry and consequently rejected by the European Court of Justice. On 30 May the European Commission proposed a new Directive on tobacco advertising and sponsorship. The Directive refers to existing regulations in Member States and will follow requirements set down by the European Court of Justice. If accepted by the Council and European Parliament, tobacco advertising will be banned from newspapers, magazines and the internet. Tobacco sponsorship of cross border (though not national) sporting events will be banned. Free distribution of tobacco products at events as a form of promotion will also be banned.

The proposed Directive can be downloaded from the following address: http://europa.eu.int/comm/health/ph/programmes/tobacco/comm283_en.pdf

The WHO framework convention

On 11 June the EC held a debriefing on the second round of negotiations for the WHO framework convention on tobacco control. It was attended by industry, Member States and NGOs. The Commission and the Council negotiate on behalf of the EU Member States at the meeting. The Commission presented the main elements of the Chair's text of the draft Convention and pointed out the Community position on this text. The next negotiation round will be held in November.

The Council's full conclusion is available at: http://europa.eu.int/eurlex/ en/dat/2001/c_174/c_17420010619en00010001.pdf

For more information about the WHO Framework Convention see: http://tobacco.who.int/en/fctc/index.html

Nicotine addiction prevention campaign

DG Health and Consumer Protection recently launched a tender for a three year communication campaign aimed at smoking prevention in adolescents. The campaign will be Community wide and all Member States must be covered. The campaign will be multimedia, using cinema, television, press, and internet. The estimated annual value is EUR6m.

For the full invitation to tender and general information, contact: jean-luc.noel@cec.eu.int

PUBLIC HEALTH PROGRAMMES: UPDATE

Pollution related diseases

The Commission adopted a programme of Community action on pollution related diseases in the context of the framework for action in the field of public health. Proposals for projects must be submitted by 31 July 2001.

For further information on the programme see:
http://europa.eu.int/comm/health/ph/programmes/call/pollution.htm

For funded projects in 2000 in the field of pollution related diseases see:
http://europa.eu.int/comm/health/ph/programmes/pollution/ph_poll_fp00_en.htm

Health monitoring

Proposals for the Programme of Community action on health monitoring must be submitted to the 15 of July.

Documents for submitting an application are available at:
http://europa.eu.int/comm/health/ph/programmes/monitor/index_en.htm

Drug addiction

Funded projects in the 'Programme of Community action on the prevention of drug dependence' of the year 2000 are listed at:
http://europa.eu.int/comm/health/ph/programmes/drugs/projects_2000/proj00index_en.htm

Cancer

For projects funded in the year 2000 see:
http://europa.eu.int/comm/health/ph/programmes/cancer/proj2000_en.pdf

Injury Prevention:

The programme can be found at website:
www.europa.eu.int/comm/health/ph/programmes/call/ojc00-286/wrkprog2001_en.pdf

HEALTH AND SAFETY AT WORK

Success is no accident

The European Agency for Safety and Health has launched a campaign named 'Success is no accident' which will be the focus of a 'European Week' in October.

The campaign focuses on activities to reduce the number and severity of work related accidents and the importance of workplace safety and health in general.

See the European Week website, http://osha.eu.int/ew2001

Accident prevention in SMEs

The cost of work related accidents is still a serious cause for concern to the European economy. About 4.8 million work related accidents resulting in more than three days absence from work and over 5,500 fatal accidents were counted in the year 1996. In small firms, the rate of fatal accidents is around double that of larger companies.

The European Agency for Safety and Health at Work provided EUR5m for an accident prevention scheme in small and medium sized enterprises (SMEs). The Agency provides grants for projects that contribute to the reduction of accident risks in SMEs. Funding between EUR25,000 and EUR200,000 per project can either be submitted by SMEs themselves or be aimed at SMEs' specific needs. SMEs are defined as enterprises that have fewer than 250 workers, small firms fewer than 50, and micro firms fewer than 10.

For the full details of the call and its eligible project activities and selection criteria see website: http://agency.osha.eu.int/calls/oshame2001.

Risk assessment and pregnant workers

The European Commission in consultation with the Member States and with the assistance of the Advisory Committee on Safety, Hygiene and Health Protection at Work have prepared a set of guidelines on risk assessment and pregnant workers.

The document, Council Directive 92/85/EEC, can be accessed via website: http://euroe.osha.eu.int/legislation/guidelines/

E-HEALTH

The Commissioner responsible for the Information Society, Erkki Liikanen, spoke on the EU's 'eEurope' Action Plan at a workshop on 'Quality Criteria for Health Related Websites' on 7 June. In order to assist Member States in reaching the stated target of ensuring that primary and secondary care providers have the necessary health informatics infrastructure in place, the 'Health Online' chapter of the Action Plan sets out four actions at EU level:

- Best practices in eHealth will be identified and disseminated, in order to assist purchasing departments in decision making.
- A series of data networks will be established to assist with informed healthcare planning in Member States.
- A communication on legal aspects of eHealth will be drafted that will clarify which existing legislation has an impact on eHealth in order to remove some of the uncertainties expressed by industry about the legal aspects of such commercial activity.
- A set of quality criteria for health websites will be developed to boost consumer confidence in the use of such sites and foster best practice in the development of sites.

Further details can be found on website: http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=SPEECH/01/268|0|RAPID&lg=EN

BELGIAN PRESIDENCY

On 1 July Belgium took over the European Union Presidency. The Belgian Government recently published their priorities for the Presidency. The priorities are:

- Deepening the debate over the future of Europe.
- Improving quality of work, advancing equal opportunity and combating social exclusion and poverty.
- Promoting sustainable economic growth and a common economic policy.
- Creating a European area of freedom security and justice.
- Promoting sustainable development and improving quality of life.
- Enlarging the European Union and strengthening the external dimension of the European Union.

Other important issues for the Belgian Presidency will be the introduction of the euro and the setting up of a permanent European unit of magistrates.

The priorities also include a strong social dimension and topics such as modernising social security and the sustainability of pensions. Priorities for health in particular are:

- Mental Health
- Food safety
- Antibiotics
- Blood safety
- Social equality
- Community Action plan on public health
- Tobacco
- Alcohol
- Electromagnetic field radiation
- Drug addiction
- E-health

See the Belgian Presidency website: www.eu2001.be

NEWS IN BRIEF