

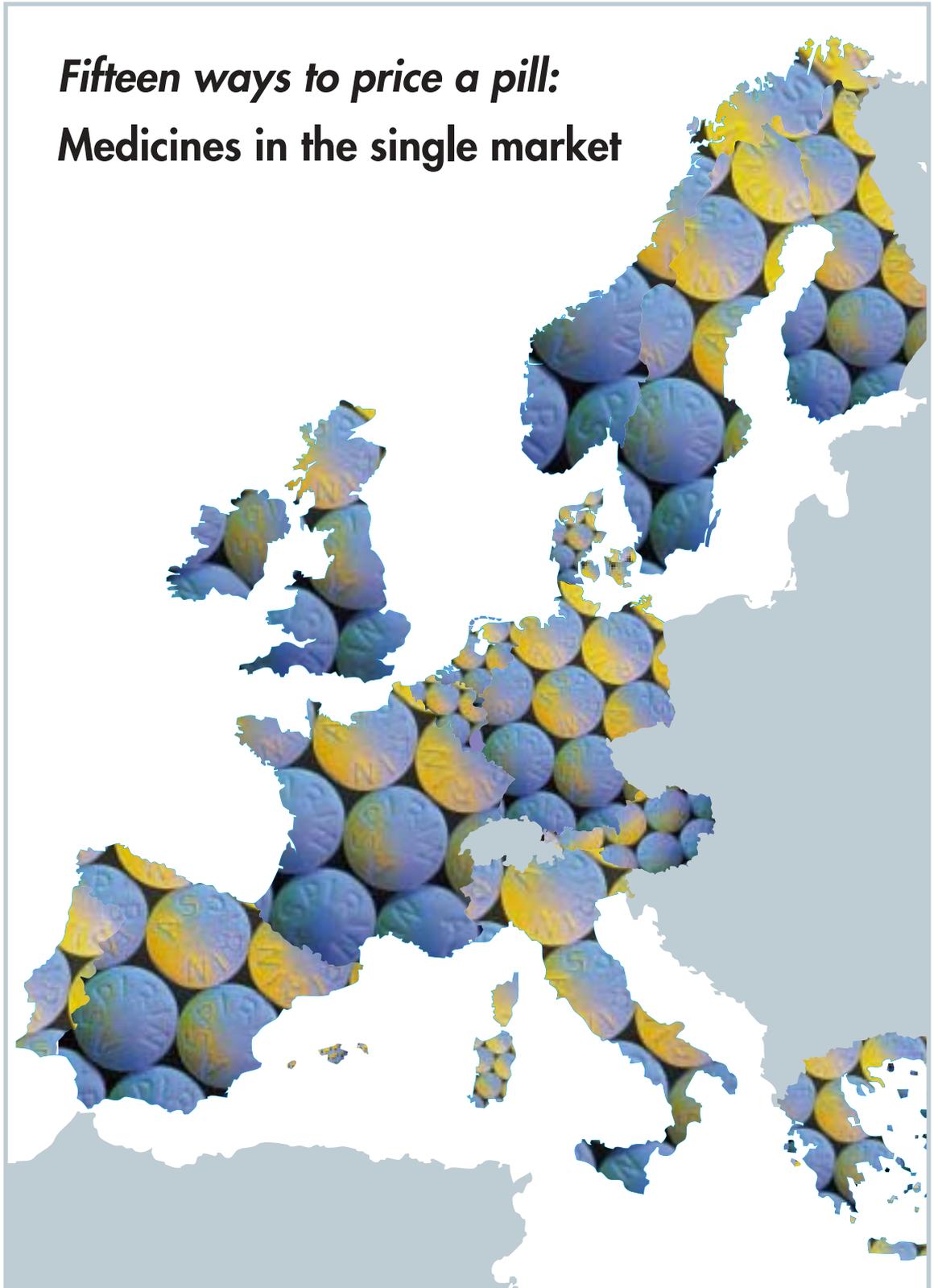
# eurohealth

## *Fifteen ways to price a pill:* **Medicines in the single market**

Developing  
the health role of  
the Commission:  
*Interview with  
Fernand Sauer*

The politics,  
economics and  
science of  
antimicrobial  
resistance

Building a  
healthy Common  
Agricultural  
Policy



## EDITORIAL

EDITOR:  
Mike Sedgley: +44 (0)20 7955 6194  
email: m.d.sedgley@lse.ac.uk

SENIOR EDITORIAL ADVISER:  
Paul Belcher: +44 (0)7970 098 940  
email: p.belcher@lse.ac.uk

DEPUTY EDITOR:  
Anna Maresso: +44 (0)20 7955 6288  
email: a.maresso@lse.ac.uk

DESIGN EDITOR:  
Sarah Moncrieff: +44 (0)20 7834 3444

EDITORIAL TEAM:  
Johan Calltorp  
Julian Le Grand  
Walter Holland  
Martin McKee  
Elias Mossialos

## SUBSCRIPTIONS

Claire Bird: +44 (0)20 7955 6840  
email: c.bird@lse.ac.uk

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# COMMENTS

## *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 signifi-  
cant 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 fol-  
lowing 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 indi-  
vidual basis, according to personal medical history and con-  
dition. 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 health-  
care administrators can also look to potential benefits of  
increased cross border care. Areas of expertise and efficien-  
cy 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 dis-  
cussion 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 implica-  
tions of the judgements in greater depth in the next issue.

*Mike Sedgley*  
Editor

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**Contributors to this issue**

ELISABETH BAUMHÖFER is Managing Director of the Österreichischen Bergbauernvereingung (BBV, Austrian Mountain Farmers' Organisation).

PAUL BELCHER is Head of European Affairs at the European Health Management Association and Senior Editorial Advisor, Eurohealth.

ALASTAIR BENBOW is a physician and Vice President of European External Relations, GlaxoSmithKline Pharmaceuticals.

JOHN BOWIS OBE MEP is a Member of the Committee on the Environment, Health and Consumer Policy, European Parliament

REINHARD BUSSE is Head of the Madrid Hub, European Observatory on Health Care Systems and Visiting Professor at the Escuela Nacional de Sanidad, Madrid.

JOANNA COAST is Senior Lecturer in Health Economics, Department of Social Medicine, University of Bristol.

JIM FURNISS is Senior Vice President of Cambridge Pharma Consultancy, Cambridge, UK.

LEIGH HANCHER is Professor of European Law, Tilburg University, Netherlands, and a Partner at Kennedy van der Laan, Amsterdam.

CLAUDIO JOMMI is Head of the Pharmaceutical Observatory, Centre for Research in Healthcare Management, Bocconi University, Milan.

TIM LANG is Professor of Food Policy at Thames Valley University, United Kingdom.

VINCENT LAWTON is Managing Director of Merck Sharp & Dohme Limited (MSD).

ERKKI LIIKANEN is European Commissioner for Enterprise.

TIM LOBSTEIN is Director of The Food Commission, London.

ALAN MAYNARD is Professor of Health Economics at the University of York and Visiting Professor at LSE Health & Social Care, The London School of Economics and Political Science.

AILEEN ROBERTSON is Acting Regional Adviser in the Nutrition and Food Security Programme, World Health Organisation, Copenhagen.

MIKE SEDGLEY a researcher in British pharmaceutical price regulation at the London School of Economics and is Editor of Eurohealth.

RICHARD SMITH is Senior Lecturer, Health Economics Group, School of Health Policy and Practice, University of East Anglia.

CHRIS VIEHBACHER is President of GlaxoSmithKline Pharmaceuticals Europe and a member of the European Commission G10 group.

HELMUT WALERIUS is Assistant within the Communicable, Rare and Emerging Diseases Unit, Directorate for Public Health, European Commission.

RICHARD WISE is Professor of Clinical Microbiology at City Hospital Birmingham and was advisor to the UK House of Lords Report on Antibiotic Resistance. Currently he is the UK Department of Health Chairman of the Specialist Advisory Committee on Antibiotic Resistance.

# EU health research: science v policy?

*John Bowis OBE, MEP*

*Member of the Committee on the Environment, Health and Consumer Policy, European Parliament*

*Paul Belcher*

*Head of European Union Affairs, European Health Management Association & Senior Editorial Adviser, Eurohealth, LSE Health*

In February, the European Commission put forward a new strategy to develop EU research policy with a proposal for the Sixth Framework Research Programme for 2002–2006 (FP6). The Commission is seeking a fundamental change by moving away from funding individual research projects towards a more integrated and structured approach that would aim to strengthen European research capacities.

However, the proposal appears to seriously neglect health issues. Indeed, as reflected in the authorship of this editorial, there is anxiety among many sections of the health policy community about the future of health services and health policy related research in particular.

## **Addressing policy challenges**

The proposal is overly dominated by the scientific objectives of the priority areas or 'Key Actions', such as genomics and biotechnology for health, at the expense of equally important policy related research. This is a step backwards from the gradual advance of policy research since the more biomedically focused programmes of previous years.

Scientific advances can only benefit European citizens if they are translated into policies for health systems and health services. This is evident in the field of genomics with its profound implications for current health policies and the organisation of health systems. Member States require the tools necessary to address this and the many other policy challenges that will confront all their health systems. This is why health policy relevance was introduced as one of the evaluation criteria in the research programmes.

## **End of 'Public Health and Health Services' research**

Under the current FP5, the section on 'Public Health and Health Services Research', has provided an important

focus for policy orientated activities on the implications of biomedical and technological advances for health policy, the improvement of health systems and better management of health services. This has been cut from the new proposal and replaced with a confusing section on 'Anticipating the EU's scientific and technological needs', which contains a small subsection on 'Policy orientated research'. This neither defines nor guarantees research on health policy and health services. Encapsulating these concerns, during the European Parliamentary research debate on May 28th it was described as:

*"...a jumble sale of a programme with a very small amount of money"*  
*(John Bowis MEP)*

The relative lack of importance given to health policy research in the Commission's proposal is at odds with the higher political profile health is acquiring throughout the Commission in order to implement Article 152 (Public Health) of the EC Treaty. This Article contains a specific reference to research in the public health field. Moreover, the new EU health strategy, which will support the implementation of Article 152, recognises the importance of policy research on health systems and health services to improve public health across the EU.

## **Insufficient funding**

The Commission has proposed 880 million euros for 'Policy orientated research'. However, this small amount must be spread over up to 20 different policy areas including health. In contrast, the 483m euros allocated to generic research under FP5 has to be shared between only seven areas – one of which is defined specifically as 'Public health and health services research'.

A further concern is related to the fact that, as the Commission proposal for the new EU health programme fore-

sees a separate budget of 300m euros, this might reduce the amount allocated to health policy research within FP6. As the health programme budget is small in comparison with its wide ranging objectives, integrating health policy issues into the research programme must form a key part of the Commission's effort to achieve Treaty based health objectives through all EU policies.

## **No ring fencing for health**

Unlike FP5, there is no ring-fenced funding for public health and health services research in the new proposal. Instead, a competitive bidding process is now taking place between Commission Directorates-Generals (DGs) to secure a slice of the 880m euros allocated for 'Policy orientated research'.

DG Health and Consumer Protection, along with other DGs, has been invited by DG Research to submit 'bids' for funding to implement particular policy goals. A possible blue print for public health and health services related research could be found in the information strand of the proposed future EU health strategy. Indeed, it is understood that DG Health has submitted a number of research proposals in line with this.

However, there is concern as to how DG Health's 'bids' will fare in the evaluation process now taking place, described as 'political horse-trading' by several EU officials. The bidding process contrasts with the priorities laid down from the outset for public health and health services research under FP5 and the Commission's often stated political commitment to health.

The challenge ahead is to ensure a strong link between the final decision on FP6 policy related research priorities and the EU health strategy. As funding for the health strategy is limited, the support of, and coordination with FP6 will be crucial in achieving the health objectives of Article 152.

# Fernand Sauer

Director, Public Health Directorate, European Commission



*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 or 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 (EMA), 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

A final point: their suggestion is not unreasonable but my message to the European Parliament and Council is that if we have to create a new institution or European health coordinating centre it cannot be done via the health programme and we would need a completely different legal basis. If they said that establishing a centre was a prerequisite, it might mean postponing the implementation of the new programme for another three years. What I would recommend is that the programme is adopted first, so that we know the tasks ahead, and then we would be able to see how much we could tackle internally and how much should be executed by new rules, which require a separate discussion.



*"... public health policy here in DG Health and Consumer Protection ... is only one part of many health related policies of the Commission"*

the Commission retaining the policy element, this would then resolve our problem of resources. This is purely speculation of course, but it would be one way to meet the expectation expressed in Parliament and Council about setting up a health 'centre', without making empty promises that cannot be fulfilled. There is no possibility of the Commission creating a large directorate dealing with public health.

Things will need time. DG Sanco itself is a result of mergers between different branches of the Commission and as with all mergers they take time to settle. Moreover, the food scares and the creation of the European Food Authority are so high on the agenda at the moment they are using most of the energy of the Commission. If there were new resources they would probably go to this area over the next two years. However, at the end of 2002 DG Sanco will be more stable, the Commission will be in the middle of its mandate, consumer and food safety affairs will be covered adequately and so there will be more time to consider public health.

**In the information strand of the new health programme you propose work on aspects of healthcare systems, best practice etc. Could you explain what the Commission is planning to do in the healthcare field?**

It is clear that when it comes to making a recommendation that would have a direct impact on the cost of healthcare, this is a very tricky area for the Commission. Who are we to give advice to, if we are not the paymasters and not responsible for healthcare? While any discussion of the issues would have to be neutral from the point of view of financing, we can help identify where the best practice is. The exchange of information that would follow would have a structuring effect without having to introduce binding legislation.

It could mean the introduction of core European guidelines and we would then leave it to Member States to put them into effect in their own context as they wished. Generally, the question is not to find new practices but to discuss what already exists

and find a consensus. So the question is more one of dissemination than imposing a new standard.

**As your programme passes through the political process, do you find these healthcare, best practice aspects are gaining support or meeting resistance in the Parliament and Council?**

Of course, Parliament would like us to go very far in this direction but a minority of Member States would prefer us to delete these references altogether. I think we should maintain the references in the text but we will be scrutinised. In the end, we should be judged by the value of our work on best practice itself and not the fact that we might want to issue recommendations.

**Recent cases in the European Court have brought healthcare to the fore in discussions about the EU Single Market and access to medical treatment abroad. DG Employment appears to be dealing with the issues from a technical and administrative perspective. Is there not a health dimension to this cross-border debate that is relevant to DG Sanco?**

Currently, this causes a dilemma for the Member States and the Commission. Will policy be governed by the courts or should there be more active involvement of policy makers? I have seen recently in Spain the migration of UK patients to find better healthcare, and such situations will lead to tension between the Member States when it comes to financing. To solve these problems, will they envisage new contractual arrangements, as between Norway and Germany for specialised healthcare facilities, or will we have to have a pan European approach?

In terms of the split in responsibility for health and cross border social security issues between DG Sanco and DG Employment, I do not believe in being territorial and I have to recognise that with the limited resources I have, my priority is not to double the activities of my staff. If the Commission wanted to put all health areas under one roof that is a question of reorganisation for the Commission, but it is not my mandate.

For me, health in other policy areas is more about making people aware of health in areas where they would not have thought about it and to enter into dialogue with us when they design their policies.

**At a practical level, are there sufficient horizontal links within the Commission in terms of consultation processes, such as the Interservice Group on health, to achieve this?**

I now chair the Interservice Group, which brings together representatives of other Commission Directorates General to discuss policies with a potential health impact. This had become a rather loose arrangement and my policy now is to have one meeting every three months. We also have several sub-groups that meet in the meantime.

**Is the group taken seriously by other Directorates General? Does it make a difference?**

We invite all the DGs we can think of and they are usually represented. Internally there has been a strong worded communication to the other DGs saying that we have to cooperate to prevent conflicts. I have now chaired a couple of these meetings and the atmosphere was rather good.

There is no question about the legitimacy of the Interservice Group. Two years ago, other DGs would not have reacted in the same positive way but now they recognise its value. Rather than having to tell them what to do, they are thinking about issues in advance. They are bringing questions to the meetings and it is not simply a matter of us scrutinising what they are doing; it is more than a routine exercise where people simply put a health slogan into their texts saying 'we are taking health into account'.

**What are your plans for the proposed consultative 'European Health Forum' which will bring together the various stakeholders in EU health policy development?**

Having separate discussions with so many partners is not only a waste of time but also the source of many misunderstandings as people will be tempted to say different things in different meetings to please people. We have got very positive feedback from our Forum proposal issued in December and we are now organising the three levels of the consultation process: a core of partners who help us prepare the Forum and a larger group of 60 to 70 who would meet on invitation to discuss issues and then maybe next year a sort of open day where everyone could participate – paralleled with a website that anybody can join. The Forum is not only to get feedback and inspiration for our policies. This will indeed be half or 60 per cent of the

*"One should not underestimate the capacity of the general public to understand the issues."*

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 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.”*

*German health policy is by no means boring. After the resignation of Andrea Fischer (Greens) as Minister of Health in the middle of the BSE crisis, her successor, Ulla Schmidt (Social Democrats), has initiated a number of reforms. Reference prices and spending caps for pharmaceuticals are two reform targets.*

## Interesting times in German health policy



*Reinhard Busse*

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.<sup>1</sup> 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) in 1999 and DM 3.6 billion (8.7 per cent) in 2000. By comparison, the sickness funds' share of pharmaceutical expenditure in 2000 grew by a total of DM 4.4 billion (+12.0 per cent). As the overall rise in the market accounts for only DM 2.5 billion (+6.4 per cent), almost half of the increase is a result of decreased co-payments.

### Reference prices

The idea behind reference prices was to establish an upper limit for the costs reimbursable through the sickness funds.\* The law stipulates that reference prices be defined for drugs (1) containing the same substance, (2) with similar substances and (3) with comparable efficacy.

The federal associations of sickness funds set the prices for drugs. Due to the lower prices set for drugs formerly above the reference price, these regulations led to decreasing prices for reference priced drugs overall. However, the pharmaceutical industry partly compensated for this through increases for non-reference-priced drugs. For the sickness funds, the savings are currently estimated to be in the range of DM 3 billion per year, roughly 9 per cent of their pharmaceutical expenditure. For patients, reference prices mean that the difference between reference and retail price has to be paid out of pocket if a more expensive alternative is chosen.

Late in 1998, the new red-green parliamentary majority introduced tighter regulations for the setting of reference prices, i.e.

legally they would now not be higher than the highest price in the lowest third of the market. For 202 out of a total of 446 drug groups with reference prices, prices were supposed to be lowered from 1 April 1999 for a saving of approximately DM 550 million. However, this reduction was stopped in the courts and reference prices in general came under legal threat when a pharmaceutical company successfully sued. Early in 1999, a court ruled that price setting by the sickness funds violated European Union cartel regulations. Regarding the latter, the federal Court of Appeals decided to ask the European Court of Justice for a preliminary ruling on 4 July.

While the Ministry of Health, the sickness funds and the physicians were happy with the current solution, the pharmaceutical industry provided strong opposition. For example, the Director-General of the Association of Research-based Pharmaceutical Companies (VFA), Cornelia Yzer, demanded: "The reference price system must be re-evaluated. Reference prices are superfluous." She gave three reasons why the system is obsolete. (1) The price reduction initially planned by the sickness funds would have led to a situation in which the prices of some pharmaceuticals would have decreased to the lowest level in all of Europe. (2) Reference prices represent an unnecessary interference with regular market price formation. (3) The reference price system is unconstitutional and violates antitrust law.

Early in 2001, the ministry undertook to put reference prices on a new legal footing i.e. to fix them through a Ministry of Health ordinance, an instrument which is quite uncommon in German statutory health insurance regulation. As the sickness funds felt that the draft bill was ambiguous about the situation from 2004 ( i.e. whether reference prices would still exist after the expiry of the new law), they decided to pass new reference prices unilaterally in March, a decision they reversed in May when the final version of the bill was presented. According to this bill, the current regulations on reference prices are only

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Reinhard Busse is Head of the Madrid Hub, European Observatory on Health Care Systems and Visiting Professor at the Escuela Nacional de Sanidad, Madrid.

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\* In Germany, the pharmaceutical industry's pricing is unregulated while the distribution of drugs through wholesalers and pharmacies and their respective surcharges on ex-factory prices are regulated in great detail.

suspended until the end of 2003. During this period, the Ministry will issue an ordinance with the aim of putting reference prices into force, enabling a saving of about DM 650 million. From 2004, the old regulations will again be in force, unless new rules to ensure the survival of delegated decision-making are deemed necessary.

### Spending caps

The spending cap for pharmaceuticals imposed a real reduction in pharmaceutical expenditure when it was first introduced in late 1992. In 1993, any excess spending up to DM 280 million would have been clawed back from both the physicians' associations (from physician remuneration) and the pharmaceutical industry. From 1994 to 1997, the 23 regional physicians' associations were liable for any overspending with no upper limit. While all physicians' associations met their cap in 1994, overspending occurred in several regions from 1995, first in the east (with almost 13 per cent higher expenditure than the west) and from 1996 also in western regions. The physicians' associations resisted payment, arguing that they could not effectively manage overall or physician-specific drug expenditure, due to untimely and unspecified data.

In 1997, the regional spending caps were abolished (from 1998) and replaced by practice-specific targets. For these practice-specific targets, the legal limit for over-prescribing and paying-back was set at 125 per cent of the target, with exceptions for certain types of drugs and patients with certain indications (i.e. opiate addicts, post transplantation patients etc.) as well as for specific circumstances within practices. When the red-green government came into power in late 1998, it retained these targets for individual practices but also re-introduced spending caps at the regional level. Physicians' associations were then liable for any over-spending up to 105 per cent of the cap. As a kind of compensation, debts resulting from the former spending cap were waived. In 1999, 10 physicians' associations did not meet their limit and, in 2000, this number had risen to 19 out of 23. For that year, the physicians' associations owe the sickness funds more than DM 1 billion – an amount of around DM 17,000 per

physician in the case of four eastern regions.

After a few days in office, Ulla Schmidt declared that the collective requirement to pay-back part of their income had negative effects on physicians and that she would therefore abolish it in favour of practice-specific targets. Obviously, this announcement was warmly welcomed by the Federal Association of Statutory health Insurance (SHI) Physicians which reassured the minister that the 'political trust' placed in them was justified. Cornelia Yzer of the VFA was more outspoken: "The deficits of pharmaceutical budgets are dramatic. This cost abatement instrument has proved its inefficiency for many years." The sickness funds, on the other hand, pointed to the fact that the practice-specific targets are not welcomed by all physicians as they constitute a more severe limitation of their freedom. Therefore, the announcement of the Federal Association of SHI Physicians should be viewed sceptically, especially as no physicians' association has yet used the instrument to review the actual prescription behaviour of its members.

While the new minister was initially very positive that pharmaceutical expenditure could be contained without a spending cap, she has already become more sceptical. Late in May 2001, she said that the 9.7 per cent increase in the first quarter of 2001 constituted a "severe danger for the financial stability of the statutory health insurance" and warned that the contribution rates might have to be raised, a danger which the sickness funds had already pointed to earlier. In June, the first major fund increased its rate by a full percentage point.

In conclusion, while no German physician has ever paid back a single mark due to surpassing pharmaceutical spending caps, the instrument did contain costs as demonstrated by both the initial drop in expenditure and the recent post-announcement increases. While there are well known potential dangers to therapeutic quality resulting from such unspecific measures as spending caps\* (and therefore other measures such as guidelines, positive/ negative lists etc. are necessary), currently it seems doubtful that a sustainable solution can be found without imposing limitations of some sort.

*"While the new minister was initially very positive that pharmaceutical expenditure could be contained without a spending cap, she has already become more sceptical."*

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\* The VFA pointed to the results of a TNS Emnid survey of 1891 people. Of those SHI patients seeking medical treatment during the past 12 months, 9.3 per cent were refused a pharmaceutical prescription or the prescription was postponed. 59 per cent of those who were refused a pharmaceutical cited the spending cap or costs as the reason for the refusal. For 84 per cent, the refused or postponed pharmaceuticals had been prescribed in the past. (Due to the methodology, the actual need for the requested prescription could obviously not be measured.)

# Price controls in France: Budgeting for medical benefit?



Jim Furniss

*“price control in France, as in other markets, has conspicuously failed to achieve its primary objective of cost containment”*

France has a complex system for controlling the price of pharmaceutical products, developed over a long period of time. While the basic structure has remained constant for the last decade and more, the way in which that structure is applied has become increasingly sophisticated as government officials have become better informed and more proficient at their cost containment task.

There is a two stage process for assessing the status of new products following market authorisation. First the *Commission de Transparence* assesses the value of the drug, from two perspectives: to determine whether it should be reimbursed under the healthcare system; and to assess the extent to which it provides an increase in medical benefit (*amelioration du service medicale rendu, ASMR*). These assessments are based primarily on clinical data, and particularly the phase-3 clinical trials on which the market authorisation is based.

The approach adopted by the *Commission de Transparence* is essentially comparative. The key comparators used are normally the market leader in the therapy area in France, the product with the lowest treatment cost, and the most recently reimbursed product in the therapy area in France. The recommendation on reimbursability is expressed in a three point scale of *service medicale rendu, SMR*. Products may be classified as 1 (of major therapeutic importance), 2 (of some therapeutic value) or 3 (of insufficient therapeutic value). Products in classes 1 and 2 are reimbursed, while products in class 3 are not.

Second the *Commission de Transparence* rates the extent of therapeutic benefit offered by the product within the context of a comparative framework. Very few products achieve the highest ASMR rating of 1 (major therapeutic advance) and most new products are listed as 3 (modest improvement in efficacy or reduction of side effects) or 4 (minor improvement in efficacy or convenience).

While the assessment is based on clinical data, a narrow view is taken of what is

accepted. Thus atorvastatin (Tahor in France) was given a rating of 5, because it did not have the long term outcomes data of the comparator product, simvastatin. While most observers would accept that on the basis of atorvastatin’s LDL-lowering performance it was reasonable to assume that the long term outcomes would be at least comparable, the *Commission de Transparence* was not willing to make that judgement in the absence of data. Hence Tahor was priced at a discount to the market leader, simvastatin.

It can be argued that it is not unreasonable that the French authorities should undertake a comprehensive evaluation before deciding whether to reimburse (i.e. purchase) a new product. Nor is it unreasonable that such an evaluation should be based on the best available evidence, the clinical trial data. However, this needs to be tempered by a degree of flexibility over how that evidence is used and interpreted. There are inevitably limitations in what is known about new products, and it is unfair that reimbursement, and ultimately price, should be constrained by those limitations. When new data does become available – for example when long term studies confirm the outcome benefits of Tahor – there is no possibility of a price increase to recognise that added value.

The reimbursement decision for new products is based on the SMR recommendation of the *Commission de Transparence* and the outcome of the price negotiations with the *Comité Économique des Produits de Santé (CEPS)*. These negotiations reflect a number of elements. The ASMR awarded by the *Commission de Transparence* is one important factor. Only products with an ASMR of 1, 2 or 3 have any real prospect of achieving a price premium over the comparator products against which they have been assessed, and even this is not guaranteed.

Other factors influencing price include the cost of the main therapeutic alternatives, the size of the target patient population and the expected cost (or budgetary impact) of the new therapy, the position of the new product in therapy (is it first, second or third line?) and the ONDAM, the annual budget, which is broken down

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Jim Furniss is Senior Vice President of Cambridge Pharma Consultancy, Cambridge, UK

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 compulsory rebates if pharmaceutical sales in specific therapeutic areas exceeds predetermined targets; at the level of the company, if company turnover exceed limits negotiated annually with each company; and at the level of the individual product, where specific price/volume agreements are negotiated, so that if expenditure exceeds the agreed level, the company is required to pay rebates to the Government, or reduce the price of the product, or both. One consequence of this increasing proliferation of rebates is that the list price – already typically one of the lowest in Europe – is in fact significantly overstated. The real revenue to companies, after rebates, is substantially lower than the list prices would suggest.

Moreover, the CEPS is developing the ability to implement creative new approaches in the attempt to achieve their cost containment objectives. Earlier this year Pfizer/Pharmacia's new anti-inflammatory, Celebrex, was awarded a price in France consistent with that in most other European markets – a not inconsiderable achievement, considering that this provided a substantial premium over the current generation of non-steroidal anti-inflammatories. The price for achieving this was the acceptance of an automatic price reduction of 18 per cent after three years in the market. The same deal was subsequently applied (after six months delay) to Merck Sharp & Dohme's competing product, Vioxx. No doubt this precedent will be used in the future for other therapeutic innovations expected to have a significant impact on clinical practice.

A frequent criticism of the French system is the lack of transparency over the basis on which the pricing decisions are made. It may not be coincidence that the term 'transparency' is applied to the body

responsible for the assessment of medical benefit, which does operate largely on the basis of "objective and verifiable criteria", to quote from the European Commission's Transparency Directive EC 89/105, but not to the CEPS. But in this respect France is no different from other systems based on negotiation, whether at the level of the individual product (e.g. the CUF in Italy) or the company (e.g. the PPRS in the UK).

Perhaps a more important criticism is that price control in France, as in other markets, has conspicuously failed to achieve its primary objective of cost containment. Every year, in France as in almost all other countries, pharmaceutical expenditure increases at a greater rate than allowed for in the budget. The response in France has been to apply the price control system ever more restrictively, to the detriment not only of the pharmaceutical companies but also of patients in France who face increasing delays in access to new medicines.

One consequence of failure is that the Government has to resort from time to time to emergency measures. The most recent example is the 'Plan Guigou' announced in June, and named after Mme Guigou, the Minister of Health. This encompassed price reductions for two categories of products – those classified by the Commission de Transparence as offering little therapeutic benefit, and innovative products in several therapeutic categories where expenditure was running ahead of forecast and budgetary provision. Thus products such as the modern antidepressants, the SSRIs, and the most effective cholesterol-lowering drugs, the statins, have been subjected to price cuts in the range 8-10 per cent, although French prices were already amongst the lowest in Europe.

Such panic measures, on top of the accumulation of price controls and rebates, suggest that the authorities are increasingly seeing the pharmaceutical companies as the solution to the budgetary problems of the healthcare system, but in the wrong way. The pharmaceutical companies argue that the effective use of modern medicines can ease budgetary pressures by reducing demands on other aspects of the healthcare system. The French Government, however, sees modern medicines as a source of revenue to be plundered whenever it hits a budgetary crisis. It is perhaps not surprising that the head of Pfizer has been musing about whether his company can continue to launch innovative products in France.

*“innovative products may become available in France only after significant delay”*

# 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,<sup>1,2</sup> 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.<sup>3</sup> 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.<sup>4</sup> 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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Claudio Jommi is Head of the Pharmaceutical Observatory, Centre for Research in Healthcare Management, Bocconi University, Milan.  
<http://cergos.uni-bocconi.it>

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\* Prices for non-reimbursable drugs have been 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.

*"the regulatory framework looks like the 'sum' of responses to different short term needs"*

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\* The CUF (Commissione Unica sul Farmaco) is the main regulatory authority of the pharmaceutical market. The CUF is made up of pharmacists, pharmacologists and clinicians.

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.

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\* 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.

Finally, the more Regions are made accountable for their health budget,<sup>5</sup> 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.

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# Profit or loss?

## Fulfilling dual aims in pharmaceutical price regulation in the UK



Mike Sedgley

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 rising cost of medicines purchased by the NHS. It remains, formally, a voluntary agreement between the two. The PPRS sets

a cap on the rate of return on capital (ROC) of companies doing business with the NHS.\* This cap is 21 per cent profit on overall business. It is intended to give companies a fair return, in line with other sectors that do business with government. Profit is determined through the submission by companies of financial data to the Department of Health. The PPRS also specifies limits for the amount companies can attribute in their financial data to various activities in the production process of their products – from research and development (R&D) to sales. There are caps, for example, on R&D costs and on promotional spending – 20 per cent and six per cent of sales respectively. These ceilings are negotiated roughly every five years, as part of the renegotiation of the whole PPRS agreement. The current scheme was signed between the Department of Health and the industry trade association, the Association of British Pharmaceutical Industry (ABPI) in 1999.<sup>1</sup>

### How does it work?

The scheme aims to achieve ‘reasonable prices’ for NHS medicines. As prices are

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\* Some companies have their profits assessed as Return on Sales (ROS). This applies to those with low capital bases. Most companies are assessed on an ROC basis.

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Mike Sedgley is a researcher in British pharmaceutical price regulation at the London School of Economics and is Editor of Eurohealth.

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.<sup>2</sup>

Each renegotiation of the PPRS has included a one off, across-the-board price reduction on all business with the NHS. The scheme therefore provides an occasional opportunity for government to keep in check the growth in the NHS drugs bill. The 1999 scheme included a 4.5 per cent overall price reduction.

In summary, the PPRS interacts with and affects the market for medicines in several ways:

- It allows free pricing at launch.
- It prevents product price increases.
- It encourages new product launches.
- By capping company profits it can potentially reduce the effect of new product launches on the NHS budget.
- By capping various aspects of company expenditure as legitimate components of

capital employed it can affect company behaviour.

- It provides a five-yearly opportunity for renegotiation of details and a one-off price reduction.
- It provides a context and an arena for a close and cooperative working relationship between government and industry.

**New pressures on the PPRS**

The PPRS is a piece of supply side regulation operated by government in two guises. First, as a purchaser acting on behalf of the taxpayer and second, in a legal capacity as a regulator of the market. The principles at work behind the PPRS are, then, first, that a buyer of such a large amount of any company's products has a legitimate right to negotiate their price; and second, an obligation as regulator to intervene in a market which it sees as uncompetitive. In other words, both the demand and supply sides of the medicines market are seen as special.

The industry has done a great deal of work attempting to persuade government that the supply side has become progressively more competitive over recent years, and this was one of the principal foci of the task force set up as part of the 1999 PPRS.<sup>3</sup> On the demand side, meanwhile, budgets have been introduced into primary care to increase physician sensitivity to the costs of medicines. This is in addition to the provision of prescribing advice to physicians through a system known as PACT (prescribing analysis and cost trend data).

PACT has been followed by another system, PRODIGY, which advises physicians and other prescribers on lower cost treatment options. The new National Institute for Clinical Excellence (NICE) aims to improve the 'cost effectiveness' of NHS care and while its conclusions are only advisory it is likely to have a significant effect on the behaviour of practitioners, and hence act as a further demand side control.<sup>4</sup>

There is significant debate about the role the PPRS plays in the changing healthcare landscape. It may be that controls and advice within the NHS edifice are able to create a demand side that emulates a more normal market and hence reduce the need for supply side regulation. Whatever the options for reform in the context of European systems of price regulation, the PPRS is already a flexible regime.

**The broader context**

As a flexible system of regulation, the PPRS can be seen as having developed

*“convergence between national systems is extremely difficult to achieve in the absence of synergy in the funding of healthcare”*

*“both the demand and supply sides of the medicines market are seen as special”*

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.<sup>5</sup> 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.<sup>6</sup> 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



*Vincent Lawton is  
Managing Director of  
Merck Sharp & Dohme.*

*“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”.*

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.<sup>1</sup> I think PICTF achieved three things.

First, it showed that different government departments can work with each other, and with the industry, in constructive joined-up dialogue. Second, it proposed a

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.

I work for an American company. Part of me is proud of this lead that we have opened up. But the UK is my market. Part of me also says to the politicians: you must take notice of these trends and learn the lessons from them.

Those lessons are spelled out well in a recent report by an Italian economist Fabio Pammolli and two colleagues, which was written for the European Commission.<sup>2</sup> The Commission has responded by setting up its own task force — the G10 group — under the leadership of Enterprise Commissioner Erkki Liikanen, to explore how Europe as a whole can become more attractive for the pharmaceutical industry.

The European pharmaceutical industry, concludes the Pammolli Report, is becoming

less competitive. Partly, it says, this is because US multinationals appear to be more successful than their European counterparts in producing innovative medicines. But this is by no means the end of the story.

The US also benefits enormously from the immense creative potential of its biotech sector. The United States more and more seems like the natural home for global research in biotech sciences. European companies, just as much as US ones, tend to look to America as the focus for their biopharmaceutical research.

The final factor identified in the Pammolli report is quite simply that demand has grown much faster in the US than in Europe over a comparable period, both in quality and quantity. It is clear that the American pharmaceutical industry benefits from having on its doorstep the most sophisticated market for prescription medicines in the world.

Michael Porter, the global guru of competitiveness, puts the point well. "Ultimately", he has written, "nations succeed in particular industries because their home environment is the most dynamic and the most challenging, and stimulates firms to upgrade and widen their advantages over time".<sup>3</sup> This is a key lesson for Europe: the strength of the pharmaceutical industry here will be directly proportional to how open European markets are to new medicines.

### **NICE**

This is why, in the UK, the National Institute for Clinical Excellence — NICE — is so relevant to the competitiveness of the pharmaceutical industry. Set up to cover England and Wales, it has already spurred an equivalent in Scotland and looks set to go further. NICE is part of a European collaborative project on health technology assessment. We are already seeing the first stirrings of 'EuroNICE' in the undergrowth.

Pharmacoeconomic evaluation, however, which is what NICE is about, should be wary of trying to run before it can crawl. The pharmaceutical industry pushed for NICE to be included on the PICTF agenda. Many of the issues remain unresolved and will be subject to a review of NICE this year. We hope that this will be a fundamental review, looking from first principles about how NICE can improve the speed of access of innovative medicines in the NHS.

*"A commitment to competitiveness is one thing. What matters is carrying it through."*

*“The United States more and more seems like the natural home for global research in biotech sciences.”*

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 NICE ‘blight’. While the Institute is spending months in judgement on a particular technology, the NHS doesn’t use that technology. The result is further delay in getting medicines to patients – further delay on top of the NHS’s already notorious lassitude in embracing new technology.

NICE is also self-defeating because its conclusions are not properly outcome-based. They cannot be. NICE intervenes at a stage too early in the product cycle to be able to assess outcomes properly. It is a sobering thought that if NICE had been around to assess the cholesterol-lowering drug simvastatin at the time of its launch in 1989, it almost certainly would have produced a negative report. The results of the Scandinavian Simvastatin Survival Study (4S) showed that simvastatin reduced heart attacks and saved lives in patients with angina or previous heart attacks. Access to that medicine would have been denied, or at best delayed, and many people would have died unnecessarily.

NICE is self-defeating because it bears down disproportionately on the first-to-market products. There have been positive NICE appraisals, but they have tended to be of well-established products, with the evidence to support them. It is very different where, as NICE intends, it assesses the market leader at the very time when that product is out on its own. At that stage, by definition, the long term outcomes data that NICE needs to do its job are not available.

The result is quite likely to be a negative or cautious appraisal. And even if NICE is prepared to give the product the benefit of its doubt, by the time judgement is given, a year or more may have passed. In today’s industry this is more than enough time for a competitor to have arrived. This is profoundly anti-innovative.

It may be argued that, in global terms, these points are of negligible importance since the UK is only three per cent of the world market. But what happens in the UK has a wider impact, disproportionate to the size of the market. Moreover, as I say, NICE might not long be confined to Britain in any case. It would be a great error for a competitive pharmaceutical industry if NICE were expanded before some of these fundamental questions can be sorted out.

**The value of competition**

Governments, let me be quite clear, are absolutely justified in seeking value from the substantial sums that are spent on prescription medicines. But value will not be best achieved through regulatory aspirations that are based upon a science that has barely progressed beyond the stages of alchemy. On the contrary, value and competitiveness are best secured through competition.

If we look just at the UK market, the evidence of competition and its effects is impressive.

- There are more corporations competing. In each of the top 29 therapy classes, accounting for virtually all sales, there are four or more companies with competing products.
- Competition is leading to the faster entry of new products. The average time between entry for a first and second product, and between a second and third, has been falling progressively for 40 years.
- Market competition leads to lower

**Figure 1**

**COMPETITION: RECENT LAUNCH PRICES COMPARED WITH THOSE OF BENCHMARK PRODUCTS**

|                    |      |                        |
|--------------------|------|------------------------|
| ZOTON lansoprazole | -38% | TAGAMET cimetidine     |
| PROTIUM pantopraz  | -48% |                        |
| COZAAR losartan    | -25% | CAPOTEN captopril      |
| DIOVAN valsartan   | -33% |                        |
| APROVEL irbesartan | -30% |                        |
| AMIAS candesartan  | -36% |                        |
| TARIVID ofloxacin  | -22% | CIPROXIN ciprofloxacin |
| UTINOR norfloxacin | -49% |                        |
| SUPRAX cefixime    | -75% | CEPOREX cefalexin      |
| ORELOX cefpodoxim  | -66% |                        |
| CEDAX ceftibuten   | -57% |                        |
| EMFLEX acemetacin  | -55% | BRUFEN ibuprofen       |
| MOBIC meloxicam    | -74% |                        |
| ISTIN amlodipine   | -50% | ADALAT nifedipine      |
| MOTENS lacidipine  | -44% |                        |

Launch prices of a selection of products launched in the 1990s, adjusted for inflation to December 1997 levels, compared with those of the original benchmark products.

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’<sup>4</sup> 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 bio-medical 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. The PPRS creates perverse incentives, rewarding those with the biggest buildings rather than the best brains. Competition would keep prices under control while providing a far more effective stimulus to truly innovative effort.

This indeed should be part of a wider process of market reform embracing NICE and the multitude of demand-side controls which the UK Government, and other European Governments, have steadily introduced into the market. These efforts seem wholly focused on reducing expenditure on medicines, rather than encouraging best value from medicines spending, through the forces of competition and informed choice.

Under former Commissioner Bangemann, Europe began to make some progress towards liberalising the market in pharmaceuticals, even if the most conspicuous feature of his so-called round table talks was their apparent circularity. With Commissioner Liikanen now at the helm, and with his commitment to a competitive pharmaceutical industry in Europe, let us



hope that deregulation will come back onto the agenda.

**Performance indicators**

A commitment to competitiveness, whether at UK or EU level, is one thing. What matters is carrying it through. This is why one of the most important and welcome outcomes of PICTF was a commitment to develop an internationally comparable set of competitiveness performance indicators. These will enable both the Government and the industry to assess progress on the goals that PICTF has set. Progress will be formally measured and assessed every year. This is perhaps the PICTF outcome that will be of greatest long term significance. It will provide the necessary pressure and stimulus to secure continued improvements in the competitive environment.

**Wake up call**

In conclusion, therefore, the evidence shows that the UK, and the EU more widely, is steadily losing out to the USA in pharmaceutical industry competitiveness. Governments, at both EU and national level, have recognised the problem. But the response is confused.

There is a need therefore for both the UK Government, and Governments across Europe to review and revitalise their overall approach to competitiveness. In the UK, PICTF was the beginning of that process. It is by no means the end.

The UK will become a truly competitive location for pharmaceuticals when we have embraced the principles of competition, deregulation and recognised the link between a dynamic and demanding pharmaceutical market and an innovative pharmaceutical industry. The UK may have started to wake up to this issue. We are still a long way from solving it.

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*Erkki Liikanen  
European  
Commissioner for  
Enterprise*

# Where next for pharmaceuticals in Europe ?

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.

## **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

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

basis. Europe has over past years seen a relative decline in competitiveness and employment in many industries. The performance and structure of the pharmaceutical sector, as a typical high technology industry has been the subject of numerous studies. In particular there has been growing concern over the lack of attractiveness of Europe as an investment centre for pharmaceutical companies.

This has been highlighted by several reports over the past few years, all of which note that whilst the EU remains the major world producer of pharmaceuticals, the US has overtaken it in terms of both new innovations and overall impetus, especially in the 'new sciences' of biotechnology.

This has led to concerns about declining competitiveness of the European industry in world markets. Whereas Europe has fallen behind the US in recent years in introducing new products, European companies have invested heavily in the US.

It is worth noting that the comparison between the EU and the US in simple economic terms often hides a crucial cultural distinction. Europe is built of Member States that share a certain set of social values – the social security systems of Europe are a direct result of the concept of social solidarity, which is much stronger in the EU than in the US.

That said, there is a considerable diversity of approach by Member States in this context, and our work in this area seeks to bring together Health and Enterprise policy – often dealt with in isolation – in a more 'joined up' way.

### The single market

Significant progress has been made during the past decade to pave the way towards a single European market in terms of scientific and technical regulation. In particular the introduction of the Community procedures for technical approval of products across the European Union. This progress gives us a substantial base for further work.

Not every challenge connected with these changes can be solved simply by legislative reform, but in most cases the legislator can ease the way forward and should provide a sustainable and predictable legal environment.

I believe that by addressing these questions in concert – Member State, industry, patients and Commission, there is scope for progress, and I think that the level of expertise of those assembled in the group

creates a solid base and impetus for the future.

### Technical issues – the Review

The new strategic approach is of course intended to complement the ongoing work that continues to demonstrate strong daily cooperation at all levels between Member States, the Commission and Industry. The review of pharmaceuticals legislation, which we launched on 18 July this year, is one of our key activities in this field.

The current marketing authorisation schemes are based on the principle of cooperation and close involvement of Member States in the evaluation of medicinal products. We do not intend to touch this principle: it would not be wise to abandon things that work well. So why review? After several years of operation it was time to take account of both technological challenges (new products and therapies: notably biotechnology and gene therapy) and political challenges (in particular, the enlargement of the European Union and globalisation), so that the European system remains up to date and is capable of tackling the changes ahead.

That said, it is nevertheless evident that there are areas where we can improve; we need to get the right kinds of medicine to patients better and faster. We have to pay more attention to the transparency of the system. In the wake of recent health scares no one would argue against the need for better market surveillance in order to maintain and indeed further strengthen public confidence.

### Conclusion

The key issue is how to achieve a Single Market that both ensures a high level of protection of public health, and promotes competitiveness, growth and employment – whilst recognising the legitimate right of Member States to control their healthcare expenditure. Considerable progress has been made in licensing and in intellectual property – although there is, as we have seen, still work to be done on the market side.

To sum up, the Community is moving into a new phase. In both technological and social terms, the environment is changing very fast. The Commission, by dealing with both strategic and technical issues at once – in direct contact with all stakeholders, is taking a broad view of what needs to be done to actively meet the challenges of the future.

*“our work in this area seeks to bring together Health and Enterprise policy in a more ‘joined up’ way”*

# The G10

## An opportunity to improve competitiveness and benefit patients



*Chris Viehbacher*



*Alastair Benbow*

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 medicines). For the pharmaceutical industry this makes Europe a difficult and complex market in which to work. The regulatory environment is risk averse, being consistently slower to grant approvals than elsewhere, lacking in transparency, using information technology inadequately and lacking the partnership seen between industry and regulatory authorities elsewhere. The science base also lags well behind that of the US. The long term competitiveness of the EU pharmaceutical industry is, as a result, in decline.<sup>1</sup> Progress is possible in a number of key areas and this is the focus for Glaxo-SmithKline input into the G10 initiative.

### Market access

A key policy objective of Member States and the European Union is to ensure that patients have access to high quality medicines and to innovative treatment that improves existing therapy and addresses unmet patient needs.

Considerable delays are currently experienced in access to new, effective medicines. There can be as long as four years between patients in the first and last Member State having access to an innovative medicine.<sup>2</sup> Equality of access to EU citizens will be improved by creating a more favourable environment for the introduction of new medicines by minimising the delays which occur during the regulatory process, the issuing of product licences after marketing authorisation, in price negotiations and in reimbursement systems. Several changes are needed:

- a fast track authorisation procedure in areas of unmet medical need;
- reduction in delays between regulatory decisions and subsequent launch;
- reduction in delays in notification of pricing and reimbursement decisions;
- to be allowed immediate direct access to the non-reimbursed market after licensing at a price determined by the manufacturers.

### Pricing and reimbursement

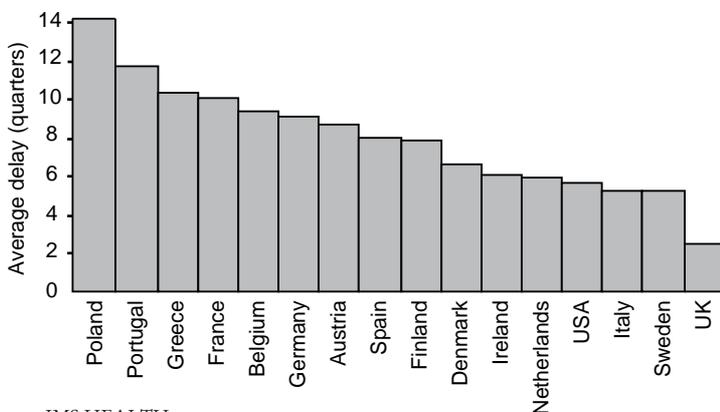
Pricing and reimbursement for medicines used in the national public healthcare systems are decisions that lie within the competence of Member States. The market structure in many Member States differs significantly from the United States in ways that damage the competitiveness of all sectors of industry, without necessarily providing benefits to payers or patients. In particular, the slower uptake of innovative new medicines and lower prices in Europe, damage both patients (delayed access to modern medicines with quantifiable impacts on health outcomes) and the innovative industry (lack of incentive and reward for innovation).

Within both EU and national policy competencies, price controls for medicines should be limited to those products that are reimbursed by Member States. By allowing the removal of controls on non-prescription medicine prices and permitting price liberalisation for non-reimbursed medicines and all medicines in the private sector, a truly competitive single market would be created in these areas.

This proposal would not impact on the ability of Member States to regulate the prices of medicines that are purchased or subsidised by the state. Nor would it have any impact on the ability of national systems to decide which products they wished to reimburse. All parties need to work flexibly together to move towards

### AVERAGE DELAYS FACING PATIENTS FOR NEW MEDICINES

The delay between receiving marketing authorisation in the first EU Member State and first consumption in each individual country



Source: IMS HEALTH

Chris Viehbacher is President of GlaxoSmithKline Pharmaceuticals Europe and a member of the European Commission G10 grouping.

Alastair Benbow is a physician and Vice President of European External Relations, GlaxoSmithKline Pharmaceuticals.

more consistent prices for patented products, at a level that rewards innovation appropriately within a framework that allows Member States to contain overall public expenditure.

### Evaluation of new medicines

We recognise the desire to assess the value of innovative medicines for public reimbursement in order to allocate public resources efficiently and inform national decision making. At present, such systems appear to support primarily the financial interests of payers (which is a legitimate objective) but not necessarily the interests of either patients or industrial competitiveness. The cost of undertaking additional studies by pharmaceutical companies and the risk of being assessed 'not cost effective' reduce still further industrial competitiveness. At the same time, developments of importance to patients – such as improvements in quality of life, reduced side effects or more convenient administration – receive little recognition from review bodies focusing on cost or formulaic innovation indices.

Any relative and cost effectiveness evaluation by Member States should remain separate from technical approval on criteria of quality, safety and efficacy. This principle should continue to be reflected in the upcoming review of pharmaceutical legislation. Differences in morbidity and mortality across Europe, different healthcare structures and different prices mean it is only possible to undertake such evaluations at a national level.

### Patients and medicine provision

Health literate citizens are an asset to society. Patients increasingly demand information about their disease and available treatments and are approaching health professionals in an informed way. Providing information to patients improves communication with doctors<sup>3</sup> and encourages better compliance with medicine use<sup>4</sup> so ensuring safer and more successful outcomes.

It is crucially important that patients have access to reliable, factual and balanced information over choices of healthcare and medicines. The pharmaceutical industry can play a central

role in providing such information. Patients seeking information about products from manufacturers should be permitted to do so across the whole of Europe.

### Intellectual property

High standards for protection of intellectual property (IP) rights support competitiveness and promote the introduction of new medicines and indications. This principle is well established. Strong IP rights are fundamental to the economic model of the research based industry. The time and cost required to bring new advances to market are such that a period of exclusivity is essential in order to justify the investment, ensure a return, and generate funds for further research. Rewards for innovation encourage continued R&D and improve the competitiveness of industry. However, without incentives created by appropriate conditions for pricing and market access, EU support for IP is insufficient to improve competitiveness and create jobs in Europe.

Enlargement of the EU raises special issues for pharmaceutical manufacturers. The candidate countries have no history of an innovative pharmaceutical sector and have traditionally low standards of IP. It is essential to ensure that they match the IP standards of the rest of the EU, and that any necessary transitional provisions fully respect the prevailing standards for each product in the current membership. The need for special arrangements most critically must take into account the ability of accession countries to maximise affordable access for their citizens.

There is a need for a level playing field across all EU Member States in IP legislation and the elimination of disparities between IP treatment of products in different countries. This includes the need for harmonisation of data exclusivity for all products and for additional clinical data.

### The science base in Europe

Pharmaceutical industry success is based on commitment to innovation and sustained research and development (R&D) investment. The pharmaceutical sector depends on world class excellence in university research

and on well trained graduates. Emphasis must be placed on longer term basic research, with closer integration between scientific disciplines.

There is potential for public/private partnerships in health informatics. Healthcare delivery systems have much to offer in epidemiology, outcomes research, technology assessment, and population genetics relating to the diseases that are of greatest importance for Europe. Exchange of human and financial resources between the public and private sectors through increased industry/academia links should be fostered.

Overall, an environment should be created which encourages pharmaceutical investment: academic scientific excellence; high quality management; technology transfer practices; flexible, science-based regulatory systems; strong intellectual property protection and the encouragement of partnership between public and private sectors.

### Conclusion

The G10 process offers the prospect of progress in improving industry competitiveness whilst bringing benefits to European patients. All those involved need to work hard to make sure this opportunity is not wasted.

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# Pricing European Pharmaceuticals:

## Can the Commission untie the Gordian Knot?

*Prices for medicines, especially prescription medicines, continue to diverge dramatically across the Member States of the European Union, with some market leaders costing up to 50 per cent more in the high price northern markets as compared to the southern European markets. The eventual accession of the eastern European countries now lined up to join the EU will undoubtedly lead to wider divergence in prices.*



*Leigh Hancher*

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.<sup>1</sup> On patent expiry, the lucrative market position enjoyed by leading branded products increasingly comes under threat from generic substitutes. Patent protection for pharmaceuticals has been weak in many eastern European countries, and their thriving generic manufacturing sector is gearing up for full integration into the EU.<sup>2</sup> Further, several accession countries are contemplating the introduction of so called Roche-Bolar type provisions in their domestic intellectual property laws to allow generic manufacturers to develop versions of patented pharmaceuticals before the patents expire. The European Parliament has lent its support to this approach.<sup>3</sup> Added to this cocktail is the impact of e-commerce and the spread of campaigns by patient advocates and health-care and insurance companies for more efficient medicine purchasing procedures – all of which will put pressure on the margins enjoyed by traditional pharmaceutical wholesalers.

### **The legal and policy framework**

The processes of intra-brand (parallel trade) and inter-brand (generics) competition are considered by the European Commission, particularly the Directorate General for Competition (DG Comp), as

essential for the eventual realisation of a single market across the EU. The Commission as legal guardian of the Treaty on European Union must safeguard these processes. In particular it must guarantee the proper enforcement of the Treaty rules on free movement of goods and competition – two of the principal pillars on which the single market edifice is constructed. If the original manufacturer attempts to protect a high priced market from parallel importation, through seeking to enforce its intellectual property rights, it may find that it has infringed Treaty rules on free movement. Attempts to reach agreements with wholesalers and distributors to restrict supplies to a market and cut off the source of parallel trade may also infringe Treaty competition rules. The Commission does not have a monopoly on enforcement of these provisions, which can be enforced by the party claiming injury through courts in each Member State.

The pharmaceutical market differs in several important respects from the market for most goods, as the consumer/patient rarely selects the product or pays or is even aware of the full price. Nor can the supplier usually set its own price: in the majority of Member States prices are regulated through a bewildering variety of techniques (see other articles in this issue). Generally, government intervention is more stringent where the volume of demand is traditionally high.

To add to the complications, the pharmaceuticals sector and the eventual creation of a single pharmaceutical market poses the European Commission particular legal problems and confronts it with several intractable policy dilemmas. Repeated claims by the research-based industry that the rise of parallel importation threatens not just short term profits but the long term investment and innovation potential of one of Europe's most important industrial sectors have found some sympathy at Commission level – in particular at DG

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Leigh Hancher is Professor of European Law, Tilburg University, Netherlands, and a Partner at Kennedy van der Laan, Amsterdam.

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 industrial policy ambitions for a strong, innovation-based European industry.

### Commission competence

These issues are not new but they are becoming increasingly urgent, especially as enlargement is likely to exacerbate the situation. An important dilemma is the nature of the Commission's executive competence to launch policy initiatives and eventually propose binding rules to deal with the phenomenon of price divergence, and with it intra- and inter-brand competition. Is this to be dealt with as an industrial policy issue, as a health policy issue or as a social security and consumer protection issue? The choice of policy focus is not merely of political importance but has a definite legal dimension. The division of competencies between Member States and the Community differs depending on whether industrial policy or public health and social security is at stake. The latter areas remain, legally and politically, the preserve of the Member States. And how should such policy choices be reconciled with the Commission's related legal duties to enforce the principles of European law? This will be a key focus for the newly created high level group on competitiveness in the industry.

The Commission may effectively protect parallel importation through a judicious enforcement of the Treaty competition rules: it can and has ruled that companies who seek to impose export bans or other restrictions on wholesalers operating in low priced countries to supply their products to higher price markets infringe Article 81(1)EC – which outlaws cartels and agreements restricting competition.<sup>4</sup> The Commission can give clear guidance as to how it interprets the Treaty rules.

Its recent decision of 8 May 2001 prohibiting Glaxo Wellcome (GW)\* from maintaining a dual-pricing scheme indicates that it is not prepared to accept the research based industry's argument that it should be entitled to take appropriate action to respond to differences in national price control regimes.<sup>5</sup> GW had notified the Commission of new conditions for the sale of all its products to wholesalers in Spain. These wholesalers would have to pay higher prices for products which they would

export than for products which they would resell for consumption on the domestic market. GW's dual pricing system was found to limit parallel trade from Spain to other Member States for the vast majority of its products and therefore interfered with the Community's objectives of integrating national markets. The Commission was not convinced by the 'consumer welfare' claims that losses incurred by GW due to parallel trade would seriously affect GW's R&D budget which it uses to devel-

*“Commission attempts to tackle the issue of price divergence at source have not found much favour from either the Member States or from the research based industry.”*

op innovative drugs. GW's dual pricing scheme was seen by many as an important test case. The Commission was confronted for the first time with agreements that explicitly sought to restrict parallel trade but which the company sought to justify on economic grounds. The policy implications are clear: companies will have to continue to live with national regulatory divergences. The Commission stressed that losses stemming from parallel trade could be deducted from budget items such as marketing costs, rather than from R&D costs.<sup>6</sup>

The findings of the recent report on 'Global Competitiveness in Pharmaceuticals: A European Perspective' commissioned by DG Enterprise<sup>7</sup> have encouraged the Commission's competition services to make such a bold statement. This Report confirmed that the European industry has declined in competitiveness compared to the USA, with large differences and trends across the Member States. The Report puts forward a number of explanations to support its finding that as a whole Europe is lagging behind in its ability to generate, organise and sustain innovation processes that are increasingly expensive and organisationally complex. Significantly the Report stresses that many national European markets are not competitive enough, and that the nature and intensity of competition in final based markets is too weak to nurture efficiency and innovation. Parallel trade is the only source of competition for products still in patent.

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\* Now merged with SmithKline Beecham to form GlaxoSmithKline (GSK).

### 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.<sup>8</sup>

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.<sup>9</sup> 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.<sup>10</sup> 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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\* 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.

# Towards a Euro-NICE?

*Does the new pharmaceutical regulation in the UK provide a role model or a warning for the rest of Europe? Either way, what lessons can be learnt?*



*Alan Maynard*

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.<sup>1</sup>

The example of NICE is an imperfect model for the development of a European wide system of health technology appraisal which informs or determines reimbursement decisions. The original vision for NICE was that it would use the best scientific advice in appraising competing technologies and rank these in terms of clinical and cost effectiveness. Such information would assist local healthcare decision makers who have to determine which, of many competing service improvements, should be funded.<sup>2</sup>

The goals of any Euro-NICE would need to be agreed carefully and its organisational structure would need to be consistent with them. Healthcare purchasers and providers do not wish to know merely that interventions are clinically effective. There are many interventions (including a glass of water!) which can improve the health status of a patient but all treatments cannot be funded with the limited resources available.

The ultimate criterion in 'rationing' resources in a public healthcare system is relative incremental cost and benefit. What is clinically effective is not always cost effective. However, those interventions which are cost effective are always clinically effective.<sup>3</sup> A failure to note and operationalise such distinctions can lead to inefficient decisions that deprive patients of care from which they would benefit. Thus

NICE guidance on the cancer drugs taxol and taxanes leads to treatments with small benefits, in terms of enhanced duration and quality of life, at high cost. Because NICE 'advice' tends to be considered by NHS decision makers as mandatory, it is rapidly translated into treatments for patients. However, many cancer patients would benefit much more if such resources were used to support psycho-social support, where the literature has demonstrated significantly greater cost effectiveness.

Thus, the first elements of any system of Euro-NICE should be the determination of the prioritisation criterion (for example, incremental cost effectiveness) and the creation of a ranked hierarchy (or league tables) of competing therapies. The next step is to agree how costs and benefits should be identified, measured and valued in a systematic way. There is much guidance and a high degree of international agreement about how economic evaluations should be carried out.<sup>4</sup>

It is likely that estimates of costs and benefits of particular technologies will vary from country to country because exchange rates do not reflect local opportunity costs or purchasing parity. Factor prices of inputs such as labour might also vary. Estimates of the patient outcome may vary internationally if there is no agreement amongst clinicians about the processes of delivering the care. Good systematic reviews should reduce this variation, provided evidence wins over opinion! Progress could be made in agreeing the methods of economic evaluation to be used by the European Union. Whilst the results of such evaluations may vary it is likely a high degree of harmonisation could be achieved.

The benefits of harmonisation could be considerable, with wasteful and inefficient therapies being rejected for reimbursement and scarce resources targeted on those interventions which give the greatest 'bang for the buck'. Only the pharmaceutical industry will be worried by such policy changes. Healthcare systems will benefit by being able to deliver care more efficiently to competing patients waiting in pain and discomfort. Such benefits should please taxpayers throughout Europe!

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Alan Maynard is Professor of Health Economics at the University of York and Visiting Professor at LSE Health & Social Care, the London School of Economics and Political Science.

# 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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Helmut Walerius is Assistant within the Communicable, Rare and Emerging Diseases Unit, Directorate for Public Health, European Commission.

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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:* Support, at Community level, educational campaigns directed at professionals and the general public to avoid overuse and misuse of antimicrobial agents.

*Action 5:* Fully apply the principle that antibacterial substances are available in human and veterinary medicine by prescription only and distributed in a controlled way in agriculture, and evaluate whether the prescription-only rule should be applied to all antimicrobial agents as a precaution.

*Action 6:* Reinforce and promote prevention programmes of infections in human and veterinary medicine, in particular immunisation programmes.

*Action 7:* Reinforce the residue monitoring system in food as regards methods of analysis, sanctions and reporting systems.

*Action 8:* Phase out and replace antimicrobial agents used as growth promoters in feed.

*Action 9:* Review the use of the two authorised antimicrobial agents in food.

*Action 10:* Ensure that GMOs which contain genes expressing resistance to antibiotics in use for medical or veterinary treatment are taken into particular consideration when carrying out an environmental risk assessment, with a view to identifying and phasing out antibiotic resistance markers in GMOs which may have adverse effects on human health and the environment.

### **3. Research and product development**

New modalities for prevention and treatment of infections and continued support for research into new drugs and alternatives.

*Action 11:* Encourage the development of new antimicrobial agents.

*Action 12:* Encourage the development of alternative treatments and vaccines.

*Action 13:* Support the development of rapid and reliable diagnostic and susceptibility tests.

**4. International cooperation** Antimicrobial resistance does not respect frontiers. An effective strategy requires close cooperation and consultation between the Commission, Member States and other involved parties, especially at international level.

*Action 14:* Encourage the development of cooperation, coordination and partnership at international level in particular via the existing international organisations.

*Action 15:* Pay special attention to candidate and developing countries by helping them put in place appropriate structures.

### **Council Recommendation**

The purpose of the proposal by the Commission for a Council Recommendation on antimicrobial agents is to contain the spread of antimicrobial resistance by prudent use of antimicrobial agents in humans.

Following the actions identified by the Commission in its strategy, the measures that are to be implemented by Member States are as follows:

- Collecting and analysing data on antimicrobial resistant micro-organisms and on consumption of antimicrobial agents available to prescribers, pharmacies, industry, health insurance providers etc. to detect potential links for intervention measures.
- Enforcing the principle that antibacterial agents should be available by prescription only, and evaluating whether this rule should be applied to all antimicrobial agents as a precaution.
- Developing guidelines and principles on the prudent use of antimicrobial agents, including principles for evaluation of applications for marketing authorisation.
- Improving prevention of infections to reduce the need for antimicrobial agents by reinforcing immunisation programmes and developing infection control standards in hospitals and the community.
- Enhancing knowledge of the problem by specialised education programmes for health professionals.
- Raising awareness of the problem of

*“The proposed Recommendation represents the first attempt at Community level to take action in the field of human medicine.”*

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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> 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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Richard Wise is Professor of Clinical Microbiology at City Hospital Birmingham and was advisor to the UK House of Lords Report on Antibiotic Resistance. Currently he is the UK Department of Health Chairman of the Specialist Advisory Committee on Antibiotic Resistance.

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 concern in the community, a different group are found in hospitals. The

media in many countries have highlighted problems with the so-called methicillin-resistant *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.<sup>4</sup>

**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, regional 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 antibiotics. Local and national bodies must have a clear view on why these data are needed. Is it required for scientific purposes (for example, to study different mechanisms of antibiotic resistance) or to influence national policies or to assist local clinicians in their prescribing? Different needs may dictate different surveillance systems. One particular need is to link prescribing of antibiotics with local resistance patterns. Currently relatively few countries have such information.

*“A coordinated European approach would be a highly worthy ambition.”*

**FIGURE 1: WHERE ARE ANTIBIOTICS USED?**

|                             |  |
|-----------------------------|--|
| <b>Total 100 million Kg</b> |  |
| <b>50%</b>                  | <b>Human</b>                             |
| <b>5—20%</b>                | <b>hospitals</b>                         |
| <b>80—95%</b>               | <b>community</b>                         |
| <b>50%</b>                  | <b>Animal</b>                            |
| <b>20%</b>                  | <b>therapeutic</b>                       |
| <b>80%</b>                  | <b>growth promoter/<br/>prophylactic</b> |

“There is a need to educate the medical and allied professions on rational antibiotic use.”

### 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 medical 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 research into strategies to avoid such resistance in the first place have been neglected!

There is a need to have a far more precise view on the way the genetic elements encoding resistance spread in a given community, and the more fundamental aspects of the most efficient means of implementing infection control procedures requires study. Expansion of information technology to link prescribing with resistance patterns is eminently achievable but as yet only minimally implemented.

Finally there is a need for the highly inventive pharmaceutical industry to produce new antibiotics. With one exception, in the past 25 years, there has been no totally new agent introduced to clinical use. We have had a plethora of compounds related to existing antibiotics. What are required are agents active against totally new targets. There is likely to be a dearth of these in the next five to ten years.

### Conclusions

All those interested in the health of the public must be seriously concerned about the current situation. The actions I have mentioned will not solve the problems. Current information suggests that resistance can develop rapidly, but once established it is slow to reverse. We also know that the new antiviral agents now coming onto the market will have the same problems: increasing use brings increasing resistance. The now almost uniform prescription of three anti-HIV agents is precisely related to anti-viral resistance. The increased costs are self evident.

The WHO recognises that the problem is international. Bacteria regularly cross international borders; an epidemic of antibiotic resistant respiratory infections in Iceland is thought to have originated in Spain. Inaction is not an option if we are to avoid a return to the pre-antibiotic era. Coordinated international action has the possibility of delaying the emergence of future problems.

Antibiotics are extraordinary drugs. They are unique in that they act against independently living organisms, the bacteria, which in their turn have developed ingenious strategies to circumvent their effects – 'survival of the fittest' in dramatic action. Equally, antibiotics are unique in that their misuse (or even their reasonable use) has a cost not only on the patient (such as possible toxicity) but upon society at large (namely emerging bacterial resistance which can be transmitted). Multidisciplinary multinational action is required in order to avoid a possible 'post antibiotic era'.

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# Antimicrobial Resistance: Can economics help?



*Joanna Coast*



*Richard Smith*

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.<sup>1-5</sup> 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.<sup>6</sup> 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.<sup>7</sup> 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.<sup>3</sup>

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.<sup>1,8</sup>

The issue of this optimal rate of antimicrobial usage can be informed, for example, by assessing the 'time preference rates' of citi-

zens 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.<sup>9</sup> 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<sup>3</sup> and a more extensive assessment of how such a permit system might operate.<sup>10</sup> 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.<sup>11</sup> There are, however, two sources of concern in relation to economic evaluation and antimicrobial resistance. The

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Joanna Coast is Senior Lecturer in Health Economics, Department of Social Medicine, University of Bristol.

Richard Smith is Senior Lecturer, Health Economics Group, School of Health Policy and Practice, University of East Anglia.

“the economics of resistance can assist in clarifying the basis for policy development”

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.<sup>2</sup> 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 analyst effectively free-rides on the current level of resistance, assuming that their one evaluation will make little difference to the overall development of resistance. On the other, the costs associated with obtaining this information for any individual evaluation are outweighed by the benefits of doing so: thus it can appear to be optimal for analysts to ignore resistance!

The second concern is that current evidence for the cost effectiveness of alternative strategies for containing resistance is extremely poor. Many assessments of the effectiveness of particular strategies have not considered the associated costs.<sup>12</sup> In part this is due to the fact that economic evaluations are only now increasing in frequency. Of more concern is the difficulty of undertaking economic evaluations in this area: the effects of policies to contain resistance may be very diffuse and difficult to

identify; effects occurring far into the future may be extremely uncertain; and some forms of outcome may be more difficult to value than others. All of these factors mean that economic evaluation of these policies may be particularly difficult.<sup>2</sup>

### Empirical and theoretical developments

Inevitably, developments in the economics of resistance are partially dependent upon scientific and epidemiological advances, but there are areas of the economics of resistance where significant progress could be made. In relation to policy development, empirical work to estimate the time preferences of citizens and policy makers over both current and future generations is required. Relaxing restrictive assumptions and thus increasing the realism of models, would also be helpful.

Policy development work by economists has been relatively limited to date. Further development of policies, perhaps using simulations or experiments, would provide a valuable source of information. Research is also needed into the applicability of these sorts of policy solutions at different levels of healthcare, ranging from individual hospital policies, through broader community and primary care policies, to collective action policies at the international level.

Finally, there are a number of options for improving the evaluation of the costs and benefits of alternative strategies. At the level of individual pieces of empirical work there is huge scope for the economic evaluation of particular interventions alongside randomised controlled trials and other studies. Despite the difficulties of such work, many of these problems will only be illuminated and resolved when health economists become involved in empirical studies. At a higher level, and in the absence of strong comparative research evidence, there is an urgent need for the development of comprehensive economic models to evaluate alternative policies. Such models would need to incorporate information about the potential long term impact of resistance, how this is affected by current antimicrobial use and how it may vary with changes to future use and socioeconomic factors.

Although further developments are undoubtedly required, the economics of resistance can assist in clarifying the basis for policy development, identify and develop policy options and, through the assessment of the cost and benefits of alternative options, help to identify optimal policy solutions.

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# Food matters

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



*Tim Lang*

*“Fear of unmanageable consumers stalks the corridors of power.”*

*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.*

I have argued before in these pages that the terrain of EU food policy is witnessing remarkable change.<sup>1</sup> 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.

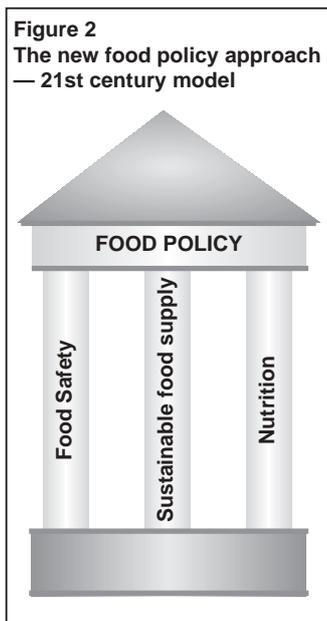
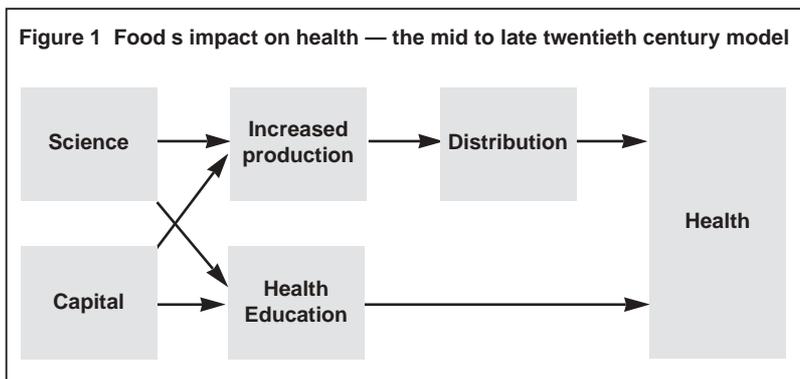
Second, there is a need to be clear about the purpose of all this is. Although there is great potential for the EFA, it is essential to keep asking whether it is necessary. Across Europe, we need to clarify what value agencies add to food policy formulation and implementation. How will this plethora 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.<sup>2</sup>

### **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

Tim Lang is Professor of Food Policy at Thames Valley University, United Kingdom.



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.<sup>3</sup> 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.<sup>4</sup>

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.<sup>5</sup> 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.

There is much to do but the stakes are high. There is a fundamental tension between the neo-liberal critique of CAP and the modern cost internalisation position. Finance Ministries favour the former, but must be persuaded of the advantages of the latter. Ecological and human health analysis of CAP has a complex story to tell.

Europe is blessed with glorious diversity of cuisine, farms and products. But it also shelters hideous inequalities of diet related ill health. Ultimately we have to ask: What sort of food system do we want? Is policy in control of the food system or is it, as seems to be the case, in control of us?

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# Agriculture policy, health and nutrition



*Tim Lobstein*



*Aileen Robertson*

*Public health experts need to pay increasing attention to agriculture policies. Agriculture can provide employment, food security, healthy diets and a healthy environment, but it will only do so when its current practices are challenged.*

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 socio-economic 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.<sup>1</sup>

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.<sup>2</sup>
- 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, low birth-weight, obesity, diabetes, and cardiovascular diseases. As a result of these observations, the World Health Organisation recommends the daily consumption of more than five portions (400g) of vegetables and fruits per day.

The supply of vegetables and fruits varies considerably throughout the European region. The greatest supply is in Greece where there is over 1000 grams of vegetables and fruit available per capita per day. Greece has the lowest rate of premature mortality from cardiovascular disease. In

*“The average family is paying some 1000 euros annually as a result of EU agricultural policies.”*

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Tim Lobstein is Director of The Food Commission, London.

Aileen Robertson is Acting Regional Adviser in the Nutrition and Food Security Programme, World Health Organisation, Copenhagen.

*“The biodiversity of our diet has declined dramatically.”*

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?**

A reformed agriculture policy should incorporate the following elements:

- Following the Rio Summit and Agenda 21, there is an overriding objective to encourage sustainable forms of agriculture, including producing foods that mirror the population’s needs, as set out in dietary guidelines for EU Member States. All dietary guidelines stress the need to increase intakes of vegetables and fruit and to decrease saturated fats.
- Publicly financed subsidies for agriculture should aim to achieve the above goals. For example, funding should go to support the promotion of increased consumption of vegetables and fruit, instead of the consumption of meat products and full-fat milk. In contrast, intervention price support for cereals (the bulk of which are used for animal feed) has encouraged farmers to convert land from vegetable and fruit production to cereal production.
- Resources for research and development into sustainable agriculture and health impact assessments should be provided. At present, most agricultural research resources are devoted to the needs of conventional methods of production (including biotechnology), and most resources for impact assessment are devoted to a narrow range of environmental concerns.

*“The EU’s system of compensatory payments to farmers distorts agricultural markets and ... encourages poor diets.”*

### **Opportunities, 1. Health Impact Assessments**

Health cannot be protected, sustained or promoted by the action of the health care sector alone. There is a need to assess and change the impact of other sectors on the health of the population, and to do this through the development of intersectoral health policies.

This need has given rise to a call for the development of a systematic approach, methodology and procedures for Health Impact Assessment (HIA).<sup>3</sup> The significance of human health and its determinants has been emphasised as an aspect of

Environmental Impact Assessment (EIA), particularly in the USA, Canada, Australia and New Zealand as well as in the World Bank.

Research into the health impact of agriculture policy is urgently needed. Under the Amsterdam Treaty, the European Union is committed to ensuring that ‘...a high level of health protection shall be ensured in the definition and implementation of all Community policies...’ (Article 152). The single largest policy operating in the EU, responsible for around half the overall budget, is the Common Agricultural Policy (CAP). As has been discussed in several documents, many of the measures under the CAP act to reduce the potential for high consumption of fruit and vegetables, and promote the consumption of meat and dairy products, sugars and fats.

### **Opportunities, 2. Enlargement**

As we have suggested, the EU’s system of compensatory payments to farmers distorts agricultural markets and encourages poor diets. If the EU’s intention is to apply these payments to the countries of Eastern Europe currently applying to join the EU, then the implications for social cohesion and public health in these countries are serious, with the following likely distortions:

1. Land prices will rise, which will make it harder for young farmers going into agriculture.
2. Production of crops and livestock will intensify, with concomitant burdens placed on the environment.
3. Absentee ownership is common in accession countries, and much of the income from EU subsidies would be invested outside agriculture. Thus, payments will be of little benefit to those working on the land, resulting in an agricultural policy that transfers wealth to a substantial number of non-farming landowners.
4. Agricultural productivity in 2000 in the accession states was only 11 per cent of the EU level. Increasing productivity will mean that less labour will be required, creating high levels of unemployment. In Poland the agriculture policy calls for the percentage of the working population engaged in agriculture to be cut from 28 per cent in 1998 to just five to seven per cent before joining the EU.
5. Food production policies during the

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.<sup>4</sup> 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.<sup>5</sup>

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, environmental protection, the improvement of rural life, the protection of farm incomes and the competitiveness of European agriculture on international markets. (Questions on nutrition and diet were not asked.) A clear majority of people thought that all the objectives were important (ratings varied between 76 per cent and 97 per cent) but the levels of satisfaction with how they were being met ranged between 16 per

cent and 57 per cent.

The protection of farm incomes and small farms were seen to be badly served, by both farmers and the general public. Food safety and environmental protection were considered to be the top priorities but the survey revealed an acute need for information about agriculture policy.

Indirectly, consumers are already protesting against agriculture policy because they buy less meat. Since the BSE crisis, demand for beef has dropped by 27 per cent on average and in Germany by 50–80 per cent. This is damaging for agriculture policy but, from a nutritional perspective, this trend may prove to be healthy if the dietary changes include the consumption of more fruit, vegetables, wholegrain cereals or fish.

### Opportunities, 4. The first Food and Nutrition Action Plan for the WHO European Region

In September 2000 the 51 member countries of the European Region of the World Health Organisation unanimously endorsed a resolution to implement the region's first Food & Nutrition Action Plan.<sup>6</sup> This document makes the case for combining nutrition, food safety and sustainable food production concerns into an intersectoral policy, and offers support to member state governments to develop, implement and evaluate such policies.

Progress with implementation will be reported to the Regional Committee in September 2002. In addition, a more comprehensive evaluation of the impact of this first Action Plan will be reviewed during the first Ministerial Conference on Food & Nutrition in 2005.

This political commitment gives public health experts an extraordinary and important opportunity to lobby both at national and European level for an agriculture policy that explicitly promotes health.

### Conclusion

Unsustainable agricultural systems have grown out of the narrow focus on productivity that has monopolised agriculture policy. Their economic costs are already becoming apparent but their human health costs – including their nutritional impact – have not received sufficient attention.

A number of opportunities for changing agricultural policy are becoming available, and public health experts are urged to ensure that their views are fully expressed in this process.

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# Society and the environment:

## A new approach to agriculture

*Elisabeth Baumhöfer is Managing Director of the Österreichischen Bergbauernvereingung (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.

### **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.

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

### Prices and pay

The distribution of subsidies to agriculture in the EU has led to excessive production of some products and increasing pressure for rationalisation. In order for high quality foods to achieve adequate prices, subsidised over production has to be reduced. In Austria, subsidies currently account for around two thirds of agricultural income. They are tied to the size of the operation and the number of animals, but not to the required labour or the preservation of the environment. In consequence, subsidies serve only to support large and intensive farming enterprises and undermine genuine competition.

We need a clearly defined system of grading and ceilings for subsidies, which will support small and environmentally conscious enterprises. In order to support employment in agriculture, subsidies should relate to the number of employees, and be based on an ecological minimum standard. No farmer in the world can produce at the artificially low world market prices that currently operate. They are in many cases lower than production costs. We are confronted with the paradoxical situation that a litre of drinking water costs more than a litre of milk and a ton of waste costs more than a ton of wheat!

In the long run food prices should cover production costs. The price structure should take into account the consequential cost of environmental destruction caused by intensive production, including the global transport of agricultural raw materials, such as animal feed, and the costs of healthcare. These costs are currently borne by the tax payers who are required to support industrial farming and not by those directly responsible – the industrial farmers themselves.

### The green challenge

Through a chemically intensive production process and enormous animal feed imports, we in the EU have an ongoing problem with production surpluses. Productivity improvements of three per cent per annum have had the effect of pushing three per cent of farmers out of agriculture annually. If this trend

continues, the number of farmers will be halved within the next two decades.

We need an effective reduction of these surpluses by restricting the number of animals per hectare to an ecologically sustainable level, along with a reduction in the use of fertilisers and chemicals. This represents a starting point for a widespread 'greening' of agriculture. Effective quota regulations and reductions are needed to reduce surpluses, as are incentives to restrict production.

### Next steps

- Abolition of export refunds and the introduction of a duty that can be collected from the big producers in the event of over production.
- Compensatory Allowances should be restricted to sustainable agricultural production processes.
- The creation of Europe's own protein plant production so that we are no longer reliant on the import of animal feed.
- The establishment of a feed bonus for cultivation of vegetable feed to replace the silo-maize bonus; abolition of the 'non-land utilisation' premium and the transformation of grain surpluses into feed and protein-plant production.
- The application of the precautionary principle and, with current knowledge, a clear ban on the use of gene technology in agriculture and food production.
- Active promotion of sustainable production processes by the European Agriculture Grants and Guarantee Fund (EAGGF) to help the greening of agriculture.

### Nutrition sovereignty

Under 'nutrition sovereignty' we understand the right of every region and nation to produce its own food. Such sovereignty forms the fundamental basis for nutritional security. This unites farmers in the developed world with those in developing countries. The conservation of biodiversity is a key factor in enabling nutritional security in the longer

term and as part of this, farming communities should maintain control over seed stocks.

The interconnectedness of the global agricultural economy means that policies in the EU can have damaging consequences across the world. The large European imports of soya from Brazil, used as animal foodstuffs, contribute to the destruction of the rainforests that are cleared to make way for soya production, while at the same time contributing to the over production of food in the EU. A vicious circle has been created in which there is hunger and environmental degradation in one part of the world and over production in another.

As a consequence, the orientation of the CAP towards the world market, rather than focusing on internal needs, has negative consequences beyond Europe. Export dumping not only undermines food production and, in turn, the existence of farmers in many regions of the world, but it threatens nutrition security and the environment.

### The rural dimension

The 'second pillar' of the Agenda 2000 programme should not be used to counter the damage caused by the CAP. Rather, it should support more integrated rural development programmes with ecological quality production, regional processing and marketing, as well as preserve and create valuable jobs. And with that, it should help to achieve a better balance between the regions within the EU.

The CPE and the BBV (Österreichischen Bergbauernvereinigung, Austrian Mountain Farmers' Organisation) are convinced that to ensure the nutritional value of our food and to preserve the ecological balance worldwide, this can only be possible with a non-industrial and responsible agriculture. For that it is necessary to support smaller scale agriculture and local rural communities. We should not allow ourselves to be played off against each other any longer, but must achieve worldwide solidarity amongst farmers and consumers.

## 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](http://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 conges-

tion 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](http://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](http://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](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](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](mailto: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](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](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](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](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](http://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/osham2001>.

### 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/>

## 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](http://www.eu2001.be)

## 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 health-care 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.ksb?p\\_action.gettxt=gt&doc=SPEECH/01/268101RAPID&lg=EN](http://europa.eu.int/rapid/start/cgi/guesten.ksb?p_action.gettxt=gt&doc=SPEECH/01/268101RAPID&lg=EN)

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## NEWS IN BRIEF

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### European Food Authority

The European Food Authority (EFA) is one step closer to being established. At the end of May, the Internal Market Council reached a common position on the creation of the EFA. The proposal has three objectives:

- to set out definitions, general principles and requirements governing foodstuffs and animal feed;
- to establish the European Food Authority;
- to determine procedures for dealing with matters having a direct or indirect impact on food safety.

The competence of the EFA has already been determined. The composition of the Management Board and the venue of the European Food Agency will be discussed later. The Council will try to finalise its common position before the end of the Swedish Presidency. The Belgian Presidency wants to have the EFA operational before the end of 2002.

*The text of the Commission's proposal on the EFA is available at: [http://europa.eu.int/eur-lex/en/com/dat/2000/en\\_500PC0716.html](http://europa.eu.int/eur-lex/en/com/dat/2000/en_500PC0716.html)*

### European Year of Disabled People, 2003

On 30 May the Commission adopted the proposal to establish 2003 as the Year of People with Disabilities. The EU will fund this initiative with EUR12m. The budget will be used to initiate projects on awareness activities, events, meetings and reports and will be complemented by other European and national initiatives.

The European Year of Disabled People is the Commission's response to the European Social Agenda adopted last December at the Nice Summit, calling for more action in this area. The first Eurobarometer survey on attitudes towards disabled people has been published.

*For more information about the European Year of Disabled People see website: [www.europa.eu.int/comm/employment\\_social/news/2001/jun/135-en.html](http://www.europa.eu.int/comm/employment_social/news/2001/jun/135-en.html)*

*For information about Eurobarometer see websites: [www.europa.eu.int/comm/dg10/epo/](http://www.europa.eu.int/comm/dg10/epo/) [www.europa.bg/en/eurobaro.htm](http://www.europa.bg/en/eurobaro.htm)*

### Parliament endorses air quality

Parliament's delegation to the Conciliation Committee voted unanimously in Strasbourg on 3 July to endorse an agreement, struck with Council after two years of negotiations, on rigorous new air quality rules for the EU. The rules will reduce acid rain and smog by setting limits on emissions from large power stations and overall ceilings to be met by the Member States for four key pollutants.

### Annual Report on Human Rights 2000

The European Union Annual Report on Human Rights for 2000 is now available. The report gives insight into the Union's policy on human rights and support for the democratic process. Important issues are: child protection, women's rights, racism, social exclusion and refugees.

*The report has been published in English, French, German and Dutch. For information about the Annual Report, contact the General Secretariat of the Council on: [public.info@consilium.eu.int](mailto:public.info@consilium.eu.int)*

### New Generalised Scheme of Tariff Preferences (GSP)

On 12 June the European Commission adopted a new Generalised Scheme of Tariff Preferences Regulation to foster sustainable development. This new Regulation supports more effectiveness in the interest of developing countries. The proposal includes duty free access for all non-sensitive products. The new regulation completes and fully incorporates the recent 'Everything But Arms' initiative in favour of Least Developed Countries, which provides for duty and quota-free access for the Least Developed Countries.

*For more information see: [www.europa.eu.int/comm/trade/miti/devel/ngsp\\_reg.htm](http://www.europa.eu.int/comm/trade/miti/devel/ngsp_reg.htm)*

### Breast implants

A report by the Petitions Committee calls for legislation to ban cosmetic breast implants on patients under 18 years. The report also demands the protection of patients' health by improving marketing and quality control. The committee recommends the installation of national breast implant registers, as a database for long term research. Advertising for this form of cosmetic surgery should carry health and risk warnings, if not be totally banned. A priority for the Committee is the need for better research programmes about the danger to people's health and results on the rupture rate of implants.

*The full report is available at: [www.europarl.eu.int/committees/peti\\_home.htm](http://www.europarl.eu.int/committees/peti_home.htm)*

### HIV/AIDS, malaria and TB

The General Affairs Council backed the Commission's five year plan for addressing HIV/AIDS, malaria, and tuberculosis which was unveiled on 21 February. The main strands of action are on development, trade and research. The Commissions' plan includes measures to make key drugs more affordable for developing countries, increase the investment in research to develop new generations of drugs and vaccines, and to build effective health systems as a foundation for reducing poverty. The G8 summit in Genoa in July also saw the formal launch of a global fund to fight Aids, malaria and tuberculosis, although promised contributions so far are only a little more than \$1bn dollars.

*The full strategy Commission paper can be found at the following website: <http://europa.eu.int/comm/development/lex/en/2001/com2001096.pdf>*

The ENHPA and HDA can be contacted at the following addresses:

European Network of Health Promotion Agencies,  
6 Philippe Le Bon, Brussels Tel: 00.322.235.0320 Fax: 00.322.235.0339  
Email: [m.matthews@enhpa.org](mailto:m.matthews@enhpa.org)  
Health Development Agency for England  
Trevelyan House, 30 Great Peter Street,  
London SW1P 2HW Email: [maggie.davies@hda-online.org.uk](mailto:maggie.davies@hda-online.org.uk)