European Federation of Pharmaceutical Industries' Associations
Fédération Européenne des Associations de l'Industrie Pharmaceutique

1991

General Assembly – Conference
Assemblée Générale – Conférence-Débats

The Single Market – Fewer Frontiers, Wider Choices ?

Le Marché Unique – Moins de Frontières, Davantage de Choix ?

Interlaken
May 29-31 / 29-31 mai

The consequences of the single market for industry/for health care

International lawyer

Lord Hacking

Les conséquences du marché unique pour l'industrie/ pour les soins de santé

Juriste international

Résumé

En tant que citoyen, je suis préoccupé par le fait qu'une industrie pharmaceutique performante devrait être capable de jouer un rôle dans l'amélioration de l'économie et de la santé en Europe. Cela requiert un esprit de coopération entre l'industrie et les agences qui la réglementent. Et cela requiert un point de vue éclairé du contexte politique dans lequel opère l'industrie.

L'exemple de la directive communautaire sur les hormones démontre de façon éclatante l'impact des considérations politiques sur votre industrie, celles-ci ayant eu la préséance sur les considérations scientifiques. On observe une tendance similaire en ce qui concerne d'autres actions ou intentions réglementaires actuelles, dans les domaines de la somatotropine bovine, du quatrième critère, voire même de la fixation des prix et du remboursement des médicaments à usage humain.

Peut-être est-il temps que l'industrie réagisse à cette dimension politique avec plus d'audace - en misant davantage, dans le contexte politique, sur la contribution majeure qu'elle a apportée et qu'elle continue de donner à la question politique prioritaire du financement de la santé et des soins de santé. Il existe de nombreux exemples de la capacité unique de l'industrie pharmaceutique à traiter, guérir et prévenir nombre des affections qui grèvent les services de soins de santé.

Le champ d'application de la coopération est vaste - politique, technique, industrielle et médicale - en vue de promouvoir une meilleure information, une prévention et une protection plus efficaces, une détection plus précoce et des soins plus performants. La coopération devrait également exister - et surtout dans la dimension politique - afin de découvrir les moyens de libérer votre secteur de la sur-réglementation, notamment en matière économique. Peut-être votre industrie devrait-elle faire la preuve de son ingéniosité dans l'élaboration de solutions imaginatives au financement des soins de santé, afin que le marché devienne, pour vos produits, plus compétitif et que les forces du marché puissent jouer plus librement, tout en tenant compte des objectifs des agences de santé, à savoir de fournir des soins plus rentables. Les problèmes que vous rencontrez en raison du contexte politique ne peuvent, après tout, être résolus que par le biais d'une action influençant ce même contexte.

I am honoured to have been asked to give the keynote address at this important international conference of the pharmaceutical industry. I do come before you with some knowledge of your business : as a lawyer, as a parliamentarian, as a consumer and last, but perhaps not least, as a doctor's husband. Essentially, however, I am simply a fellow citizen – a citizen of my own country and of the European Community – whose concern is that a major, profitable and successful industry should be supported for the betterment of our economy and our health. I am particularly concerned that, where possible, you should work in co-operation and not confrontation with government and that government should similarly work with you. You should not exploit us nor us you.

Let me break down the points of my interest. As a lawyer I have acted both for and against your industry. Therefore, let me share with you the facts of one case ... which I prudently select from amongst those when I was on your side ! I refer to the EC hormones case which the veterinary arm of your industry took to the European Court. I was charged with the responsibility for the conduct of that case.

Since the Second World War demands of

growing populations have increasingly imposed upon farmers the need efficiently to produce reliable supplies of good quality food. To meet these needs in animal foods for human consumption anabolic agents were developed as growth promoters during the 1950's and 1960's. During these years, the livestock farming industry in Europe and certain other countries of the world (via Australia, Canada, Japan and the United States) developed the technology of implanting animals with hormones to improve the production of meat and meat products.

These anabolic agents included compounds called stilbenes known, under its generic abbreviation, as DES (diethylstilboestrol, hexoestrol and dienoestrol). As later recognised, stilbenes are potent hormonal substances which, when applied to animals, persist within the animal body tissues for long periods and can remain potent when eaten by humans. These concerns, relating to stilbenes, arose in the early 1970's in the United States not, in fact, in the context of animal growth promotion but of therapeutic treatment for humans. In the late 1970's other concerns arose in Europe following the discovery in Italian baby food of stilbene residues which were assumed to have originated from the use of stilbenes in the fattening of veal calves. It was, therefore, in response to a perceived danger to public health in their use in animal husbandry that the European Community adopted the 1981 hormones directive which prohibited the administering to animals of stilbenes and substances having thyrostatic action. At the same time it was thought prudent in this Directive to regulate the use of all substances in animal husbandry having oestrogenic, androgenic or gestagenic action. Pending, however, their further evaluation the 1981 hormones directive permitted the continued use of the five hormonal substances which had been developed as growth promoters : oestradiol 17 beta, progesterone, testosterone, trenbolone and zeranol. As you will know the first three hormones are endogenous and the last two xenobiotic.

Also in this Directive the Commission was specifically instructed to submit to the Council "a report on the experience ... and scientific developments" relating to these five hormones and, in turn, the Council was charged "acting unanimously on a proposal from the Commission (to) take a decision as soon as possible on the administering to farm animals (of the five hormones) for fattening purposes.

Pursuant to the instruction given in this Directive the Commission took advice from their scientific committees (the Scientific Veterinary Committee, the Scientific Committee for Food and the Scientific Committee for Animal Nutrition) and set up a Scientific Working Group on Anabolic Agents in Animal Production under the chairmanship of Professor G. E. Lamming of Nottingham University. The Lamming Committee, as it became known, was thus convened under the aegis of the Commission and had a representative in its membership from each of these three scientific committees. Indeed it was constituted with the most eminent scientists in the European Community in endocrinology and toxicology.

Apart from the corpus of knowledge possessed by its members, as a result of their own research and scientific investigations, the Lamming Committee collected information from the available scientific literature, from research programmes and also from data, normally confidential, drawn from pharmaceutical companies and various national licensing authorities.

On 22nd September 1982 the Lamming Committee agreed an Interim Report in which the three endogenous hormones were found to be safe when administered according to proper husbandry practice. Although the Lamming Committee considered that the large volume of evidence before it on the xenobiotic hormones did not reveal a potential danger to public health it requested in its Interim Report that additional data on those hormones should be supplied before a final evaluation could be made concerning their safety. The Lamming Committee's First Interim Report was considered by the Commission's scientific committees in late 1982 and early 1983 and adopted by

all three committees. The Interim Report was eventually published by the Commission in 1984.

By October 1985 the Lamming Committee had completed its evaluation of the xenobiotic hormones and prepared a draft final report for their meeting which had been convened by the Commission to take place in Brussels on 30th October 1985. The content of the draft final report was communicated to senior officials of the Commission. However, just five days before the Lamming Committee was due to hold its final meeting on 30th October, telegrams were sent out to each of its members ordering the Committee's suspension. Other than the statement contained in the telegrams that the Commission "following the Opinion recently received by the European Parliament... (was) reconsidering its position" no reasons were given for the suspension of the Lamming Committee. All requests thereafter by Professor Lamming to reconvene his committee, to enable it to complete its final report and to publish its finding, were refused.

In the meantime another event was taking place in the European Community. The stock of beef in intervention (the surplus beef required and stored by the Community) had risen from 290,000 tonnes in April 1984 to 600,000 tonnes in December 1984. The immediate cause of this doubling in intervention stocks of beef was the result of extensive slaughtering of dairy cattle following the introduction of milk quotas in April 1984. The surplus beef in intervention continued to rise in 1985 and by the end of the year had reached nearly 1 billion tonnes. In about July 1985 officials in DG VI (the Directorate-General for Agriculture) made it plain to the visiting Assistant Secretary at the U S Department of Agriculture that a decision had been taken to ban the hormone growth promoters in an attempt to reduce beef production and the surplus of beef going into intervention. This conveniently coincided with the growing opposition in the European Parliament to the use of growth promoters which, while expressed in the terms of consumer anxieties, really reflected the concern of small farmers. So it was that the Commission withdrew the new drafth hormones directive which (based upon the Interim Report of the Lamming Committee) it had had under consideration since June 1984 and which would have permitted the use of the three endogenous hormones. In its place the Commission rushed through another directive, adopted by the Council on 31st December 1985, which banned the use of all five hormone substances. It did so, according to the recitals of the Directive, on the basis that the "assessments of (the) effect on human health (of the hormonal substances) vary" and that the hormonal substances do not "correspond to (the) anxieties and expectations" of consumers ! !

Those who may have been in doubt over the political dimension of this decision to ban in the European Community the use of hormone growth promoters – whose safety has also been cleared by the WHO/FAO Joint Expert Committee on Food Additives ("JECFA") and by a number of national licensing authorities including the UK Veterinary Products Committee, the French Ministry of Agriculture Group of Experts and by the US Food and Drug Administration, should note the words of Agriculture Commissioner Andriessen, at a press conference in London on 21st November 1985 :

> "The use of hormones in beef and other meats is a political question. ... Everybody knows in the Community that ... this is a very delicate issue which has to be dealt with in political terms ... the Commission has taken its responsibility – its political responsibility".

I have, therefore to tell you, nearly six years later, this is how it remains. A political decision, with which the European Court was not prepared to interfere, superimposed over (and effectively overuling) the marketing authorisation test of safety, efficacy and quality.

I have dwelt for some time on the EC hormones case because it is, I think, the most potent example of the political dimension which has thus far been imposed upon your industry. Other

examples exist with the veterinary industry. The current delay over the issue of product licences for the veterinary milk enhancing drug, bovine somatotropin ("BST"), has a strong political element even though the Commission did drop its proposal for a moratorium on BST. Again, the proposed socio-economic test ("the fourth hurdle") for veterinary pharmaceuticals, although currently withdrawn, is nothing more nor less than a threatened political intervention in the market place. Nor is the political dimension restricted to veterinary pharmaceuticals. It already exists in different ways (albeit thus far to a lesser degree) for human medicines. For example, Member States have different policies with regard to some forms of treatment. I am told that the use of abortificients, and the availability of oral contraceptives are highly sensitive in some countries. As I am also told, national variations in medical practice can be marked – the use of anti-depressants is higher in the north of Europe than in the south, the use of antibiotics is higher in the south than in the north. As I understand it, consumption patterns vary markedly from one side of the channel to the other – being very low in the UK and high in France. Less obviously, Member States can limit the availability of certain types of treatment by refusing to include them in reimbursement, or fixing the level at which reimbursement will be made.

Thus the operation of pricing (or reimbursing) for pharmaceutical products has in every Member State of the Community, a political dimension. Even the debate in the UK over the EC patent term extension proposals for pharmaceutical products has fallen firmly into the arena of political debate. More alarmingly some have suggested that the fourth hurdle can be extended to human pharmaceuticals !

In making this comment to you I am not telling you about anything of which you were not already fully aware. My question, however, is whether your industry should be seeing the political dimension as a friend or foe ? Undoubtedly your immediate answer will be "foe". You can rightly look towards the politicians and the European Community, which they have created, with some scepticism. Yes, it is a big single market of 320 million – some 70 million bigger that the USA. Yet it is hardly a market (of the present or future) where you can market your goods in a regime of free competition. In every Member State you face different price control or reimbursement systems, different market authorisation procedures (and different periods for the evaluation of your products) and different patent term protection. Even if uniformity of patent term protection and marketing authorisation (whether by a central system or mutual recognition) were obtained, still prices and profits will be subject to Commission or national government intervention. Nor does your experience with parallel trading exactly make you an apostle for the freedom of movement for goods, under which it is justified, as enshrined in Articles 30 to 34 of the Treaty of Rome ! It has, therefore, to be acknowledged that it is not possible to provide, in any true sense, the benefits of the Community's single market to your industry as long as national government, and the Community as a whole, continue to take responsibility for the health and welfare of their citizens. Is this not, however, a political dimension in which you are a close participant ? After all, is not government reacting to you rather than you, at least in the first place, reacting to them ? It is you who produces the product over which government then seeks to place price and distribution controls. It is you who offer the solution for the prevention, treatment or cure of illness and government who then seeks to supervise the application of that solution.

As my reading has told me, in preparation for this paper, the cost benefit to society of your products is immense. I read in a copy of one publication of UK Office of Health Economics that the reduction in premature mortality from strokes, due largely to better treatment of hypertension, is estimated to have contributed an extra £ 322 million to the British economy in 1985. Other significant contributions to the economies of western nations through the use of pharmaceuticals in the treatment of serious disease, such as cardiovascular disease, is well documented. Let it be added,

considerable benefit has also been received by sufferers of serious disease in the improvement of the quality of their lives ! Nor, as I read, have cost savings been limited to major illness. I understand in France the cost of the treatment of acne has been reduced from 20,000 French francs per case to 2,300 French francs per case by the new substance isotretinoin ! Then there are the cost savings which arise out of clinical treatment replacing surgical treatment such as in the treatment of ulcers. More sophisticated anaesthetic drugs enable patients to be discharged earlier from hospital at considerable savings of hospital costs. Better still there are the savings made in the use of preventative drugs such as the hepatitis B vaccine which in Japan achieved a saving in medical costs alone of 86 %.

It is not for me to tell you about your achievements. It is, perhaps, for me to remind you that, in your negotiations with the government, your credit account is in pretty good shape. Are you, however, seeing to it that you sufficiently benefit from your good credit account ?

The fact of the matter is that, as the custodians of our health and welfare, every government in the European Community has got a problem for which it has not remotely got a solution nor can it get one without your cooperation. I refer to the multiple increases in the cost of providing health care. In 1970 the total cost of the National Health Service in the UK was £ 2,040 million, in 1980 £ 11,900 million. For 1990 it has been estimated at £ 29,227 million and for 1995 at £ 44,537 million (an increase of 2,200 % in 25 years – a figure which defies even the inflationary economies of South America !) and both of those estimates take into account all the cost and budget restraints which the UK government is valiantly – or some would say less than valiantly – seeking to impose ! In his admirable address to you in Paris in 1989 my colleague Patrick Jenkin, Lord Jenkin of Roding, put his finger, as he unerringly does, on the demographic change which is the cause of the problem. It is good news. At least I hope it is. We were all living longer ! As Lord Jenkin cited, the Queen only sent, when she first came to the throne in 1951, 270 telegrams each year to those who reach their hundredth birthday. Now she send 2,700 telegrams or (as they now are) "telemessages" ! I do not know if the Presidents of France and Switzerland send congratulatory messages to their hundred year old citizens but if they do they will have had to get increases in their birthday budgets ! For example in France, although the total rate of population growth from 1960 to 1982 did not exceed 17 % those over 65 years increased by 28 % and those over 85 years by 50 % !

These demographic changes have had an enormous impact upon the cost of medicines. It happens in two ways. First there is the greater use and second is the greater cost per drug of the medicine which will bring relief and cure to the older sufferer. For example in the United Kingdom the annual cost of medicines varied in the period 1986-87 from an index of 100 for those in the 16-64 year group to 266 in the 65-74 year group and 375 in the over 75 year group. In 1970 just under 12 % of the population of Europe were over 65 years old. In 1990 14 % are over 65 years and it is not unreasonable to expect that 17 or 18 % of the European population wil be over 65 years in 2000. Perhaps by 2050, as Lord Jenkin suggested, medical advances, better diet, healthier lifestyles, better housing and safer work conditions will enable our citizens to live to 130 years like some of those citizens of the valleys of the Andes !

The question which then has to be asked – although I confess I have already given my answer – is whether the solution offered by, for example, the UK Government in NHS cuts, budget controls etc, can possibly bring about a solution without a fundamental change in our attitudes to health care and the way in which health care costs are met. If the working population cannot reasonably bear the future financial strain of health costs, other solutions should be sought – and these may involve radical change for government, industry and the patient. Of course we can attempt to change or discipline any system but there comes a time when the question has to be asked whether the system itself works sufficiently or whether it should be replaced

or, if not replaced, subject to more radical treatment.

There is nothing shameful in asking that question of, for example, the UK National Health Service. It is not to suggest that the effigy of Nye Bevan should be burned but it is to suggest that he founded the National Health Service in wholly different health and welfare conditions than now prevail in our country. I do not offer solutions, let alone radical solutions, to the health systems in other countries in the European Community (or elsewhere) simply because I do not know enough about them and talk from me would be an impertinence. If, however, my comment about the UK National Health Service is comment which can be adopted in other health systems in the European Community, please take it away. I give it free to you, although I should add, as a lawyer, with full disclaimer from liability!

My generation in the United Kingdom has come to expect good health for ourselves, our parents who survive, and our children. Chiefly due to your industry, there has been a large reduction in the diseases which a generation earlier caused death and distress in childhood and young adulthood, like diphtheria, tuberculosis and polio (or, as I know in my youth) infantile paralysis. Disease is no longer that dark thing over which there were whispers in the patients' bedroom but sparse information to the patient or his family. Above all now there is the concern to keep good health by sound diet and exercise and by regular medical checks. Predominantly, however, these benefits are provided not in the public sector but the private. Yet if, for example, medical checks and health discussions, could effectively take place in the public sector, there would be enormous cost benefit to society. I mentioned at the beginning of this address that I have, last but not least, the interest of being the doctor's husband. I learn, therefore, of patients entering the public health sector, inflicted with serious or fatal illness, which could have been earlier prevented or cured if only there had been sufficient information flowing from the patient to the doctor and, I add, the doctor to the patient. There is benefit, therefore, not only in the patient better informing himself about his health but in the doctor imparting more information to the patient.

This is not an attack on the counselling skills of doctors. It is particularly noticeable, as the years have gone by, how much more doctors tell patients and their families about the patient's illness and prognosis – gloomy though that may be. I remember well, in the mid-1950's, when a young uncle of mine was inflicted with Hodgkinson's Disease. As a fifteen year old I just knew he was unwell. Neither he nor his wife were much better informed. His doctors had diagnosed his illness but felt they could neither tell him nor his wife who was pregnant with their second child. So it was my mother, as his eldest sister, who was told and told on the basis that the news should not be passed onto him nor his wife until she had given birth to the unborn child. This simply would not happen now! No, I am directing this comment to the need for more general information about the prevention and identification of disease – information which could be given in short pamphlets available in the doctor's surgery or even advertising. Think, for example, of the lives which could be saved if the general public was aware of the early symptoms of cancer of the colon and persuaded then, and not later, to seek medical advice. I choose this example because I understand this form of cancer responds particularly well to early treatment.

Is there not, therefore, a case for health authorities, doctors and others in the health sector including your industry, joining together to provide a much better platform of information for the prevention and detection of illness. As has recently been shown, it can be done with a major scare like AIDS. Why not with other diseases?

Are there also other changes in which your industry can be involved? Should not, for example the pharmacist have a greater role in the treatment process? I know when I and my family are on the Continent and have a minor malady, such as a sore throat, allergy or stomach upset, we seek advice from the local pharmacist and are well served.

recognise it is the role of the doctor to make the diagnosis of the patient's illness – and he also has the important personal knowledge of the patient – but, having made the diagnosis and identified the treatment, if the medicine is available in a generic form, could he not leave the pharmacist to discuss with the patient what medicines at what price would best suit him on a cost – benefit basis as the patient, as a normal consumer, does every day in shopping for other goods in the market place ? Are there not too many medicines which can only be obtained on prescription ? If the public is better informed, why cannot there be a wider exercise of choice left with the customer ? For prescription drugs why is there the total prohibition on advertising to the public ? If the citizen is better informed about his health, why should he not be better informed about alternative treatment available to him ?

I have lived long enough to witness heresies becoming gospels. Do you remember the outrage of the opticians when, in the deregulation proposals, their patients were going to be permitted to buy spectacles in the supermarket ? Proposals, as you know, which were approved by Parliament. I remember too the entrenched opposition of my profession against advertising. Well now, such is our enthusiasm for it, you cannot meet an English lawyer (be he a barrister or solicitor) without having glossy brochures pressed into your hands ! Look out : I have some in my suitcase upstairs !

As I understand it the central concern of your industry is to have reduced the amount of regulation which is imposed upon you. You are indeed heavily regulated and have a good case for deregulation so that you have, in a competitive market, greater freedom to set prices for your products. Indeed less regulation, in the field of pricing, could well result in lower rather than higher prices for your products. It seems, therefore, if you are going to achieve deregulation that it can only be done in the frame of the political dimension. This means understanding the problem of Government, which is to preserve society's health at reasonable cost, and by laying out plans to help. Of course you are doing a lot already. As a result of research and development of long ago, there are many reasonably priced drugs which are available for use. Then there are the drugs you have produced, which, by keeping the patient out, or for a reduced period, in hospital save hospital costs. There are also the host of diagnostic products for the detection and identification of disease. You would be well entitled to stop there. After all it is not medicines which are the chief burden on the Community's health bills. In 1987 in the United Kingdom hospitals took up 58 % of the National Health Service expenditure against 10.3 % for pharmaceuticals. To take the more graphic example it has been calculated in the U.K. in 1990 that the cost per patient in hospital came to £ 918.50 per week, while the average cost of a week's prescription for a drug was £ 6.70. Taking into account that, on average, prescriptions come to £ 7.80 per year per head of population, it can be calculated for 1990 that a whole year's prescriptions per head of population only came to £ 47.12 against the week in hospital for one patient, as I have stated, of £ 918.50 !

Changing the dynamics of access to information is often fundamental in changing existing systems. A better informed doctor and a better informed patient is essential to the future. At present, I think it would be fair to state that your industry's role in providing information is strictly circumscribed and there is a prohibition on providing other than approved and limited information to the patient. New ideas, which open up the availability of information are central to the sharing, and transfer, of responsibility (including financial) from the suppliers of health care (doctors, pharmacists and yourselves) to us the recipients ... a sharing and transfer, which I believe to be so necessary.

The demographic changes – the scourge of AIDS permitting – are here to stay. People who live longer, will require more medical treatment. If cured of one illness, we will, before we die, be smitten by another. If cured of that we will be smitten by yet another. Then, as we come towards our end, we are likely to require much medical resource and at cost. These facts are not for changing !

Yet, as I tried to identify, in the evolving and highly politicised environment in which we all are, your industry has a real role to play beyond the making of high quality products. As I repeat, your account is in credit ! Do use it, in developing imaginative schemes which government sees as helping them to deal with their problem of maintaining health care without escalating costs.

I understand your need for a more competitive environment but this involves radical change in every Member State. In the face of the constant rise of health costs, every means for their containment must be explored by government. Nor will the expectations of patients decrease. Your industry is in the political dimension and, as long as you are in the market place, cannot escape nor would wish to do so. The achievement of greater competition means keen pricing. It also means research to find the products which meet the needs of the patient as an individual and society as a whole. And the needs of the first should not absorb the needs of the second.

None of what I have said is intended to cool the great dynamism of your industry, let alone to blunt your debate at this conference as you examine the single market with "fewer frontiers" and "wider choices". On the contrary I have tried to stimulate your debate into the political dimension. I look forward to the next two days in your company. Unless you are shouting me out of town, I hope this can be reciprocated !