

The need for self-medication: an opportunity for the pharmaceutical industry

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I am happy to be speaking to you in Berlin today as Berlin is a place deeply associated with German history, and for anybody who has been associated with Federal German politics it is a very special place. What have we achieved in all those years in which I had responsibility on the European Commission for industry in general and in particular for pharmaceuticals? And what have we not achieved? Where have we got to today and what are we going to be seeing in the next few years?

I think we have certainly achieved some of the things we set out to achieve. At last year's annual meeting of the AESGP in Athens, I mentioned a number of aspects we were discussing at the time in the Commission, with the Member States and with the pharmaceutical industry such as:

- Benchmarking
- Coordinated price policies
- Electronic commerce

Now, a year later, we cannot exactly claim that all is "peace and harmony", but we have certainly made progress. Above all, and this was the most encouraging sign, we managed under the UK Presidency to address these questions at the Internal Market Council in May last year. That was I believe for the first time that, at an official level (i.e. the Council), we generated an awareness of the

importance of this industry and the problems associated with the issues confronting it.

Round Table meetings

We carried out three Round Tables and, piece by piece, demarcated the territory we had set out to tackle. The Commission has published the results in a Communication issued in November 1998, and also in some of its legislative measures.

Agreement was reached on the fact that:

- Single Market obstacles still exist. Barriers to trade in medicinal products in Europe are a disadvantage not only for manufacturers but also for patients and healthcare systems. Once we manage to explain to our colleagues in the Member States that these obstacles for the industry lead to limitations in provision (i.e. many important medicinal products reach the patient either too late or never at all, and they are certainly more expensive than they need to be), then we have achieved a lot. That is why it is important that these round tables continue.
- The existing price controls have to be relaxed and ultimately abolished. It is important for politicians to understand that price controls have not led to a lowering of the average price of medicines in the European Community. Price levels would be even lower in the absence of any price control mechanisms.
- We need more market elements in the pharmaceutical area, and here self-medication has an important role to play. Whenever patients are able to take on more re-

sponsibility for themselves, the market and market mechanisms will make the breakthrough.

The focal theme for the discussions at the three round tables have been that the Commission proposed a distinction between the three market segments as this defines our access to solutions and facilitates those solutions.

- Over-the-counter or OTC products for which there already is competition
- Off-patent products (products no longer protected by patents) where there is competition in principle
- In-patent products. Because these products are protected by patents, they are not open to competition.

It is of course difficult to find an ideal solution and even though a little progress has been achieved and we attempted to introduce some practical solutions in regulatory form, we saw that people started getting cold feet. We therefore have to propose solutions to which industry can subscribe, and have to be more persuasive towards those who still have doubts about self-medication. Only then will we be able to eliminate the existing price controls on prescription-free medicines and introduce associated measures to increase competition, and improve the presentation of these products.

When looking at the measures proposed by the Member States to reform their reimbursement systems, then I believe there is room for improvement. Some of these proposals may even have the reverse effect and deteriorate the existing situation, above all in the provision of medicinal products.

Electronic commerce

In the last two years, there have been many discussions on the subject of electronic commerce. It remains a difficult subject, especially for pharmacists, as the services of the pharmacist make up a relatively high percentage of the consumer price of a medicinal product.

However, it is absolutely clear that the advance of new distribution technologies cannot be stopped. Nobody should subscribe to the illusion that perhaps in Europe or somewhere else a fence can be built or an island created which cannot be reached by products sold by electronic commerce. That would be the biggest mistake we could make. It is therefore important that this development is not ignored as it is above all of interest from a point of cost effectiveness.

Of course, there are rules and regulations in force today which envisage certain restrictions on electronic commerce. For instance, for prescription-bound products this is totally banned, and for non-prescription medicines it depends on the Member States whether they wish to ban that trade or not.

Let me say without any ambivalence that this is not going to be satisfactory as a regulation. Because of the different legal situations in the Member States, there is bound to be legal insecurity. I have great doubts, for example, if electronic commerce is allowed in one Member State, whether a consumer from another Member State going there or ordering in that other Member State be prevented from doing so even if this form of distribution is not permitted in his own country. Patients are certainly

not allowed to suffer if they want to take advantage of the offer of obtaining their supplies in another Member State.

Study on electronic commerce

At the last Round Table in Paris, we had a very interesting discussion based on the preliminary findings of a study carried out for the Commission to examine where the problems in electronic commerce lie. The study demonstrated that there would be considerable advantages to be gained for patients: invoicing is quicker, there is more information about the product, etc. The medical supervision which the "virtual" doctor or the pharmacist is able to offer – and I know that this may sound provocative – is in no way worse and very often even better than the traditional consulting when people have to actually visit the doctor or the pharmacist in order to get this information. There are many openings here for advice and consultation. We can therefore not tolerate the argument that a "classical" pharmacist offers a better advisory service than a mail order company. There are moreover wholesale advantages due to logistics, etc.

Of course, there will have to be regulations to protect patients from the abuse of e.g. data about the patient, but this is a general problem encountered throughout electronic commerce. As this topic is so important and will affect all of you in the coming years, we have set up a working group which will soon be making some concrete proposals.

Development of the self-medication market is lagging behind the prescription market

In spite of all the efforts which both you the pharmaceutical industry and we the European Commission have undertaken, the market for self-medication has not developed in the same way as the market for prescription-only medicines. There are many reasons for this which both yourselves and we will have to address. This may be due to inappropriate presentation of OTC products or insufficient information reaching the consumer. The latter deficiency could however certainly be filled by appropriate use of the new media, including telematics. A good example of this is the Community-sponsored project called "Telematics Services in community pharmacies for responsible self-medication" (Tesemed), which aims to communicate better information on self-medication products to consumers and pharmacists in the pharmacy setting. The European self-medication industry and the European pharmacists (PGEU) are together participating in this project.

What can the European Commission do to create an appropriate framework to promote self-medication and to protect consumers?

1. Education and information for the consumer and greater market transparency. The measures on labelling and leaflets have in this respect let to progress: all medicinal products now include this information in consumer-understandable language and the industry has a major responsibility in enforcing these regulations.
2. In September 1998 we set an important step towards a regulation on changing the legal status of a medicine by the agreement, within the Pharmaceutical Committee in September 1998, on the so-called Switch

Guideline, which is an important document in the pharmaceutical harmonisation process.

Restrictions on brand names

However, in spite of this important step forward there remains an important hurdle on the way towards a single market for pharmaceuticals, i.e. the fact that certain Member States do not allow medicinal products to retain the same trade name which switching from Rx to OTC status. I regret that the Commission's proposal to resolve the issue through an addition to the Switch Guidelines did not receive the backing of all Member States at the April 1999 Pharmaceutical Committee. I hope that the dissenting Member States can as yet be convinced to abandon their position and that in general a more liberal trade name policy can be achieved.

Advertising

On the subject of advertising, an area also related to consumer protection, Council Directive 92/28/EEC allows under certain conditions the advertising of OTC products in all media. I should mention here that the Commission is of the opinion that a reference to the package insert is more effective than detailed information in OTC advertising.

Advertising control

The control of this form of advertising is in our opinion better conducted by self-regulation, and the promotion of industry self-regulation is a particularly appropriate and effective measure to safeguard consumer and industry interests. Member States are of course free to retain certain forms of advertising control, but experience shows that self-regulatory control systems avoid strict state control processes. I should add that – in light of recent developments in e.g. electronic commerce – the European Commission is likely to decide on the setting-up of a working group in the near future to consider possible changes to the pharmaceutical advertising directive.

Marketing authorisation

In the area of marketing authorisation, the current system is excellent and the European Agency for the Evaluation of Medicinal Products, whose Executive Director is with us today, delivers top-quality work. Increasingly the Agency's work is gaining in confidence and approval from the Regulatory Authorities in the Member States, which has led to some gratifying collaboration.

Deficits in the mutual recognition procedure

However, certain deficits persist – particularly in the mutual recognition procedure (MRP). Problems have specifically arisen because the Member States have very divergent opinions of what constitutes a serious risk to public health. We welcomed in this context the very useful proposals AESGP put forward some months ago of how this area could be more clearly defined. On the basis of these proposals, the Commission has encouraged Member States to look for ways to define the criteria of what constitutes a serious risk to public health more clearly.

Switch applications in the centralised procedure?

In March 1999, I initiated work on an "audit" to examine how current restrictions on the centralised procedure can best be lifted. Manufacturers of OTC products would of course also like to use this procedure for certain products, and in particular for so-called "switch applications".

Herbal medicinal products

In the area of herbal medicinal products, the existing working group within the EMEA needs to be even better equipped and more adequately funded. More legal provisions need to be geared towards this special category of products, as already proposed by the Commission.

Future outlook

In general, the most important task for the Commission is to bridge the difference in thinking between governments, politicians, citizens and industry. Governments are still not convinced that citizens or industry can behave responsibly and reasonably. We should therefore get away from the idea of the "caring" society.

In spite of the enormous achievements of the past decade, certain obstacles still need to be removed, which may prove particularly difficult in the area of pricing.

The main challenges in the coming years will certainly also include:

- **Electronic commerce.** Please do not underestimate this. All the estimates carried out by us and the figures provided by the industry – including major wholesale and retail chains – have consistently been too conservative. In the coming years this sector will become increasingly important, including for the pharmaceutical industry.
- **Enlargement of the European Union** is a very important topic. We have made it possible for all potential candidates to apply, but they have to take on board the *acquis communautaire*, i.e. all legislative measures adopted within the Community, including those on medicinal products, will in future have to apply to new members of the European Union. This is not going to be simple as many existing rules in those countries have either much weaker provisions or do not yet exist.
- Efficient **promotion of innovation** is the "alpha and omega" of the competitive edge of the European pharmaceutical industry. The European Union must do all it can, of course without lapsing into a rather senseless protectionism, to encourage this sector.
- A very thorny issue we have to address is finding an appropriate **demarcation between the area of medicinal products and that of foodstuffs**, where a clear delineation and definition are indeed necessary, as are specific regulations. We should take a fair and honest approach to this and look at the specific applications of food and medicines without disguising the following basic distinction: food is essentially there to guarantee survival whereas medicines are essentially there to combat disease or potential disease. This is also in the interest of the food industry. It would be

quite wrong to assume that we would be doing the food industry a favour by confusing the issue and fudging the boundary.

Conclusion

Let me conclude by saying that globalisation will concern your industry. The many different existing regulations and the need for cooperation by industry as the markets grow together (partly again because of electronic commerce) will confront us with completely new problems. We will have to repeat on a much wider level what we have been “rehearsing” in the European Union for the European Member States. Step-by-step, new regulations will have to be put into place across the globe which are harmonised, and here the Millennium Round will be of particular importance.

Change of mentality needed

Our most important task is to bridge a difference of thinking still prevalent between political authorities and industry and consumer. This is the wrong conviction, especially held by politicians, that they have to guarantee

the “reasonableness” of the two other sectors. They do not believe that the individual is capable of being reasonable out of his own interest and they do not believe that the industry is bound to be reasonable even if its main objective may be defined as “making a profit” (nothing is wrong with that). But these days, in that intermingling of media and education of the consumer who wants to have a free choice, one of the big issues is not that he is protected by an Agency but that the Agency gives the consumer a free choice. For this we have to fight, a more or less philosophical fight against traditionalists who believe that individuals can only live if someone in the bureaucracy is caring for him. I believe this is totally wrong and that it is rather the other way around.

As already announced, I will be leaving the European Commission in a few months. However, I will continue to follow with interest developments in the self-medication sector and hope to meet you all again in the future.

