
CONCLUDING PERSPECTIVES ON SELF-CARE IN HEALTH POLICY

Health policy in Europe

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It is my great pleasure to speak to you today on the occasion of this joint conference of the World Self Medication Industry and the Association of the European Self-Medication Industry. For me as a Member of the European Parliament (EP) who comes from Berlin, it is especially a pleasure to welcome you all in this wonderful city.

Being just one hour away from the eastern border of the EU, it reminds us in this city more than in any other place in Europe (except perhaps Vienna) that the biggest task ahead will be the enlargement of the Union. Of course, this can only be accomplished if the EU starts to reform itself first. The institutional framework, which was initially made for six countries and has not fundamentally changed over the years, has now reached its limits. It might still be suitable for 15 member states, but it will definitely not work with 20 or more.

The EU-enlargement will of course also be a challenge for the self-medication industry, as it will change the political and economic framework fundamentally. But we do not have to look at the future in order to find some challenges. There are already today major tasks we have to tackle like, for example, the full completion of the single market in the pharmaceutical sector, the increasing costs of the healthcare systems and new distribution methods like the Internet.

But before I come to this let me just say a couple of words about the role of the European Parliament.

1. The increasing role of the European Parliament in the EU's legislative process

It is widely recognised that the European Parliament plays an important role in the legislation process of the European Union, especially if we are talking about pharmaceuticals. Many from you who have come to the European Parliament and especially to the relevant committee (Committee on the Environment, Public Health and Consumer Protection) will have noticed that you can hardly find any unoccupied seats in the audience, espe-

cially if there is a debate about issues which concern pharmaceuticals.

This is an obvious indication that the European Parliament is now taken very seriously by everybody who is involved in the healthcare and the pharmaceutical sector. The EP's influence has dramatically increased during the single market legislation. And since the Maastricht and Amsterdam Treaties, the European Parliament is now equal co-legislator with even more rights than before. Therefore, the MEPs are probably the most lobbied parliamentarians in the whole EU. Industry, patient groups, healthcare professionals, and others have learned to address their interests not just to their national governments and the Commission, but also to the European Parliament.

The European institutions are of course only allowed to be active on the basis of the treaties. And while the EU already has the most competence in the field of environment and consumer protection, we still lack major influence in health policy. This still seems to be a national exclusivity, with Member States wanting to retain this competence. I believe, however, that social security should be decided at the European level.

On the other hand, it becomes more and more difficult to distinguish clearly between health policy, consumer policy and common market policy, as the current example of the dioxin in feeding stuff shows us.

The European Parliament will definitely play a major role in the future, but let us take a look on what the EP has done so far in self medication.

2. The role of EP in self-medication

The European Parliament has been particularly involved in the development of the legal framework for self-medication as part of the single market programme at the beginning of the 1990s and also in different health policy and industrial policy statements in the more recent past. Of particular importance were:

- The adoption of the directive on classification (92/26/EEC) in March 1992. This directive clarified for the first time in the European Union that medicines

should be classified as prescription or non-prescription. Only if certain criteria are met, a product is classified as prescription-only. The "normal" status of a medicine is non-prescription.

- At the same time, a directive on labels and leaflets (92/27/EEC) was adopted. This directive considerably improved and harmonised the requirements for consumer information in the European Union by standardising the issues which have to be mentioned on labels or in leaflets. Unfortunately, the wording of many leaflets is still not in a good consumer language, which has to be improved as soon as possible. Also consumers are sometimes faced with different sizes and presentations of medicine packages which could lead to confusion.
- Many of you might recall that I have been very active in the adoption of a directive on public advertising (92/28/EEC) in March 1992. This directive has clarified that in principle for all non-prescription medicines advertising is possible in all media and is therefore an important basis for the marketing activities of the OTC industry.

Particularly important also were the conclusions on self-medication in the resolution of the European Parliament for an industrial policy in the pharmaceutical sector (16 April 1996) which stated:

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"Considers that responsible self-medication should be further promoted, which will foster the growing desire of the European Union's citizens to take responsibility for their own health and to reduce health expenditure. In recent years, responsible self-medication has been identified as an important element in long-term health policy by the institutions of the European Community. As part of the process of improving the legal environment for non-prescription medicines, it will be important to establish more transparent procedures which define the method by which prescription medicines can be transferred to non-prescription status."

This has recently been confirmed by the Resolution on the Communication from the Commission on the single market in pharmaceuticals adopted by the European Parliament on 4 May 1999.

3. The Role of OTCs

Self-medication and OTC medicines have become an important part of all healthcare systems in the European Union. For example, in Germany over 17% of the total pharmaceutical market is accounted for by self medication products (1996). This makes us number three in the EU. Contrary to the development of the prescription market, the self-medication market has been not increasing over the recent years, perhaps also due to strong restrictions in comparison to other countries in the world.

However, recently the European Union has made progress in improving the framework on defining how prescription medicines can be separated from non-prescription medicines. Based on the classification directive of 1992 (see above) a guideline on the change of classification status came into force on 1 January 1999.

This guideline will hopefully better clarify the situation and lead to more harmonisation. The basic criteria in this guideline for moving medicine from prescription to non-prescription, is the safety profile and this is very much in line with the general policy in the European Parliament. Creating better possibilities for products to switch from prescription to non-prescription status could support self-medication and could lead to the situation that more innovative products become available in existing self-medication treatment areas.

4. Problems regarding non-harmonisation of reimbursement and pricing rules

One of the biggest problems for pharmaceuticals in the European context remains the harmonisation of the reimbursement and pricing rules. Contrary to the area of marketing authorisation where also through the European Agency for the Evaluation of Medicinal Products (EMA) we have seen more and more harmonisation for the registration, the decision-making concerning reimbursement and prices has been mainly left to the national authorities. Due to the very different price levels imposed by the authorities in some European countries, a quite lively market of parallel imports has developed which, due to the principles of the European Union is difficult, if not even impossible to stop. Logically, this issue can become even more important once the European Union has gone through the enlargement process to the Eastern European countries, where the price level for medicines is still considerably lower. After the elections of the European Parliament and the nomination of the European Commission, we all have to see how to make progress on this very difficult topic.

Meanwhile, I welcome that the Commission has initiated a round table process to address many of the outstanding issues relating to the single market in pharmaceuticals. This process has brought together the Commission, Parliament, member states, industry, patient groups, healthcare professionals, and others. Indeed, this process is not always easy but it should be continued as it gives a good forum to discuss the current problems.

As part of the roundtable process, the different pricing rules have been identified as a major problem. For example, some governments (Austria, Belgium and Greece) still decide how much is the price for Aspirin. I think this is not the correct approach and suggest that the Commission should come up with a proposal how to tackle the problem of government price-fixing especially in the OTC and off-patent sector. This would serve as a step not only towards completing the single market, but could also lead towards a better allocation of resources, which is more and more important in times where the costs of the healthcare systems explode. I know that price freedom is by no means the biggest issue facing your sector of the industry, but it is, I believe, an important symptom of its underlying problems with regulation.

5. Challenges of the new distribution systems (Internet)

The European Parliament has been heavily involved in several legislative initiatives to clarify the issue of new media and medicines. We have fully supported the general ban on teleshopping of all medicinal products. How-

ever, with regard to mail-ordering and electronic commerce we have taken a more careful approach, as it did not seem to be appropriate to completely ban non-prescription medicines from these possibilities. This however should not be seen as undermining the importance of the pharmacist. I come from a country where the pharmacy-only status has traditionally been very important and I fully believe in this. We therefore have to see in the future where deficits may occur and I am sure that the European Parliament as well as the European Commission will continue to pay particular attention to this issue. Certainly all the debates will also be a challenge for the pharmacist to verify their performance, in particular also with regard to OTC medicines and an appropriate presentation in pharmacies. In order to cope with these new challenges, solutions should be agreed between industry and pharmacists.

I must admit that I have mixed feelings, if I look at the potential of electronic communication media and the impact of the Internet especially in the area of pharmaceuticals. This does not concern OTCs so much. Here I see the possibility for the greater availability of information for patients. But I see some danger for consumers when they buy medicines via Internet which they can normally only get on prescription. I do not really believe in "cyber docs", I still prefer the real thing.

6. Other challenges for the future

For the future, there are also many other issues which need further clarification. Just to mention a few which might be of particular importance:

- The area of herbal medicinal products has got a lot of attention within the European Parliament and the increase of the contribution by the Community budget to the European Medicines Evaluation Agency by 1 million Euro voted by Parliament was particularly linked to the work related to herbal medicinal products. Unfortunately, only a very small proportion of this increase is going to be contributed to herbal medicinal products and there is a feeling that this work in the EMEA is still considerably lacking in resources. Although the European Parliament certainly appreciates the good functioning of the centralised procedure for innovative medicines at the EMEA, more attention needs to be paid to traditional, including herbal medicines, which are an important part of healthcare in the European Union and especially in my country.

- With regard to marketing authorisation in general, there still seem to be deficits in the functioning of the so-called mutual recognition procedure, as sometimes Member States do not accept a market authorisation from other countries. It needs careful monitoring to see whether Member States authorities are getting more and more prepared to recognise each other's national authorisation or if other systems have to be put into place instead to make this system work. Otherwise, there is an increasingly competitive advantage for those products which have the exclusive possibility to go through the centralised procedure (i.e. biotech and innovative medicine – no OTCs). In any case, the envisaged revision of the current marketing authorisation procedure should include a debate on whether more products should have the right to go directly through the European Medicines Evaluation Agency and get a Europe-wide authorisation.
- The area of food supplements and functional food has gained particular attention with manufacturers of non-prescription medicines. In some countries, the claims and advertising made by food products goes considerably beyond what OTC medicines would be able to say. It therefore seems to be important to re-discuss the appropriate balance between medicine and food in particular in the vitamin/mineral area. The manufacturers of OTC medicines are logically interested in finding an appropriate balance which also recognises the value of marketing authorisations from a consumer protection viewpoint and which avoids disadvantages in the market towards the less regulated products in the food sector.

7. Conclusion

As I have outlined, there are still many challenges the self-medication industry has to face in the EU. The single market is completed but not yet for pharmaceuticals. The European Parliament will work together with you and all others involved in trying to close these existing gaps. This process must of course have as its overriding priority the guarantee of safe, effective and high quality pharmaceutical products for the public, and therefore the dual aims of improved public health and industrial and economic development must go hand in hand. You may however rest assured that, in the next European Parliament, I will certainly be on your side.

