MINUTES OF THE WORKSHOP ON "ACCESS TO HIGH QUALITY PHARMACY SERVICES"

Brussels, Centre Albert Borschette, 15 October 2008

1. BACKGROUND

DG MARKT organised the workshop on "Access to High Quality Pharmacy Service" in order to pursue a constructive dialogue on the Internal Market for pharmacy services with Member States and stakeholders.

The structure of the workshop was as follows:

- Opening speech by the Director General of DG MARKT;
- Presentation of studies on the pharmacy sector;
- Presentation of positions by European-wide associations;
- Plenary discussion with all stakeholders and Member States; and
- Plenary discussion exclusively for Member States.

Mr Jean Bergevin, Head of Unit MARKT/E2, was the Chairman of the workshop.

2. PRESENTATION OF STUDIES ON THE PHARMACY SECTOR

Following the opening speech by Mr Holmquist, researchers presented a number of studies on pharmacy services within the EU.

Mr Hodek of the *Leibniz University of Hannover* presented an independent economic study on the potential impacts of a hypothetical pharmacy deregulation in Germany. According to this study, the German sector is at present not competitive, in particular because there is no free market entrance, no free price setting and no free choice of distribution chain. Deregulation, would lead to increased price and quality competition and most probably also to increased concentration levels. The latter should not be to the detriment of competition, since beneficial economies of scale and scope would result. Deregulation would also not endanger the independence of pharmacists, but would improve accessibility, safeguard affordability and further drive quality.

Mr Boras from *Antares Consultancy* presented a study on the pharmacies sector in Spain that had been commissioned by the Spanish Pharmaceutical Order. The study emphasises the special nature of pharmacy services and argues that deregulation would lead to over consumption of medicines. The Spanish system, on the contrary, was considered to ensure a good geographic coverage and had resulted in price decreases that were not observed in other Member States.

Mr Canoy from *Ecorys Consultancy* presented an empirical study on the impact of national pharmacy regulation across the EU that was commissioned by the European Commission. He noted upfront that the numerous restrictions may serve public interests, but that many of them are driven by lobbying or reflected the historical development of the sector. The study assesses a large variety of regulations affecting pharmacies against three performance indicators: quality, productivity and market efficiency. It concludes that there is a negative statistical relation between structure, regulation (ownership and location restrictions) and performance. There would be ample room for improvement, but this would not necessarily imply full liberalisation. Mr Canoy claimed that a more thorough assessment of the extent to which certain regulation meets its invoked public interest objectives, would have been possible if the pharmacy orders had been willing to release more data to the consultants.

Ms Habl from *ÖBIG* outlined the main results of a study on community pharmacy in Europe, which had been commissioned by the PGEU. This study examines the pharmacy sector in three relatively deregulated EEA Member States (IE, NL, NO) and three heavily regulated Member States (AT, FI and ES). By comparing the *pharmacies* price for four OTC blockbusters (thereby excluding OTC blockbusters in for instance supermarkets) in these Member States, it concludes that liberalisation would not necessarily lead to lower prices. Although the study observes a strong increase in the number of pharmacies in those MS that have liberalised, it also observes a certain degree of urban clustering. Ms Habl recalled the importance of avoiding conflicts of interests, ensuring accessibility and ensuring quality, but did not propose a specific regulatory model.

3 PRESENTATIONS BY EUROPEAN-WIDE ASSOCIATIONS

Mr Chave, representing the *Pharmaceutical Group of the European Union* (PGEU - the European organisation representing independent pharmacies) started off by criticising aspects of the studies conducted by Ecorys and Leibniz University of Hannover. He then made a comparison between the financial sector and the pharmacies sector and suggested that strict regulation is highly necessary. According to Mr Chave, deregulation could notably lead to abusive use of over-the-counter medicines.

Mr Hjertqvist of the *Health Consumer Powerhouse* formulated the question that lies at the core of the debate as follows: "Do we need any regulation at all and, if yes, which ones?". He remarked that potential conflicts of interest for employed pharmacists would not materialise if consumers are actively informed and if alternative channels of distribution are developed. The best way to ensure accessibility would be by enforcing the freedom of establishment and by allowing for mail order delivery of medicines. Similarly, the best way to ensure quality would be to have pharmaceutically highly qualified people.

The *European Patients Forum*, represented by Ms Radulescu, did not express itself explicitly about specific forms of regulation, but mentioned the importance of accessibility, highly qualified staff, confidentiality, qualitative medical advice and information.

The European Association of Pharmaceutical Full-Line Wholesalers (GIRP), represented by Mr Jenny and Mr Van Gelder, focused on the deregulation experience in the Netherlands, where independent pharmacies still represent the vast majority of pharmacies. Fears of high concentration levels proved to be unfounded in the Netherlands. Moreover, deregulation lead to an increase in the number of pharmacies (22 percent) and longer opening hours and hence significantly improved access to the service.

Mr Cornély from the *European Union of the Social Pharmacies (EUSP)* drew attention to their White Paper on pharmacy services. It states there is no relation between ownership of pharmacies and independence of pharmacists. It also argues that (geographic or demographic) location restrictions are not suitable means for ensuring good geographic coverage. Finally, it outlines the importance of training standards, standards of good practices and free competition in the patients' interests.

4. PLENARY DISCUSSION WITH STAKEHOLDERS AND MEMBER STATES

Independence

A number of participants expressed their view that in order to ensure pharmacists' independence, ownership of pharmacies should be restricted to pharmacists. *MEP Gutiérrez-Cortines (EPP/ED-ES)* argued that that what she called "the traditional social model" would be the only suitable model. Mr Bohater of the *Polish Pharmaceutical Order* added to this that liberalisation in Poland had caused very fierce competition and had eroded pharmacists' independence. Mr Capilla of the *Spanish Pharmaceutical Order* pointed out that a pharmacist should own a pharmacy, since pharmacies serve a public health interest and are fully integrated within the Spanish national health system. A colleague from the Spanish Pharmaceutical Order added that retail chains would only be interested in profits and that therefore employed pharmacists would never be independent in their decision making vis à vis customers.

A number of participants defended the view that a prohibition on non-pharmacist ownership would not be suitable and, secondly, not necessary for ensuring the independence of pharmacists. *MEP Donnici (ALDE/IT)* recalled that there are strong interests and pressures in the pharmacy sector, but that we should not close off to new ideas. Reforming the sector would be necessary, in particular to enhance the perspectives of young pharmacists. Ms Aparicio from *Plafarma* confirmed that many pharmacists at present can not exercise their profession due to rules that claim to protect the independence of pharmacists. Mr Purcel from the *Irish Competition Authority* pointed out that there is no evidence of a causal link between ownership and pharmacists' independence. Pharmacists are already members of a body that controls their ethical behaviour and therefore they should be subject to an independent regulatory authority. On the contrary, in his opinion there is no need for current measures that are simply protectionist. Finally, Mr Pezzoli from the *Italian Competition Authority* argued that a fear of excessive market concentration as a result of ownership deregulation is unjustified. He pointed out that in, for instance, the UK, independent pharmacies still have a market share of 43 percent. Regular competition rules should also apply to the pharmacies market.

Accessibility

The debate focused exclusively on geographic accessibility since time did not allow for a detailed discussion of other important dimensions of accessibility. On geographic accessibility participants were largely divided on the best regulatory model.

Some participants pleaded for location restrictions as a necessary means for ensuring accessibility. Mr Bohater, from the *Polish Pharmaceutical Order* for instance supported location restrictions because the abolition of these restrictions in his country lead to an *increase* in the number of pharmacies by about five percent per year, which he considered to be a negative development. He repeated that pharmacy chains would only be interested in money. Mr Capilla from the *Spanish Pharmaceutical Order* took the view that the absence of location restrictions would lead to clustering. Because of location restrictions, 99 percent of the Spanish population now had a pharmacy in their local town. Moreover, of all EU Member States, he claimed that Spain had opened up the most pharmacies in the last 10 years.

Other participants considered that location restrictions are not beneficial to geographic accessibility and can actually be harmful, particularly to rural areas. *French pharmacists* who were not represented by the French Order first drew attention to their personal situations: one was refused an authorisation to open up in a rural area and another had to close her rural pharmacy due to location restrictions. They considered that French location restriction would not serve the real population's needs, but would merely serve to protect established pharmacies. The French administration would have disregarded patients' needs and would have decided to make location restrictions even stricter in order to bring down social security expenditures. They were of the opinion that patients and rural areas would actually benefit most from enforcing the freedom of establishment.

This opinion was shared by Mr Di Vito, from the *Italian National Movement of Free Pharmacists*, who defended the freedom of establishment as a means to serve the general interest. Accessibility could be ensured through subsidies paid from the excessive profits of some urban pharmacies. The freedom of establishment would be beneficial to patients, but also to young pharmacists who at present can not exercise their profession. The *National Association of Italian Para-Pharmacies* confirmed that in Italy a partial deregulation in 2006 had lead to an increase in the number of pharmacies, reduction of medicines prices and better quality to patients. Finally, a *Spanish pharmacist* speaking against the Spanish Order, suggested that location restrictions should be lightened or removed in order to ensure that everyone has access to high quality pharmaceutical care.

The chairman remarked that the Commission had never received data concerning the geographic coverage of pharmacies. It received figures concerning pharmacies per head, but no figures that could reveal their geographic location and the actual distances that patients have to bridge in order to reach a pharmacy. The chairman asked the national pharmaceutical orders if they would share such information with the Commission. The Spanish Order replied that they would be happy to do so.

Quality and affordability

The chairman introduced this session by outlining that demographic changes, new forms of medicines and other developments lead to significant challenges for pharmacists.

Mr Capilla, from the *Spanish Pharmaceutical Order* again highlighted that the Spanish regulatory model would perform best, also in terms of quality. Mr Santos from the *Portuguese Pharmaceutical Order*, expressed his concern about the development in his own country regarding OTC sales. According to him OTC products can be sold by people who do not even have a primary school qualification, which according to him leads to significant quality problems.

Mr Brett, from *Celesio*, a pharmaceutical retailer and wholesaler, who had previously worked as an independent pharmacist, argued that quality in the UK pharmacy market had developed thanks to the pharmacy chains. Rather than deregulation he called for "optimal" regulation that would provide the safeguards but would encourage competition and drive quality.

CONCLUSIONS

The chairman thanked all participants for their very useful contributions. He suggested to exchange information between stakeholders and Member States on a more regular basis, for instance through the creation of a virtual platform and noted that the Commission would ask the Orders and Member States for the geographic to date, in order for it to improve its analysis.

5. PLENARY DISCUSSION WITH EXCLUSIVELY MEMBER STATES

(SHORT SUMMARY)

Independence

The Chairman highlighted the importance of the scientific independence of pharmacists' decisions. He argued that independence is not necessarily guaranteed by prohibiting third party ownership and that "independent" pharmacists can be under significant commercial pressure, particularly when they have committed themselves by loans in order to finance the substantial costs of buying and operating a pharmacy. He stressed that the purpose of the afternoon session on independence was to exchange experiences on regulation in this area and mentioned experiences on the sanctioning of infringements of deontological rules by national orders as a point of particular attention. He finally recalled that in infringement procedures the Commission has not accepted prohibitions on third party ownership as restrictions that are justified to safeguard the independence of pharmacists. He therefore called upon Member States to discuss the existence of suitable and less restrictive means to ensure full scientific independence of pharmacists' decisions.

A majority of Member States taking the floor supported the idea that independence of pharmacists should be safeguarded by other means than a prohibition on non-pharmacist ownership. One Member State argued that the key to independence would be that pharmacists are not regulated by themselves, but by an independent regulatory authority, taking care of any potential conflicts of interest. A number of Member States did not explicitly support the idea of opening up ownership to non-pharmacists and argued that there is no clear evidence of the benefits of a deregulated system compared to a regulated system.

Accessibility

The Chairman stressed the importance of approaching the question of accessibility with a wide view. One could wonder whether location restrictions would form the best means to ensure good geographic coverage. But in any event, one should look further than geographic coverage and look at, for instance, issues such as opening hours, home delivery and accessibility via internet.

A number of Member States shared their experiences of regulating the sale of medicine via the internet. Member States emphasised the importance of transparency and the possibility of identifying legal internet sales.

Regarding geographic accessibility, a number of Member States reported to have experienced a deregulation of location restrictions. These Member States had observed increases in the number of pharmacies in both rural and urban areas. Two Member States took the opinion that location restrictions should be maintained in order to ensure the profitability of pharmacies.

Quality

There were a number of Member States who noted that they were trying to develop quality benchmarks to assess the performance of pharmacy services. They recognised that this was at an early stage of development and welcomed the idea of exchanging experiences between themselves.

Conclusions

The chairman observed that consensus had been reached on the fundamental role of the pharmacist, in particular in an ever more challenging environment. As regards independence, he noted that pharmacy services are generally remunerated according to the sale of products and not according to delivered service. He noted that one Member State had presented an interesting idea of an independent regulatory body in order to safeguard pharmacists' independence. He also recognised that views on the need for ownership to ensure independence were divided and that the Member States with no such restriction did not believe that it had affected quality but that on the contrary it may have increased it. In contrast the Member States with such ownership restrictions felt that these were the cornerstone of an independent and qualitative level of service provision.

As regards accessibility, he noted that this was multi-dimensional. It consisted of both physical proximity to the patient, opening hours and home delivery/distance ordering possibilities. He recalled that in its infringement procedures, the Commission had not contested the need for regulation on location as such but had contested simple distance or per capita quotas that seemed to be very aggregate and therefore not very suitable or proportionate measures.

As regards quality, he expressed and noted a number of Member States' interest in the development of common quality indicators.

The chairman considered that the workshop had been a very fruitful exercise, in particular because the objective of the workshop had been to exchange best practices. He finally recalled that the objective of the Commission is not to regulate, but to facilitate reforms in the interest of patients.