SECOND SESSION

Chairman

Mehmet Domaç, Pharm.

The President of Turkish Pharmacists' Association

Aidan O'Shea, İreland

The Second President of the Pharmacists Group of the European Union

Philippe Liebermann, France

French Pharmacists' Union, President of the European Commitee

Eckart Bauer, Germany

German Pharmacists' Association Director of Economical and Social Works

MEHMET DOMAÇ Pharm. (The President of TPA)



he Turkish Pharmacists' Association which is a member of the International Federation of Pharmacy has been accepted as the observant member to the Pharmacists Group of the European Union last year. When we have attended the Pharmacists Group of the European Union as an observant member, the president was Aidan O'Shea, we'd like to thank him again for accepting us to be an observant member during this presidency.

Besides, our relationships deepened during this process and we are gathered altogether at this meeting.

Aidan O'Shea, born in Ireland in 1943, graduated from Dublin University Division of Pharmacy at 1964, has been a member of the Pharmaceutical Society since 1965, selected for the Board of Directors in 1984. Aidan O'Shea is a community pharmacist in Ireland and the second President of the Pharmacists Group of the European Union.

We'd like to thank him for accepting our request for coming to our country and informing us about his country. Please Mr. O'Shea, sire.

AIDAN O'SHEA (The Second President of the Pharmacits' Group of the European Union)



r. Chairman and Delegates, I thank you for your invitation to your beautiful country and to speak to you today. I believe that it would be helpful if I give a brief overview from a European Union perspective before offering the case study of the situation in Ireland. Europe is not a super-state. It is an amalgam of many national cultures and languages. Among the European Union's at present 15 member states, there is a constant and liably debate on the appropriate balance between enlightened national self-interest on the one hand and the growing cohesion of European policy on the other hand. This debate is given further depth and further urgency by the prospect of 10 member states joining the Union in 2004. That is why today's meeting is timely, because at citizen and at professional interest group level, we must also have dialog. This dialog will help us to define our common professional goals as community pharmacists working within individual national cultures. PGEU, of which I have the honour to be vice-president this year, is the forum and the collective political voice of community pharmacists in 28 European states. Turkey is one of our most recent members. Where does human health stand in the EU scheme of things? EU policies, directives and regulations work to protect the individual citizen in a variety of ways; in matters of education, of employment rights, of training, of environmental protection, of political freedom and a freedom to work and travel throughout the European Union. These rights contribute to human health and well-being of course, but the actual delivery of health care including community pharmacy services is a national competence. This is in accordance with the important principle of subsidiarity. Subsidiarity defines on an issue-by-issue basis. The extent to which regulation and policy is made at local, at national or at European level. In most member states, health care is funded significantly either by national taxation, by insurance or by a mixture of both. Therefore, the funding political controls and policy decisions on health care remain at national, rather than European Union level. Let me now tell you about the situation in Ireland. Ireland is an island nation of 3.84 million people. We are situated on the western rim of Europe, just as you are situated on the eastern rim of Europe. The next stop from Ireland travelling westwards is the United States. Ireland has been a member of the European Community, now as you know called the European Union, since 1973. In that time, we have been transformed from a mainly agricultural economy with low incomes to a vibrant modern society with income levels above the EU average. The economy has grown by 50% in the last 4 years. That's in a period when inflation was averaging 2% per annum. But key to this transformation has been the ability to adapt our education our telecommunications and industrial base to levels compatible with European norms. The change is not without problems of course, in terms of urban congestion, rising house prices and inflation. But the overall experience has been positive, teaching us how to have a broad view of

European and world events. We can better resolve our national problems in the light of our European experience. Each member state brings its own sweet of talents to the European process. I think that's one of the most important things about the European Union experience for the citizen. By dialog throughout a larger community, it reinforces one's sense of individual nationality and gives one also a wide view of the world. That improves the way in which we tolerate other ideas in which we influence our own policies, in my view, in a very positive way. It gives you like a dual level of citizenship: national and European, That's quite significant in political and in emotional terms as well. The pharmaceutical manufacturing industry has been a major element in Ireland's economic growth and is now our second most valuable export industry after telecommunications. Ireland's success derives from a stable political system, a skilled labour force competent in English and a low corporate tax rate for export industry. The success of the pharmacectical industry in terms of employment and exports means that its relationship with government is benign. This is quite significant in terms of our sector. National agreements of pharmaceutical prices for the health services are reached by the mutual consent. Ireland's sovereign state since 1921 has inherited many elements of British law and custom. This is also true of community pharmacy. In my opinion, it is a floored inheritance. In Ireland today, community pharmacies may be owned by individual proprietor pharmacists like me, limited companies owned by pharmacists, other limited companies provided that a pharmacist supervises, thus multiple chain or ownership is committed. Community pharmacies in Ireland traditionally sell a range of non-medical

products such as cosmetics and photographic products. There is also a general sale list of medicines including parasetamol, and talcids and vitamins which are on sale in all retail outlets, not just pharmacies. Private pharmacies contract their services to the state for state-funded schemes. So, you can see that we have a liberal ownership structure, rather like that of the United Kingdom or the United States. In Ireland, we use the phrase "Do we want to be more like Boston or Berlin?" Boston being the American model of liberal capitalist economics and Berlin being the social democratic and European model. One would have to say in regard of pharmacy ownership in general in Ireland; it's tending towards Boston, rather than Berlin. In Ireland, we have 11060 community pharmacies. That means 1 pharmacy per 320 persons. Just for comparison purposes, that is the 10th lowest population per pharmacy of the European Union members at the moment. The 10th lowest! Of these pharmacies, 698 are independent single pharmacies like mine, 371 are in chains owned by pharmacists, and 35 are owned by multinationals including the UK Boots and the German company GmbH. Therefore, 35% of Irish pharmacies are in chain ownership. But these estimated that that 35% represents about 50% of the market. We are therefore in a delicate balance. Some would say, a struggle between a system dominated by individuals to a one dominated by corporate ownership. This change is accelerated by Ireland's economic growth, making it an attractive prospect for multinational companies. Let me tell you about the contract which the pharmacist holds with the state authorities for the supply of community pharmacy services. Irish community pharmacies hold a contract with the state authorities

for the day provision of state-funded or state-subsidized primary care services. This contract was revised in 1996 to include conditions of minimum population and distance for the issue of additional state contracts. For a new contract to be granted; a population of 2,500 in a rural area. of 3,500 in an urban area had to be identified; and a distance factor of 250 meters to 400 meters from an existing pharmacy. These restrictions were also accompanied by new initiatives of the quality of the service to be given by the pharmacies. These included, for the first time in our arrangements with government, a defined role for the pharmacist in therapeutic review and in pharmaco-vigilance. An explicit duty on the pharmacist to review the safety and efficacy of jobs being supplied, be they on prescription or without prescription in relation to the patient's illness which will be capital funded by the state and to use the American phrase rolled out over time to integrate the entire primary care system ultimately in a large intranet of intercommunicating practitioners. But that is at the early stage of development at right now. And also and importantly I think from our point of view is structured a provision of continuing education for pharmacists throughout their walking careers. And this also is funded by the state. We mean that a fundamental platform in our renegotiation of the contract that we were not looking merely for protection of population, protection of distance but also qualitative measures as well. Subsequent events are not so simple however. The contract which was negotiated in 1996 came under considerable political pressure. Chain pharmacies challenged the regulatory restrictions in the courts and young employee pharmacists complained that the new regulations discriminated against their

chance to compete in the market. Finally, the Consumer's Association, which is a powerful independent lobby in group argued for the deregulation of the location of new pharmacy contracts. On January the 31 last, the Ministry for Health and Children faced with these pressures and further court challenges abolished the population and distance criteria for new pharmacy contracts. A political storm followed in which pharmacists alleged bridge of the contract arguing that deregulation would lead to domination of the sector by chains; so we organized a petition with these citizens and over 300,000 citizens assigned the petition in their local pharmacy opposing this unilateral political decision. At this moment, we were trying to negotiate new elements which would not include population or distance, but would offer new contracts preferentially to non-contract holders. New standards for premises and equipment are also in prospect. It remains to be seen how these discussions will progress. So it is fair to say that Irish community pharmacist sector is in a state of some political shock and uncertainty right now; and that powerful corporate forces are opposed to the position of the independent community pharmacist. We know that multinational companies dominate in many sectors of industry and retailing. Some of us see community pharmacy as something of a last frontier against this globalization trend. We question that the nation state might corporate control of a large segment of primary care that is community pharmacy. Are we trying to build a market model or a patient-focused primary care model or a market-driven multiple dominated pharmacy sector? That is the question. Turning to remuneration, in Ireland, we have a network of schemes; rather complex. But I'll give them in

outline and perhaps develop them on the question time later. Irish citizens pay for the health care in a variety of ways. National taxation funds the capital development of our hospital care and funds about 70% of hospital treatment costs. The remaining cost is paid by middle and higher income families via health insurance. In this mixed private public model of hospital care, the private patient gets a faster treatment. But that is not a deal. In primary care, 30% of the population; including most pensioners and low income families have free GP care, free doctor and free prescription drugs on the general medical services. This 30% of the population generates 70% of the prescription demand. This is a key statistic. The pharmacist is paid zero markup on the cost of the drug plus a dispensing fee per item of Euro 2.84. For the 70% of the population at low or middle to upper income, the average GP visit costs Euro 40 and prescription costs average Euro 12 per item. This can create high costs for patients and families with chronic diseases such as hypertension or asthma. These payments are made from taxed income at a time and the family may be affected by illness. For families (not individuals) whose monthly prescription bill exceeds Euro 53, the pharmacist claims the balance from the state. This co-payment system shares the cost between the citizen and the state. The cost of medicines to the citizen is a big political issue in Ireland and in every country and there are always pressures to extend free eligibility to new categories and new age groups. So, we have a tutor system. It is also tutor in terms of the terra structure. As I've already explained, for the 70% of the market under GMS, the pharmacist receives no markup and a fixed fee of Euro 2.84 per item dispensed. For private prescriptions and

the co-payment scheme, the pharmacist has a profit of 33% on the drug and a lower fee of Euro 2.49 per item. In addition, we have smaller schemes for methadone treatment for patients who are coming off opiate addiction; for very high cost, high-tech medicines such as Bitiferon; and for supplying drugs to doctors in remote rural areas without a pharmacy. The pharmacist negotiators have been pragmatic in adapting to new schemes in response to changing social needs. So, let me try to give you the overall picture. Overall, pharmacies have a gross profit of 28 to 30% on their total activity. If you have any question about the details of these schemes. I shall be pleased to answer them. Let us talk about the personnel in Irish community pharmacy. Pharmacists in Ireland take an undergraduate course approved by the European Union. This course consists of 4 years at university, followed by 1 year of pre-registration trainee under the supervision of a tutor pharmacist. At present, Ireland's only school of pharmacy at Trinity College, Dublin produces 70 graduates per annum. But this number is not sufficient. Many Irish students study pharmacy in the United Kingdom and then return to practice in Ireland. Because of the acute shortage of pharmacists, community employee's salaries average Euro 50,000 per annum and pharmacy is a very popular career. There are unfilled posts in the hospital and in the industry. To meet this shortage, two new schools of pharmacy are at the planning stage. The College of Sergeants, Dublin course begins in autumn 2002 and University College is planned to begin in 2003. These new schools will create a total of about 120 extra pharmacy graduates per annum. It should be mentioned also that many Irish pharmacy graduates work

and study in the United States, in Australia and the United Kingdom particularly carrying on a voluntary basis these are of immigration which was compulsory in older times when Ireland was a very poor country. And the Irish people went to live in the United States, Australia and in Britain. Now they go voluntarily more for the adventure and come back after some years bringing additional experience with them to Ireland. We also have a 2-year pharmacy technician course which is recognized in hospital and community pharmacy sectors. Technicians work at all times under the direct supervision of a pharmacist. The ICCPE is an agency founded by the state and it works to improve the quality and range of continuing education for pharmacists including masters programs, distance learning, and face-to-face courses. In my opinion, pharmacy personnel in Ireland are well-trained and motivated. Practice standards are high with particular emphasis on consulting with patients. As a tutor I spend a lot of time with my graduate pharmacy; the patient comes first, the human factor comes first. The technical knowledge is fine, the product knowledge is excellent, but the patient comes first. Laws and professional ethics are observed and competition among pharmacists is on location, service standards and hours of service rather than on price. Employee community pharmacies, pharmacists rather, numbered about 330 in 1996; but now number 568. This growth reflects the increasing number of multiple pharmacies and the growing volume of counselling and dispensing work. No longer do we have so many nuclear pharmacists as I call them; pharmacists who have no other professional person in the pharmacy, but themselves. There is always a competent staff member to advice on safe and effective

medication use both for prescription and non-prescription medicines. And so what of the future? As my analysis has shown, Irish community pharmacy is in a transitional stage. Market-driven changes of ownership are gathering momentum. We have a deregulated ownership and distribution structure in which multiples are growing. The general economic conditions remain good despite the slowdown following the atrocities in the United States on September the 11th last. Community pharmacy is a small player in a globalized consolidated pharmaceutical sector. Ireland has a small open economy showing considerable resilience. So, I can conclude that we shall have to accept, watch challenge and change and to assert at all times intellectual and professional integrity of the pharmacist. The pharmacy leaders and spokesmen must recognize the mixed coalition of ownership interests. And in conclusion I hope that international dialogue and solidarity will help to define, refine and optimize our future. Thank you.

MEHMET DOMAÇ Pharm. (The President of TPA)



hank you very much Mr. Aida O'Shea. If there are any questions, we will gather them at the end of the meeting in written.

Now it is time for Mr. Phillippe Liebermann for his speech.

Phillippe Liebermann, born in Strasburg, graduated from Strasburg University Faculty of Pharmacy in 1974, worked at the university hospital, got his PhD degree at Pasteur University in 1978, received the Certificate of French Pharmacist in 1978, was vice president of the Basreyn Pharmacists' Federation between 1985-1988, is Second President of Pharmacists Union of Alsas Mussel District since 1987 and President of the Basreyn Pharmacists' Federation since 1988. He has been a member of the International Federation since 1998.

Now, I'd like to invite, Dr. Pharm. Phillippe Liebermann, please Mr. Phillippe Liebermann, sire.

PHILIPPE LIEBERMANN (French Pharmacists' Union, President of the European Commitee)



Ladies and gentlemen, Dear Presidents and Dear President of the Turkish Pharmacists' Association: I thank you a lot for having invited me to Istanbul, a very beautiful city which I already knew but which I always enjoy to see again and finally for being again with my colleaques, because our predecessor General Charles de Gaulle had defined Europe going from the Atlantic to Urals, therefore we are all Europeans and we hope that your wish to join European Community, European Union will be done in the best conditions for the satisfaction of all, and of the Europeans. I am also really glad of beginning to speak after my colleague Mr. O'Shea who has talked about the subject of variation in Europe, which shows that the systems in Europe are very very different from each other. Then, before going on a bit about the system of social protection in France, which is a bit the subject of my conference, I want to open a small parenthesis related to the pharmacy, in France that is really different from the Irish system because it is not at all liberal. Indeed, the pharmacists in France are owners of their pharmacies and this in a way exclusive and the authorization to install a pharmacy is defined by some number of inhabitants, and this results in the sense that today we have a pharmacy for approximately 3000 inhabitants, a little bit like in Ireland, which makes approximately 23 000 pharmacies inside the territory. The pharmacists who are carrying on in the pharmacies have a duty to employ other pharmacists and pharmacy technicians according to a level of business capacity. All of this is defined by the state and in a country in which the freedom is put ahead of everything, our regulations are excessively strict and severe.

But now, I will go on my conference, talking about the social security in France. Indeed, you could have maybe read in the press recently that the system of care in France has been characterized by the World Health Organization as the best in the world. So, I do not know if it is the best in the world, according to the side of death rate or the expectation of life of French people; but in all cases, it is surely an excellent system in the side of reimbursement and of the possibility for our citizens to obtain cares.

Then our system, compared with Germany if we want, it is a system excessively recent since it dates only of after the Second World War, only after 1945 when General Charles de Gaulle has imposed this system and which has been made by Pierre la Roche, which has been established. Then this system was foreseen for the whole of the French people but it has complicated itself throughout passing years. Therefore we have established in 1945 a case for the paid workers, it is the principal case of France which covers approximately 60, 70% of French people.

But other administrations have been set: these are the administration for farmers, the administrations for free professions and the special administrations because in France we have particularities which are the railways, militaries and some number of other administrations which are very peculiar and this results in the sense that in France, we have 16 big administrations of social security. The administration of social security was not reimbursing the whole of the obligations and therefore rapidly has been set additional systems. Indeed, people not being reimbursed at 100% have chosen systems to make them reimbursed in a higher way; these are systems of private insurance, these are the aid institutions, these are systems different within each other. So this fact allows today for the most part of the French people to be reimbursed at 100% of the whole of the cares that they consume in the country.

The big change that has occurred in France recently, as a consequence of the diverse politic problems, is that we've passed from a system in which people joined a case of disease because of their job to the universal disease cover. Universal disease cover means that each person living in France in a legal way obtains reimbursement of his\her cares even if he\she does not work, therefore this is today one of the politic problems to be solved in the future and especially the financing of this problem.

So now, what interest us a bit more must be reached: The politics of medicine in France. The politics of medicine in France, which is as I was saying really a liberal country, have an excessively accurate regulation. Indeed, for a

medicine to be sold in France, of course an authorization of setting into market must exist, in the past these were national but now they are more and more European as it is for all the countries, and so this is the first industrial step. The second step that it must obtain is what we call the returned medical service. The medicine is examined to see which services it will give in terms of cares and to obtain a number of quotations. At the time this quotation obtained, the disease insurance would be able to go and discuss with the authorities of social security to obtain the reimbursement price which will be a function of the returned medical service defined previously. But when an industrial obtains a price, he must also define the volumes that he hopes to sell in France. By the way there is an agreement between the state and the industry, so no longer with the social security; which will define the industrial price of the medicine as a function of the expected volume. If the industry exceeds this volume during the years, there will be additional taxes to the state.

When we define the industrial price in France, what about the price of sale in the pharmacy. The margin of the distributor wholesale dealer, the margins of the pharmacists are foreseen and therefore a price of sale as a function of the industrial price, that cannot be changed, is obtained. The discounts that the pharmacist can obtain at the sides of the distributor wholesale dealer are at a maximum of 2.5% and are defined by the laws and cannot be exceeded. So how is installed the price of the medicine in comparison with the industrial price? Today, there is a fixed share of 0.5 Euro at first place plus a margin of 23% above the industrial price till an industrial price of 23 Euro

approximately. Inevitably when this system had been set the medicine of industrial prices more than 23 Euro standed for only 10% of the side in pharmacies. Today this number increases and we are actually at approximately 20% this being the reason for some number of difficulties for the disease insurance.

So this morning your minister told you about the generic medicine that I put a little bit apart because effectively their margin system is a little bit different when compared with the others since the pharmacist obtains the same margin in Euro on the price of the equivalent as on the principle medicine plus an additional discount of 10% instead of 2.52% previously expected. So effectively the chemist has slight, little profit while selling equivalent medicine rather than principle medicine. Indeed, since three years already we have the right of substitution that is, when a prescription comes to the pharmacy the pharmacist can substitute the principle medicine with the generic medicine. This according to a list defined by a medicine agency that has defined exactly the products that we can substitute. This fact is really of less importance in other countries like Germany where there are much more generics, in France for example Aspirin and the Paracetamol are not substitutes therefore we can not change them. But there is some quantity of old medicines on which we can do this and we hope that this list will increase in order to make economies to the social security.

Then, how do this system articulate itself in France, how does it go on? We have established in France since a few years, with big financial acts since this has cost excessi-

vely expensive, the system "sesamedital". So, each professional of health has a professional card which he\she inserts in a reader and which in addition defines what his\her activity is, of what type he\she is (that is, if he\she is a doctor, a chemist), for the relations with the disease insurance. Each insured person also has this famous card sesamedital which the health professional will read in his\her reader and which will give the rights for each insured person; we know then from which case he\she is. which is his\her type of reimbursement, what will happen. On this fact, for the information to go from the health professional, from the pharmacy to the social organism, if we take care of the number of administrations since we have 16 big administrations and several thousands of additional cases we cannot do this individually to each case and each additional organism. Therefore we have a network of social health and concentrator organisms to which we send the information and who will do then the distribution through different organisms.

So the system, which has been established is very interesting because it gives us obligations of teletransmit the information to eliminate in the sense the paper, we no longer make use of paper, but especially it gives obligations to disease insurance cases too. Because when the information is welcome to the disease insurance case, in an electronic form, the disease insurance case has four days to pay the health professional. These delays are fixed by the law and therefore cannot be exceeded and the system that has been established some time before shows that we can little by little respect these four days and that this is going on relatively good in spite of the complexity of the French system.

So I will begin the conclusions. I am going to give you some transparencies in order to explain you a little bit more our excessively complex system. Because today this system which seems to be really favorable, which allows to each French to go and see at much doctors as he\she wants in the day, to choose his\her hospital, to have all the freedom to consume as much as he\she desires, opens the way to some problems; the cost of this system, how will we finance it? How this happens? So until now, this system was so that each person being working was giving some fees because of his\her work, and the employer also paid fees for his\her employees. But inevitably today this is insufficient to cover all of the needs of French people and the taxes that are taken above the total revenue of French people contribute with an increasing importance to cover this health organization. Inevitably beginning from the moment when this is the taxes which finance one part of the social protection, it is evident that the state take more and more care about the system and therefore was defined already seven years before, just after the reelection of Jacques Chirac, the "Objectif Nationale de Depenses de Sante" called ONDAM (National Objective of Health Expenditures) and which is voted by the parliament. So how to act to make understand to the representatives of the nation, to our parliament members, that the product expected at the brut of the country is increasing approximately by 3% and that the expenditures of health will make in the years approximately 6 or 7%. This is an insolvable problem today and therefore since the last seven years the members of the parliament are voting regularly an expenditure objective of 2 or 3 % according to the national conjecture and very often this objective is largely exceeded, at least doubled so therefore, for this

moment, we can not really understand why the members of the parliaments are voting this one and furthermore passing several days to discuss about this problem whereas it is not respected. The punishments had been foreseen by the first government of Chirac at the period, against the health professional in the case the objective would be exceeded; these punishments have never been applied. Otherwise I do not know how we would have to act. But it is evident that today health professionals cannot stop the consumption appetite of French people. If French people are willing to consume medicines or prescriptions or going to the doctor or attending medical treatments or whatever you want, we cannot do anything; they are coming themselves and even so we cannot refuse them.

Now I will just show you some transparencies. So this is in order to indicate you a bit in the price of a medicine the part of the industry which is now the two third of the medicine price; the margin of the pharmacy of approximately 3.5%, the distributors 3.5% and the state who takes inevitably its part over the taxes which is 6%. But with the new medicines which appear more and more expensive day by day and of which the margin of the chemists is less, and by the way the industrial part increases more and more, nearly 15 years ago, the share of the pharmacy was more than 30%, we are today at a rate of approximately 26% and this is regularly decreasing each year which is in all normal, it is the industrials who take the biggest share.

These are the numbers of social security and we can see how the whole of cares are distributed. Therefore in the French system the expenditures of health insurance in year

2000 if you exchange for Euro because I still have the quantities in French Francs because you know French people have passed to the Euro in a way really very concrete, but for the transparencies we take pain to change them therefore for the moment they are still marked in French Francs but this corresponds to 84 billions of Euro for the year 2000, inevitably these numbers are increasing every year. The public hospital represents 40% the private ones 6% and the share medico-social 7%. Therefore for what we call city cares, that is, the payments of doctors, and the payments of other practitioners and for the medicines we are at 47%. The medicine, the share city care in the whole is at 26% and that share is more and more important, the new treatments that you know also with the new cares for the AIDS and for other illnesses will cause an important increase in the share of medicines in the budget of the social security.

So how these 84 billions are financed? 66%, the two thirds are financed by the social security, by the compulsory administrations, by the 16 big administrations; 20%, it is by additional insurances and it remains therefore about 14% from which a part is the not-reimbursed products because some medicines are not repaid like the Viagra, some contraceptive pills of third generation so therefore this is what is represented, and some people did not have the additional coverage, which is the reason why we arrive at 14% of not reimbursed in France. Here is where the system is.

So what is the future of our system? Finally the conclusion is a bit about this. So, you know well that in France we have really frequently election campaigns. We have had one for the election of the president some time before, we are continuing with the parliament; to sum up we are always in an election campaign in France. Therefore the politics, whatever is their politic color are always very favorable to the system of social protection in France and are willing to continue it because today, even if it does not have more than 50 years, it is really in the heart of French people. The French people are very tied to this coverage and to be perfectly reimbursed and to be able to consume whatever they want and whenever they want. Therefore I believe that if we look from this side, it will not be attacked but how to finance it, this is the question and therefore the share of the taxes in the financing of the social security will become more and more important. Otherwise the prices are fixed by the state, this means that today the state can diminish or augment the price of taking a medical advice or the industrial price of the medicine and diminish the margins of the pharmacies. If today it decides that it is no longer 23% but 17%, it makes this with a pen line and it is applied the day after in the morning. Therefore we are always at the intersection of ways and we do not know how to react to get behind this fact.

So today what are our possibilities in front of this increase of consumption? Increase of the consumption, we must notice this fact as caused by the increase of the population too, or caused also by the increase in the average age of the population which result in the way that people consume much more cares. We are thinking today that 20% of the girls which are born in France will be in need of cares in a century and therefore this will make that peo-

ple will consume much more cares which will be, by the way much more expensive.

So I think that for the pharmacy and in order to stay independent and in the neutral center, there is some number of points that are particularly important. Today we have an obligation of continuous formation and I think that it is only with professionalism and with the formation that we will justify our place at the breast of the French health system. The second point is the right comprehension of the information and the electronic transformation trough the disease insurances. This has been a very long and big brawl many years ago but we are staying today owners of our transmission of information systems through the insurances and I think that this is the first important point for the pharmacies to be determined as a needed passage of the system of cares in France and in order to make the skip of pharmacies impossible.

Therefore today this system can maybe be protected by the virtual pharmacy, the e-pharmacy, we will see the developments in the future since then there will be European developments that will certainly be present. The other principle is to propose as pharmacists to make economies to the system of disease insurances, this is the development of generic medicines about which we have already talked this morning because effectively it is a system that permits to diminish the cost of reimbursement of the social security while taking care for the pharmacy's economy and not make it hurt. Therefore we have to mobilize in order to persuade French people and make them accept the equivalent medicines, this is not always

easy. The other acts of thought of our syndicalism organizations are to say that going a bit farther and obtaining additional remunerations over the medical file of the patient are needed actions. Today the pharmacists can regroup the information about his\her ill, coming from different doctors who the ill has gone and seen, and the different treatments that he\she has obtained. The pharmacist can have an effect particularly effective in the iatrogenie with regard to the important consumption in France and be successful in diminishing some number of medical consumption, this done in exchange of the different remunerations that the disease insurance will offer. We are in discussion about this subject in order to make diminishing globally the consumption but inevitably without effecting our remuneration because otherwise we would be loser in the system.

These were the acts for the future with the hope that we will keep inevitably the monopoly of the medicine because I did not say it but it is going on a good manner for us, that is, all the medicines in France are only sold in pharmacy, the discussion is to know if vitamin C is a medicine or not is always present but this has slice one time in one direction and the other time in the opposite, however, except the vitamin C all the remaining is at the pharmacies, you can find medicines only in pharmacies in France.

MEHMET DOMAÇ Pharm. (The President of TPA)



e'd like to thank Dr. Phillippe Liebermann for his presentation.

Now it is time for Eckart Bauer for his speech. Born in Essen in 1970, graduated from Kiev University Division of Economy in 1995, worked as a research assistant in the University of Federal Armed Forces and Hamburg, later in the year 2000 sonra appointed for the German Pharmacists' Association as the Director of Economical and Social Works. He is still at that position. He has published many papers in Germany and USA regarding the pricing and distribution of pharmaceutical products.

Please Mr. Eckart Bauer.

ECKART BAUER (German Pharmacists Association Director of Economical on Social Works)



would like to begin with sending the greetings of the president of the union of German Associations of Pharmacists through Mr. Hans Günther's wishes his best. For many economic data on German pharmaceutical system and the situation of pharmacists in Germany, I'd like to refer to the leaflet-Pharmacist Figures data facts I have many copies of it with me, so that I think I will be able to present it to each one of you. When following Mr. O'Shea and Mr. Lieberman, I'd like to begin with few information concerning German pharmaceutical system. In Germany every pharmacist is allowed to own a pharmacy at a single one. There are not any multiples and there are no corporate owned chains of pharmacies. The distance sale of drugs is strictly prohibited. The reason is public health. There is a tendency of mail-order pharmacies who would like to supply pharmaceuticals to the drug market especially from the Netherlands. Until now, we are able to offend officers' risk for our community pharmacists. And at the moment we have petition towards our customers and we have got more than two million signatures of our customers. They support us that depend on the distance sale of drugs should be prolonged. I would like to start with giving details on the price of pharmaceuticals in Germany. It will give you an impression how they are priced and what the pharmacist is reimbursed for.

Official Freedom in Estimating the Price

HOWEVER: There are some important classifications on the issue of drug pricing.

- ◆ The law on drug pricing
- ◆ The Press of Official Health Insurance System
- ◆ Reference price system
- Negative list (being arranged)
- ◆ Positive list (being prepared)
- Drug guides

Formally, the pharmaceutical manufacturers in Germany are free to set the prices for pharmaceuticals at will. In fact there are mature restrictions on this freedom. These restrictions come in the form of the drug price ordinance, the pressure of a statutory health insurance system, reference price system and negative list that is permanently under reconstruction; then there is the idea of a positive list; it is in preparation and this has remained in preparation for a long time, because there are large problems connected with it. And there are pharmaceutical guidelines for some of the physicians, too; except different restrictions on their behaviour. For in the drug price ordinance first there is the expectorant price of a drug, then there is a wholesale markup and a pharmacy markup. So the result is the net pharmacy retail price. And in this net pharmacy retail price, the value added tax of 16% is added as a result of the gross pharmacy retail price. A few

details on the wholesale markup: it is the statutory maximum markup on expectorant prices. It has a decrease in margin that starts with 21% for the lowest priced drugs and ends with 3% plus 61.63 overall. The overall average in 2000 was approximately 14.8%. Then there is a pharmacy markup. It is a statutory markup on the expectorant price. It has a decrease in percentage of the expectorant price. Its starting was 68% for lowest price drugs, but the price is less than 1 dollar therefore, really not large number of drugs any longer in Germany. And the maximum charge is 28.263 persons plus about 118 overall. The overall average in 2000 was approximately 39.6 persons. It is important to stress. I'm looking for the German pharmaceutical market, that about 50% of the turnover of pharmacies is made by about 10% of the drugs. And therefore this is what attracts the distance sales of pharmaceuticals to the German market. You can have to handle only a limited number of drugs, only a limited number of receipts, but well at the same time earn good money. And therefore the act for human health German Association of Pharmacists is presenting ideas how to change the pharmacy markup system; so that lower priced drugs will

The Law on Drug Pricing (Arzneimittelpreisverordnung)

Factory outlet price

- + depot's profit
- + pharmacy's profit

Net price of pharmacy retail sales

- + Value added tax %16)
- Total price of pharmacy retail sales

get higher markups, while higher priced drugs will get lower pharmacy markups. Well, then there is something rather uncommon in Europe, in Germany.

We have a value added tax in pharmaceuticals at the normal rate of 16%. Banking for example is taxed at 0%; circus presentations are taxed at 7% because of the cultural impact, but life-saving drugs are taxed as luxury goods. Well, the German pharmacists oppose to this. The German Secretary of Health opposes to this, too. They do so whatever party affiliations I have, but the Secretary of Finance says he needs money whatever party affiliation he has. Therefore the governments come and change, but the drugs are taxed as luxury goods in Germany. We think it is a rather uncomfortable situation, but we are not able to change it.

Official Health Insurance System (I)

- ♦ Covers %30 of the natives
- ♦ Covers %63 of work amount of the pharmacies
- Political centre of power
- Produces financial stress on doctors, drug manufacturers and pharmacists

When speaking of the German pharmaceutical market, it is necessary to gain an impression of the powerful statutory health insurance system. It covers about 90% of the all population and about 70% of the turnover pharmacists is paid for by the statutory health insurance. You can imagine that this financial impact of the statutory health insurance is politically powerful as a political powerhouse

and it uses its muscles and always says what it wants and well, one thing it always wants lower prices. The statutory health insurance system puts financial pressure on physicians, on pharmacists, the pharmaceutical manufacturers, the politicians. I want to present a few truths I present on the pharmaceutical system. Let's go to the next transparency. First there was a drugs budget for a long time in Germany. Well, it was abolished at the end of 2001, because of public pressure; except the given selfhelp in groups said that there was the restrictions, there was a rationing of the use of innovative drugs. The physicians said they tried to prescribe cheap drugs, but were not able to fulfil their budget. We have in Germany a rather high percentage of generic drugs; in about 70 to 75% of all cases, where generic drugs are available. These generic drugs are prescribed. That means, further saving is rather difficult to get. Well, and then the drug budget rolled at technical, radical and logical floor in itself that made the application rather difficult. There was always the risk that someone might go to court and find out that he is able to overcome this drugs budget. Therefore, there was a good pressure to abolish it and at the end of 2001 it was abolished. Well, at the same time, the politicians decided that they needed the money anyway for the statutory health insurance system, so we have a statutory discount of 5% on the gross pharmacy retail price and this was increased to 6% at the beginning of this year. Formally, it is only a temporary restriction for 2002 and 2003. It remains to be seen whether this rate of 6% is abolished in 2004. We hope so, but at the moment it is more of a question of hoping. At the beginning of 2002, further regulations took place to limit the expenditure for

pharmaceuticals. There was the statutory discount in pharmaceuticals that was increased from 5 to 6%. There were the extra payments, called voluntarily payments of the pharmaceutical producers of about 210 million overall for 2002 and 2003. This was their method to overcome restrictions on the pricing of pharmaceuticals and at the beginning of this year, the generic substitution was now permitted on a regular basis. But due to pressure from physicians and other groups, the pharmaceutical press to say this directly or the press covering the physicians there were many restrictions on the try to generic substitutions so that in fact there is any chance that the number of generic interchanges remain extremely limited in Germany. In the future more or less decrease in the price level of generic drugs will happen. Well, and at the beginning of this year it was a tougher application of the reference price in system, so that prices became lower. To give you an impression of the reference price system, we have three groups. The first group is the most important one. It is composed of drugs with the same active ingredients. The group two is composed of drugs with therapeutically compatible active ingredients and group three is composed of drugs with compatible pharmacological profile. Only the cheaper drugs are reimbursed. If a patient has a receipt for a higher priced drug, he has to pay the difference between the reimbursement price and the price of the product for himself. Besides, there are co-payments for the pharmaceuticals in Germany of 4, 4.5 and 5 overall package depending on the size of the package, while these numbers have been changed in the last years with changing governments. One tendency has always been there. Nowadays about 50% of all prescriptions are

exempted from co-payments for social reasons. The German pharmacists are really unsecure whether Germany is so poor that 50% of the population are not able to have any sort of co-payment. But we will find out whether the government is able to remain on their course for the next years to come. There are pharmaceutical guidelines for the physicians; that these pharmaceutical guidelines give an idea of what you could prescribe as a physician when the patient has this or this illness. They are sorts to limits as a freedom of physicians to prescribe. In fact it is very difficult to have any proof of that the physician prescribed too expensive drugs. Therefore, they aren't extreme importance at the moment.

Official Health Insurance System (2)

♦ Negative list

- Order of the drugs that are referred to as "ineffective"
- The drugs that won't be paid back are being organized

Positive list

- Order of the drugs that are referred to as "effective"
- The drugs that will be paid back are being prepared

We have a negative list. It is a numeration of pharmaceuticals or illnesses that are called inefficient pharmaceuticals only for minor illnesses. They are not to be reimbursed. This list is under reconstruction. They are always looking whether they can prolong this list. It proves to be rather difficult, because the very easy, likely illnesses are already in this list; example given through headache. Then there is an idea of a positive list that should be implemented; the numeration of all those drugs that can be paid for by the

statutory health insurance system. The idea of the positive list is rather old. The technical problems to compose this list are extremely large. There are many pharmaceutical manufacturers who might be affected by this list; because if their product is not on this list, they might find themselves out of the market and they have already said that they would go to the court, if anything like this positive list will come. The government was hopeful that they would be able to present the list at last years and they were sure they were able to present it in June or July of this year. Nowadays, they think they will present it in the next year after the next general election; then we will have to look whether this government will be able to present anything then The German pharmacists do not have any problems with the negative list. But they think that the positive list is not senseful. There is a possibility that the drug is senseful in any special circumstances, then it should be reimbursed. If this drug is never efficient, never senseful to dispense, well, why is it on the market? That's our position. And we think it is logically right.