> SECOND DAY / THIRD SESSION

PRESENTER- Hello again. I would like to invite Mr. Serif Boyacı, Head of the Auditing Committee of the Turkish Pharmacists Association, to deliver his speech on "Pharmaceuticals Track and Trace System". (Clappings)

Pharm. ŞERİF BOYACI
(Head of the Auditing Committee of the Turkish Pharmacists Association)

Actually, you would have to hear this speech from a bureaucrat today but he could not join us due to his excuse. You will listen to a presentation from a pharmacist's point of view. We will focus particularly on the current situation of pharmaceuticals track and trace system system. Afterwards, I will try to explain the benefits that it would bring to us and the risks to pharmacists. I will lastly tell about the road map of the Turkish Pharmacists' Association.

In the current situation, pharmaceuticals can be tracked on serial basis. However, it is not possible to track the drugs after they are given to patients from pharmacies. Because, the current technology does not enable us to track the drugs on chest basis. We are not able to prevent the economic losses and crimes connected with fake barcodes. Around a thousand colleagues faced this problem last year. Thus, our main approach has become to support this track system. On the other hand, the drugs that are decided to be collected cannot be controlled. It is not possible to track whether those drugs are still available or are drawn back from circulation. It is not possible to track due to side effects of drugs, drug-drug and drug-food interactions.

In addition, fake drugs and fake drug cuttings cannot be tracked as well. As you know fake drugs have the same name as the original ones but are not produced by the qualified producer. It is impossible to track fake production.

Even if the drug is original, sometimes they are marketed with fake chests. The medicine is not fake but the chest is. Thus, the cutting is fake too. The pharmacists has responsibility to determine the fake drugs and has losses in reimbursement process.

The Ministry of Health initiated "Medicine Track and Trace System" to improve drug safety and fight against drug forgery that are threatening human health. We need to evaluate the benefits and risks of this system separately. Let's look at its benefits first.

Different than other consumption products, drugs should be tracked in every stage of their movement in the market. As I have already said, it is not possible to track them with the information that the drugs have on them at the moment. Thus, all the information needed should be defined for each drug in electronic environment. Drugs can be tracked efficiently only after those information in the electronic environment are gathered in a database and updated continiously.

In order to put the system into practice, our Ministry of Health prepared the Regulation Regarding the Packaging and Labeling of Medicinal Products for Human Use with the amendments. It was brought into practice after it was published in the Official Gazette on 02.02.2008. In consequence of Drug Barcoding Guidance was issued on 11.02.2008 with the confirmation of the Ministry. We were expecting that the Medicine Track and Trace System would come into force firstly in industries and pharmacies on 01.01.2009 and in the following year until 01.01.2009 the barcoded products in the market would be consumed and then the products with squarecode would started to be used completely. However, it was delayed six months. The products without squarecode can be put on the market until 01.06.2009. In sum, consumption duration of the products without squarecode was decreased to six months from one year.

The barcode that has already been used, a secondary identifier and the notifications in the identifier made to the center of the system will take place in the medicine track and trace system.

DataMatrix Tip 2D Barcode:
(SQUARECODE)

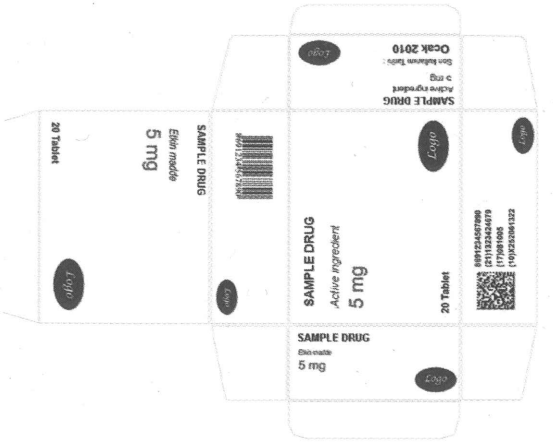
Primary Identifier:

2 dimensional barcode that will be used in the Medice Track and Trace System; Called Squrecode that is an automated data identifier with a matrix structure which is able to store more data in a narrower area.

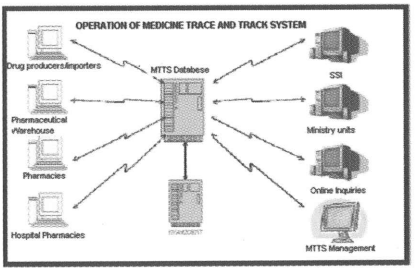
Secondary Identifier:

Identifier to be put on the packages of drugs in different dimensions. Secondary identifiers and the readable information on the product packages would be located as follows.

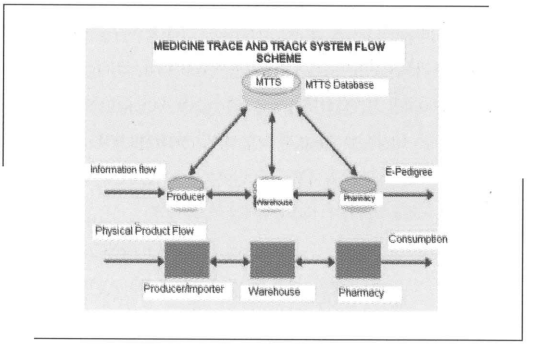
This is a sample of squarecode design. Two dimensional barcode to be used in the medicine track and trace system is named squarecode here. It is an automated data identifier with a matrix structure which is able to store more data in a narrower area. However, when we look at the drug packages we see the secondary identifier in various dimensions. The readable information would take place on the package of the drug as follows. What is that? 1. The barcad of the drug. 2. Serial number. 3. Lot of batch number that is the old serial number or expiry date. The outlook of drug package will change in that way. We will have the old barcode and new squarecode information.



In the operation of medicine track and trace system, the information flows to the database from drug poducers, drug stores, pharmacies and hospital pharmacies besides Social Security Institution, departments of ministry, departments responsible of online inquiries and administration of medicine track and trace systems. There will be a back-up unit disaster protection unit. I do not know where will it be located, maybe in Konya.



Let us have a close look at the operation of the system. The process operates as follows: In the first stage, the database of the Medicine Track and Trace System links all the printed barcodes to the producer companies through activation system. Afterwards, the producer companies should give a feedback about the notified two dimensional barcodes to the database of the system. This does not need to be online because it can be done when they produce. The notified barcodes will be printed on the drugs during production. The producer companies should also give feedback to the database of Medicine Track and Trace System as soon as they sell the drugs. In the third stage, drug stores will give feedback about the drugs they buy to the database of the drug track and trace system. This notification should also be confirmed by the producer company.



Track drugs means the pedigree of drugs. The central system to be established aims to track each drug at every point it goes. The Ministry of Health will track the drugs thus collects the data.

Every sold drug should absolutely be notified to Medicine Track and Trace System. None of the drugs will be out of Medicine Track and Trace System. However, majistraller and radiopharmaceuticals will be out of this system for a while. It is compulsary to give notification to the producing authority at every stage for every sold drug. Notifications will be made on digital environment by using web services or web pages. In every stage of the process, each unit has to make notifications both during buying and selling. The pharmacies are the last link of the circulation so they will give feedback to the database of the Medicine Track and Trace System when they sell drugs.

Let us explain its benefits. It is estimated that the profit gained from fake drugs is around 5 billion dollars in the European Union countries. It is impossible to find out how much it is now. We do not have the any figure concerning it for Turkey. There are only the products confirmed by the reimbursement institutions. According to the publications of World Health Organisation, around six percent of the drugs in the world are fake. Therefore, the major benefit is to prevent the fake drugs and fake cuttings so as to avoid the damage of public health. Each package of a drug would be paid only once by the security institutions. The smallest defect in the pedigree of a drug can be seen immediately and found the source of it. The system can easily find the serial numbers of the stolen drugs from pharmacies and drug stores. Thus, robbery would be prevented.

It will also bring benefits in terms of pharmacovigilace. It would allow to track the expiry dates of the medicine and thus prevent the capital loss. That has really become a serious problem for the pharmacies. As I said before, it will allow us to track the stolen, smuggled and fake drugs. The drugs, which are controlled when purchased, can be tracked easily and they cannot be sold without a prescription. We would assure a rational stock management in our pharmacies. We will not have to cut clippings anymore that takes too much time and effort. To sell drugs out of pharmacies would be prevented. This system would not allow the supermarkets to sell drugs anymore.

We will not face problems about companies who do not share information. Because, when we apply to companies in connection with a fake cutting they blamed the pharmacies on the allegation that the cuttings did not belong to them. Of course, it is very easy for the companies to find with help of the serial number where they sold the so called drug. How can they find it? They can find it by the serial charge number on the drug. Unfortunately, they have always been unlikely to share this information.

As I have already mentioned, we will not have an informal medicine economy anymore. We would be able to know the number of drugs without prescription sold by pharmacies. It would prevent undue prescribings such as writing repetitive prescriptions or prescribing repetitive drugs. Of course, there is a public interest here. Emerging data can provide a huge area for researchers as the data of the illnesses in Turkey can be obtained by this system.

Based on the production serial numbers, we will be able to know which medicines are distibuted to which areas, even given to which patients in the country. Expiry date would easily be distinguished. The stock of drugs, whose expiry dates are soon, will be revealed easily on the country level.

Besides the above mentioned benefits, there are also several risks as there is in every operation. The first one we can foresee among these is the huge capital to be invested. In which areas will the capital be invested? Software, technical infrastructure, computers, cash register, readers, uninterrupted power supply or generator.

The work burden in pharmacies will inescapably increase. Every single drug should be entered in the system. They should be recorded in the systems of the Social Security Institution and the Ministry of Health when they are sold or given back. All these works should be carried out by very speedy mechanisms. If the provision system and/or the system of the Ministry of Health do not work there might emerge the problem of coordination. Because, we are facing this problem in our pharmacies now even when there is only one institution. The programme sometimes works very fast, sometimes suddenly stops. It either works very fast or stops. There is nothing in between. This problem has not been eliminated until now.

The stocks will definitely increase in pharmacies, which will bring the problems of additional capital investments for them. The number of services that the drug stores provide to the pharmacies might decrease due to the increase in their work burden. Due to the need of more drugs allocated to the provision system, the increase in stocks so more capital investment will be compulsory. Because, only the existing drugs will be read so it will not be possible to get into debt to the system like now.

There are also risks in the issues related to the Tax Procedure Law. Pharmacies can barter drugs at the moment but it will be difficult with this system but will not be able to do that anymore. However, we are negotiating on it. This was accepted as a real problem that should be eliminated and the Ministry of Health was convinced. It would not be wrong to say that we have advanced to create an opportunity for barter by putting an additional button on the system. There might appear some problems concerning drug return. There might be unconformity in serial numbers when drugs are returned to the stores due to closure of pharmacies and any other reason. As we all know today, the stocks are more than needed in pharmacies. This problem develops not because of our faults. The discount drugs are seen with the former high prices on the shelves, thus the number of the stock seems higher when checked periodically or at the end of the year. For example, the price of a drug decreases 10-20 percent, but it should be hold with the former price in the inventory. Drugs sold without prescription can sometimes be seen in the inventory as well. Problems related

to the changes in the inventory should be eliminated. These problems should be solved together with the Ministry of Finance after the medicine track and trace system is brought into force.

Another problem might be the excess production of drugs without squarecodes in 2008 and loading them in the pharmacies by the drug stores. Pharmacies might face problems if they cannot consume those medicine until the due date. In other words, pharmacies and drug stores might have drugs without squarecodes in their stocks after January 1, 2010. And, there might be insufficiency in some drugs in 2009.

Let us come to drug stores. There is also an approach that excludes them from the system as they are against it. The system will bring additional costs to drug stores and there are risks for them like being unable to adapt to the process immediately and decrease of the quality of their services. The work burden in the drug stores will increase. They will spend more time on invoicing and control of drugs and will not be able to serve the pharmacies as much as before. Bringing service to pharmacies four times in a day might decrease to three or the 15 minute time for bringing drugs to pharmacies might increase to one hour. In sum, the quality of service which is provided today might be deprived.

With the squarecode application, the prices will not anymore be printed on the drug packages, which might bring ethical problems to pharmacists. In other words, there might be different prices for the same drugs. There are also risks related to offline operation of the system. There are risks that would arise due to late ascertainment of several problems such as fake cuttings and fake drug.

When the newly received drugs are read by barcode readers in the pharmacies, the drugs will be notified to the medicine track and trace system. However, the information about the drug store that the drugs are bought from might not be notified as there is a probability that drug stores are not included in the system. After the notification, the information about the drug, whether the drug is recorded in the system or not, whether there is more than one notification can be followed online over the database of medicine track and trace system.

The prescription will be entered into the provision system and thus the Social Security Institution will be informed about it. The Social Security Institution will respond online after checking the drug information. Pharmacies should send information both to the databases of Social Security Institution and Medicine Track and Trace System after they give the prescribed drugs to a patient. Meanwhile, Medicine Track and Trace System will generate a selling code for each sold drug. After the notification of the pharmacy, web services of the Social Security Institution will connect to the web services of Drug Track and Trace Services and check whether the selling code is generated or not. First we check whether the drug is fake or not and then wait for confirmation of the prescription by the Social Security Institution. The selling notification code from the medicine track and trace system together with the confirmation of the reimbursement by the Social Security Institution are sent to the pharmacy. Social Security Institution will finish the registration to allow payment. When a drug is sold in a pharmacy the squarecode number on the drug should be notified to the database of the medicine track and trace system. The agreement we should make with the Social Security Institution is not certain yet. According to me, a prescription that is confirmed by the Medicine Track and Trace System does not need to be investigated more, but some might think it is necessary. I know there are authorities in the room, they may produce some ideas. Maybe we will not have to clip cuttings. Our hand corns might start recovering. We can be saved from scissor expenses.

Pharmacies will not be allowed to sell prescribed drugs without prescription. The drugs sold without prescription will have to be notified. Because, when a drug enters our pharmacies it stands alive. When we do not sell it with notification, in orher words when we do not kill it, it would stay alive in our pharmacies. Therefore, notifications of the drugs sold without pescriptions should be made as well.

What will be need in our pharmacies within the framework of this system? First of all, we need a barcode reader that can read squarecode. The softwares we use in our pharmacies should be accorded to this system. Because, the current readers cannot read new barcodes. Pharmacies need to integrate the system

until the day they will start to sell only products with squarecodes. The pharmacies which do not accomplish the integration will continue with cuttings. Of course, this will be a temporary measure and they will not be allowed to do that permanently. They should assure the integration in any case. Therefore, it is better to do it as soon as possible. The cuttings of the drugs without squarecodes will have to be clipped until 01.01.2010. We have to clip cuttings if there is no squarecode.

Let us have a look at the road map of the medicine track and trace system. Let us have a look at what the Turkish Pharmacists' Association has done and faced concerning the medicine track and trace system. Central Board of Turkish Pharmacists' Association completely supports this system and is going on participating in the meetings of the Monitoring Committee of the Medicine Track and Trace System that involves Pharmaceutical Manufacturers Association of Turkey, Turkish Pharmaceutical Manufacturers Association, Association of Research-Based Pharmaceutical Companies, Association of Medicine Stores. Drugs would be tracked, safety of drugs would be ensured and sources of the problems would be determined easily when this system is put into force. As I said before, pharmacies will not suffer from these problems anymore.

Social Security Institution should provide the necessary support concerning reimbursement and ensure the fast and online operation of provision systems integrated to the medicine track and trace systems. The software and infrastructue of the provision system should be improved in order to be able to make notifications over the provision system of the Social Security Institution during the transition process.

National pharmaceutical industry and medicine stores are the main components of this system but they are problematic in this system. In order to ensure efficient operation of this system and eliminate the responsibilities of pharmacies about fake drugs, the medicine stores should be integrated to the system immediately. The solution can be described as folllows: pharmaceuticals should be sent to medicine stores as packets from medicine industry and there should be the lists of drugs in the packet with 2D barcodes. Those lists should be entered in the

system in once in the medicine store. I know that pharmaceutical industry is working on this issue. They started to put 20 or 10 boxes of drugs in packages instead of 50, which is an important progress. However, the pharmaceuticals will not have the same packages when pharmacies receive them from drug stores. Those packages should be opened and each medicine should be read by barcode readers. As I said before, this will create several problems in terms of labour and time.

The system should work online, in other words the database of medicine track system and access to it should operate on real time basis. They should work on gathering all the institutions that we send prescriptions under the same provision system. Medicine track and trace system and provision system of the Social Security Institution should be compatible. They should work for the integrated operation of the e-health and squarecode, and prevent the need for a new regulation when the e-prescription comes into force.

The stocks that pharmacies will have on 01.01.2010 is another issue to be handled. We need to make negotiations with the pharmaceutical industry and work on the Tax Procedural Law. I said before what should be done. The protocols to be made should be synchronized with the medicine track system. If we have to clip cuttings or bacodes after we are integrated with the medicine track and trace system these problems should be solved in a logical way.

Solutions for medicine barter between pharmacies that are compatible with medicine track and trace system should be produced. Pharmaceutical companies should develop a flexible packaging system. Otherwise, overstock in pharmacies would be inevitable. Clarification should be made in order to overcome the doubts in society about different prices that may result due to the lack of printed prices on the packages of drugs. If not, we might face serious ethical problems. New regulations concerning legal amendments should be made in order to enable the Ministry of Health to adopt a convenient system for pharmaceuticals subjected to control. Pharmaceutical companies shoud change the products without 2D barcodes with the new ones or take them back after the transition period.

Turkish Pharmacists' Association should work on related issues as well. It should prepare a standard technical infrastructure for the pharmacies to overcome certain problems. What can the TPA do? It can provide support to its members for equipment procurement such as procurement of barcode readers and provide credits for the investments to be done in the pharmacies.

TPA's programme Tebeos can be synchronized with the medicine track and trace system and then sold to pharmacies at a discount. If these can be completed in time, a unique programme is ensured to be used in pharmacies.

All our members should complete the information and software needs for full integtarion in order not to face any problems in transition process. Central Board of Turkish Pharmacists' Association issued documents and published announcements and updated information in its offiicial web site www.teb.org.tr in order to acquaint its members with the latest developments. That is all I would like to say. Thank you for listening to me. I would like to answer your questions now if there is any.

QUESTION- First of all thank you for the presentation. In fact, I do not have a question but a little problem. The barcode system is actually a better system. You have already told its deficiencies, one has to hold the barcode device tam karışında of the drug package for reading. It is certain that it will bring more work burden. They insisted on the RFID system but did not make it compulsory. It is certain that such problems would be eliminated if the RFID system and medicine track and trace system are integrated in the future. It is possible to reveal how much medicine you have in your stock without counting them one by one as the RFID system enables us to enter the drugs in the system untll the expiry date. I just wanted to disclose my ideas. Thank you.

Pharm. ŞERİF BOYAÇI- Thank you. That is right. A pharmacist should make all the necessary controls before putting the medicine on shelves, which is indispensible. The radio frequency identification system might be used in the mechanism to identify the fake medicine. However, we are not the authority that would give a decision about it.

QUESTION- Thank you very much, Your presentation was very informative. I hope my colleagues can forgive my ignorance but I just wonder whether it will be possible track also the patients within this medicine track and trace system. For example, sometimes a patient comes to a pharmacy and says: "I bought this medicine from you but it has not help me." Will be able to check whether that patient bought the medicine from our pharmacy or not? Will that create a safety problem?

You gave information about tax procedures. I think I did not understand it, is it something related to overstock? Sometimes excess stock goes unnoticed and are not invoiced. Is it related to these points? Can you please explain it more?

Pharm. ŞERİF BOYACI- I am not in the decison making mechanism. As far as I know, it is not possible to revive a medicine after it is killed in the pharmacy. So, it is not definite whether the patient bought the drug from you or from any other pharmacy but if it was given to a patient after being read by barcode reader that medicine should be a reliable and safe one. We as Turkish Pharmacists' Association and pharmacies believe that the pharmaceutical stores should be included in the system in order to be able to know where the medicine was bought from. Secondly, it should operate online. The system should definitely work online. Becuse, while we are giving a medicine we should be able to get the information whether it is fake or not in a short time. If this is not possible the system has no meaning for us. If I will stay under the risk of counterfeiting, if the system will not send me a note about it then what is the meaning of medicine track and trace system for me as a pharmacist.

QUESTION- I did not refer to fake medicine. I would like to give an example. I experienced some years ago. A patient came and bought 10 Duocid (1 gr) for intravenous use. After some days she came again and wanted to give back 6 of them on the allegation that the physician decided to change the prescription. How can I know that she bought that medicine from my pharmacy? Where did she buy it?

Pharm. ŞERİF BOYACI- I would like to say something about Tax Procedural Law but let Mr. Sami explain it.

SAMİ KIRAÇLI- I will explain these points in the next presentation.

Pharm. ŞERİF BOYACI- The things related to the Tax Procedural Law will change as well. All products in pharmacies will seem alive until they are shown as sold. In order to kill a product you have to show it as sold. Therefore, an unregistered sale will not be possible. All the sales will have to be entered in the system. In this sense, pharmacies have over stock resulted from the former system. If we cannot consume this overstock it will come with us forever and cause serious problems. We will always face that problem. We will be a sector that will sell totally registered product then let us determine a date to give an end to it. We will negotiate it with the authorities.

QUESTION- First of all thank you for your presentation. I would like to ask about the record of the prescribed medicine to the in the system, which is the most important thing for us in the medicine track and trace system. There should be a synchronization between the cash register besides 2D barcode reader and softwares. This is a difficult technical work so I am not sure if it can be solved until 01.01.2010.

Secondly, prescriptions are repeated for some chronical diseases abroad. For example, a patient suffers from hypertension or rheumatism can get drugs several times based on the first prescription. As far as I know, their system allows to connect online to the first prescription. Medicine tract and trace system was tried for a while in Italy and then annulled. This system is not applied in any part of the world. Have you considered these problems? I think the cash registers will change completely.

Pharm. ŞERİF BOYACI- I want to make a personal comment. It is of course preferable to have compatible cash registers. But, if you do not have a compatible one, it is possible to make out a manuel invoice.

QUESTION- Sorry, I referred to another point. I am trying to imagine it. A patient who has chronic hypertension comes and wants to get her drugs without payment over social security system. When we enter that drug the system asks

prescription. If you do not have a compatible cash register that drug cannot be tracked. Therefore, you have to enter the prescription that necessitates a connection between the computer and chas register. So, everything has to be changed.

Pharm. ŞERİF BOYACI- I understand, we might face these problems in the future. For example, The Ministry of Health can bring a regulation that allows to sell medicine in several ways. The main approach of the Ministry of Health is to prevent the sale of drugs without prescription and sale of prescribed drugs with prescription. As pharmacists, we cannot be against that but of course another solution should be found for chronical diseases.

QUESTION- First of all, I would like to thank you. Unfortunately, the questions in my mind increased after your presentation. On the one hand, the period that the pharmacists should deplete the medicine decreased to six months. Pharmacists have had to cover up the changing points in the system. We are going to demonstrate against it on 21th of this month. It is still thought that pharmacists should cover up the difficulties. What should the TPA do for that? What are its plans?

We will follow the expiry dates and our stock from now on. But what will happen to the expired medicine in the new system? Shall we ask money after entering medicine in the system? Patients who are in economic distress have right to know the price of drugs. Some people have difficulty in paying their medicine. The price will not be printed on the drug. Will we get the price of a drug by heart?

Pharm. ŞERİF BOYACI- You will see when the barcode is read.

QUESTION- The patient might not buy the drug after the barcode is read. Am I going to repeat the work many times for only one prescription? I have another question: will there to be squarecodes in the blister pack or on the drug?

Pharm. ŞERİF BOYACI- Yes, there will. Firs of all, my presentation was about medicine track and trace system but not about the tasks of the TPA or what

should it do about that. I already said what should the TPA do. We are thinking on the solutions. We are negotiating with the Minister of Health and the pharmaceutical industry. They postponed the implementation for six months upon the complaints of the industry. Similarly, they can prolong the period for us as well. We have to consider the stock cost while buying medicine from now on. Otherwise, it would create a great problem in pharmacies. I think it would be better not to buy more for the promotions. We have one year for transition and it is not correct to buy medicine that we cannot sell within one year. I know some drugs cannot be sold even in one year but we have to buy one or two boxes, which does not bring an economic burden. But, still, this problem has to be solved, we do not have another option. As the TPA, we think in this way.

I wish you never experience a fake medicine case but as an executive member I hear such dramatic fake medicine cases. For example, you sell the drugs you received from the pharmaceutical store but one or two months later the Social Security Institution cancels your agreement on the allegation that one of the four drugs -let us say Tarka- is fake. Do you prefer to live such a risk for 365 days and 24 hours or support the drug track and trace system. We have to think about it. Most of the colleagues whose agreements are canceled are about to close their pharmacies due to the costs either of court or another. Around 1000 pharmacists have experienced such problems. You have to support such a system if it brings a solution for the problem that 1000 of your 24.000 members face. The solution of this problem may bring an extra work burden on you like registering the drugs when you receive from the pharmaceutical store. When you consider the bigger problem on the other side it is not correct to complain about that burden.

QUESTION- You said the integration will not be realized immediately. Then how can I prove that I bought the medicine from that store without integration?

Pharm. ŞERİF BOYACI- Now, everybody is talking on these issues. We represent pharmacists in the negotiations. We have two red lines: the system has to include the stores and be online. We have to see clearly that the new system will bring a huge extra burden on the stores. There are representatives of pharmaceutical in the hall. Maybe they can give us information.

QUESTION- You expressed the inclusion process of the stores very well. The work flow will go slow very much with the inclusion of the stores in the system. This slowdown will also effect the pharmacists. What is in mind is the registration of the drugs as soon as they are received from the store and then confirmation of them in the database. By this way, the store that provides the drug is recorded in the system and confirmed in the database. Similarly, when the pharmacist gives the drugs to the patient online process starts for the second time. The probability of delay for drug stores will decrease.

Pharm. ŞERİF BOYACI- When the Medicine Track and Trace System gives the notification of 1 million drugs, there would be 1 million drugs in the pool. Afterwards, 100 thousand of the drugs are sold to a store, 500 thousand are sold to another one, which are also tracked by the system. There is only one issue left: when pharmacies want few drugs then the packages should be opened which needs more effort then before. The integration is enough to save you. It is not a problem for you because it would already be seen that you bought from a certain store. The place of a single drug is known. It stays alive until it is killed at some place. The place where the drug stays is also known in the new system.

QUESTION- You said that pharmacies have one year for transition. But, as far as I know, some companies are going to pass to this system after new year. Pharmacists do not have to integrate this system and have squarecode readers. We will not clip cuttings of the products that will come after new year and we will not have former barcode readers. Do pharmacists need to integrate to the system? Some pharmacists will not continue the old system but just will use the squarecode system.

Pharm. ŞERİF BOYACI- The Ministry of Health should think about it. I am not in the decision mechanism.

QUESTION- They can send both of them if they wish. As far as I know, 3-5 firms will send only squarecode drugs to pharmacies after 01.01.2009.

Pharm. ŞERİF BOYACI- The Ministry of Health presumably found a solution for that. I bought two 2D barcode reader and use them in my pharmacy.

QUESTION- Assume that a presciption comes from the Social Security Institution but there is a drug in the prescription that the Social Security Institution does not pay for. We do not know whether the patient will buy that drug because the price is not printed on it. Do I kill the drug when the barcode reader reads it in order to learn the price?

Pharm. ŞERİF BOYACI- No, no. The system asks for your confirmation.

QUESTION- It means that the drug is not killed automatically when it enters the system. It means that we can make amendments. Thank you.

QUESTION- I begin to speak again but I want to ask when everybody is here. As far as I know, the price has to be written clearly on every product according to the consumer protection law. Are we not running into a contradiction even if the patient does not create a problem? World Health Organization discloses in its documents that the fake drug rate is around 6 percent. The number you gave corresponds to 4-4,5 percent if I calculated correctly. Is it really a severe problem for Turkey?

Pharm. ŞERİF BOYACI- I am talking about the number of pharmacies: Some 700 pharmacies in 25 thousand.

QUESTION- Maybe it is over but still evocatory. Thank you.

QUESTION- Thank you very much for the presentation. We again understand from your presentation that the community of pharmacists are confused about this matter. There might not be price labels on the drug but may it cause the reduction of retail prices totally to the prices put by the Social Security Institution in the future? In other words, will the invoice and accounting forms received from the stores change?

Secondly, it is assumed that the drugs will be conveyed to pharmacies in one year. However, we give the medicine or the active ingredient in the package to patients. We will have to throw away the medicine due to a change in the production package or barcode. How much is compatible with a healthy economy? This approach really surprised me.

Thirdly, you represent us there and believe you do it very well. But I would like to share my point of view here. You are confused with the questions we ask here. You cannot give clear answers like Mr. İbrahim Nayır from General Directorate of Pharmaceuticals and Pharmacy whom we asked questions during the congress in İstanbul. As pharmacists, how can we support the medicine track and trace system to the end? I wish everything was clear but it is not, as far as I see. Pharm. ŞERİF BOYACI- I am going to repeat what I said a while ago. If around a thousand of your colleagues face with the accusation of counterfeiting and if a system can prevent this then it is very logical to support that system as an executive. I am not talking about the prices but about the risks of fake cuttings and drugs. When the drug is read by a barcode reader the price can be seen on the monitor of the cash register. In addition, you can use two-sided monitors that displays the prices of the drugs that patients ask. These problems have solutions, as far as know, but I cannot understand to live with the risk of being charged with counterfeiting. As executives, we have to support a system that prevents it.

QUESTION- It is a very good system but I have a question: of course Social Security Institution is the biggest purchaser in Turkey but pharmaceuticals without prescription can be sold at retail price also apart from the Social Security Institution. I think nobody is against the necessity of prescription. But I wonder if we might loose in the future due to the dictation on retail prices? Will the provision systems be sufficient in this sense?

Pharm. ŞERİF BOYACI- The prices are printed on the drugs now but Social Security Institution have a free hand to determine the prices. It does not matter whether it is printed or not for Social Security Institution. We can discuss it later because we have already used the 15 minutes of the next presentation.

QUESTION- There is a regulation that stipulates putting surcharge stickers on the non-imbursed drugs. So, you can put surcharge stickers if the drug is not paid back.

QUESTION- Some pharmacists faced problems. We all need to develop empathy. We should think how we react when we face such a problem. Because, it is impossible to run a pharmacy only with retail sales. My question is this: the discounts of public institutions are made over pharmacists by the provision system. If the stores will become a part of medicine track and trace system then the 1, 2 or 3 percent losses of pharmacies might be prevented. I think we need to work on that. Secondly, every new system brings additional expenditures on pharmacies. Can we overcome those work burden with the existing profit margin? Can you inform us about the attempts to solve this problem? Thank you very much.

Pharm. ŞERİF BOYACI- We are working on all these issues. I have tried to conduct necessary negotiations with the related institution about the low profit rates during the lunch. We are working on this issues, we do not hide from this. But, as I said before, it is aimed to prevent fake drugs and fake cuttings with the medicine track and trace syste. If it succeeds our colleagues will not face their agreements being cancelled in connection with fake cuttings. Thus, we support this system. Thank you for listening to me.

PRESENTER- I think you have many questions on medicine trace and track system but we have a limited time. We will have a discussion debate between 4 pm and 6 pm during which you can ask your question. You can also ask during the coffee break. Now Mr. Sami Kıraçlı, from Social Security Institution, is going to inform us about e-prescription and smart card applications.

SAMİ KIRAÇLI
(SSI Technology and Business Development Department Head)

Distinguished participants; I'd like to extend my respect on my behalf and on behalf of the Institution. As Social Security Institution (SSI), we are a part in the health system, we are a sub-system. We all know that we are an important part because we are the reimbursing institution after the service is provided. Therefore, production and implementation and share of payment policies are among the responsibilities of this institution.

Before the presentation, I would like to touch on the medicine track and trace system explained in the previous speech. Mr. İbrahim Nayır was mentioned in the speech. We are working and develop software with his team as well. I have to underline that there will not be any change in the current system of pharmacies. They will enter the drugs and then we will receive it over the system. However, the pharmacies will need the confirmation of the Ministry of Health for the notification. We will get the confirmed information from the Ministry of Health but not from the pharmacies.

When are you going to make the drugs definite? You'll have 2-3 days following the notification to Ministry, for dose correction and drug correction. We'll only reimburse the drugs approved by Ministry at the end of each period; consequently the relation is not exactly online. However, some concerns may arise during the implementation.

The most significant concern is that the Ministry's system is not in a position to respond promptly to the queries. If this is achieved, we'll be able to execute the tasks without much trouble.

Now, I'd like to share another dimension of the policy. This is about a system to be applied in order to ensure provision of the healthcare services to the right person by the right provider. The first step for this was taken by a protocol with TUBITAK in 2006. On 4 July 2007 the project was enlarged to involve Interior

Ministry Population - Citizenship DG and MoH, while its name was changed as "Electronic ID Verification System". Citizens can now receive services showing their id cards. We, as SSI, constitute a component of the project. This project was officially initiated in Bolu province in November 2008.

The pilot in Bolu will cover 10 thousand people, to be enlarged to 300 thousand people later. The Prime Ministry circular designates that the project will be initiated at the health and social security fields. So far, the project has been carried out in cooperation with the pharmacies and a state hospital in Bolu.

This is a TARAL (Turkey Research Field) project financed by TUBITAK. At first, it was planned to last for 30 months with a budget of 10.7 billion dollars. Then, with the inclusion of other institutions, the project was extended by 18 months and 17 million YTL extra budget. TUBITAK National Electronics and Cryptology Research Institute drafts technological and operational progress reports which are then forwarded to the Scientific Board following an examination by our side. The project continues if the scientific board approves these reports. No problem has arisen so far. The final report is being examined by our department currently; then it'll be sent back to TUBITAK.

Provision of the service to the right person by the right party is important from our perspective. Otherwise, erroneous payments cause a loss for our institution and our country. We should be in a position to know for sure that the receiver of the service is at a certain place at a certain time; and the service provider has contract with us, hence the qualification to provide this service.

Receiving service in the name of someone else is a significant problem for us. Provision of service violating the current legislation is another. The most frequent concern for us is health carnets and relevant fraud. False prescriptions and reports, false price tags for drugs, doubtful acts in diagnosis and treatment are some other problems influencing us.

In order to avoid those problems, we firstly question if this person is a right holder. We check if the act is in line with the legislation. Despite all these

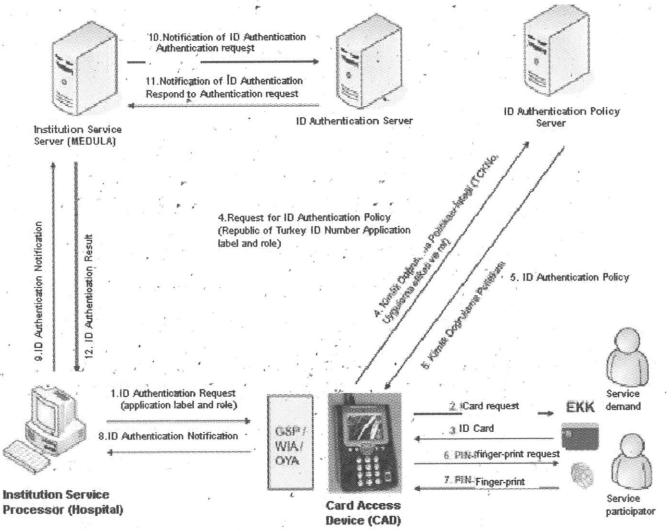
measures, we still fail to ensure reliable id check. Therefore, we aim to perform id check with a cryptographic, sound, reliable, unalterable card. This is the basis of the project. The validity of this card will be guaranteed by the state; and in this way we will know that the owner of the card is certainly there at the point of service provision. The actions of the card holder will be automatically registered to our system. This id card is designed in a way that no third person can use it and it also involves electronic signature. Normally, a person requires a service from us via you. After the person introduces herself, we decide if this person is suitable to receive the service or not. We make a commitment to provide the service if the person is right holder.

The electronic id verification system to be applied in Bolu is a smart card based system. Now I'd like to mention some elements of this system. The first is an electronic card with microchip. This smart card carries id information, fingerprint and id verification certificate of a citizen. Secondly, we have the card access device which reads the mentioned card. This device works connected to the computer of the relevant institution, family doctor or pharmacy. Third, we have an id verification server connected to the system in our institution. Finally, there is a central server which evaluates and verifies the results coming from card access devices for SSI. These four elements are installed now. The structure is internet based. Primary and secondary healthcare institutions and pharmacies will have access to our system through web.

I'd like to briefly explain the technicalities of the system. First of all, service provider should be ready to perform the task and our systems in Bolu have been organized accordingly. Patient will produce the card when she arrives at an institution. There is another professional card belonging to the service provider. The professional will introduce both cards to the system, and then these cards will be matched by our system. The id verification server will be active at this point. If this server verifies that this person is right holder, service will be provided. This structure may seem complicated, but only difference from the current system is the introduction of the smart cards that you see below.

Front side of the id card

Back side of the id card



The form of the card has been amended since the preparation of this presentation, but the general structure remains as it is. This structure was developed by TUBITAK with contribution from DG Population and Citizenship Affairs. The card contains nothing about the health state of the person; **only identity information**. The only health related info is the blood type. The card works with a password in the same way as the credit cards. The fingerprints are not being taken in the practice in Bolu. This will be implemented in the further stages. The fingerprints will not be kept by the system; they will remain on the chip of the person's card.

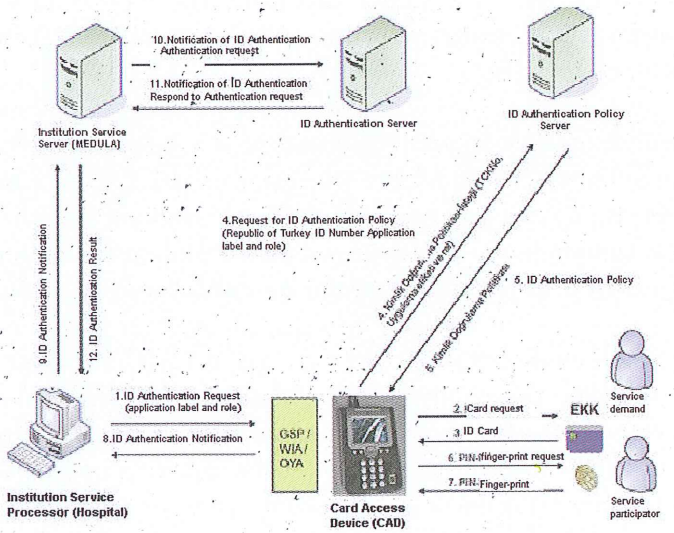
I'd like to briefly talk about our activities since November 2008. First, TUBITAK developed secure card access devices and a national operating system which was in turn written on the chip. TUBITAK, again, built relevant card security systems and tested the operability of the chip. Then, the system was tested bilaterally at the stations installed at Social Security Institution and MoH from the perspective of prescription and drug provision in the hospital. Later, these systems were carried to an office created in Bolu by DG Citizenship Affairs. We have made a list of people who have family doctors and also receive health assistance from the SSI. These 12 500 people have been provided with cards by Interior Ministry. Card readers were installed at 65 pharmacies, 6 clinics and 8 family doctor offices in Bolu.

The transactions are shifting from paperwork to the digital environment with cooperation of MoH, SSI and Interior Ministry. Our aim is to have electronic prescriptions instead of paper ones to be registered to the system from the hospital. **The system is not as advanced as we wish at the moment, but the introduction of e-prescription can be considered at a later date.**

If the paperwork is eliminated from the pharmacies; the problems about illegible, erroneous or altered prescriptions will be overcome. All the elements of a prescription will be on the screen of the pharmacist automatically. The prescriptions made at the hospital will be instantly saved to the electronic patient registry of the citizen. The pharmacy will be able to see the previous prescriptions of the patient and their dates from the system.

Front side of the id card

Back side of the id card



The form of the card has been amended since the preparation of this presentation, but the general structure remains as it is. This structure was developed by TUBITAK with contribution from DG Population and Citizenship Affairs. The card contains nothing about the health state of the person; **only identity information**. The only health related info is the blood type. The card works with a password in the same way as the credit cards. The fingerprints are not being taken in the practice in Bolu. This will be implemented in the further stages. The fingerprints will not be kept by the system; they will remain on the chip of the person's card.

I'd like to briefly talk about our activities since November 2008. First, TUBITAK developed secure card access devices and a national operating system which was in turn written on the chip. TUBITAK, again, built relevant card security systems and tested the operability of the chip. Then, the system was tested bilaterally at the stations installed at Social Security Institution and MoH from the perspective of prescription and drug provision in the hospital. Later, these systems were carried to an office created in Bolu by DG Citizenship Affairs. We have made a list of people who have family doctors and also receive health assistance from the SSI. These 12 500 people have been provided with cards by Interior Ministry. Card readers were installed at 65 pharmacies, 6 clinics and 8 family doctor offices in Bolu.

The transactions are shifting from paperwork to the digital environment with cooperation of MoH, SSI and Interior Ministry. Our aim is to have electronic prescriptions instead of paper ones to be registered to the system from the hospital. **The system is not as advanced as we wish at the moment, but the introduction of e-prescription can be considered at a later date.**

If the paperwork is eliminated from the pharmacies; the problems about illegible, erroneous or altered prescriptions will be overcome. All the elements of a prescription will be on the screen of the pharmacist automatically. The prescriptions made at the hospital will be instantly saved to the electronic patient registry of the citizen. The pharmacy will be able to see the previous prescriptions of the patient and their dates from the system.

During the first few days of the implementation, the most frequent problem has been about adaptation to the system by SSI units, hospitals, family doctors, as well as by the patients using the card. When there is a new technology, work load seems to be increasing in the beginning; but after a while workload will be diminished almost by half and we will not want to give up the new systems.

I know this by experience. There might be concerns about getting to know and use the new hardware and software, as well as the installment cost of these. Difficulties in altering the electronic info once it's entered might be challenging for us at the outset. In my opinion, the major problem is the harmonization of the legislation to the new technologies.

These decision making support systems will provide the flow of information through the electronic means. That will ensure accurate information management and minimize bureaucracy and red tape. Everybody will be sure of one another when the electronic structure is established. People will have access to up to date information that they need. The system will ensure that the services and drugs are given to the right person and minimize the fraudulent alterations and misuse. Most importantly, the right holders will receive the high quality services and treatment they deserve.

I presented you the technical substructure of the pilot project of Social Security Institution in Bolu briefly. If you have any questions, please do not hesitate to ask. Thank you.

QUESTION- Thank you for your presentation. I haven't seen Bolu yet, so I wondered if there is no paper in the pilot application going on in Bolu, do they just see it from the card?

SAMİ KIRAÇLI- The application has not started yet. Just the equipment were set up, and the cards were distributed. We need to go there to start the application, so we are waiting to go there.

QUESTION- When you start, it will work just with card, won't it?

SAMİ KIRAÇLI- Of course.

QUESTION- For the matters of diagnosis check or related specialist, will the system warn doctors, while entering the prescription, or should we control it by ourselves?

SAMİ KIRAÇLI- I could say that: the current electronical prescription we are talking about now, is not the one that we imagined. The checking of whether one's social security covers medicine or one has the medicine in hand will not be made in the hospital, it will still be conducted by the pharmacist. We will move on to that structure later on. The mere difference of the present application is the card. This structure will be developed to apply for 300 thousand people. It is already the main purpose of the pilot project. We will shape the structure according to the results we get from here.

QUESTION- Is there any study to resolve the grievance of patients, in case the identity authentication server does not work properly?

SAMİ KIRAÇLI- The system will work as it is now. Actually, we as Social Security Institution suffer as much as you. Don't think that we do not take you into account. We behave especially sensitive in the issues that you are sensitive. Studies on updating the current operating patterns of the systems are being carried out. The thing we call identity authentication inquiry is already the present working pattern in our systems. The working pattern here gathers three separate institutions. In the past, you were working for just one of Emekli Sandığı (retirement fund For civil servants), Bağ-Kur (Pension fund for self-employed), or Social Security and Insurances Institution. Now, we inquire the prescription you give from three different institutions. The three different systems are actually still separated. The problems derive from these, so we struggle to resolve these. When these problems are resolved the "how" question in your mind will be resolved automatically.

QUESTION- As I understood, you say that the primary issue in this trial phase includes identity authentication and fingerprint as a result. I would like to ask that how will the authentication process proceed with patients who are not able to come to the pharmacy by themselves, how will it be checked?

SAMİ KIRAÇLI- Yes, it will. It also has a solution. The thing we call identity authentication server will already verify the person's identity when one is there. In cases which the patient is not there the person's relatives will be able to operate with their own cards. The patients who are not able to come will be given a status of being able to operate with another's card.

QUESTION- The person will come with two cards then.

SAMİ KIRAÇLI- No, no the person will come with the same card. But because this will be determined by TUBİTAK after that policy, the person will get the service according to that definiton.

QUESTION- I also would like to ask something, as I understood the equipment in Bolu is ready; but the applications have not started yet. However, as you know for now when the provision system is broken we are capable of entering the data to the system, after giving the medication to the patient accordingly with the prescription. Then, If we assume that the provision system is broken everyday for a few hours do you have any preperation concerning how to see the prescription when the application starts in Bolu?

SAMİ KIRAÇLI- We are thinking of alternatives to that. It is already one of the biggest problems. Since the prescription will be processed in the hospital instead of pharmacy, the person may be given a print-out before coming to the pharmacy. Then we will look at the progress in Bolu. We have in our minds to keep the essence at a certain level. At this moment we just don't have the opportunity to precribe when the system in the pharmacy does not work.

QUESTION- Thank you for your presentation. Those were the pieces of a huge project. We have been listening to you since yesterday, and it's been very useful.

You have the vision of making the system go like clockwork; but I have concerns about the shareholders. Although you say that you act together, I have the impression that each shareholder acts independently. I would like to say a few words from the pharmacist point of view: firstly, you said, in the pilot study in Bolu, e-prescriptions will start reaching to pharmacies. So, is there any special software in pharmacies, how will they receive this e-prescription?

SAMİ KIRAÇLI- It has done.

QUESTION- Is this something included in the pharmacy packaged software?

SAMİ KIRAÇLI- No. Think of the current system in your pharmacy. This software is made to work by electronic card. Now, you are actually able to work with two softwares simultaneously. You could run the old application with people who don't have cards on one window, while running the new application on another window with those who have e-cards. As soon as the card is inserted the alterations of application that lines up your prescription will be done. You won't do it manually, the prescription will cdome to your screen automatically. This structure has been written in the frame of tests in Bolu, and it is ready to use.

QUESTION- As my friend already said, if provision system does not work the burden on the pharmacist will increase. You have also accepted that the burden increases at the beginning and than relaxes. I admit that one should first experience difficulty and than everything goes smoothly. My request would be that the pharmacy softwares are integrated to the system and we should be ready. Since yesterday, we talk about HL-7 standards, I mean all these softwares; pharmacy software, hospital software, should be able to communicate in order to maintain information flow. Therefore, you should at least give the standards of systems which will be used in pharmacies to the producers; so that R&D is done. When the system is realized, as you mentioned very well, I suggest that, field should be prepared for determining how the decision-making-support-system will be; and, procedure of this job should be shortened, and, quality should also be increased.

SAMİ KIRAÇLI- I accept that as a suggestion rather than a question. We have already started conducting a research about it. Present pharmacy system is technologically too old. We are not able to use many of the applications. We are conducting a new research in the institution. It will be anounced soon. Both those and your studies will be based on web services. Our progress will carry us into a whole new technical dimension. Nevertheless all these will be realized step by step, you should not wait a rapid progression. As I said earlier, we check for provision from three different sources for now. If there is a problem in one of the sources, we stop you, and have to terminate the source. We are trying to solve this problem. However, as you would appreciate, it is not a simple problem to be solved. Bringing three diffrent set of data from three different dated institutions and combining them into one means we restrain you from working for two years, we complete the work in 1.5 to 2 years and then open the pharmacies again; this is of course impossible. Therefore, we bear the burden all together.

If the prescription is written in the hospital, the report is given from the hospital and the responsibility to write and save the prescription is given to Ministry of Health, you get rid of many problems. You send the prescription back, but it returns to you. Proper work of the system is conditioned on the settlement of electronic medium -but this will take time.

QUESTION- So I will make the clearer, thank you for your additional explanations but I couldn't get the answer about my actual concerns. Pharmacies need some kind of softwares. There are many firms working on hospital automations, aren't there? And you gave their standards, didn't you? These firms produce accordingly with those standards and they compete with each other. However, these standards have not been defined by pharmacies. I would like to ask whether those are defined or not by any other people?

SAMİ KIRAÇLI- Yes, there are many studies going on, as I said before. For instance, Farmacom, White or any other firm is going to work on medicine trace and track system and they will also carry out the procedures by themselves

instead of Ministry of Health. Therefore, they could also use web services that we prepared. You could either work with the screen we provide or prefer the mediation of the firm to send the data to us via web services.

QUESTION- What is the policy of the institution on this issue?

SAMİ KIRAÇLI- There is not a definite policy. The point we focus on is that everyone produce data and send to us more easily, clearly and properly. Because we will pay with respect to these data. We also have institutional problems. We have to take electronical precautions to resolve these troubles, this is the policy actually.

QUESTION- The important point is that, we as pharmacists are the stakeholders trying to give the best health services, but we have some kind of problems and financial responsiblities when doing this. A pharmacist should keep an account and inform the patients about the process. Except meeting the parameters which you demand, from pharmacist point of view, we should perform our job in an optimal work force using the time efficiently. So, we need some kind of tools in order to give the best service to the patient. In other words, will SSI provide any software to the pharmacists, or pioneer the producers prepare softwares as it is done in the case of hospitals, by foreseeing that there will be a need?

SAMİ KIRAÇLI- That was what I meant. We are now developing an application. Think of a pharmacy as an autonomous machine, not a hospital. There is a server in the hospital, there are 20 computers or 2 thousand machines connected. So there works a hospital information management system that is set by a firm. Therefore, we ought to admit the differences between starting an application in a hospital and in a pharmacy.Pharmacy works autonomously, you may be working with many different machines but you have the opportunity to use those machines separately. So that, in the current structure, you have to use the screens we provide. But it is possible that you develop other applications by yourselves to keep the data in your system. You could also make someone develop these applications for you. However, in the new project this issue will

come into question in a few months time. Therefore, you will produce the data in the background, and send it to us. You could do, or make someone do for you, this production process in whatever way you want and use that data in purpose of decision supporting, stocking or billing.

QUESTION- Dear Kıraçlı, firstly I would like to thank you and the other presenters. I, as an academician, benefited so much. However, I have a question mark from the very beginning. I hope you wouldn't blame me for being too romantic. The first speaker, Ivana, mentioned in the first sentence "The most important thing is the benefit of society, all these electronical processes and e-health are for the benefit of the patient". Why do we do programs on health? Because there are fake medicines, doctors precripting wrongly, and unprogressive system. Indeed, these are realistic and natural facts, what if we are not aware of some important points. Because, in the end, when this spreads to 70-75 million we may have to inform the patients via TV or other mass media. However, we need to give this message to them: "Both you and we, as pharmacists, will suffer but all these are to decrease the frauds or for the benefit of patients rather than financial gain.Of course, here we all know that this is for the benefit of the patient but it needs to be declared. If I exagerrate you might attribute it to my romantism but in school when we are talking about the e-health system we emphasise this point to the students and we tell that the main purpose is to surveil the patient in order to serve better.

SAMİ KIRAÇLI- Of course you are right, but e-health is a broad structure. Perceive this as a system, Like Ministry of Health and the other health institutions SSI is also a subsystem in this. Just lilke all other subsystems SSI also would like to protect itself by its own means. In general, the main purpose is to protect the system. Patient is also a subsystem in this broad system. Electronization of the system will already bring what you mean. We will have access to the background information of the patient and you will be able to operate instantaneously. You will have access to the electronical patient records, but you have to decide the limits. SSI concerns itself with payment. If we were to be interested in the electronical patient records we will have conflict with Ministry of Health. So, we should act accordingly. We, as SSI, have been focusing on

this side of the system. However, at the end, we should share the output. What you mention will be realized, when we share. Thank you.

PRESENTER- We would like to thank Sami Kıraçlı for his contributions to our symposium. Following a short coffee break we will continue our symposium with discussion session. By the way, you may have your participation certificates from registration desk. We appreciate your participation and contributions. See you soon.