PROCEEDINGS FIRST INTERNATIONAL MEETING

EUROPEAN PLATFORM FOR SUPERVISORY ORGANIZATIONS

(EPSO)

12th -14th June 1996, Noordwijk, the Netherlands

Rijswijk, The Netherlands
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I Introduction

In Europe a growing amount of cross-border activities is rapidly developing and this also concerns medical affairs. Traffic of medical professionals, of patients, of blood(products) and of organs may lead to public health- and/or health care-problems.

Another important issue is the development of quality systems in health care. This may have - and in some aspects already has - consequences for cross-border health care as well as for supervision.
The effect of the EC regulations on health care requires international co-operation and communication. General criteria for the operation of bodies performing inspection (CEN/CEN-ELEC 45004) may also have consequences for inspection methods of health care inspectorates in the EC countries.

Because of these developments it is becoming increasingly important for the different health care inspectors or other officials concerned with state supervision on health care, to have adequate communication channels to their colleagues in other European countries. In urgent matters this can prevent delay in advising the government about necessary steps.

Earlier investigations by questionnaires and telephone consultations in EC and EFTA countries have revealed that the organization of state supervision varies widely in the different countries. Nevertheless in many countries key figures made it clear that they are interested in getting to know other key figures concerned with state supervision.

The Dutch Inspectorate for Health Care therefore decided that the time was right to organize a meeting on European supervisory organizations in health care. The meeting was aimed at setting up a network of key figures in state supervision of health care. This initiative is strongly supported by the Minister of Health Care in the Netherlands, as she made clear in her introductory speech at the first day of the meeting. In the beginning of 1996 invitations were sent to the different EC countries. Almost all the selected people responded to the invitation; at the end representatives from Sweden, Denmark, Finland, England, the Netherlands, Belgium, Germany and the province of Bayern, France and Portugal attended the meeting.

The program of the EPSO meeting consisted mainly of presentations on supervision systems in the participating countries and on subjects concerning cross-border health care. After all the presentations, at the end of the second day, the contents of a draft declaration of intent and plans for the continuation of the EPSO meeting were discussed. The question was raised if the participants agreed with the idea of having an international network on *supervision and inspectorate functions, especially from the point of view of state responsibility*. The guests from the different countries were unanimous about the usefulness of this network.
A more complex question that followed was what the contents of such a platform should

II Opening

Dr. E. Borst-Eilers,
Minister of Health, Welfare and Sport,
The Netherlands

Ladies and gentlemen, it is my great pleasure to open this conference and I think it is very appropriate to establish a European network of all those officials who have the task to inspect and monitor the quality of health care in their country. So I think it is an excellent initiative to start to establish such a network today. The reason why I think this is an important meeting is that it is essential that the medical inspecting bodies from all the member states of the European union share their problems and solutions and in that way try to learn from each other. We have, of course, free movement of goods of persons in the union and that involves also free movement of medical problems. And I think it is also essential that in all the member states the task of supervision will be intensified in the years to come because there is still room for that. What I always say is that the health inspectorate are the eyes and the ears of the Minister of Health. In my opinion these eyes and ears should always be wide open. It is bad policy to look away from problems, to hide them, however painful it may be to bring them into the open. We owe it to our patients, to our populations, to be open about all things that do not go well in health care and that we have a duty to try to improve them. I have seen that you are going to discuss several important issues today, issues where better co-operation throughout the union could significantly improve the quality and the safety of health care and I would like to briefly mention a few of these issues.

First there is the quality of blood and bloodproducts, which will also appear on the agenda of the European Ministers of Health in Ireland this year. The main issue here is the forthliving cell containing blood preparations because, as we all know, the plasmaproducts with a long shelve live are dealt with effectively within the European directives. There are a few important principles concerning blood transfusion. First of all non-profit donation; we should try to keep that in Europe that way because it assures safer blood. This has been proved over and over again. Then in view of new health threats as well as from the point of view of human rights, donors and selection criteria need continuous consideration and updating whenever necessary. The Dutch Health Inspectorate will tell you later this day which progress has been made in the field of quality improvement in blood transfusion. An appropriate use, appropriate prescription of bloodproducts should also be improved because at this moment not every physician in our countries is sufficiently aware of the potential risks of blood and blood products; risks especially from the immunological point of view.

A related subject to blood is the issue of human organs and tissues of transplantation. Our ethical aspects here are that there are ways to lessen the scarcity of organs. I think that is a field where we could co-operate more efficiently. There is also the quality aspect. And the same rules as for blood donations should also apply here. It is my strong personal opinion that trade in human organs and tissue should be forbidden.

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Then there is another important topic: that of pharmaceutical drugs and medical devices. Patients are living longer than they ever did in human history and they are taking all sorts of pills to overcome their health problems as they grow older. Or they are wearing artificial devices to support essential life functions. Or they carry a transplanted organ within their body. It is very important we think that essential drugs and devices and transplanted organs can be traced and tracked from the manufacturer or the donor to the patient, for instance because the Aids epidemic amongst hemofylics has learned us that medical practice fails to trace the link between the contaminated badges and the patient. In many countries it was not possible to identify those patients who had received transfusions with the blood from the contaminated badges.
The same problem can be recognized with defected heart valves. At this moment there are still patients with a potential deficient heart valve, the Björk-Shiley type; patients who have not been identified as such. So nobody is able to trace them to tell them about the risk and to replace the deficient device.

Another important task of supervisory organizations and inspectorates is to guide the quality of professional practice. I think that we can say that in all our member states the quality of professionals is generally high. But nevertheless, there are small numbers of professionals, who under different judicial systems lose their licence because of unprofessional conduct. And it is our experience that such ex-professionals will try to keep practising, for example, as a doctor in other countries. Chief Inspector Siemons will give you a presentation on this subject and on the way in which this unprofessional conduct can be prevented.

The last topic I want to mention is another area of cross border problems, namely the supervision and the combating of infectious diseases. Micro-organisms and other disease producers won't be stopped by national frontiers and cross them freely. Already we have seen a number of initiatives for networks and services to bring about a better co-operation throughout Europe and it would be a good thing to extend these activities.

Ladies and gentlemen, I am sure you are going to have an interesting and rewarding conference and I hope it will be the start of a new and successful European network.

III Introduction theme

J. Verhoeff (chairman EPSO meeting)
General Head Inspector for Health Care
Inspectorate for Health Care
The Netherlands

The programme is a mixture of two aims. First of all it is to give each of the representatives the possibility of bringing forward something about the situation in which they are working, responsibilities, the tasks, etc. The other one is to work out some of the issues relevant in relation to the international context of the supervisory organizations. The two aims will be mixed through each part of the programme in the morning, in the afternoon and tomorrow morning. At the end of this meeting we will try to work out a very simple and not too highbrow draft of intention.

One of the main problems of organizing a meeting like this, was to find the people who have an inspectorate function in the different countries. It was quite an awful task. It took one and a half year. One and a half years to find names of people responsible for a supervisory function in European countries in Europe. That made it quite clear that we had to build in this programme a possibility for each country to tell what is the function and how is it put down in the administration, what are the responsibilities and what are the tasks, what are the aims, perhaps what are the problems and possibilities. I hope to find during this meeting some general lines in what is told about the situation in Europe.

IV Presentations by the participating countries

1. the Netherlands (R.M.W. Smeets)
2. Denmark (S. Quist)
3. Germany (M. Friedrich)
4. Finland (J. Karvonen)
5. Sweden (G. Fahlberg)
6. Belgium (A. Doms)
7. United Kingdom (W. Thorne)
8. Portugal (A. Moreira Rodrigues)
9. Germany (E. Kriener)

1. The Netherlands

R.M.W. Smeets
Head Inspector for Health care
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I would like to give you a general presentation of the situation in the Netherlands and of the tasks and mission of the Inspectorate.

The Netherlands is a country of 15.2 million inhabitants with a surface of 40 thousand square kilometres and about 10 thousand square kilometres of water. So you have an idea of how many people are living together on such a small surface and what kind of health problems that will give. The population is constituted as follows. Between 0 en 19, the young people, about 25%. 20-39 years about 33%, and 40-65 years 30% and above 65 years of age 13%. As you can imagine the shift towards the older and the younger is still going on. However, the number of younger people not originally from Holland is relatively growing fast. We have a working population of 6.610.000.

How are the health care facilities proportionally divided over the different beds? We have general hospital beds - 4.1 per thousand inhabitants. The amount of psychiatric beds, these are beds in general psychiatric hospital, is 1.6 per thousand inhabitants. For the mentally handicapped we have a proportion of 2.1 beds per thousand inhabitants. For the elderly we have 3.5 beds per thousand inhabitants.

How is the financial insurance system in the Netherlands organized?
We have a mix of private and public insurance systems. About 60% of the population (this is the group of people with an income below 56.000 a year) uses a compulsory insurance system. About 40% of the population uses a private insurance. Then there is the AWBZ; this a law where every person is paying taxes, that is an insurance system in which all non-insurable risks are covered. Everyone pays for this insurance system.

How is the health inspectorate organized in the system of health of government in the Netherlands?
The Minister of Health is the head of two different organizations. One is the directorate-general. This is the organization that makes policies, prepares laws and falls directly under the Minister. The other is the state inspectorate that has as task the supervision health care and that falls under the Minister too. So you see there is a distinct separation between the policy making part of the Ministry of Health and the supervisory part of the Ministry of Health.

There are two different sections of state supervision. One is the inspectorate of health care and the inspectorate of health protection. The inspectorate of health care supervises all health care facilities and all problems in health care and the inspectorate of health protection focuses on the risks of products for health.

How is the inspectorate for health care organized?
The organization is divided in eight locations. There are about 320 staff members. The headquarter is in Rijswijk, near the Minister. The seven regional locations are located in the different parts of Holland. The actual supervision of health care is done in the regions and the headquarter has the task to see that all these ways of supervision are on one line and that all the findings of supervision will be aggregated centrally and be put in an advise that is directed towards the Minister.

What is the basic task of the Inspectorate of Health? What is the mission state?
The mission is that we as Inspectorate of Health Care have to superintend on public health, on health care and health care systems, on a collective and an individual level, all on the basis of different laws. That means that we have to advise and report, to stimulate and protect the public health and the health of the individual. So you see it is a mission state that is rather broad.

Of course we have a task in maintaining the laws on the fields of health care and we as inspectorate of health care are responsible for maintaining sixty health laws and on the basis of these laws are entitled to take the necessary measures to see that these laws are enforced.

On the basis of this mission the core business of the Inspectorate for Health Care is supervision.
First of all, of course, we supervise the quality of the delivered care.
Secondly we supervise development of quality in health care organizations. That means that the supervision of the quality of delivered care actually inspects the delivered care, the quality of it. And on the basis of our findings we advise the Minister or propose sanctions to the care delivers so that their quality of care will be higher. And on the development of the quality in health care organization we stimulate to develop that quality and see to it that the new developments in that field are of high quality.
The third part of our supervision is the detection of groups of people that are not detected by our health care organizations. In my field that will be the homeless schizophrenic patients that wonder if the health care organizations in that field have treatment programmes directed to them. So that is one of our core businesses, seeing that health care reaches all the persons who need that care.
The fourth supervision activity is on the health state of the populations. So we have a task to see that health care organizations have their part in seeing that health state of population is becoming better.

2. Denmark

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I have been asked to inform on the position, organization and tasks of the supervising bodies of health care in Denmark. The administrative organization is described in 'Health Care in Denmark', issued by the Ministry of Health, which you presumably have received prior to this meeting. I will, however make a few further comments.

Data collection of health and health care systems is performed both by the National Board of Health, by the department and by DICE, The National Institute for Clinical Epidemiology.

The Patients' Complains Board was established in 1988 and deals with specific types of professional misconduct in patient care and treatment. I am not using the word malpractice because it to me associates with the British and American liability systems. Until 1994 the Patients' Complaints Board made its decisions on the basis of a statement from the National Board of Health.

Since 1994 the patients' Complaints board has its own medical and law officers and advisors from different medical specialities. Therefore, a statement from the National Board of Health is no longer needed but can still be requested in special cases. The local state medical officers are conducting the investigation on behalf of the Patients' complaints Board and make a statement in approximately half of the cases.

In 1992 a no-fault insurance regarding hospital treatments was established with completely independent bodies of decision. This year even medicinal products were included.

The National Board of Health
My following presentation of the main supervisory body in health care, the National Board of Health (NBH) may be obsolete next week. The former director general resigned in December 1995 and the Ministry of Health conducted a survey on the functions of The Board. The new director general Mr. Einar Krag and the Minister of Health are these days deciding the future organization. One of the probable results might be that the Medicines Division is made an independent body.

At present, the NBH employs approximately 150 people in division 1-6, 20 in the National Institute of Radiation Hygiene and 170 in the Medicines Division. In addition, the NBH has 30 advisors from different medical specialities working in health care but advising the Board on a regular basis. The regional state medical officers (52 in 15 regional offices including office workers etc. a total of 90) are employed by the Ministry of Health but

belong professionally to the NBH.

The NBH in its present form was established in 1909. Of course there has been many structural changes since then and the organization has been growing, but its main obligations are unchanged as stated in the Act of Central Direction of the National Health Service, and they are the following: advising the minister of health (and other authorities), keeping up with public health, being updated on medical professional knowledge and reporting on deficiencies in health and health care and offences of health legislation. In short, advising, monitoring and supervising the health care service and public health medicine.

The 1st division deals with health promotion and prevention, especially lifestyle related diseases and risk-factors including cardiovascular diseases, cancer, alcohol and other drug abuse, accidents as well as with muscular-skeletal diseases and asthma/allergy.

The 2nd division plays a role in health education, controls authorizations and supervises dental care. The division has recently established a corps of inspectors of postgraduate medical (i.e. specialist) education. The members of the corps are appointed by the different medical scientific societies.

The 3rd division has primarily an advisory role towards counties (and municipalities) providing health care, due to the rather independent status of these bodies (the Ministry of Health negotiates with the counties on expenditure demanding changes). The NBH is e.g. advising on the health plans, the counties must now make and has issued guidelines on continuous quality development, technology assessment and on highly specialized functions in secondary health care. In addition, the division has issued reports on diabetes, breast cancer and heart surgery just to mention a few.

The 5th Division is advising on general hygiene and public health medicine and supervises the Regional State Medical Officers.

The medical statistics (6th) division collects data on secondary health care, on death causes, births, abortions etc.
Apart from pharmaceutical products the Medicines Division supervises the blood banks and medical devices/appliances.

The 4th Division is supervising epidemic diseases, biotechnology, individual health professional performance and other legal matters concerning health care, namely patients rights, transplantation and autopsies, compulsory treatment in psychiatry, driving licenses in connection with health problems, quackery and alternative medicine.

The actual data collection on **epidemic diseases** is done by the National Serum Institute on behalf of the NBH and is based on (compulsory) individual patient's reports from doctors and reports from microbiological laboratories. The division has standing committees concerning vaccination/immunisation and blood products.
The main issues in **patient's rights** are information and informed consent, self access to

patient's files, secrecy/professional confidentiality and life will. The NBH has issued a Circular entitled "Physicians' Duties and Patients' Rights" and the main principles are now incorporated in legislation.

The supervision on individual health professionals is divided in three main areas; professional performance/misconduct, drug abuse and illness, and prescription of euphoriant substances.
The regional state medical officers are initiating investigations on behalf of the NBH in these matters. Reporting from health care is only obligatory if medical mishaps or maltreatment have a lethal outcome. The evaluation is based on statements from health professionals who are directly involved or otherwise may enlighten the case. Direct inspection is not done on a regular basis. In serious cases the police is asked to make the investigation.

If the regional medical officer finds that a health professional has misconducted himself according to the Practice of Medicine Act the case is sent to evaluation and further decision in the NBH (if there is a formal complaint from a patient the case is sent directly to the Patients' Complaints Board).

Professional Performance
The individual physician (and likewise nurse etc.) is 'bound to show care and conscientiousness' according to the Practise of Medicine Act § 6 and is liable to punishment if 'guilty of gross or repeated negligence or carelessness" (§ 18). I am not going to give examples of the many different ways violence of the Practise of Medicine Act can take place. I will however mention that service and behaviour is not an object of investigation for NBH (nor for the Patients' Complaints Board) as it is in Sweden. These matters are for the employer to deal with.

The NBH can express a milder disapproval of the involved professional, usually through the regional state medical officer. When NBH finds reason for criticism according to the Practise of Medicine Act the case is sent to the Patients' Complaints Board who makes the final decision or eventually sends the case to the public prosecutor.

The Complaints Board thus investigates and decides in cases risen from a patient's complaint and decides in other cases forwarded by the NBH. The Patients' Complaints Board can express its opinion only in individual cases and thus gives disciplinary sanctions. The NBH is the body setting guidelines and general standards for proper 'care and conscientiousness' according to the Practise of Medicine Act. The decision from the Patients' Complaints Board are used by the NBH for insight in the functions of health care.

The last couple of years there has been a growing awareness that an investigation concentrated on individual performance seldom contributes to improvement of the health care system. The individual who is criticised is often made a scapegoat and the organization behind loses interest in improving matters.
Therefore the NBH has begun the development and implementation of methods to investigate serious and complex incidents in health care. The regional state medical

officers are educated in using the so-called MTO-analysis (Man, Technology and Organization) which originally was developed to investigate accidents and near-accidents in space and nuclear industry. The NBH has had valuable help in this from a medical officer from our Swedish counterpart.

At the present we are making plans for development of an integrated, 'system-aimed' supervision. Integrated because we want to look at the mixture of personal, organizational and technical conditions that sometimes predetermine mishaps. Aimed at the system because we would like to expose the conditions that can be improved in order to prevent future mishaps instead of disciplining a health professional who just happened to be in the wrong place at the wrong time.

Drug abuse and illness, most often psychiatric diseases, is the second area of individual supervision and the dominant not to say the only cause of restriction or withdrawal of authorizations. Usually this is done voluntarily as a renouncement although it can be forced to court.

The restrictions grade from ordered information of place of occupation, urine controls, abuse and/or psychiatric treatment and restriction in prescription rights.

An authorization can be withdrawn on the basis of serious professional inability but this possibility is seldom or never used. In a few cases the court has withdrawn full authorization because of fraud on the public health insurance.

Prescription of euphoriant substances (i.e. narcotic drugs and flunitrazepam) is monitored by the district state medical officer using computerized data from pharmacies. It is solely directed towards the doctors prescription, not the patients' medication.
The last two areas are primarily for the NBH to decide and are not brought to the Patients' Complaints Board.

3. Germany

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First of all I will tell you something about the structure of the public health service as shown by the environmental protection (appendix II, sheets). On the top level, then under the national level or federal level. They are the federal authorities and one of these authorities is the Minister of the Health. Then the Bundesgesundheitsamt, the federal bureau of public health. This has been destroyed a short time ago because of the blood scandal in Germany. There are some following institutes, one of them is the Rubert Koch Instituut, RKI. This is for infectious diseases and non-communicable diseases. Another Institute is that of Water-, Ground- and Airhygiene.
We have 'Länder' laws and federal laws (for instance the federal law on epidemics and the pollution control act is a federal law).
On the Länder level we have again ministries and health departments. There is a board for the leading medical officers. There are two academies, one in the north in Dusseldorf and one in the south in Munchen for educating health officers and health inspectors and related professions. The law on public health is a Länder law. So we have very different public health laws in the different Länder. For instance in the lower Saxon Lande we have a law from 1934. Almost all the other Länder have new laws in the last 10 or 15 years. So we have a very federal structure and in every Land it has the construction as in sheet 1, appendix II.

This is the vertical inspection, the pathway, the middle authorities, the regional government with their hygiene laboratories (they belong usually to the state). On each local level there is a health department and they have to co-operate; every county has a health department of its own. They are co-operating with the social affairs department, the environmental department and the veterinary department.

Now I will show you roughly the function of a health department. A health department is headed by the Amtsarzt (that is a medical officer, for example a district physician, which is my function). For instance I am in a town of 150,000 inhabitants. I am the Amtsarzt and in my department I have 60 persons that are working with me. Eight of them are doctors, some psychologists, nurses and social workers and even the health inspectors and health engineers.
This is not my health department but a scheme (appendix II, sheet 2) that was a recommendation by the federal government to all counties. They should take it as a pattern.
In section 1, the central leading and the government administration and this is supervision in the health system. Here control of the papers of the doctors etc. takes place, but not to the extend as you are doing it, because the doctors are supervised by the German Medical Association. It has a chamber status.
The second one is hygiene, ecology and environmental hygiene. This is the sector where

the health inspectors are working, that is environmental hygiene. Then supervising the traffic and trade with food, cosmetics and toxics. This is even partly done by the veterinary departments and environmental hygiene. The third is social hygiene, prevention and health aid. This includes social psychiatric service for the mentally ill. The service for children and teenagers is the school service, including the kindergartens. This is an advisory board for handicapped. In my department we only do it for the handicapped but even for people who are suffering from cancer, for women who are pregnant.

The next section is a dental service. The dental service is different in every Land because the financing is very different. In our lande we have a combination between private and public financing. In general we are financed by the public but the dental service is partly financed by the insurance companies because they have an interest.
The last one is clinical diagnostic expertising and the central lab.

On the next transparent you can see at the top the organization which I am representing: the federal association of the physicians in the public health service. We have about 1,500 members in all Germany and we are public physicians from the local level up to the national level working in health departments, ministries and regional governments.
We made a paper some years ago to make clear our main tasks for the politicians and interested people and to show the perspectives until the year 2000. What is really important is that we made a change from the health police to health service. It is a change in attitude and what we think would be our best situation to do our tasks.

Up to the top there is health planning, health promotion according to the Ottawa charta and the next one is social medicine, especially for the pregnant, young families, in conflict situation and the elderly.

This is about environmental health protection, or environmental medicine and environmental hygiene. You will see it is free expressions, because this is a very crucial point because there is always a field of tension with the environmental departments and it is always a fight who is doing this and we have in our community the regulation that we are doing the environmental protection related to human beings and environmental department is doing environmental protection related to technical affairs.

The next one is hygiene and control of epidemics. This consists of the classic infectious diseases like salmonella, tuberculoses. I think you have the same problem in your countries. It was a diminishing problem but now it is growing again, especially with the migrants we have a lot of problems. For instance we have a asylum seeker with a tuberculoses that is resistant to all antibiotics and we cannot treat him. One of the main tasks was the aids problem and we are very proud that we could manage the aids problem without any repression only by anonymous testing by explaining, educating and counselling. And so in Germany the last three years the number of new infections is declining. We are very proud that we could accomplish this without repressive acts.

Social psychiatry is a very big task of the public health because as you in the Netherlands and other European countries as well, we try to make the mentally ill to stay in their

accustomed surroundings and not to go to hospital. They should go to a hospital only if it is necessary but we try to give them support and their relations the support to live outside an institution in the old neighbourhood.

Next service is the service for children and teenagers (starting from the baby up to the teenagers) and we regard ourselves as occupational health service for kindergartens and schools.

The next sheet shows the dental service. I told you already we get it financed partly by the insurance parties.
The last function is the main task is expressing the medical officer as in insurance medicine, social medicine, social psychiatric traffic and occupational medicine.

4. Finland

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The National Board of Medicolegal Affairs does the same duties as the former Finnish National Board of Health. Our National Board of Health was quite similar as the Danish National Board of Health and very similar to the Swedish one. The Finnish National Board of Health was disbanded in 1991. Thereafter the National Agency for Social Affairs and Health was established, but it lasted just one year. Since 1992 health care supervising, excluding pharmaceutical affairs, has been done by the National Board of Medicolegal Affairs.

The National Board of Medicolegal Affairs does licensing, registration and supervising, matters belonging to forensic psychiatry and abortions, sterilisations, castrations, etc. We give statements to courts and also other authorities. The National Board of Medicolegal Affairs supervises individual health care professionals. It is not our duty to supervise hospitals and some institutions, these are supervised by the provincial boards. Our aim is also to improve the quality of Finnish health care professionals, advise foreign health care professionals moving to Finland and be in connection with health care authorities of other countries.

The Finnish population is 5,1 million. In Finland there are over 14.000 practising medical doctors. Our doctor density is one doctor per 350 people. The density of dental practitioners is about 1/1000. The number of health care professional groups is at this moment 34. Four years ago, followed by a big discussion, an act on health care professionals was renewed. The recommendation of our health care authorities was that it is better to have few supervised health care professionals groups, but people representing not supervised health care professional groups began to lobby in the Parliament and suddenly instead of 8 or 9 groups we had 34 groups and 6.000 new applications in front of us.

In 1993 and 1994, the number of patient complains to National Board of Medicolegal Affairs has been almost similar. National Board of Medicolegal Affairs can transfer complaints to provincial boards. Just the more important/serious cases are investigated by the National Board of Medicolegal Affairs. For example if somebody complains that a doctor has been unpolite, we transfer it to a provincial board.

The majority of consequences of complaints are so-called administrative consequences as admonition or serious admonition. The number of these consequences has been equal in these two years; the same concerns the few restrictions and removal of rights. We have also written warning and it is used, if a health care person has distinctly worked against the law. If somebody looses his or her rights, to get them back is rather difficult. Just one or two doctors or dentists have got back their rights in each year.

In Finland doctors coming outside of the European Union have three kinds of licences. In the beginning they have a licence to work in a hospital under supervision of a competent colleague and thereafter their licenses can be enlarged and finally they receive a full license to serve as a doctor. Written and practical tests can also be used before authorization of health care professionals coming outside of the EU.

Before Finland joined the European Union we had a discussion about that "our good Finnish doctors" will move away and doctors from foreign countries replacing them. Later on was really to be seen, that Finnish doctors were leaving Finland all the time, but very few were coming to Finland to replace them. In 1994 the number of doctors from European Union Member States working in Finland, excluding the Scandinavian countries, was just 22 and in 1995 it was just 20.

Concerning immigration of health care professionals it is quite typical that doctors are migrating between neighbour countries. For example in Sweden and Finland a reason for moving is that in Finland we have a quite large Swedish minority and correspondingly in Sweden there is a quite large Finnish minority. But if we go further, to Denmark, in 1995 there have been very few, just two Danish doctors in Finland and eight Finnish doctors in Denmark. In Norway there have been 13 Finnish doctors and in Iceland none. Very many Icelandic doctors are going away but probably not to Scandinavian countries. From East Europe there have been 137 doctors in Finland but just two Finnish doctors working in the former socialistic East European countries.

How many doctors have migrated between the EU Member States, for example, to Germany, the UK, Belgium, Denmark and Greece? A lot of medical people, nurses and doctors, and other health care professional groups are continuously migrating between the European Union Member States. For example about 10,000 doctors have moved during doctors directive from the other EU Member States to the UK. The education of a doctor costs at this moment in Finland 800.000 Finnish marks, that is 250.000 German marks and roughly 100.000 pounds. This immigration concerns also migration of billions of pounds, marks or crowns and a very great human capital.

5. Sweden

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First let me explain that I am not a doctor. I am a legal officer and I will show how the National Board of Health and Welfare is organized and explain where I am placed in this scheme. As you can see we have a big surveillance with a supervision body in the National Board of Health and Welfare. We also have a health and medical care body and the social services body. There is no supervision or pharmacy in this National Board of Health and Welfare. We have a special authority dealing with the control of pharmacists and the like. This health and medical care body has special methods to work with and the social services body has its own social field to deal with. But I am going to talk about the surveillance system and my place here is as chief of the staff. I am one of the deputy director generals.

The National Board of Health and Welfare is an authority directly under the social department. We have an independent status so to speak and we deal according to the different laws; the ministry cannot and tell us how to do things.
The surveillance system functions on basically four different laws or acts. (One of these acts is not into function until the first of January 1997.) The four acts are:

. Health and medical services act
  that is an act that tells the county councils and the local communities what the responsibilities are.
. Obligations for Medical personnel Act
  this act states what the responsibilities for the medical personnel are.
. Disciplinary punishment Act
  this act tells us how to deal with disciplinary problems with the medical officers, doctors, physicians, nurses. We have at the moment different kinds of medical personnel who have special authorization. Doctors, nurses and dentists are of course the most important ones.
. Surveillance Act
  this act has been taken by the parliament just a few days ago and is going to be in action in 1997; it will give us better power over the local communities and over the county councils; I will explain this act later on.

The main functions of the board are:

. Supervision of:
  . health, medical and dental care
  . social services and care
  . public health and hygiene

I will deal mostly with the supervision of health, medical and dental care here.
In the other two departments of the National Board the supervision body has the following functions:

. Active follow-up by country
. National follow-up and evaluation
. Official statistics and annual reports on health and diseases, health and medical services, and social services and care.

The overlapping goals for all health and medical care are as they are put out in the acts that I presented to you earlier here.
. A good health for the population.
. Health and medical care services to all inhabitants on the same conditions.

Even if we have 24 different county councils and about 280 local communities in Sweden, we have this law that says that all inhabitants in Sweden are entitled to have the same good health care, and one of the goals for the National Board is to see to that the population gets the same medical care so that it cannot differ too much in the different county councils.

The subgoals here are:
. security and quality;
. accessibility and availability;
. continuity.
When we have the possibility we give out orders to the county councils and especially to the doctors and nurses about how to go on with their tasks so that everybody can get the same care on the same level.

These are the main tasks of the surveillance:
. quality and safety;
. co-operation;
. structure of health care;
. leadership;
. legality.

We have different tasks and different things to deal with in my department and in these six regional departments of supervision and we deal with all these types of problems. We have these six regional offices which in their region are entitled to deal with all the problems of dental and medical care and with professionals not acting legally or with good medical care. They have to take actions.

My position as staff officer is to try to co-ordinate all the information and different things that the regional officers have to deal with.
How do we get information? We have a special obligation to report if something happens at hospitals or in a local office for medical care. We have to report to the National Board if there is a risk for the patient to get hurt. We get something round about 1500 such reports every year to deal with. About 20% of these reports we bring as a disciplinary case to a special board.
We also have a database of adverse events. This database is accessible for everyone so people are able to see what the risks are for different things if something happens.

We also have an active surveillance. We have national registers.
Of course we have a lot of individual complaints. Patients write us to ask if it's possible to take action against doctors, nurses or dentists who acted wrongly.
There also is object surveillance. We go out and look at special things; sometimes without telling in advance that we are coming.

We try to do unannounced inspections once or twice a year. We bring all our staff members out in the field to look at special things. So far we have done five of these unannounced inspections and we are planning for one more this autumn, but of course I cannot tell you what it is.
After these unannounced inspections are done we also give out reports. If someone is keen to get a report of these unannounced inspections, please write to me and I will try to send it to you (the language of the reports is Swedish).
The purpose of the earlier mentioned risk data base is that it can be used by all doctors and all nurses and so on to look and see what kind of risks there are in a special field.

What legal actions we can take against personnel? We in the National Board of Health and Welfare cannot make any disciplinary punishment ourselves. There is a special disciplinary board that we have to go to. In this disciplinary board the national Board of Health and Welfare can bring up a case; patients or close related persons can do the same. It is more like a court and if you do not like the decision of the court you can up to another court as well as to the supreme court. The disciplinary punishments are admonition and warning, of which the warning is the strongest punishment. The National Board can deal with other measures, but there it is only the National Board of Health and Welfare who has the right to go to this disciplinary board. If you want to withdraw the authorization or limitation to prescribe drugs for a doctor or dentist, the patient or colleague or the employer cannot go to this disciplinary board. Only the National Board of Health and Welfare can enforce a withdrawal of authorization. We can withdraw authorization of two cases: when there is a manifest unsuitability to deal with patients or when the health care professional has a mental illness or drug addiction. And of course there is the possibility to limitate the right to describe drugs if the professional is misusing prescriptions.

As from January 1st 1997 we can take legal actions against county councils, local communities and private contractors. If we find out that in a local community or a county council medical care is not good enough, we can go out to the local community or the county council or the private contractor and tell them that the care is not sufficient; after that we can give them order to and tell them how to improve the conditions. If we find out that the care is not good enough and the professional in question doesn't improve the situation, we can take the decision to close down this special activity that is not good enough. Of course it will create alarm if we for instance go out to a county council and say: "You should not deal with heart transplantations because heart transplantations in your county council aren't good enough. You have too many deaths here so you have to stop it." Because of this next year these actions will not be taken without careful consideration.

6. Belgium

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In order to describe the organization of Belgian health care in clear outline it is absolutely necessary to survey the powers the different authorities possess in the light of the state reform.
Belgium: ± 10 million inhabitants (1 mln Brussels, 3,2 mln Wallonia, 5,8 mln Flanders)

A. The Belgian state structure

The originally unitarian Belgian state has gradually developed into a federal state ever since 1970.
At present the Belgian state is structured as follows:
1. apart from the federal authority
2. there are three Communities, being the Flemish Community, the French Community of Belgium and the German-speaking Community.

The Communities are competent for education, culture and the so-called personal matters such as social welfare, care of the elderly and health care (which we will be focusing on later on).

3. there are three Regions, namely the Flemish Region, the Walloon Region and the Brussels Capital Region.

The Regions are competent for territorial matters such as town and country planning, environment, housing, public works, transport, economics (to a certain extent).

I am not going to dwell upon the situation of Brussels, which is a Region but not a Community, for this is food for specialists and does not contain indispensable information for the theme of this speech.

The respective bodies of the Communities and regions are autonomous within their scope: they are authorities which are not subordinate to the State and they can for instance autonomously change former federal laws pertaining to matters within their scope.
Flanders merged the respective Community and regional bodies into one Government and one Parliament of Flanders.
This has not been the case in Wallonia: there are two governments and two parliaments (Community and Region).

I myself work at the Ministry of the Flemish Community, at the Health Care Administration to be precise.

I will try to present a general survey for the whole of Belgium. My exposition, however, will be influenced to a certain extent by the situation I work in. Thus I will not focus on the organisation within the French Community of Belgium so as not to complicate my exposition.

If desired I can give more information to the persons interested.

B. Health care

1. Sickness and Invalidity Insurance
This task of the social security system is organized on the federal level. The central body managing the sickness and invalidity insurance is RIZIV (National Sickness and Invalidity Insurance Institute) which is led by the social partners (employer - employee) with important participation of sickness insurance organization and professional organizations.

One of the two Sickness and Invalidity Insurance branches is the health care scheme, under which every patient obtains from their sickness funds reimbursement of medical and paramedical services rendered by the various health care providers. In some cases, the latter can also be paid via the third-party payer system, in which the health care provider is directly paid by the sickness funds.

RIZIV houses lots of control bodies which are, incidentally, steadily increasing in number. They supervise budgetary spending, observance of administrative rules, the number of health care provisions rendered by the individual health care providers. Recently, a system is started up, which gives a higher price to doctors who prove to have followed some supplementary education, conferences, local peer groups.
It goes without saying that all this has a great impact on the competencies of the federal Minister of Public Health and the Flemish Minister of Public Health.

2. The federal authority
Is competent for the matters explicitly mentioned as exceptions that are not within the scope of the Communities.
These "exceptions" are very extensive, though:
- the organic legislation relating to the provision of health care services
- the financing of the exploitation (the charges per patient day in hospitals are fixed by the federal Minister of Public Health)
- basic programmation rules, financing of infrastructure
- accreditation norms which have repercussions on the financing.

Also the way of practising medicine and paramedical professions, the practitioner-patient relation, the organ transplantation Act, the policy with regard to the pharmaceutical industry are national competencies.

3. Community
Although the Communities are principally competent for the whole of the health care

system, the many exceptions leave them the following areas:

- health promotion and prevention of illnesses (including school medicine centres)
- concrete application and implementation of national regulations in the field of programmation and accreditation in hospitals, nursing homes, psychiatric nursing homes and "sheltered living" projects
- granting of subsidies for the infrastructure of facilities
- outpatient mental health centres

C. Inspection services

1. In general
Neither on the federal nor on the Community level is an organizational division made between policy-making (which is done by the administration assisting the minister so as to implement the lines of policy) on the one hand and
supervision of the observance of the decreed regulations and the policy assessment (of the effects the policy had) on the other hand.

Each administration combines policy-preparing as well as policy-implementing and policy-assessing tasks.
Compared to the Netherlands for instance, there are less funds available to carry out comprehensive scientific research and policy preparation in general. Policies are made in a pragmatic way, by making compromises on the field and with the parties concerned. The very same administrations advising the minister on the policy to be adapted, also participate at the concrete elaboration of the regulations, their implementation, the supervision of the health care systems and the health care services rendered as well as the assessment of the policy implemented.

The introductory note I made, may have led you to suspect that the partition between the various instances that actively participate at making health care policy are inspired by and based upon the division of competencies resulting from the state reform.

2. As I mentioned before I will not focus on the diverse RIZIV inspection and control bodies.

3. Supervisory bodies at the federal ministry of public health (which is now the merged Ministry of Social Affairs).

Federal Health Inspection
Its tasks have been considerably reduced by the state reform.
Is still charged with drawing up regulations relating to international vaccinations
- organizing aid in the event of catastrophes

supporting provincial medical commissions active under the Act on the practising of medicine and the tasks of which include the organization of guard duties for practitioners .

Veterinarian inspection
This is a semi-governmental body, namely the Veterinarian Inspection Institute, which has been repeatedly in the news for some months now, in Britain as well as in Belgium. It employs about 130 civil servants-inspectors and more or less 700 veterinarians-inspectors who carry out inspections on contract-base.

Food inspection
This body employs 20 inspectors (industry) and 24 controllers (commercial companies) for the whole of the country. They inspect the food quality and the alien substances in the food.

Pharmaceutical inspection
Inspection and controller of the implementation of the legislation concerning the trade of toxic substances, narcotics, drugs, (registration of drugs, import, trade) the distribution and functioning of pharmacies.

Hospitals
On federal level, there is also an inspection on the patient-day price. This is an purely financial control, based on the file send to Brussels.

4. Supervisory bodies in the Flemish Community belonging to the Health Care Administration
This administration is part of the Welfare, Public Health and Culture Department, one of the seven departments constituting the Ministry of the Flemish Community.

Prevention and Health Promotion
a) Health inspection: there is a field office in each province.
This service has various supervisory and advisory tasks in connection with the implementation of environmental legislation. Environment is, as 1 mentioned before, a regional competence: the Environment Administration belongs to another Department of the same Ministry.
Examples: the quality of the drinking water, the housing quality, cemeteries, camping sites and all kinds of health problems on the local level.

These health inspectors also have advisory and supervisory tasks as to the granting of permits to dangerous industries and as to the measures to be taken against the spreading of contagious diseases.

b) This division also has an inspection team charged with the accreditation and subsidizing of medical examinations in schools, teams for home care and palliative care networks.

c) Apart from that this division also carries out various tasks in connection with health promotion, primary and secondary prevention (vaccination policy, sound sports from a medical point of view).

Nursing institutions
An inspection team consisting of about 13 physicians and paramedics is charged with the supervision of the accredited institutions such as

- hospitals (general, university and psychiatric):
- general hospitals are 58% private and 42% public
- psychiatric hospitals are 75% private and 25% public
  (all are financed by public means)
- nursing homes
- psychiatric nursing homes
- "sheltered living" communities
- Outpatient Centres for Mental Health Care

The same administration advise the Minister in the field of:

- planning and programmation of institutions
- the granting of building subsidies (financed to 60% from the respective Community budgets and to 40% via write-downs in the federal patient-day price)
- the supervision of the law on the protection of the mentally ill (compulsory admission)

The Flemish Community is presently preparing a legislation on **quality Management** in health care institutions.
It aims at modernizing the accreditation policy and introducing the "Total quality Management" philosophy in health care institutions by way of the quality systems developed by the institutions themselves. This decree will considerably innovate the task of the inspection services, for they will be supervising the institution's quality system and/or the quality of the health services rendered rather than only inspecting detailed norms relating to architecture, functioning and organisation.
At the same time more efforts will be done in the public administration so as to follow up the health status of the population by all kinds of registrations and submit scientifically motivated policy advice to the Minister.

Each year we examine and publish the results of all kinds of registrations as a base for motivated policy advice to the minister:

- health indicators, based upon the birth and death declarations at the communes
- registration in school medicine centres and outpatient mental health centres.

Other registrations will be set up, as

- registration about abuse of illegal drugs
- registration about the pathology and activities in hospitals.

Conclusion
Since in Belgium the competencies in the field of health care are divided over various authorities and this division of competencies has not been stabilized yet, but is still being discussed, it is not simple to go into a full consideration of the nature, size and methods of state supervision within the scope of this survey.
I do hope, however, that this overview has led you to a better understanding of the situation in Belgium.

7. England

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The UK does not have a central organization such as those described by my colleagues which acts as an all encompassing supervisory body. That does not mean that we have no mechanism for regulating quality of health care products and services - we certainly do - but these functions are carried out by a variety of organizations, by professional organization, by agencies and within the health service itself. I shall illustrate this by using the three examples which were suggested on our invitation to this Conference:

- blood and blood products
- free movement of health professionals
- infectious diseases

Control of blood and blood products in the UK

The UK has a comprehensive system of controlling medicinal products by means of licensing, both of products and manufacturers. The responsibility for controlling medicinal products in the UK lies with the Medicines Control Agency (MCA), an Executive Agency of the Department of Health.

In England and Wales there are 15 Blood Transfusion Centres responsible for collecting plasma, testing it and sending it to the Bio-Products Laboratory (BLP) for fractionation. (There is also the Army Blood Supply Depot, which operates in a similar manner to the other transfusion centres). In Scotland there are 5 Transfusion Centres supplying plasma to the Protein Fractionation Centre (PFC) in Edinburgh. There is 1 centre in Northern Ireland which also supplies plasma to the PFC.

BPL and PFC are required to hold Manufacturer's Licenses and medicinal products produced (from fractionating human plasma) are required to have Product Licences. In order to be granted and retain such Licences, the facilities have to operate at an acceptable standard of Good Manufacturing Practice verified by inspections which are carried out by Medicines Inspectors from the Inspection and Enforcement Division of the MCA.

The MCA is funded by charging fees for inspections and for processing Licence applications.

Standards are set by application of Volume IV of "The Rules governing Medicinal Products in the European Community", which is the Guide to good manufacturing practice for medicinal products. Annex 14 of the Guide deals specifically with the manufacture of products from human blood and human plasma.

Sanctions for non-compliance include suspension or revocation of licences or removal of a site from a licence.

Free movement of health professionals
Regulation of health professionals is effected by a number of statutory and professional bodies. If I describe one or two of the mechanisms which exist, it will give you an idea of the diversity of our arrangements. Let me first give you a brief description of the General Medical Council.

The General Medical Council
The General Medicine Council (GMC) is an independent statutory body whose constitution and functions are regulated by the Medical Act 1983. It exists to protect the public interest by regulating the medical profession. It performs this function by:

- overseeing medical education
- keeping and publishing the register of qualified medical practitioners (registration is mandatory for practise in the UK)
- issuing guidance to the medical profession on standards of professional conduct and on medical ethics; and
- taking appropriate action when a question arises concerning an individual doctor's fitness to practise.

The Council's jurisdiction covers the United Kingdom.
The Council currently comprises IGZ members. Fifty-four are elected directly by the medical profession; thirty-five are appointed by universities with a medical school and by the Royal Colleges and Faculties and the Society of Apothecaries; and thirteen (known as lay members) are nominated by the Crown, none of whom are medically qualified. The lay membership of the GMC will shortly increase to 25. This will be achieved by a corresponding reduction in the number of appointed members.

Much of the Council's work is carried out through Committees which exist to consider policy questions and determine cases in pursuit of the Council's functions. Four of the Council's Committees - the Education, Preliminary Proceedings, Professional Conduct and Health Committees - are required under the terms of the Medical Act 1983. The others - e.g. the Overseas Committee and Registration Committee - are set up under the Council's Standing Orders.

The GMC receives no grants from public funds and derives most of its income from fees paid by doctors on being granted registration or for the retention of their names in the Register.

Under the Medical Act 1978 the Council was given a general power to provide "in such a manner as the Council thinks fit" advice for members of the medical profession on standards of professional conduct or on medical ethics. In response to this duty the Council set up a Committee, now known as the Standards Committee, whose remit is to

keep under review the Council's general guidance to the profession on a wide range of subjects.

Three Committees are involved in the exercise of the Council's responsibilities in relation to professional conduct and fitness to practise. They are:

1. Preliminary Proceedings Committee
2. The Professional Conduct Committee
3. The Health Committee

The Council has the power to direct the Registrar to erase, suspend, or attach conditions to the registration of any doctor convicted in the British Isles of a criminal offence or judged to have been guilty of serious professional misconduct.

The Council's Health Procedures are designed to secure a sick doctor's voluntary co-operation with any medical supervision and with any limitations on medical practise which are considered necessary to protect the doctor's own health and safeguard patients.

General Practice

The relevant supervisory body for general practice is the Joint Committee on Postgraduate Training for General Practice. This is the single Competent Authority for general practice and was named in statute in 1979.

The Committee is chiefly comprised of representatives of the Royal College of General Practitioners, General Medical Services Committee together with smaller representations from other interested professional and educational bodies. It is funded for its certification functions by a direct grant from the UK Government. Its functions are to supervise training which includes inspection and monitoring of training provision.

Standards are determined by the profession which, through the Competent Authority, sets structures and determines the syllabus/curricula.

Sanctions are applied through the withdrawal of educational approval from individual posts or trainers, training establishments or, in extreme circumstances - the Regional training establishment.

Pharmacists

In Great Britain pharmacists are regulated and registered pharmacies are inspected by the Royal Pharmaceutical Society of Great Britain under the authority of a Royal Charter. In Northern Ireland registration is carried out by the Pharmaceutical Society in Northern Ireland but inspection is the responsibility of the Department of Health in Northern Ireland.

The Royal Pharmaceutical Society is funded through membership fees and a premises registration fee. Similar arrangements apply in Northern Ireland.

Standards are established by the professional bodies and published in the Code of Ethics

and these are used as the basis for the standards for inspectors.

Sanction for professional non-compliance rest with the Statutory Committees of the professional bodies. The ultimate sanction is removal of the professional person's name from the Register. The Royal Pharmaceutical Society of Great Britain is currently seeking an amendment to its Bye Laws to take powers to "fine" the professional person for failing to comply with professional standards.

These are just some examples of the organizations involved in maintenance of professional standards. There are many more.

Infectious diseases
The Secretary of State for Health has ultimate responsibility for Public Health.

Local authorities have diverse powers through local government and public health legislation. Their responsibilities include port health, food inspections and food hygiene, some aspects of animal health, pest control, health and safety at work and notifiable diseases. Most local authority duties, particularly those relating to food hygiene, are performed by the Chief Environmental Health Officer and his team.

Public Health law requires the notification of certain specified diseases to the local authority's "proper officer", now normally the Consultant in Communicable Disease Control (CCDC), which is a joint health authority/local authority appointment. It also gives the proper officer various powers of investigation and control, e.g. excluding a child from school and power to examine a person to see if he or she has, or has recently had, a notifiable disease.

Health authorities are responsible for a range of services contributing to the prevention, control and treatment of communicable disease and infection, including health education, health visiting and immunisation. Health authorities, Trusts and GP's, are of course also responsible for the treatment of people suffering from all types of infection whether notifiable or not. For many notifiable diseases other than those which are food or water-borne (e.g. TB, meningitis, diphtheria) the burden of work falls to the health authority, even though it is the local authority which is responsible for receipt of the notification and for the exercise of reserve powers under the Public Health Acts. Responsibility lies with the Consultant in Communicable Disease Control.

Individual physicians have a statutory responsibility to notify patients suspected or confirmed to have certain specified "notifiable" diseases.

The Public Health Laboratory Service was established under the National Health Service Act 1946. It's responsibilities include the national surveillance of communicable disease, provision of specialist reference laboratories and a network of local public health laboratories, and the provision of advice and assistance, and if necessary co-ordination, in the investigation of outbreaks of communicable disease.

The Health and Safety executive has statutory powers under Health and Safety at Work legislation, including under the Control of Substances Hazardous to Health (COSHH) Regulations.

In Scotland, Wales and Northern Ireland the arrangements are basically the same, although organizational structures may be different, for instance, Scotland has Health Boards.

Organization and funding
Local authorities and Health authorities are responsible for their own budgets. The PHLS and the HSE are centrally funded, PHLS by the Department of Health.

Standards are set through a mixture of professional guidelines accepted best practice, codes of practice and legislation.

8. Portugal

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1. - Origin and development - Background

1.1 The current Inspectorate General for Health (Inspeccao-General da Saude - IGS) is a central service in the Ministry of Health that has its own technical and administrative autonomy, as laid down in article 1 of Decree-Law 10/93, date 15 January, and article 1 of Decree-Law 291/93, dated 24 August.
It succeeded the Inspectorate General for Health Services (Decree Law 312/87, dated 18 August and previous Decree-Law 384/80, dated 19 September), which in turn, succeeded the Inspectorate for Health Services, created in 1975, directly dependent on the Secretary of State for Health (Decree-Law 403/75, dated 25 July). This in turn was the result of the Inspectorate Services of the General Secretariat of the Ministry of Health and Assistance (Decree-Law 413/71, dated 27 September), and, these were the successors of the Inspectorate for Social Assistance (Decree-Law 35108, dated 7 November 1945), for those duties relating to the inspection of Ministry establishments and institutions conducting health activities and under the control of the Ministry.

1.2. In parallel to the growing responsibilities that the State was gradually assuming in providing direct health care for the community, through an increasingly wider network of services and public health establishments, there was also a growing need to develop an internal inspection service, to supervise the fulfilment of laws and regulations.

1.3. For several years the work of the Health Inspection Services involved juridic-disciplinary matters almost exclusively.

1.4. Although Decree-Law 384/80, dated 19 September, subsequent to the previous Inspectorate for Health Services, already mentioned "controlling and inspecting the practices of those bodies and services dependent on the Secretary of State for Health or subjects to its control" as one of its competencies, the fact is that little was done by way of prevention.

1.5. The experience that in the meantime was being acquired, recommended a sharp change in that tendency (in disciplinary matters) to better observe practices in establishments (in preventative matters) particularly in management and economic-financial control.

1.6. It was therefore decided, in Decree-Law 312/87, dated 18 August to introduce changes into the basic working of the Inspectorate General for Health and the way in which it operated, covering the needs felt by services and attributing the

Inspectorate with the competencies and technical and human means to allow it to carry out the work of inspection-prevention, without neglecting its traditional work in disciplinary matters.

1.7. Despite this, due mainly to the difficulty and delay in hiring and training new advance level technical staff and the need to deal with disciplinary action, it was only in 1989 that the IGH could be effectively structured into two distinct, although complementary, sectors (the Inspection Service and the Disciplinary Action Service), and the respective staff were then allocated and the work of inspection programmed.

2. Description of the Inspectorate General for Health as laid down in the current organic law and in its activities

2.1. With the new organic law published with Decree Law 291/93, dated 24 August, some important changes were made such as abolishing class 2 category inspectors, creating the career of advanced inspection on a special basis, and extending the competencies of the Inspector-General, in particular the power to have management audits done.
The aim of these changes was both to add dignity to the work of inspection and to allow the IGH to take what was eminently preventative action in hospitals. This covered practically all areas of management, aiming to give more responsibility to the different agents involved, particularly supervisors, and bringing about a consequent improvement in the quality of services provided to the community, by making innumerable recommendations based on the results of these actions.
In the past two years, several management audits were duly planned and carried out, all of them with frankly positive results, which were indeed recognised by the actual departments audited.

2.2. It was also agreed that the two sectors, Inspection Service and Management Auditing, and the Service for Action and Disciplinary Auditing, should be interdependent and take concerted action. This move contributed towards good results, not only in co-operation between the specialists in both sectors, but particularly in pursuing the overall objectives of the IGH and drawing maximum benefit from existing means.

2.3. It should be emphasised that activity indicators show that in recent years there have been considerable gains in productivity, and an increased budget and increased spending have lead to far higher percentage increases in work done.

2.4. Despite this, it is still recognised that there are some difficulties in responding rapidly to all requests and needs for intervention, not only because of the yearly increase in the number of processes filed, but also due to the lack of inspection staff (currently 25 inspectors working in the IGH to cover 44 units).

2.5. In the Service for Inspection and Management Auditing, the IGH, with the

exception of extraordinary inspections, acts according to annual or multi-annual plans, drawn up internally, covering the different types of action required (inspections and management audits), selecting the respective topics (when it is a question of theme inspections) and covering a specific number of previously selected establishments that, wherever possible, are representative of all establishments.
With the inspections (done in each establishment included in the respective IGH plan, based on a specific inspection guide), the aim is to check the global or partial running of services. After each inspection specific recommendations are made to the establishments for corrective measures for irregularities or shortcomings detected (and the adoption of which is accompanied by the IGH itself).
When the different inspections planned by the IGH have been done, the latter produces reports or recommendations for the specific supervising authorities, in this case the Ministry of Health, so that standard guidelines can be issued for establishments.
Under this heading, inspections were carried out on "waiting lists in hospital services", the "consulting room for the hospital user", "emergency services", "working systems and organisation of doctors timetables", "private clinical work in State hospitals", "bids for acquiring goods and services", "hygiene and hospital waste", "psychiatric departments" and "human approach and patent attendance in health centres", "radiology/scanning services", "bloodbank services", "acquisition of concentrates and other human plasma derivatives" and "hospital and ex-hospital dialysis units".
Ordinary inspections were done in health centres.
With regard to management audits, also the object of internal annual planning, begun in 1994 and still at the stage of adjusting respective objectives and methodologies, the aim is to make a correct, effective approach to the most relevant aspects of managing hospitals and clinics, in order to correct anomalies and detect eventual irregularities. This includes examining accounts and the legality and regularity of operations done (strictly financial auditing), as well as looking at results against plans or projects for activities (auditing financial management).
As part of management auditing, targeted audits were begun this year into only one or a few management aspects.
In this sector, at the start of each year, actions are programmed and at the end of each year results evaluated, stressing the recognised teaching nature of these actions, that are indeed well received by most hospitals.
More than inspecting, it is often important to find solutions to small or major problems, or resolve specific questions by making simple recommendations, giving advice or suggesting guidelines.
This is a sector that must be further developed and extended, since the activities it covers contribute considerably towards improving the quality of services. However, it demands a careful approach and the constant need to give vocational refresher courses to inspectors, for training and technical and legislative revision, so that their understanding can be extended to areas as

varied as management of installations and equipment, supplies, accounts, information systems, etc.

2.6. In the Service for Action and Disciplinary Auditing, a growing number of disciplinary procedures have been filed (investigations, enquiries and disciplinary action).
The Inspector General for Health has the jurisdiction to institute such disciplinary procedures and to apply disciplinary penalties (with the exception of the penalty of dismissal from public duty, which is submitted to the ruling of the Minister for Health), involving any staff member or agent in any of the hospitals and clinics under the National Health Service, and observe the execution of these penalties by the respective establishment.
Jurisdiction in this area is exercised at the initiative of the Inspector General, when complaints are submitted to him, or when there are signs of irregularities of which he is made aware by other means.
When a significant number of complaints are made by the users of health establishments regarding the actual technical practices of the medical and nursing staff, the IGH works with two medical doctors, in the IGH itself, during the investigation stage of the proceedings. These two doctors examine the clinical files of patients and help draw up the enquiries to be submitted to medical specialists, distributed among the different medical specialities, individually appointed for each specific case by the Inspector General.
This examination made by the IGH of the technical practices of medical professionals, with a view to ascertaining eventual disciplinary responsibility, has not been calmly accepted by the medical class as a whole, that claims that examinations should be done only by their peers (by the association of the medical class - the Order of Physicians and Surgeons).
But the fact that the IGH systematically uses medical specialists in such cases has allowed the system to proceed along normal lines.
Only recently, in 1994, the Disciplinary Statues for Physicians of Surgeons were published (Decree-Law 217/94, dated 20 August), that established the mechanisms for bringing into effect disciplinary responsibility laid down by the Order of Physicians and Surgeons, but explaining in article 3, no.1, that "disciplinary responsibility laid down by the Order of Physicians and Surgeons co-exists with any other responsibilities laid down by law".
Despite recognising the importance of the public ends pursued by the Order of Physicians and Surgeons, to make enrolment in the Order obligatory and attribute the Order with deontological duties and disciplinary power, the law-maker did not introduce any restraints or conditions in bringing into effect disciplinary responsibilities for physicians and surgeons by public administration itself, for those physicians and surgeons in public health hospitals.
Here the competence of the IGH covers ascertaining disciplinary responsibility and bringing it into effect, bringing before the courts situations in which possible criminal responsibility may also have occurred, and leaving it to individual initiative to file civil proceedings in the competent courts for the purposes of compensation.

In this Service for Action and Disciplinary Auditing, training is important in juridic-disciplinary matters as well as in administrative procedures for staff in these services and, in particular, for those called upon to carry out examinations in proceedings for investigations, enquiries and disciplinary action. And this activity is required increasingly for services to work well, although it demands regular observance by the IGH.

3. The organic law of the Inspectorate General for Health
(Decree Law 291/93, dated 24 August)
- Competencies and Services -

3.1. The IGH is a Central Service of the Ministry of Health with its own administrative and technical autonomy. Its legal attributions involve ensuring that the laws and regulations of the health system are fulfilled (a system that covers not only those public health establishments that are part of the National Health Service, but also private health establishments linked to the National Health Service through contract). The aim is to provide well run, quality services, defend the legitimate interests and well being of users, safe guard public interest and correct any legality infringed.

3.2. The IGH works in four fundamental areas:

- Management auditing, in those establishments that are part of the health system;
  Inspection, in entities in the health system and private entities not part of the health system (but, for the latter, only on ministerial order and in co-operation with the Directorate General for Health (DGH);
- Disciplinary auditing, the object being the National Health Service;
  Disciplinary action, again the object being the National Health Service.

3.3. The IGH is administered by an Inspector General with the assistance of two Sub-Inspectors General.
The duties of the Inspector General are to:

- Superintend all services and activities for which the IGH is responsible;
  Draw up plans for activities, namely the plan for ordinary inspections and theme inspections.

9. Germany/Bayern

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I take part for Mr. Weinig as the chairman of the Union of the Bavarian Hygiene Inspectors. The federal structure of Germany - 16 counties, each having its own public health organisation structure - make a common public health strategy difficult. Therefore, also a European teamwork in public health is difficult for Germans.
None of the 16 German counties feel, e.g., responsible for communication with the Netherlands.
The structure of public health organization is formed by different laws of each of the 16 counties. They resemble each other because of the same main tasks.
In following, I will talk about Bavaria.

Institutions of the State Public Health Service are the

- Public Health Offices (Gesundheitsamt)
- Veterinary Offices of the State (Veterinamt)
- District Administration Board (7 in Bavaria)
- The Bavarian State Ministry for Work, Welfare, Family, Women and Health (Bayerische Staatsministerium für Arbeit, Sozialordnung, Familie, Frauen und Gesundheit).

As a Laboratory and as a "Intelligence Bureau" for Hygiene and Environmental Hygiene in Bavaria, there are the

- Landesuntersuchungsamt Nord-Bayern, and the
- Landesuntersuchungsamt Süd-Bayern.

In Bavaria, in the 71 State Public Health Offices, without the 3 now municipal Public Health Boards, in 1993 were working 1667 employees, divided in 289 physicians, 374 social workers, 118 (child)-nurses (called Assistentinnen), 172 health inspectors (im Gesundheitsdienst: AGD), they are non-physicians, 87 technical assistants (for laboratory and X-ray), and of course administration workers.

As for the physicians, we have around 1 per 35.000 inhabitants in the Gesundheitsamt; for the health inspectors we have 1 [er 50.000 inhabitants.
It should be emphasized that the health inspectors are responsible for hygiene and environmental hygiene.
In this field the health inspectors as non-physicians work in own responsibility, or together with physicians. The Chief of the Public Health Board (Gesundheitsamt) is a physician.

The "Gesundheitsamt" surveys or inspects

- the hospitals;
- the institutions of transport for patients;

- the Bloodbanks and the blood-providing procedures, in respect to the needs of correct hygiene; they are also inspected by the pharmacist of the district government (repeat: 7 in Bavaria).

The "Gesundheitsamt" also surveys and inspects

- the drinkingwater-supplies
- the correct removal of waste-products like garbage and sewage;
- the bathing- and swimmingfacilities, no matter if closed or open air, including hygiene of the bathing- or swimmingwater;
- all over-night facilities and campingplaces;
- schools, kindergarten, homes for children and elderly people, including nursing facilities;
- sport facilities and children-playing facilities
- harbours and airports
- teamwork in city- en village planning
- teamwork for planning of setting with a potential for environmental pollution.

The "Gesundheitsamt" also has many tasks in social medicine and social hygiene. Its is responsible for counselling the population and individuals in respect to prevention in health in general, and especially for mental illness. Other tasks are for addiction of alcohol and drugs, and infectious diseases as salmonella, enterotoxic hoemorrhagic, escherichia coli and HIV. For the last one everybody can go to the "Gesundheitsamt" for counselling and bloodtest, without any costs and always without giving her or his name.

The "Gesundheitsamt" also does the medical assessment for individuals and for the court, as far as provided by the law; when the law says that an examination by the persons' own doctor is not accepted. This is also a wide field that shall not be expanded. The Gesundheitsamt also examines each school-entering child in the time of half a year before entering the school, does vaccination in schools and co-ordinates prevention - meetings and other supplies.

Starting 1996, the "Gesundheitsamt" in Bavaria is integrated in the local administration board called Landratsamt. An independent commission and the interest groups of the professionals working in the Gesundheitsamt had favoured to hold the Gesundheitsamt as a Board for themselves, but making larger boards putting two or three together. The Minister President decided to put each Gesundheitsamt into each Landartsamt and the leadership of the politician called The "Landrat".

The Hygiene Inspectors in the Gesundheitsamt are non-physicians, but have a not unimportant role, because they work for hygiene and environmental hygiene and the leadership of the chief physician of the Gesundheitsamt. They mostly get a nursing training and are related to medicine, or have a profession related to medicine. They bring their professional experience with them to the Gesundheitsamt. When they enter the Gesundheitsamt, it normally takes two years including four months in the Academy for Public Health in München, before they are fully able to do their job.

There is an initiative of the Federal Association of the Hygiene Inspectors of Germany, to

come together with colleagues of the other European Union countries to learn of each other, to draw comparisons and even to associate with others in the future, as well for learning and pursuing common interests. This can be, for instance, working for common standards for the persons doing their profession in health inspection.
We will ask for your help, if this year or next year, a letter will be sent to you concerning the professional matter of health, hygiene or environmental hygiene.
Please would you be so kind as to give that letter to Oskar Weinig and other interested persons working in the field of hygiene inspection.
Oskar Weinig is given the opportunity to speak to the Bavarian Parliament, Section Public Service, end of this month.

V Presentations on cross-border health care issues

A. Assuring the quality of care in times of market orientated health system reforms
(Dr. N.S. Klazinga)

B. Medical practice and disciplinary measures in the European Union
(Prof.dr. H.D.C. Roscam Abbing)

C. Free traffic of health care professionals
(G.H.A. Siemons)

D. Inspection program for blood(products)
(P.H. Vree)

E. Certification and supervision in health care
(Drs. H. Gundlach)

A. Assuring the quality of care in times of market orientated health system reforms

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It is a pleasure to have the opportunity this morning to discuss with you the topic of quality of care and its relation to the inspectorate of health. I will speak about examples from the Netherlands, but I will try to present it in such a way that you can see whether what I bring fits into the picture of your own country.
The title of my presentation will be assuring the quality of care in times of market oriented health system reforms. This means I will try to give an overview of the changes that are going on in most of our Western European health care systems. When you remember two messages at the end of my presentation I will be very glad.

The two messages are:

1. When you make your health care system more market-oriented there is more and more reason for a government to regulate quality.
2. If you go through changes of introducing more market elements you should change the profile of you controlling bodies. They should not control on structure alone but they should be more system-oriented and supportive to the improvement potentials of the system itself.

Those are the two main points, but I shall try to tell now why I think those are important. Luckily enough I am not alone on the first point. One month ago a book was issued. It is titled "New rules regulation markets and the quality of American health care". The book is written by T. Brennan, who is a professor in health law at Harvard School of Public Health, and D. Berwick, a specialist in quality systems and continuous quality improvement in health care. They give an overview of the situation in the US. There has been an interesting change between the activities of the profession and management of health care institutes and the government in the USA. They come to a conclusion. When you read the last page of their book, even the last lines, it says: "We propose to move to responsive regulation because we believe the market alone cannot produce incentives for high quality care. One of our greatest concerns is indeed that the market may overemphasize costs to the detriment of quality. If anything regulation has a larger role as the market evolves, not a smaller one."

That is their opinion, but does that apply in our Western European health care systems?

First we have to address the question : <u>what is quality of care,</u> and, of course, you can say a lot about that but I just want to pinpoint some key elements of the issues that are usually hidden behind the word 'quality' when politicians or managers or professionals speak about the quality of care.

I think you should make a distinction between the quality of care looking at the health

system as a whole and the quality of care as delivered in specific services. On health system level we usually mean access or equity, that is regulated through the insurance mechanisms or, when you have an government based system, the access people have to the facilities. Another element of quality on health system level is the availability and traditionally that has been a role of governments through planning. To plan sufficient hospitals, nursing homes, doctors. An additional issue is acceptability, that has to do with the ethical debate. Do we really want technologies, the things that are now offered by medicine. And a very important last element of the discussion whether you try to make a health care system that is being responsive to the actual health needs of the population. So you try to figure out what are the morbidity and mortality patterns of the population, what kind of diseases and illnesses are prevalent and how to create a system that addresses those needs. So far the concept "quality" on health system level.

When you look at health services level, you see that we speak about efficacy. Do the technologies and the drugs we are using really work? Efficacy means it has been scientifically proven that this is a good technology, a good drug or a good advise. We speak about safety. It could be a good advise, but how do we make sure that it is used correctly? And we speak about competence. When we let people work in the health care fields, doctors, nurses, are they competent to deliver specific services? Those are more quality aspects which have to do with the structure you create. You allow drugs on your market, you allow bloodproducts to be used and you allow professionals to practise.

When you actually speak about the performance of the health care services, you usually speak about the three elements:

- the effectiveness - do they really cure patients, is the health care effective;
- is it efficient;
- are the patients satisfied.

Again you can put the emphasis differently. But I think these are the main aspects of quality of care when we start to talk about it from a policy perspective.
You can also see which things are addressed by an inspectorate of health. Here in the Netherlands I think they are addressing effectiveness and patient satisfaction. They are very focused on efficacy, safety and competence. But they are also involved in several of debates, especially on acceptability and to a minor extent on availability. And through information on the state of the health care they try to be involved in the debate with government on the fact whether the health care system meets the needs of the population. So an inspectorate is involved in several of the elements of the "compound notion quality".

Now we shall take as example the Dutch care system culture. We have a culture of parties sitting together, trying to cut deals rather than being in continuous conflict. There is a strong interdependency between the state and the professions and that goes back to the 19th century. When you see how the present system has evolved you will find its roots at the beginning of the 19th century, where state and profession together started to regulate things on national level. The medical association was founded in 1848 and the law which is still behind a lot of things physicians are doing now is from 1865. That law also