introduced the inspectorate of health. It was there already at the end of the past century and it is not only focusing on public health, as is the inspectorate in most countries in Europe, because that is the classical role after the second half of the 19th century of an inspectorate to emerge and being focused on hygiene and public health. But our inspectorate has traditionally also been involved in the control of medical performance.

What are the main underlying features. I think these historical roots are very important. Many of the things we now have for quality of care are based on the gradual professionalization in the professions. A lot of today's activities and the relatively large autonomy of the profession go back to the way the professions have developed themselves.

Another part of the present quality assurance activities is based upon the way management has developed in our health care institutes. So that has also to do with the tradition of private ownership. There is a management tradition on the local ownership of hospitals or nursing homes. This tradition is embedded both in the economic and cultural context of the Dutch health care system.

Lets now look at the way government has tried to influence quality assurance activities in the past twenty years. You see a gradual shift in the thinking about quality. And it has also been put on the political agenda on a national level. In the '70's, because of the economic reasons, leading to cost containment, government got more and more involved in trying to regulate the system because costs were too high. In 1974 we had a series of laws that were based on the policy idea that you should plan things. Planning regulation, rate setting, planning of facilities and a licensing system for health care institutes evolved from that. So it resulted in a strict licensing system based on planning thinking. But the costs were rising and rising, so in 1983 a budget system for hospitals was introduced. Costs were going down a little bit, but were still too high. So 1987 we started a debate on marketization. There was a growing awareness that planning regulation on national level was not sufficient. It was too inflexible, it was not good enough. There were examples in other countries, so we started a reform. We created more flexibility between parties, meaning that we also started with deregulation.

At that time a lot of parties had the idea that the focus would now be too much on cost containment. So on a national level the initiative emerged to have a national conference on quality of care. We had the first one in 1989 and second one in 1990. The different actors in our health care system agreed together on a common policy on quality of care. And the main things they said was: it is the responsibility of the providers to build quality systems to show that they assure the quality they are offering. But they should do it in such a way that they are accountable to the insurers and the patients. And the role of the government would be to support that development. I am now summarizing a large paper in two sentences. But that was the basic idea? Government followed. They came with a policy paper in 1991. The secretary of state, Mr. Simons did this. Then, in 1992, we started a national debate on critical choices in health care, the Dunning report. There was an awareness that we should have this discussion. In 1994 there was a second step of trying to control the costs when Mr. Biesheuvel came with a report which was endorsed

by the government, that is very simply saying proposing to budget the specialists costs and trying to make specialists stay within the budget of the hospital.
In 1995, after five years of national policy, we had the third national conference, where everybody was more or less positive about the results that were achieved. Having all these market oriented changes on the one hand, but on the other hand having a kind of national policy debate on quality of care. This part became more visible, even in a law that is now effective since April this year. A new law on quality in health care institutes. I will speak about that a little bit later.
But what you see is that the moment you start speaking about a more market- oriented system, you start to discuss on quality policies and the necessary regulation in that respect.

I have a small figure to show you the relations. What we try to do is to work on quality, but it is in this triangle of providers, patients and financiers. Government is a little bit more at a distance but tries to set the rules for the way these parties interact and thus produce quality.

Now I want to mention very briefly some of the activities that are going on in the Netherlands. Some are similar to activities in your countries. I will present what government is doing at the moment to assure the quality of care, what the profession is doing and what the health care institutes are doing. And I will then come back to the role of the inspectorate for health care.

Quality assurance activities of government include the following. As I said, traditionally government and the inspectorate focus on the structure. We look at the efficacy and safety through drugs regulation and regulation on medical devices. We had a very strict drug regulation and when the regulation of the European Union was set up and the parallel import was introduced, our own regulations seem to me to be more forceful, more powerful than the European ones. With medical devices it is a little bit the other way around. We had a law but we did not really work with it, so it was an incentive to be in the European Union and the regulations there to make that regulation more stronger, more effecitve. But there is a lot of regulation in that field. There is some regulation with respect to availability, especially to new technologies. We still have the planning laws from the '70's. We have one article which is still used by our Minister of Health which is article 18 that states that you need a licence to have certain types of facilities. For example, liver transplantation, heart transplantations. So if you want to do that as a hospital you need a licence. This is still a possibility for the government, at least in some way to control the abuse of new technologies. But as you can see these things are mainly based on whether the drug or technology is safe or effective. For article 18 we combined it with more and more technology assessment studies. So we also tried to include CEA's in the decision making. There is also a role here for the health insurers. Because they have to decide whether a certain technology will be reimbursed, yes or no.

What seems to be even more important is the way the government tries to influence the effectiveness. And there we saw, as a part of the quality policies three types of new laws emerge. I already mentioned the law on quality in institutions. It has replaced a lot of the

more planning oriented detailed regulation laws and actually is a very simple law by itself. It states that every health care institute should have a quality system. The quality system should be focused on responsible care, meaning it should address the effectiveness, the efficiency and should be patient oriented. And there are some obligations; one of the few is that you should write an annual report on your quality activities as an institute. And what is important for the inspectorate: it gives the inspectorate more possibilities to intervene. In the old system they had only extreme measures at the end, now they can intervene more in detail and earlier.

So this new law is different than the way in which the issue of the quality of care has been dealt with in legislation in some other countries. I know in the Gesundheitsamt you just entered one paragraph about quality for hospitals. The same as in France, just one article, just an additional thing a hospital should do, which is a little bit similar to the UK, where medical audits and clinical audits became mandatory in 1990/1991. What we did in the Netherlands was to device a totally new law, which is more based on the system thinking, and at the same time try to get rid of a lot of more detailed regulations.

A similar type of thinking is behind the present law on professional performance (BIG). It roughly states that the professions are recognized by law and also enforces reregistration and a system for disciplinary law. And we have seen the past years several laws that are enforcing the position of the patient. Laws which have to do with the position of the patient, patient rights, privacy and complaint handling.

So these laws are more or less supportive to this national quality policy. And of course there are the traditional things like education and research. We have the inspectorate of health who sets the control function and there you see that they get more and more interested in developing indicators. The inspectorate wants to have some information which tells them something about the quality of care in addition to the general information about morbidity and mortality. And traditionally government still plays a very important role in prevention and health policies because public health is still a domain which is not deregulated to the market.

What is the medical profession doing? Well, to start with the traditional things, the basic medical education and post-graduate training. In the Netherlands, the speciality training is primarily the responsibility of the medical profession. We have this new law on professional practise, which enforces reregistration, which has been introduced for all doctors since four years now. And I think after Norway, we were one of the first countries to introduce an obligatory reregistration for all doctors. Another activity are the professional profiles, trying to make explicit for every profession what they are doing. We had that more development for the paramedical professions in the past period of 10 years. Each of them has made explicit what exactly is the profile of an ergotherapist or a physiotherapist. There is a growing interest in norms and standards/guidelines. Apart from the rules of medical conduct you see a whole movement of clinical guidelines, with two national programs, one for specialists and one for GP's. And roughly speaking you see the emergence of external quality systems and an example could be the visitation programs of our scientific societies. Meaning that, for instance, the college of surgeons has a program

where it visits every 5 years each group of surgeons in every hospital in the Netherlands just to evaluate their practices. Close to what others would call accreditation, but we call it visitation because it is set up within the society itself. Programs exist now for all specialities. Somebody from your peergroup is coming to see how you are doing. And you have the internal quality systems, these are traditionally more focused around peer review. We have a national program for peer reviews since 1979.

A similar list can be made for institutions. As I said we have a new law on quality in health care institutes. Here you have the same distinction between external and internal mechanisms. There is the debate on certification and accreditation. And the next speaker this morning will tell you about that in more detail. We do not have accreditation for hospitals at this moment. But we are considering it and there are pilot programs. We have some type of certification for nursing homes and homes for the elderly. So in all the sectors it is evolving. It is a similar debate which I recognize in some other countries. I know that France has just been very forceful in pushing the idea of accreditation. I know that in Spain an accreditation system for hospitals has been running now for about six years.

Again, like you have professional profiles, some types of services try to make national profiles of what their institute is actually doing. For a hospital that seems more or less clear but for a home care organization that is less clear. So they make national profiles. And here there is a whole series of internal assurance quality mechanisms hidden behind words like developing a quality system. I do not have sufficient time to explain all of that but the figures show in our hospitals we have a lot of committees and activities in addition to the national policies for assuring the quality of care. And that goes from the traditional meetings to hospital wide quality improvement programs.

Finally, what is the role of the inspectorate of health in all this. I think it is extremely important and it will become of growing importance. One of the things that we try to create in our system is the right balance between self-regulation and accountability. As I showed to you the systems are developed but in such a way that providers should be accountable to patients and insurers. That is a point the inspectorate of health should guard. They can enforce this, especially the accountability component and can see whether this balance is still there or whether the profession is like an oyster, keeping things to itself or that the hospital management is also like an oyster, trying to keep things for itself. There is a growing awareness now that one should be accountable, and the annual report on your quality policies in the new law is just one of the instruments to achieve this.

One can also notice that the inspectorate is changing from a more incident assessment oriented system of control towards a system oriented approach. So they start looking more at the functioning of the quality systems and try to be one of the external incentives for developing them. You see that more and more information on quality of care is becoming available. Not only through these annual reports but also a lot of studies are done and a lot of thinking is done on how to develop indicators on a national level that tell you something about quality of care. I can tell you that it is extremely difficult. You can

get an indicator for your health situation or in general how things are going, but especially on quality of care on national level it is very difficult to develop valid and reliable indicators. Nevertheless, we try to assemble that information. Furthermore responsive regulation, as I mentioned earlier, needs the inspectorate to be flexible. Not only having very severe measures like closing a whole hospital. Now they should be able to say for example, "well this operation room is not in accordance with the standards, you must make it in order. It should be better in one or two weeks time or we can just close this operation theatre, not the whole hospital, just a theatre". That is necessary if you want to work in such a system. To conclude I think that instead of the traditional control oriented inspection, inspection should gradually, when the system is up to it, move towards improvement based inspection. Perhaps you think that all is all too theoretical, but I come back to the two points from the beginning. I think our system, like many health care systems, is going to a situation where we introduce more market elements and that needs more attention to quality and control of quality. But at the same time it is necessary for an inspectorate to be less traditionally control oriented and become more focused on the improvement potential of the system itself.

B. Medical practice and disciplinary measures in the European Union

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Introduction

One of the assets of the European Union is the possibility for free movement of patients and doctors. Patients can in principle receive medical treatment in another country than their own. Doctors can practise in another country than that of their degrees. This is to be encouraged, if only for highly specialised and highly technological parts of medicine. Why should high technology facilities and highly skilled medical doctors not be shared? Sharing of scarce resources among countries supports processes of rationalisation of health care delivery which are
presently ongoing in the member states of the EU. In co-operating across national boundaries scarce resources both in terms of manpower and in financial terms may be used more efficiently. Application of new methods of communication, like telemedicine, stimulates even more this process.
There are of course prior conditions to be fulfilled for cross frontier co-operation in the field of medical care within the EU.
The most important requirement is that there ought to be sufficient guarantees for the patient that health care delivery meets with quality standards, irrespec-tive of the place where, or the person by whom the care is delivered. A high level of consumer protection is one of the requirements to be respected by the European Commission and Council in accordance with the Union Treaty (article 129a in particular applies). *
This means first, that medical doctors should meet similar educational requirements throughout the EU before being admitted to the Profession.
Second, once admitted to the medical profession, professional conduct should meet with necessary quality requirements.
In line with the primarily economic orientation of the EU, I like to refer to these two preconditions as:
- the premarketing requirements (= qualifications to practise)
- Post marketinq surveillance (= maintenance of professional standards during practice).

The rules

Both aspects are addressed in member states and from a European perspective:
The medical profession is subject to qualification requirements, quality standards and quality control systems in the member states of the European Union. In addition, in order to facilitate the free movement of doctors throughout the European Union, the Council of the European Communities has set legal conditions in a directive.

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* Article 153 since the Treaty of Amsterdam.

There are restrictions to the free movement which are related to qualifications and to disciplinary, administrative or penal sanctions.
As you all know, the Directive aims at mutual recognition of formal qualifications through co-ordination of training requirements. National qualifications thus have a legal effect within the communities, without training requirements being harmonised. The directive also contains some requirements relating to good character and good repute to be satisfied on first taking up the medical profession.
These conditions fall under the first set of conditions I indicated, namely the premarketing requirements.

The second requirement, post marketing surveillance, is much more difficult to deal with at a European scale.

The EU Directive contains some clauses intended to guarantee safe health care delivery of sufficient quality. It does not address questions of quality assurance in medical practice as such, like quality norms and standards and instruments to promote their observance (like medical auditing, quality reporting and the like).
The relevant rules of the Directive relate to good character and good repute to be satisfied to practise as a medical doctor in a host member country, including the possibility to require a certificate of physical or mental health.
The Directive establishes an information system among the member states in case of establishment. Information is required on roughly speaking disciplinary or administrative measures or penal sanctions from the member state of origin to the host member state. Knowledge of misconduct should be communicated
from the host member state to the state of origin.

In case of provision of services the host member state may require proof of qualification of a doctor wishing to provide services. It may also ask for a certificate stating that the person concerned lawfully pursues the activities in the member state of establishment. In order to guarantee quality of medical care delivered, the rules of conduct of a professional or administrative nature of the host member state apply to a doctor who provides services. Any measure adopted pursuant to those rules or knowledge of any fact that runs counter these rules shall be forwarded to the member state where the doctor is established.

The practice
The purpose of the rules regarding good character, good reputation as well as information on measures taken because of professional misconduct is to protect the public against possible harm by preventing unauthorised and incompetent medical practice.
In reality, these requirements have proven to be insufficient, either in substance or in their follow-up.
The mutual information on disciplinary or administrative measures taken is a weak point. The rules do not preclude a doctor to move from one member state to another, pending a procedure in the first member state.
There is little information on what a member state considers a serious enough measure

for disciplinary or administrative sanctions.
The sanction systems are different, regarding the competent bodies (public or private), the underlying norms and the nature of sanctions.
To give an example: According to the Austrian medical disciplinary regulation no disciplinary prosecution will take place in case the blame of the doctor is small and his behaviour did not or hardly have any consequences. This is unlike the situation in the Netherlands under a forthcoming law. During a disciplinary proceeding one looks essentially at two questions:

- The degree of care taken by the doctor:
  did the doctor exercise due caution in his relation to the patient and his close relations.
- Whether or not the conduct has been incompatible with the interest of good medical practice.

There is a variety of sanctions in member states, including: an admonition, a censure, a fine, conditions to practise, restrictions to activities as a doctor, temporary suspension of registration or use of title, deregistration. Not all member states have a possibility of conditional suspension, partial deregistration, suspension of registration pending further proceedings and the like.
One member state (Ireland) considers the failure to pay the retention fee as professional misconduct worth of erasure or suspension.
Another member state (Finland), allows for precautionary action, through the National Board of Medicelegal Affairs, next to possibilities for sanctions in case of professional misconduct: if there is a good reason to presume that a health professional is no longer capable of exercising his profession, the Board may order the professional to undergo a medical examination in a hospital (investiga-tion of capacity for work). If there is good reason to presume that the professional skills of a health care professional are inadequate, the Board may order the professional to sit an examination (investigation of professional skills). To my knowledge there are not many countries with a similar precautionary system.

Discussion
Does the Directive provide sufficient guarantees for a high level of consumer protection in case of medical care? In other words: are there sufficient guarantees that medical practice complies with professional standards irrespective the member state the medical doctor comes from?
There are two important questions to be addressed:

- Are the rules of the Directive sufficient
- Does the information system work satisfactorily?

Are the rules sufficient?
Between the member states, there is incontestably a difference in supervisory systems regarding professional conduct, including the norms and sanctions. There may of course be differences in judgement of what amounts to professional misconduct, and what is to be considered serious professional misconduct.
Moreover, only suspension or withdrawal of possibilities to perform activities as a

doctor may lead to refusal of establishment or rendering of services in a host member state.

What are the consequences in case conditions are attached to the retention of the name of a person in the register as a fully registered medical practitioner who then decides to establish himself in another country?
For example - I now borrow from the report over the years 1989-1994 of the Medical Council of Ireland - in case there is a condition of supervision of medical practice? Or in case the doctor in order to maintain registration is required to submit to inspection of manual records and satisfy the Medical Council as to his standards of practice? Or when the doctor is not to engage in treatment of drug addicts?
Is this kind of information forwarded to the other member states and if so, on what basis? Routinely like in the UK or upon request? If routinely, is it effective?
What can the other member states do with the information? Can they attach the same conditions to the pursuance of activities of the doctor who makes use of his right of establishment?
In case of rendering of services there seem to be very little possibilities for the host member state to prevent a doctor to carry out activities on its territory unconditionally in case of preceding disciplinary or administrative sanctions other than suspension or deregistration: the only condition which may be imposed is the possession of a legal right to pursue the activities in the member state of establishment!
Another possible situation:
In case the retention of the name to the register of a doctor has been attached to conditions because of diminished physical or mental ability, that doctor can easily move to another EU member state which does not require a certificate of mental or physical ability.
I would say that, at least in theory, from the perspective of the protection of the patient there is ample reason to doubt the effectiveness of the Directive. The directive does not pay any attention to the possibility of conditions which may be attached to the pursuance of activities of a doctor. Whether in practice the risks of this gap have materialised is, of course, another matter. There has been very little research into this question so far.

Second question: Does the information system work
Regarding the question whether the information system works satisfactorily, there is more information available. My colleague dr. Siemons will present you with some pertinent cases. I will therefore only refer to the problems met when a legal procedure is ongoing. Not long ago, Luxembourg has in fact found that a doctor who set up practice in Luxembourg was suspended from practice in another member state after his establishment in Luxembourg. This information was not communicated to Luxembourg authorities. This example shows that the information system does not function optimally. It shows also that there can be a problem when a doctor is subjected to disciplinary (or penal) proceedings and he decides meanwhile to move to another member state under his right of establishment. The question arises whether there should not also be an obligation to provide information on the fact that proceedings are ongoing.

Though the quantitative range of the problem is unknown, the fact remains that from a point of view of high level of consumer protection the situation is unsatisfactory.
There are, of course, various possibilities to remedy the situation: improving the de facto functioning of the information system, so as to prevent those whose possibilities to pursue activities as a doctor have been revoked, suspended, restricted or made conditional, to practice in another member state.
To change the directive is another possible solution. Whatever the options chosen, they should be focused upon protection of patients from professional misconduct. The situation is not different from for instance measures directed towards safety of foodstuffs.
In order to guarantee safe medical practice within the European Union, and in order to maintain trust of the public in the medical profession, additional protective measures are necessary. Your meeting might contribute towards this. My colleague will present you with some concrete suggestions.
I will therefore leave it with a kind of Post Scriptum: the Dutch ministry of health during the chair of the EU the first half of 1997 will convene a symposium on the subject matter. As I am in charge of preparing this symposium I am presently gathering as much information as possible from the various member states. I would therefore highly appreciate any information or suggestions you might think could be useful.

C. Free traffic of health care professionals

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Health care stands on a high level in Western European countries. For a part this is relevant to the fact that the education is good and that there is a good post-graduate schooling. In spite of these facts in our country there is a minority of non-good functioning professionals who come in contact with the Inspectorate.
When expelled from the occupation several times a year in Holland; he looses his competence. We know that such a person sometimes tries to get work as a doctor somewhere else in Europe. Also we have at least one experience with a doctor who was expelled in another country and came to work in Holland.

Let me start by presenting you three examples.

Case 1 A family physician
In 1985 the doctor, who also had a pharmacy, was found out to use cocaine, which he ordered through his pharmacy. My service, the Public Health Supervisory of the Netherlands, warned the doctor and put an end to his use by seeing to it that no distributor delivered any drug that came under the regime of the Opiate Law. In 1993 this doctor crossed again the path of my service. He again used drugs; his quality of practising medicine was less than minimal and casualties had been the result. This time an indictment followed.
In court he was sentenced to loose his license to practise lifelong. The doctor appealed to a higher court and lost. Then he appealed to highest court and eventually lost. These procedures came up to two years. In penal court he was also sentenced; his appeal there is still pending.
Directly after the first verdict he appealed and moved to Spain. In my country a verdict is up till now, not final in these cases, when an appeal is still awaiting judgement. Therefore he legally still had the right to practise when the Spanish authorities requested for information.
In the Netherlands he could not practise, because no insurance company would contract him. In Spain however, he could treat Dutch citizens who stayed there during the winter. The case started in 1993. The first verdict dated from spring 1994; the Spanish authorities were informed of the definitive verdict in February 1996. The Spanish authorities then had to act according to the Spanish Law, which, as I understand, opens new possibilities for legal action by the doctor in question. What I try to say is that it is not that easy to stop a doctor from practising medicine quickly. In this case it took more than three years!
That this is not only happening in Spain; I hope to demonstrate this in the next case.

Case 2 The plastic surgeon from Belgium
A Belgian plastic surgeon had been granted permission to practise in The Netherlands. This was found upon his Belgian certificate and his Belgian license. The surgeon practised during a certain period in both countries. His specialisation was recognized by our Board of Plastic surgeons. In Belgium he was accused of a number of cases in front of the Medical Judicial Court, early 1991. In all the cases he was accused of, severe professional misconduct was proven in the eyes of the judges. He was sentenced to loose his license for the period of one year.
In Belgium that sentence was also open for appeal. He ran out of appealing possibilities in the last month of 1994. The sentence remained the same. Then the Belgian authorities informed my service. In the Netherlands the register of all licensed physicians is held by my service. Based on the information of the Belgian authorities, the plastic surgeon was removed from that register for the period of one year.
In April and May 1995 he started a civil and an administrative legal case against the State (i.c. my service), stating that the removal from the register was illegal, as he had not been sentenced in the Netherlands and that in his opinion the verdict in Belgium had no extra effect. In the end he lost both cases, because the Dutch judge stated that the Common Law and its translation into Dutch law has the inherent effect that a loss of license in a member state means the automatic loss of that license in the Netherlands. Providing the license in the member state was the foundation of the license to practise in the Netherlands.

As you see, in both cases the end was not the definitive verdict in one of the member states. Fortunately as it is, the whereabouts of the physician in question were known. When this would not be the case, there is a good opportunity for a malpractising doctor to practise in one of the member states, as I will show you in the third case.

Case 3 The Iatrosophic physician
Short outline concerning this physician
During medical study (completing housemanship) he already became interested in the "Collegium Iatrosoficum", founded by a guru. A sectarian society which propagates a form of treatment in which elements are incorporated from all wind directions: homeopathy, anthroposophy, eastern forms of treatment. During his medical study (Utrecht) he followed, like his partner, already lectures at this society.

Medical treatment of patients, who often followed lectures given by the guru, took and takes place by pupils of the guru, under his rather direct supervision.
The first case that leaded to a disciplinary case against the iatrosophic physician, was the one in which his help was requested by the guru for the treatment of a patient, also pupil of the guru, who suffered from a severe otitis media, complicated by a bronchopneumonia. The usual homeopathic treatment was not successful, and the patient refused the treatment of a regular doctor. The guru asked the iatrosophic physician for a consultation. The iatrosophic physician came, judged that the patient was seriously ill, hold the opinion that she had to be hospitalized, but under pressure of the guru one waited in the first place. Finally also the guru agreed to a hospitalization. Patient was hospitalized in state of shock and hardly survived the pneumonia, for which

only in the hospital antibiotics had been given.
Patient lodged a complaint against MTC. This finally led, through further appeal, to a suspension of three months. One of the considerations was that the iatrosophic physician, as a doctor, had let himself be led by the opinions of a non-doctor (the guru).

Second case reported to the Inspectorate:
Gynaecologist reported that a women was hospitalized with a sepsis puerpueralis. Patient was in state of shock, non-approachable, high temperature, and suffered from neurologic falling out symptoms.
One week before she gave birth to her third child. The pregnancy was supported by the iatrosophic physician, who lives in Utrecht. Patient lived in Tilburg (85 km). The iatrosophic physician could have been in time for the delivery, but had, amongst others, in relation to the distance, left control of the delivery to another iatrosopher (non-doctor), living in Tilburg. The woman got fever during delivery. This fever was seen as curative by the Tilburg iatrosopher. Whether he consulted the iatrosophic physician is not quite clear. Patient became in a more and more worse condition at home. She and her husband decided that she will have a period of rest in a sort of iatrosophic rest home in West-Brabant. This home is directed by the guru, from the Hague. In this home the patient diminishes more and more; one day after hospitalization she is in coma and she has neurologic falling-out symptoms. The iatrosophic physician comes from Utrecht and tries, in spite of the patients' condition, in mutual agreement with the guru, to do something with homeopathic medicine. Finally the patient is hospitalized, more dead than alive. She stays there for several months, and still has neurologic residues.

Also patient and her husband lodged a complaint at the Inspectorate. They declared that however they themselves were responsible for the choice of therapy but that they thought that the fact of the iatrosophic physician being a doctor was a guarantee for sufficient quality.

Consideration of the complaint in three authorities: MTC (Amsterdam), Amsterdam Court, and the Supreme Court. Very long-lasting consideration in all authorities because of the hard line taken by the iatrosophic physician and the guru, who adduced all remedies at law. The total the amount of hours of session for this case was 120. This is a record level in disciplinary jurisdiction. The pronouncement: disqualification, which was stated already by MTC, has been confirmed by all authorities. The iatrosophic physician lost his qualification as a doctor indeed, but it is difficult to control if he still practises, because his partner, who is still general practitioner, practises iatrosophic from the same address.

The cases of these three malpractising doctors demonstrate that free movement of professionals has its negative aspects too. In order to protect our citizens from dysfunctioning doctors we, as government agencies should find a way to keep each other informed about cases like these ones. A central "basket for all our bad apples" might be the answer to this problem.

D. Inspection program for blood(products)

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1. Historical developments in the Netherlands

Legislation

- 1961: Human Blood Act

  Aim:
  - to prevent commercial handling of blood and blood products (not for profit)
  - to restrict blood (products) only for medical objectives
  - to protect blood donors and to respect their interests
  - to guarantee the quality of blood products
  - to guarantee the quality of transfusion materials

  Characteristics:
  - key role for the Red Cross Organization
  - absence of supervision paragraph, only violation will be persecuted
  - recommendations of Council of Europe

- DIR 89/381 EC

  Aim:
  - to harmonize legislation on blood products in the EC in order to foster free trade of blood products.

- 1988: Blood Transfusion Act;

  Replaced the human blood act because:
  - it did not fit to the grown practice of blood banking,
    In 1960 only CLB, plasma campaigns;
    each hospital had a blood transfusion service; only full blood was given;
  - there was a need for a Steering Committee on quality and provisions
  - it did not fit to the European approach of drug legislation

  Introduction of this law gradually from 1988 till 1994.

Transmission of viral diseases

Before 1980 blood as a medium for transmission of diseases was only a minor item: syphilis, malaria. The physicians screened his patients on clinical aspects: a donor should be healthy. Each doctor did this in his own way.
Doctors were aware of unintended effects of blood transfusion because of immunological reasons.
Traditionally blood banks in the NL were active involved in preparation of plasma products.

There was not only a national facility (CLB), the plasma fractionation plant, in the seventies also regional blood banks entered this field.
In the 1980's the AIDS-epidemic revealed the risks of blood as a carrier of transmissible diseases.
Also Hepatitis B, C, HTLV.
Viral problems overwhelmed the immunological aspects.
There came a need for (inter)national guidelines for donor selection.
Starting 1985 is was known that transmission of HIV could be prevented by heat treatment of plasma products.

International co-operation
The first activities in the co-operation between European countries in the field of blood transfusion took place in 1953, when following floods in the Netherlands the local authorities experienced difficulties in using blood and blood products supplied by various countries.
The idea of effective co-operation, and therefore product standardisation, led in 1958 to European Agreement no. 26 on the Exchange of Therapeutic Substances of Human Origin. This agreement enshrines the guiding principles which have since governed all of the Council of Europe's activities relating to blood transfusion availability on a non-commercial basis, mutual assistance and technical co-operation.

In 1962 the Committee of Experts on Blood Transfusion and Immunohaematology was set up. Its first objective was to unify blood transfusion in Europe by setting standards allowing movement of blood products. Major achievements were the Agreement on the exchange of blood-grouping reagents in 1962 and the Agreement on the exchange of tissue-typing reagents in 1974.

Also reports on the clinical indications of plasma derivatives were published with a view to harmonising therapeutic practices.

In 1983 the Council of Europe affirmed its leading role in transfusion safety by a historic recommendation on preventing possible transmission of AIDS from affected blood donors to patients receiving blood or blood products.

In 1990 the Council of Europe initiated a debate on European self-sufficiency in blood and plasma, which led to a new recommendation.
Last year, the Member States of the Council of Europe adopted two recommen-dations: on the protection of the health of donors and recipients in blood transfusion and guidelines on the preparation, quality assurance and use of blood components.

I will conclude this paragraph by referring to the Resolution of 2 June 1995 of the Council of the European Union to develop a Community blood transfusion policy. This will deal with issues as:
- donor selection;
- quality assurance;
- inspection of blood transfusion services;

- clinical use of blood;
- haemovigilance systems;
- dissemination of information to the public.

2. Inspectorate procedures

Methods of inspection

General or systematic supervision

A visit of a team of competent inspectors inspects all aspects of the institute:

- the quality system
- the facilities
- the level of competence of the personnel
- operating procedures
- documentation
- compliance to their own quality system

leading to oral and written recommendations to the management; sometimes corrective actions are imposed

Thematic supervision

A visit or an inquiry on one or more specific aspects to a representative group of institutes leading to a report to be published.

Interventional supervision

A visit to the institute because of an serious incident, a report, a recall of a product, or a calamity, with the aim to see whether corrective action, if needed, is taken.

Development of standards and guidelines

The Health Care Inspectorate fosters the development of standards and guide-lines in a specific field of medical practice by specialists from that field.
Only exceptionally the Inspectorate itself will draft guidelines.

3. Activities of the inspectorate starting 1988

- **1988: check of heat treatment by factor VII producers**
  Heat-treatment of factor VIII was introduced in 1985 by all manufacturers. The Registration Authority made criteria for the evaluation of the dossiers of the products. The Inspectorate made a round along the manufacturers to verify whether they were compliant to these procedures.

- **1990: start development GMP for plasma fractionation plants**
  This activity was undertaken as a result of a meeting of the Pharmaceutical Inspection Convention in Copenhagen.

- **1991: audit on bloodbanks for compliance to viral safety measures**
  The introduction of the obligation to test donor blood for Hepatitis C Virus prompted the Inspectorate to make a round along the blood banks to see whether this measure was correctly implemented.
  Also some modifications in the heat treatment of plasma products had came into force and were verified.
  This was done because the Inspectorate had learned after 1988 that some blood banks had taken more than a year to implement heat-treatment for reduction of HIV.

- **1991: Development program for systematic inspections**
  The Director-General announced the coming into force of the paragraph on the licensing of blood banks. At that time the situation was that there was no licensing system. Every Red Cross Blood Bank could do its work. 1993 was proposed as the year of implementation of this part of the Blood Transfusion Act. The DG asked the Inspectorate to give criteria for the licenses and to advice him in conformity with that criteria.
  It was recognized that European legislation asks for GMP-compliance.
  So the Inspectorate set up a program for systematic inspections.

- **1992: General inspection of 23 bloodbanks**
  All 23 blood banks were inspected in one year. It seemed not quite correct to take a too long time for that licensing procedure. Thus, all blood bank were visited in one year.

- **1992: Action on GMP-failure factor-VIII production**
  NL had entered the PIC as an candidate-member. In this way NL got a report of another member-state that a Dutch manufacturer had shipped to a manufacturer in that member-country a heavily contaminated cake of factor VIII concentrate. It resulted in a adapted preparation method in the factory abroad and in a corrective action in the Dutch plant.
  This incident strengthens the importance of international co-operation.

- **1992: Pilot inspections distribution of blood products in hospitals**
  The Blood Transfusion Act does not only reflect the preparation of blood products, it also give room for setting rules for the proper distribution and use of blood products.
  To support the Director-General the Inspectorate performed five pilot-inspections in hospitals on the distribution and use of blood and bloodproducts. It resulted in a royal decree in which e.g. is stated that each blood product should be delivered only on prescription of a physician. Also a tracing and tracking system was introduced, or in other words, it is possible to make a administrative link between the name of the donor and the name of the acceptor.

- **1993: collection points**
  The blood banks are collecting blood for their own needs. The residual plasma is delivered to the plasma fractonation plant of the CLB. Some blood banks have also collection sites only for the plasma fractionation plant. The need for plasma is larger than the supply by the blood banks, so the CLB has also its own plasma campaigns, organized by local Red Cross volunteers.
  To all 600 points a inquiry was sent, 30 of them were inspected. It included hygiene, privacy, selection procedure, presence of a physician and so on.
  In the license of the blood bank or the plasma fractionation plant the condition is lead down that each plasma collection point should meet the quality standards.

- **1993: EU GMP-annex for blood products**
  In 1992 EU DG III asked the Dutch inspectorate to draft the GMP-annex on blood products. This document was finalized in 1993 and accepted by the Inspectorates Working Party.

- **1993: Viral safety issues**
  Although the viral safety of blood products was increasing more and more by better selection of donors, testing procedures and heat treatment, there remained a problem with the donations collected during the window-period. The risk on a contaminated blood product was roughly estimated as being less than 1 out of 100.000. The introduction of a waiting-period before the plasma donation can be used reduces this risk. Cell-containing blood products can not be made safer in this way.

- **1994: advice and instruction of hospitals: distribution and transfusion services**
  Starting 1994 the Blood Transfusion Act came in full action. The implementation took place in this year. The Inspectorate organized instruction meetings for bloodbank personnel, hospital pharmacists, clinical (chemical) pathologists and so on.

- **1994: Recall CJD-donation**
  A manufacturer in the USA recalled four batches of factor VIII-products because it appeared afterwards that in the plasma pool that was used one donation was given by a donor who had become a CJD-patient. The Inspectorate consulted Dutch specialists and concluded that there was no indication of a risk for transmission of CJD by blood products, a position that some months later, was also taken by the CPMP.
  In this whole consulting process the Haemophilic Patient Society was able to take part in the discussions.

- **1995: start 5-year program systematic inspection of bloodbanks**
  Three years after the first round, the Inspectorate felt it was necessary to include blood banks in the systematic GMP-inspection program. It aims to visit each blood bank 1 in 2 to 3 years.