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# Hospital Pharmacies in the European Union

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**European Association of  
Hospital Pharmacists (EAHP)**

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## European Association of Hospital Pharmacists (EAHP)

### ■ What is EAHP ?

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EAHP is a working community of national associations of hospital pharmacists.

Its membership includes representatives of all fifteen European Union member states, in addition to seven countries outside (for the moment) of the European Union. Membership is increasing each year and at present, EAHP represents the interests of over 12.000 hospital pharmacists all over Europe.

Our association was born in The Hague on the 6th of March 1972. The founding members were France (the first president was French), the Netherlands, U.K., Belgium, Germany and Denmark. In 1973, Ireland and Spain joined EAHP, soon followed by Norway, Greece, Austria, Sweden and Switzerland. In the 90's, Italy, Portugal, Hungary, Luxembourg, Finland, Slovakia, Slovenia and the Czech Republic became members. Further links are now being developed with Eastern European countries like Poland, Romania, Bosnia ...

### ■ The goals of our Association are :

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- to promote and further develop hospital pharmacy and to obtain and maintain general joint pharmaceutical principles and a joint pharmaceutical policy, in the interest of public health
- to promote co-operation with other organisations in the domain of public health
- to promote the position and function of hospital pharmacists
- to support and uphold the interests of hospital pharmacists from the member states of the European Union with that authority
- to support and uphold the interests of hospital pharmacists from the member states of the Council of Europe with that authority

- everything related to the above that may be conducive to realising the purpose.

### ■ How does EAHP achieve its goals ?

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In order to achieve these goals, EAHP is working with tools of which some have been created in 2001.

- EAHP has prepared and issued Policy statements in relation to important aspects of hospital pharmacy practice in Europe. Beside other documents, the most important we produce is certainly "Education for specialisation in hospital pharmacy".
- In 1995, EAHP established an official journal, known as European Hospital Pharmacy.
- In 1996, EAHP established an annual scientific congress, open to all hospital pharmacists. This congress takes place on an annual basis each spring in March. The first was organised in Amsterdam in March 1996. The following were organised in Porto-1997, Edinburgh-1998, Nice-1999, Madrid-2000, Amsterdam-2001. The 2002 EAHP Congress took place in Vienna.
- EAHP has also developed a Survey of Hospital Pharmacy in Europe. The first was carried out in eighteen countries in 1995. The second was carried out in the autumn of 2000 and the results were presented during the 2001 Congress in Amsterdam. The survey provides an important benchmark that can be used to objectively assess the progress made in each country. It also provides national associations with a wealth of important comparative data, which can be used by them in individual countries to promote local developments.

The beginning of this twenty-first century is important for the association because, this year, EAHP achieves many projects :

- The creation of the EAHP website: <http://www.eahponline.com>. Everyone will find on it much information about EAHP activities and about the Congress, some European news, many links between other associations and the EAHP site, a bookstore and an interactive forum.
- The creation of the EAHP Foundation.  
The aim of this Foundation is to foster research and educational activities to allow hospital pharmacists of every European country to

develop their activities in a general setting of public health in Europe or in their country.

Through these initiatives of research, educational programs, consensus conferences or rewards, EAHP Foundation wants to make the hospital pharmacy progress, improve its integration in healthcare systems of every country and improve healthcare given to the patients.

One of the contributions of the foundation is to help the hospital pharmacists, either in a position of hospital practitioner or in a position in research or at a University, and to get recognition of their work by publications. Another contribution consists in helping in the organisation of consensus conference on specific topics related to the pharmaceutical practice, in organising surveys, educational programs...

Priority will be given to programs that have a high impact on improving the best use of therapeutics for in- and outpatients.

These programs aim at helping the hospital teams for better prescribing, dispensing, administration, information and management. They include medicines, medical devices and other pharmaceutical products.

Dr Patrick Rambourg  
President EAHP  
April 2002



### **Standing Committee of the Hospitals of the European Union (HOPE)**

The Standing Committee of the Hospitals of the European Union (HOPE) is a non-governmental European association, which was created in 1966, and since 1995, has been an international association for social gain. It includes national hospital associations as well as representatives from the national health systems of the 15 Member States of the European Union, plus Bulgaria, Cyprus, Hungary, Malta, Romania, Slovakia and Switzerland, as observer members. So HOPE is working for 14.000 hospitals which employ more than 6 million employees and are 24 hours a day at the disposal of 375 million European citizens. These hospitals are in a process of transforming the bed centred institution into a health centre as part of a wider health care network.

The constitution of 1995 states that it is the Standing Committee's mission, as an NGO, to promote improvements in the health of citizens throughout the countries of the European Union and a uniformly high standard of hospital care throughout the EU and to foster efficiency, effectiveness and humanity in the organisation and operation of hospital services, with the following objectives: 1. to act as a principal source of advice on hospital and health affairs to the institutions of the EU; 2. to develop and maintain information about the planning and operation of hospital services and the health systems within which they function; 3. to advise members on matters relating to standards of provision, organisation, and operation of hospital services and the health systems within which they function; 4. to promote exchange programmes and training within the EU and elsewhere in the world; 5. to maintain links between health professions in the EU; 6. to liaise and cooperate with international bodies concerned with health affairs, particularly with the World Health

Organization (WHO), the Council of Europe and with other international health organisations; 7. to engage in any other activity designed to further the best interests of hospital services in the EU and the health systems within which they function.

In order to achieve these objectives the necessary structures are: the Plenary Assembly (PLAS), the decision making body; the Executive Committee (EXCOM) comprising the presidency and the heads of the national delegations and two Sub-Committees, one on Coordination (SCC) and the other on Economics and Planning (SCEP). The first Sub-Committee deals with quality and community law related issues, the second with quantity and economics related matters. Several working groups and ad hoc projects are linked with them and look into current issues such as the quality of hospital care, cross-border care, waiting lists, enlargement of the EU, European health care data, health as a growth factor etc. The President and Vice-President lead the Standing Committee and the Secretary-General is responsible for the day-to-day management of activities from the secretariat in Leuven (Belgium).

With limited means, the Standing Committee is pursuing its associative mission through information, representation, exchange, study and education. Through the above mentioned work of its Sub-Committees, HOPE demonstrates that there is a European dimension to health care. Since the "European Charter of Rights for Hospital Patients" appeared in 1979, HOPE has published a long series of studies. The most recent ones are: The Quality of Hospital Care in the EU, (1996); Role of the Hospital (1996); On Solidarity in changing Health Care Systems - Europe in Search of a new Balance, (1997); Trends in Hospital Financing in the EU (1997); Measures to Reduce Surgical Waiting Lists (1998); Hospitals and Emergency Care in the EU, (1999); Hospitals and Occupational Health in the EU, (2000); Hospitals and Health Care Rationing (2000); The Quality of Health Care / Hospital Activities (2000); Disaster Medicine in Europe - Organisation and Trends (2001); Prevention at the basis of quality of cancer care in the EU (2001). The list of publications can be found on HOPE's website [www.hope.be](http://www.hope.be).

Between 1987 and 1998 Hope published its biannual Information Bulletin in English, French and German with national health care news and news on the official developments in health care in Europe. Since 1998 the Official HOPE Reference Book "Hospital Healthcare Europe" has been published yearly in collaboration with Campden Publishing Limited (London). It replaced Hope's Information Bulletin.

In the HOPE agenda exchange is also very important. Since 1981 a HOPE Exchange Programme has been running for Hospital Professionals who are willing to do a managerial training for 4 weeks in another EU country or in Central and Eastern Europe. It aims to lead to a better understanding of the functioning of health care and hospital systems and, in particular to facilitate co-operation, the exchange and free movement of staff.

In 1989, after the abolition of the Berlin wall, HOPE initiated as well East/West hospital co-operation and twinning by organising joint seminars with WHO and participating in PHARE and TACIS programmes. For some time now the UN Secretariat of Health in Kosovo is also co-operating with HOPE in order to set up twinning/partnership between the 6 major hospitals in Kosovo with 6 hospitals in the European Union.

HOPE is also cooperating with the other health (care) organisations by organising biennial European Health AGORAs (since 1991) and various HOPE seminars.

"Hospital Pharmacies in the European Union" is the first HOPE-publication produced in active collaboration with a European colleague association. HOPE is keen to continue its cooperation with the European Association of Hospital Pharmacists in the future. The hospital pharmacy has indeed a key function in the delivery of quality services to the hospital patient.

Jorma Back  
President HOPE  
April 2002

Prof. K. Schutyser  
Secretary-General

## "WHEN MEDICINES CONCERN NOT ONLY STATES..."

### An attempted comparison between Community drug law and international drug law

By Emmanuel Cadeau \*

Medicines are a concept clearly defined by law. At first they seem to be ambivalent products, relating simultaneously to both commercial and health values. Being objects of life and of hope, drugs are also goods, objects of trade and of profit. Moreover, they present a paradoxical nature: if their first function is to cure or to relieve, they can also cause death or disease when they are defective or badly administered. These are the "shocks" that can result from the clash between economic and health logic in the field of drugs, which explain why this "health good" also constitutes an object of law. Thus many states, rather early, worked out a pharmacy and a drug law intended to reconcile the protection of public health and economic profitability

But, where drugs have for a long time been only an object of national law, variously interpreted in each national legal order, they have now become an object of law with supranational character, in other words an object whose legal status escapes for an increasingly significant part from strictly national state logic. The study of the history of medicinal discoveries already reveals this "supranationalisation" phenomenon, universal history, in which exchanges between national scientific cultures play an essential role. Right from the start, the international transmission of scientific knowledge on drugs was accompanied by a "standardisation", a coding of the scientific standards necessary for their manufacture notably in the shape of pharmacopoeias.

More recently, from the second half of the 20th century, the development of international drug

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markets has reactivated problems in relation to the ambivalence of drugs and, correlatively, led to the reformulation of methods of legal framing of pharmaceutical products. Indeed, the importance of the investments necessary for Research and Development, for the development of new molecules, requires access to an international market, being the only one that enables profitability of committed investments. In this context, the drug industry strongly fears the legal variations resulting from unco-ordinated steps. Since the end of the Second World War, indeed, in all parts of the world, the legal systems have developed which are applicable to the registration of drugs, having the same objective of medical security, but using more or less different means and methods to achieve it. Consequently, if in view of the internationalisation of pharmaceutical activities law is expected to provide for the procedures required for the protection of public health, it should not slow down either exchanges of drugs between national markets or even optimise them.

Thus, in this field, two great sets of legal regulations, with a supranational nature, have developed since the second half of the 20th century, marking a phenomenon "of externalisation" of the sources of drug law.

We can first identify "Community drug legislation" corresponding to the entirety of the legal rules, taken pursuant to the Treaty of Rome of 1957, which establishes the European Economic Community, intended to ensure free movement of drugs in the Community's economic space. Secondly there is also "international drug law", which is much less complete than Community drug legislation and which is making progress, but is still under construction. It is produced mainly within the framework of the World Health Organization and multilateral forums such as the International Conference on Harmonisation (ICH), which brings together industrialists and regulatory authorities of some countries or regions. Regional governmental organisations, such as the Council of Europe, and non-governmental organisations<sup>1</sup> can to

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<sup>1</sup> Namely: the Council for International Organizations of Medical Sciences (CIOMS); the International Medical Association; the manufacturers associations (EFPIA, FIIM etc.); the associations of pharmacists

different degrees be involved in the production of this law.

Whatever the legal order concerned (international or Community), the problems in relation to the legal framing of drugs are centred around the concepts of "health security", "health risk" and more precisely in the case in question of "medicinal risk". These concepts are not recent as shown, for example, by the study of the history of the construction of drug law in France<sup>2</sup>. Simply, "health security" is a concept with a variable impact, according to the concept that a given company, at a given time in its history, has of public health. Thus, within the internal legal order, drugs have been understood in legal terms as an object of law and order. In most nation-state companies it is primarily by the development of administrative policies that health security is taken into account in the face of the risks related to the various activities involved in the manufacture and distribution of drugs.

The question which can then arise is to know in which way, by the implementation of which legal techniques, the supranational laws that are currently being developed will take into account medicinal risk? More precisely, how far can the externalisation of the sources of drug law go? Can a drug policy, comparable to those developed within the framework of the nation states be implemented at supranational level? If so, under which conditions? If not, why and which other legal instruments can be drawn upon to ensure health security at this level in the face of medicinal risk?

A partial reply to these questions can be found by comparing what were probably the two most significant experiments carried out as from the middle of the sixties, in the international legal order, on the one hand, and in the Community legal order, on the other hand<sup>3</sup>. Comparison is particularly useful

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<sup>2</sup> In France drug law has been established as from the XIVth century, conveying a first collective awareness of the concept of "medicinal risk". Cf. CADEAU (E) *Le médicament en droit publique*. L'Harmattan, coll. "Logiques juridiques", Paris, 2000, 514 pages.

<sup>3</sup> The contribution of other organisations with regional vocations such as the European Association of Free Exchange (EAFE), the Organisation of African Unity (OAU) and ASEAN is far too limited to be directly faced with Community law and international law in this field.

here, because in the field of drugs Community law is much more complete than international law and appears a priori as a possible model for the elaboration of international rules of law.

However, if the problems which underlie the elaboration of these two legal systems seem identical at Community and international level (I), the legal instruments available to deal with them are not the same in the two legal orders concerned. This has decisive consequences not only for the method of development of the rule of law but especially for the possible degree of completion of each of the two systems (II). However, the duality of the ensuing legal logics can be relativized because in the end it seems that the effectiveness of the implemented supranational legal devices remains in both cases largely dependent on the role of the national authorities agree to play. The process of externalisation of drug law thus implies the reformulation of this role, which presupposes the adoption of new logics implying the invention of new regulation mechanisms capable of overcoming the blocking effect of the "Nation State" (III).

## I. IDENTIFICATION OF THE PROBLEMS

What is at stake in the construction of supranational drug law is the liberalisation of this important economic and commercial sector without this liberalisation undermining public health. However, as regards the protection of public health, each state seems to develop views that suit it. Some countries thus base drug law on a liberal approach, others prefer to enclose the economic and health care activities relating to it in a denser and stricter body of rules. The diversity of these approaches constitutes in itself a major barrier to the development of regional or global pharmaceutical markets. Given such disparities between national regulations, the accomplishment of supranational drug law presupposes the implementation of a process that can federate and reconcile state pluralisms, so that the states can no longer take refuge behind public health protection preoccupations in order to protect their national market. This objective will then be achieved by the implementation of a system of rendering credible scientific reports.

Awareness of the need to implement an independent and reliable drug evaluation system before medicines are put on the market did not arise everywhere at the same time. In the United States, in the thirties a tragic error in the composition of a syrup for children was the origin of the creation of the Food and Drug Administration and the regulation of drugs. In Japan the registration of all medicines before they can be sold has been obligatory since the fifties. In many European countries the phenomenon that led to the reinforcement of drug regulations was the thalidomide tragedy in the sixties. The latter revealed that, if new generations of synthesis medicines constituted great instruments in promoting health, they could also cause illness or death. In many countries the sixties and seventies were thus marked by an extension of the regulations intended to reinforce the systems for assessing the quality, effectiveness and harmlessness of newly manufactured drugs.

At the same time the pharmaceutical industry accentuated its international dimension and tried to develop new, more global markets. Yet, the registration of drugs and the delivery of marketing authorisations remained the responsibility of individual states. Although the different regulation systems are based on similar requirements as regards quality, effectiveness and harmlessness, the technical details required differ considerably from state to state, thus forcing the industry to multiply the very expensive and often very long tests necessary for marketing products.

The fact that requirements differ from country to country is in the first place justified by the diversity of approaches to the concept of public health, although this can mask protectionist attitudes leading to the setting up of competitive barriers imposed by health security demands. Moreover, in the specific case of Community law, even if the Treaty of Rome does not justify the diversity of national approaches, it implicitly admits them by authorising the Member States, in individual cases and under the control of the Community judge, to oppose the implementation of the principle of "free movement of goods" (article 30 of the Treaty of Rome) for public health reasons (article 36), thus giving the States the possibility of masking certain considerations of an economic

nature by the "justifying" demand of public health protection.

In this context the rationalisation of national regulations thus appears increasingly urgent in view of the increase in both health expenditure and the cost of Research and Development (R&D), in view of the pressing demand of the public that new and effective drugs be put on the market at short notice. Thus it is a question of framing the scientific and economic pluralisms underlying national legislations, so as to allow a greater opening up of the market. Yet, the Community experiment in regard to the registration of drugs shows that the idea of scientific objectivity does not make much sense, because the scientific evaluation of drugs before they are put on the market is likely to be disrupted within the national framework by factors of an economic, scientific or more broadly cultural nature.

What is at stake in the construction of supranational drug legislation therefore lies in the reliabilisation of scientific expertise which is the basis of the administrative decision about putting a drug on the market, namely in such a way that this health policy decision cannot be used as an alibi for the purely economic protection of national markets. This implies the implementation of a "harmonisation process" between national economic and health requirements, making it possible to globalise both demands (economic and scientific) of free movement of goods and public health protection by situating them on the same level. Such a procedure would then depend less on the progressive disappearance of the differences between the national approaches than on the search for a consensual conception of freedom of movement of proprietary medical products. This approach is possible precisely because all those involved are concerned by the treatment of the problems in question: the countries because their stockpiling depends on international trade, manufacturers because the adoption of common standards facilitates marketing procedures in a large range of countries by reducing the cost of evaluation considerably, and finally the competent international organisations which, when their acts are favourably received, prove that their mission has been achieved.

If it appears that the construction of Community and international drug legislation is based on common problems, their treatment relates to two clearly distinct legal logics. With the same problem there corresponds a duality of experiences.

## II. DUALITY OF THE EXPERIMENTS

The experiments carried out within the framework of Community legislation to deal with the above-mentioned problems differ considerably from those carried out at an international level. While Community drug legislation is constructed by juridicisation of scientific standards (1°), international law proceeds by dissociation between legal rules and scientific standards (2°).

1° - The inadequacy of the consensual approach on the basis of which the Community's legal framework was first achieved was quickly denounced, from the beginning of the eighties, as not having made possible the elimination of the "greatest number of technical obstacles to the free movement of pharmaceutical products". As from the beginning of the nineties it was replaced by a new approach, which was based more on a logic of standardisation.

The first Community directive concerning drugs came from the political choice not to challenge immediately and frontally the diversity of national public health conceptions. The adoption of a drug policy at Community level thus led to the search of a middle path based on an essentially consensual procedure, implying respect for each national approach, which an attempt was made to reconcile rather than to unify. The objective of harmonisation was then legally translated by the determination of a flexible legal framework, i.e. a coherent whole of fixed rules common to each Member State which allowed them to frame their national legislations by leaving them the possibility to express their own public health conceptions in their internal law.

Community drug policy thus conceived postulated the existence of a "scientific objectivity" which would lead all Member States in the long term to the same degree of transposition of the Community directives, i.e. the adoption of identical qualitative requirements for each pharmaceutical speciality. The disparities of the relevant national rules would hence be ironed out

automatically and allow the realisation of the domestic drug market. However, the expected ironing out of differences was slow and ultimately not very satisfactory with regard to the objective of freedom of movement of pharmaceutical specialities. From the early eighties the awareness of the incompleteness of the single drugs market therefore resulted in the elaboration of a "new approach" the first legal fruit of which was the Council Regulation of 22 July 1993<sup>4</sup>. This marks a turning-point in the development of Community drug legislation. Breaking with exclusive resorting to the directives of 1965 to 1993 as legal instruments for implementing Community drug policy, it reorientates the latter towards an objective of uniformity of the technical standards in regard to the marketing of proprietary medical products. It finally stresses the process of Community globalisation of the national pluralisms started in 1965.

In the first place, the regulation of 22 July 1993 established a European Agency for the Evaluation of Medicinal Products, whose primary task is to provide the Member States and the institutions of the European Community with the best possible scientific advice on any question relating to the evaluation of the quality, the safety and the efficacy of drugs for human and veterinary use, which is referred to it in accordance with the provisions of Community legislation. According to article 51 of regulation 2309/93/EEC, this scientific advice aims at promoting the protection of human and animal health and of consumers of medicinal products throughout the European Community, and to complete the internal drug market through the adoption of uniform regulatory decisions based on scientific criteria concerning placement on the market and the use of medicinal products.

In the second place the regulation of 22 July 1993 laid down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use. It thus modifies substantially the authorisation system for drug marketing in the European Community. Except for certain specific products, the manufacturer of an innovating drug who wishes to obtain a marketing

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<sup>4</sup> Council Regulation no. 2309/93/EEC of 22 July 1993, Official Journal of the European Communities no. L.214/1 of 24.8.1993.

authorisation, has henceforth a choice between two procedures, one called "centralised Community procedure" and the other "decentralised procedure", which is based on the progressive extension of marketing authorisations delivered by national authorities.

But the effectiveness of the legal system thus implemented within the framework of the European Union is directly related to the specific characteristics of the Community's legal order, which makes it possible to a certain extent to impose a framework on national sovereignties. As regards international law, it draws its force more from consensualism. Its capacity to impose standards in the field of drugs is less strong than that of Community law. Moreover, the force of Community law is also due to the very important role played by the Court of Justice of the European Community in the construction of Community drug legislation<sup>5</sup> in face of the persistency of national resistance to Community integration, a jurisdictional role which does not exist in international law.

2° - The characteristics of the international legal order are clearly different from those of the Community legal order. The international rule of law, which has been worked out on the basis of consensualism, does not have the same force as that of Community law. It generally rebounds on international health law, which has the character of a "soft law"<sup>6</sup>, and a fortiori on international drug law, which corresponds to a primarily "declaratory" law essentially worked out within the framework of WHO, in other words a collection of standards to which it is not intended or to which one cannot immediately attach a socially organised sanction, but which is nevertheless considered as a direct source of reorientation and a source of inspiration for the substantive law in force.

The question which then arises is that of the range of such a body of standards. It is posed all the more clearly in regard to pharmaceutical legislation which,

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<sup>5</sup> See: CADEAU (E) and RICHEUX (J.-Y.), "Le médicament et le juge communautaire" *LPA*, January 1996.

<sup>6</sup> M. BELANGER, "Droit international de la santé", Paris, Economica, 1983, p. 201.

although according to WHO's Constitution, the World Health Assembly has three categories of acts to act normatively (convention, regulation and resolution), has so far set the standards of international health law relating to drugs only by means of resolutions.

And, even if certain authors consider some of these recommendations to be "quasi-obligatory", in particular those relating to the D.C.I. of drugs, they only have the legal value of a simple opinion and their "quasi-obligatory"<sup>7</sup> nature only follows from the politico-scientific consensus which justifies their contents and from the favourable reception that the national authorities give them. WHO resolutions essentially have "an inciting dimension". Their role is "to initiate dynamics in order to co-ordinate the legislations of the states"<sup>8</sup>. Yet, "to co-ordinate" does not mean "to harmonise". WHO remains above all a steering and co-ordinating authority, it is not a supranational organisation. It results from this observation that the essence of WHO's normative activity is largely of a non-compelling nature. It appears to have a reduced and indirect impact on industrialised countries with established legislation relating to pharmaceutical products. On the other hand, as E. Mondielli remarks, "in a developing country the needs are greater, legislation often being more recent and fragmented. For these countries the contribution of WHO's resolutions can be considered to be more important in the field of national law".

It is consequently understandable that big laboratories directly interested in the development of pharmaceutical markets between industrialised countries have tried to initiate, not to contradict, but to parallel WHO's "declaratory" law, a more efficient process of standardisation based on conventional framing of the scientific canons on which the national rules are based, by creating an "International Conference on Harmonisation" (ICH). It is probably in this that the effectiveness of international drug law lies at present.

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<sup>7</sup> MONDIELLI (E), "La prise en compte des normes OMS par le droit français", *Revue Générale de Droit Médical* n° 1, 1999, p. 89.

<sup>8</sup> idem.

The late but real success of the process of harmonisation of regulatory requirements in the field of drugs, initiated by the European Community since the mid-seventies, has shown that rapprochement of national laws was achievable. Thus, at the end of the eighties bilateral discussions were held between Europe, Japan and the United States on the issue of harmonisation.

It was, however, on the occasion of a WHO Conference bringing together the pharmaceutical administrations (Paris, 1989) that a first action plan was adopted. A rapprochement between the regulatory authorities and the International Association of Pharmaceutical Industries could thus take place, leading to conception of an ICH. The birth of the ICH took place in Brussels during a meeting organised by the European Federation of Pharmaceutical Industries' Associations (EFPIA) in April 1990. The representatives of the regulation agencies and industries' associations of Europe, Japan and the United States could thus establish the working and organisation conditions of the ICH<sup>9</sup>. A Steering Committee, which meets at least three times per year, was set up on this occasion. The first meeting of the ICH Steering Committee made it possible to identify the regulatory matters that were to be the priority subject of harmonisation. They were classified in three categories: "security", "quality" and "effectiveness", corresponding to the three essential criteria upheld by the national regulations on the authorisation of new drugs. A working party made up of experts from the six member parties of ICH (Expert Working Groups - EWG) was also created to discuss the scientific and technical aspects of each of the harmonisation topics.

Four series of conferences on harmonisation have been held since 1990. They made possible the

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<sup>9</sup> The ICH is composed of six parties: European Commission (EU); European Federation of Pharmaceutical Industries Associations (EFPIA); Japan's Ministry of Health and Welfare; Japan's Pharmaceutical Manufacturers Association; US Food and Drug Administration; Pharmaceutical Research and Manufacturers of America. It is also worthwhile mentioning that WHO, EFTA (European Free Trade Area) and Canada participate in the ICH as observers and that IFPMA (International Federation of Pharmaceutical Manufacturers Associations) is acting secretary of ICH.

expression of a real scientific consensus leading to the adoption of a significant number of "guidelines" proposing a harmonisation of the main standards referred to by the American, European and Japanese public authorities in authorising drugs. The fourth conference (ICH 4), which was held in Brussels in July 1997, marks the completion of the first phase of ICH. The second phase, which the Steering committee launched in Washington in February 1998, should make possible, on the one hand, the harmonisation of the new technical requirements relating to the development of research and placing on the market of products stemming particularly from biotechnologies and, on the other hand, the updating of "guidelines" previously adopted. In addition this second phase will probably consider the enlargement of the ICH to other States concerned with harmonisation from an industrial and/or administrative point of view.

The assessment of these ten years of experience in the field of international harmonisation shows that the key to the success of ICH is certainly the commitment of the parties to the constant search for objectivity but especially to the adoption of a method of harmonisation (ICH Harmonisation Process) rigorously defined and based on systematic concertation. And we can consider that this process is complete when the recommendation made within the framework of ICH is integrally incorporated in the national or regional regulation systems (in the case of the European Union). Even if the Member States finally keep a quasi-total decisional autonomy regarding the standard resulting from the ICH procedure of harmonisation, experience developed over ten years within the framework of this conference has gradually introduced between the national medical authorities a logic of exchanges based on a scientific culture of consensus<sup>10</sup>. Yet, the optimisation of the international or Community experience implies the simultaneous implementation of new approaches which can accompany the

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<sup>10</sup> The International Conference of Drugs Regulatory Authorities (ICDRA) was established after the same model. It also favours exchanges between these authorities. These discussions are liable to accelerate the development of the harmonisation of pharmaceutical regulations worldwide with the participation of WHO.

reformulation of the role of the State in regard to regulation of pharmaceutical markets.

### III. THE NEED FOR NEW APPROACHES

The idea of a supranational administrative regulation, based on institutional co-operation between the health authorities of the States is not necessarily a utopia. The experiment undertaken within the framework of what can be called " Europe of the drug " illustrates this. As regards drug evaluation, it is translated by the progressive construction of a transnational administrative network. But it should be understood that the implementation of such a network essentially supposes the transformation of the regulating State into an operating State.

The Community regulation of 22 July 1993 launched the creation of an administrative Community network based on the one hand, on the creation of a real Community pharmaceutical administration in the form of a European drug agency, and on the other hand, on the cross intervention of this Community administration and the national administrative authorities concerning marketing of drugs and pharmacovigilance.

The primary task of the European Agency for the Evaluation of Medicinal Products is to provide the Member States and the institutions of the European Community with the best possible scientific advice on any question relating to the evaluation of the quality, the safety and the efficacy of drugs for human and veterinary use, which is referred to it in accordance with the provisions of Community legislation.

Article 50 of the regulation specifies the composition of the agency. It comprises in the first place two existing bodies: the Committee for Veterinary Medicinal Products, responsible for preparing the opinion of the agency on any question relating to the evaluation of veterinary medicinal products, and the Committee for Proprietary Medicinal Products, in charge of the same task for medicinal products for human use. The bringing together of the two committees in the same institution must make it possible to lend them better logistical support so that they can optimise their work. To this end, a common

secretariat has the task of providing both committees with technical and administrative aid and to ensure adequate co-ordination of their work. Finally, the agency is led by an executive director appointed by a management board of directors consisting of two representatives from each Member State, two representatives of the Commission and two representatives appointed by the European Parliament. Article 56 specifies, moreover, that one representative has specific responsibilities relating to medicinal products for human use and the other for veterinary medicinal products.

Since the creation of the European Agency for the Evaluation of Medicinal Products, an administrative network which is both transnational and competitive has thus developed. It is based on an intertwining of administrative regulation competencies between State and Community authorities. More precisely, two series of intertwinings appear, one being related to the activity of drug marketing authorisation and the other one to pharmacovigilance.

As regards marketing authorisation first, the "decentralised procedure" rests on the progressive extension of marketing authorisations delivered by national authorities. It supposes that the administrative authorities of the Member State take account of the result of the drug evaluation performed by the administration of another state. Moreover, the implementation - through the regulation of 22 July 1993 - of the new centralised Community procedure corresponds to a phenomenon of progressive tightening of the Community framework. This leads to the transfer of an administrative police activity so far carried out within the national framework, to the Community authorities, henceforth competent to deliver, under certain conditions, a Community A.M.M. valid in all Member States.

Moreover, the regulation of 22 July 1993 also relates to "monitoring" the drugs that have received marketing authorisation. It initiates the setting up of a Community pharmacovigilance network. The pharmacovigilance system, the aim of which is to monitor the risk of adverse effects resulting from the use of drugs, is based on three requirements. The first corresponds to the requirement that a person in

charge of drug marketing has to have near him permanently a person qualified in the field of pharmacovigilance. The second is based on the requirement that the person in charge of marketing has to notify the competent authority of any presumption of a serious adverse effect. Finally the Member States must ensure that notifications of presumed serious adverse effects be immediately brought to the attention of the European drug agency. The interest of the installation of a pharmacovigilance system is to allow the national and Community authorities to detect products that present a danger to human health and to withdraw them from the market if necessary. Hence Community legislation holds that, when a Member State considers it necessary to modify, suspend or withdraw the marketing authorisation following the evaluation of reports on adverse effects, it should inform the European Agency immediately of it.

The intertwining of national and Community competencies in the field of marketing authorisation and pharmacovigilance thus implies very thorough co-operation of the European Agency with the administrative authorities responsible for the evaluation of drugs. Since the Community Regulation of 22 July 1993 came into force and the European Agency was created, the national authorities in charge of the evaluation of drugs have thus been led to fit gradually into a transnational administrative network. In France, the integration of this network is carried out by means of the Drug Agency, which is thus involved in its function as relay institution in allowing the adaptation of the traditional methods used for enforcing the administrative regulations regarding proprietary medical products, to Community legislation requirements. But the development of this network thus leads to a confrontation, in terms of decisional effectiveness, between the national administrations, on the one hand, and the national administrations and the European agency, on the other hand. This Community administrative network thus takes on a competitive character. The insertion of the French drug agency in this network should then also be understood as the implementation of an institutional valuation technique, not only for the French pharmaceutical administration but also for the national industry. In other words, it is the figure of the

operating State which replaces that of the regulating one.

The progressive construction of supranational drug legislation, combined with the renewal of the problems relating to the legal framework of science in this field, is compelling national legislations to recompose themselves. A central recomposition axis thus seems to result from a reformulation of the protective role traditionally played by the State in the field of drugs, around the idea of the "operating State".

Applied to the State, the idea of operator does not mean marginalisation or reduction of its role. It rather implies a redefinition of its decisional functions in the sense of a revaluation of its executive and transmission functions. The State is no longer the single supervisor of the system, but becomes its main operator - that which constitutes the central part of the system - and ensures its functioning.

The concept of operating State consequently implies the existence of a legal regulation system with both intra- and infra-, extra- and supra-national ramifications, and suggests the emergence in this system of other operators whose functions are partly defined in relation to those of the State.

We can thus observe in Europe in a general way a recent phenomenon of reorganisation of the public health protection systems marked by the creation of regulation and monitoring agencies not only for health products but also for foodstuffs. If the creation of these institutions corresponds first to an institutional treatment of scientific and health problems, it also allows the operating State to play the role of intermediary in the transnational and competitive administrative network required for the optimisation of the international mechanisms for the health security of drugs.

In the end it seems, however, that the transformation of the regulating State into an operating State is really only possible by means of a range of extra-national pressures of a political nature. This is revealed by the long and difficult history "Europe of the drugs". Yet, contrary to Community law, international law remains the fruit of a confrontation

between autonomous and equal national sovereignties. The development of international drug law is no exception to these problems and hence depends largely not only on the commitment of the big economic operators that are the pharmaceutical laboratories, but also on the acceptance of industrial claims by the States.

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### STUDIES

#### The pharmacists' curriculum

Studying to be a pharmacist takes five years (including a diploma thesis) at the university of Vienna, Graz or Innsbruck and results in the degree of "Magister pharmaciae". After completion of the studies there is one year of training on the job in a community pharmacy or a hospital pharmacy (Aspirantenjahr) with an accompanying theoretical course (Aspirantenkurs) and a final exam (Aspirantenprüfung). The successful completion of this training is required to be entitled to work as a pharmacist.

#### Specialisation in hospital pharmacy

There is no specific specialisation degree in hospital pharmacy. A proposal for a postgraduate specialisation in hospital pharmacy according to 85/432/EEC Art. 3 has been developed by a working party within the Chamber of Pharmacists and submitted to governmental authorities.

### THE HOSPITAL PHARMACIST

There is no formal differentiation between the staff members of the hospital pharmacy.

### MEDICINES AND MEDICAL DEVICES

Except from certain OTC products, the distribution of drugs is the monopoly of pharmacies ("apothekenpflichtige Arzneimittel").

Some hospitals are using ATC classification of drugs. The European Pharmacopoeia is used together with the Austrian Pharmacopoeia.

There is no legal separation between drugs for hospital use and drugs for community use. Because of economical reasons pharmaceutical companies try to avoid mix-up between the two channels of distribution. Hospital pharmacies are entitled to supply drugs only to inpatients, outpatients in situations of urgency or emergency and to other hospitals without a hospital pharmacy of their own. Changes in the legal situation (e.g. supply to community or other hospital pharmacies) are

necessary to improve the future situation of hospital pharmacies.

Packaging is usually not different from the drug packaging available in community pharmacies. Pricing, however, is different from that in community pharmacies. It results from the consultations and bid invitations made by hospital pharmacists to the pharmaceutical industries or purchasing groups.

Every medical device on the Austrian market has to fulfil the CE requirements. The EEC directives on medical devices and implantable devices have been implemented in the Austrian regulations.

### THE HOSPITAL PHARMACY PRACTICE

#### Regulations

To include a pharmacy within its structure, a hospital must ask for special authorisation. The licence (Apothekenkonzession) is delivered by the County Major (Landeshauptmann).

#### Financing

The cost of the hospital pharmacy service and medicines is covered by the global hospital budget.

#### Hospital pharmacists' activities

Hospital pharmacists are responsible for the ordering, purchasing, storage and supply of drugs, certain medicinal products, chemicals and reagents.

They also manufacture drugs, on an individual basis, on a small scale as well as on a large batch scale (powders, capsules, topical forms, ophthalmics, cytotoxics, parenteral nutrition fluids, radiopharmaceuticals other IV-fluids, irrigations, disinfectants, reagents etc.). The relevant GMP regulations are applied to all kind of production. Batch scale production is controlled by analytical quality assurance.

Pharmaceutical services include drug information, participation in multi-disciplinary teams (Drugs and Therapeutics Committee, Nutrition Team, Wound Management Team, etc.) and participation in ward rounds.

### THE DRUG CIRCUIT AT HOSPITAL

Hospital pharmacies purchase drugs mainly from pharmaceutical companies and only to a minor extent from wholesalers. Hospitals without a hospital

pharmacy of their own get their supplies from a community pharmacy or a hospital pharmacy (circumvention of the applicable law is quite common).

Drugs are usually stored alphabetically within the pharmacy storage area. Medical device products with large packaging (i.e. infusions) are stored separately. Some products may be stored outside the central pharmacy, but still under its responsibility (i.e. fluids for dialysis and medical gases). A few hospital pharmacies have started to use chaotic storage systems and bar code technology.

Unit dose systems are not established in Austria to date. Prescriptions are submitted in paper form, by telecopy or electronically to the pharmacy department. All hospital pharmacies use computerised systems for ordering, storage and distribution.

Transportation to the ward is performed by ward personnel or the hospital transportation services.

Administration of drugs to the patient is the responsibility of medical doctors and nurses.

It is the pharmacist's responsibility to implement a quick stock rotation to avoid drugs going out of date. Unused drugs may be returned to the manufacturer before the expiry date if the packaging is not damaged. Out of date drugs are destroyed by the hospital.

### **THE OTHER ROLES OF THE PHARMACIST IN A HOSPITAL**

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The hospital pharmacist is part of and often the president of the DTC Committee which defines the hospital drug policy. Drug formularies and/or formularies for special indications (e.g. antibiotics, clinical nutrition) are well established in most hospitals

Drug information is given by hospital pharmacies on an individual basis or by information bulletins. In some of the larger hospital pharmacies drug information centres are established.

The traceability of blood derived products and vaccines is the responsibility of medical doctors (documentation by self-adhesive labels to be added to the patient records), but most hospital pharmacies document batch numbers on a voluntary basis.

Pharmacists are usually involved in the field of hospital hygiene (participation in the hygiene team) and in product selection.

Being involved in the vigilance of drugs and medical devices, and in the Infection and Hygiene Committee, the pharmacist also contributes to security and protection of the environment.

Other roles of the hospital pharmacist are in the field of clinical activities, clinical trials, quality assurance and quality assessment, vigilance concerning drugs and medical devices, nutrition, educational activities and (in some hospitals) bromatology and pharmacokinetic activities.

### **THE RELATIONSHIPS OF THE HOSPITAL PHARMACIST**

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The pharmaceutical staff works under the responsibility of the Pharmacist who is Chief of Department. This chief may delegate part of his responsibility to other pharmacists in his team, but he remains responsible over them.

In his relationship with physicians, the pharmacist is used to drug replacement. He has a long tradition of buying generics and working with the international common denomination of the drugs.

The pharmacist is usually not part of the administrative team.

The relation of the hospital Pharmacist with the insurance organisation is very occasional, and on very specific points.

Other relationships of the hospital pharmacist are nurses, nutritionists, staff from the sterilisation services, staff from the computer services, staff from the technical services and transportation services of the hospital and staff from the prisons (for the general hospitals in charge of providing treatment for the prisoners).

### **FACTS AND FIGURES**

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Number of hospital pharmacists versus community pharmacists: 228/4.104

There are about 50 hospital pharmacies, mainly in the larger ("focus hospitals") of the 330 hospitals. They employ 228 hospital pharmacists and 482 other staff members (figures 1999)

**STUDIES**

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**The pharmacists' curriculum**

Pharmacy is a university degree. The studies take five years, including six months of practice, and result in the diploma of "Apotheker", "Pharmacien".

**Specialisation in hospital pharmacy**

Specialisation in hospital pharmacy takes an additional year of university study, including three months of practice.

**Mutual recognition of diplomas and free circulation of pharmacists**

To be recognised as a hospital pharmacist, the Belgian legislation formerly required an extra year of hospital pharmacy training at one of the Belgian universities. Since this was in conflict with the European legislation on free trade of goods and services, this obligation has been replaced by the requirement of at least 500 hours of training at university level. To remain acknowledged as a hospital pharmacist the pharmacist must also have a permanent accreditation.

**THE HOSPITAL PHARMACIST**

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Hospitals must have at least one hospital pharmacist (full-time) for every 150 weighted hospital beds. Weighting depends on the specificity of the hospital service (e.g. intensive care represents more value than chronic disease services).

**MEDICINES AND MEDICAL DEVICES**

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The pharmacy has a monopoly on buying and distributing 'drugs' (are considered as drugs: patent drugs, magistral preparations, the current pharmaceutical products, antiseptics and disinfectants, registered diet products, sterile medical and surgery products, implants and prostheses, products under clinical trial and medical samples for hospital patients).

The hospital pharmacy can only deliver drugs to inpatients, or to ambulatory patients, as far as these drugs are used during the examinations or in the one-day clinic.

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Medical devices on the Belgian market fulfil CE marking.

## **THE HOSPITAL PHARMACY PRACTICE**

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### **Regulations**

Every hospital is obliged to implement a hospital pharmacy within its structure in order to qualify for authorisation.

### **Financing**

Staff and other expenses to run the pharmacy are covered by the global hospital budget. Refunding of medicines by the health insurance scheme is done per product, while the patient fee is fixed as a lump sum per hospital day.

### **Hospital pharmacists' activities**

The hospital pharmacist is responsible for the individual drug dispensation (i.e. personalised dispensation of drugs under a nominal medical prescription).

The pharmacist is also responsible for the supply, storage and appropriate conservation of drugs and the analysis and quality control of raw materials and drugs.

Another task of the hospital pharmacist consists in sterile and non-sterile drugs. By "preparation" is understood, any manipulation of raw materials or ready products in view of obtaining a reconstitution, a new composition or a new form of administration. The pharmacist supervises the galenic preparation of injectable radiopharmaceutical solutions.

## **THE DRUG CIRCUIT AT HOSPITAL**

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The hospital pharmacy service receives drug supplies directly from manufacturers.

Drug supplies are stored in the pharmacy service. Some products (cf. medical gases) may be stored outside the hospital pharmacy, but remain under the responsibility of the pharmacist.

All drugs are dispensed on medical prescription.

Specific regulations apply for narcotics.

Dispensation shall, whenever possible, be carried out by using unit dose presentations. The number of individually dispensed units will never exceed the number required for a treatment period of maximum five days.

Transportation to the ward is performed by the hospital pharmacists, ward personnel or the hospital transportation services.

Administration of drugs to the patient is the nurses' responsibility.

The hospital pharmacist is responsible for implementing a quick stock rotation to avoid drugs going out of date.

## **THE OTHER ROLES OF THE PHARMACIST IN A HOSPITAL**

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The hospital pharmacist takes part in multidisciplinary workshops, in particular in the field of parenteral and enteral nutrition, oncology, infectious diseases and dermatology. He also takes part in clinical tests.

The hospital pharmacy supplies all necessary pharmacological, toxicological and pharmacotechnical drug information to the medical and nursing staff, each in their respective field.

There is active collaboration with the nursing staff on the procedures for drug manipulation and the practical recommendations for the safe use of drugs and their administration to patients.

In collaboration with the medical staff, the hospital pharmacist organises and promotes pharmacovigilance, which includes the collection and analysis of reports on adverse reactions to drugs, the transmission of such reports to the National Centre of Pharmacovigilance within the Ministry of Public Health and Environment and providing information specifically oriented toward adverse reactions to drugs.

The pharmacist also provides sanitary assistance to both hospitalised and discharged patients.

He makes antiseptics and disinfectants available for the various hospital departments and guarantees the quality of the daily activity on central sterilisation.

In collaboration with the Senior Physician, the hospital pharmacist prepares an annual report on the consumption and the cost of drug based therapies, and on the relation between drug consumption and the diseases treated within the hospital.

## **THE RELATIONSHIPS OF THE HOSPITAL PHARMACIST**

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The hospital pharmacist collaborates closely with the hospital manager as well as with the staff responsible for the various aspects of hospital activity and in

particular with the Senior Physician, the physician-chief of department, the chief of the nursing staff and the paramedical, administrative, financial and technical services of the hospital.

In respect of questions concerning pharmaceutical activity, the hospital pharmacist offers his collaboration to the Medical Council of the hospital, to the Nursing Council and to the Ethical Committee. The hospital pharmacist participates actively in the activities of the Committee for Hospital Hygiene, the Medical-Pharmaceutical Committee and the Committee for Medical Supplies.

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## STUDIES

### The pharmacists' curriculum

The legal basis for the formation of pharmacists is the "Approbationsordnung für Apotheker" (License regulations for pharmacists) of 19.07.1989 which has been issued on the basis of §§5 and 14 alinea 3 of the "Bundes-Apothekerordnung" (Federal regulations for pharmacists) of 19.07.1989. The formation as a pharmacist was newly regulated with the "Approbationsordnung" with due regard to the pharmacist directives of the EU (85/432/EEC and 85/433/EEC).

The pharmaceutical formation includes:

1. a four-year pharmacy study at a university including theoretical courses in form of lectures and seminars as well as practical training with the scheduled standard number of hours. The chronological distribution of the theoretical courses over the individual study subjects is left to the local universities. It is the examination office of the Land, to which the application for admission is to be made, that decides on the admission to the individual examination segments.
2. an 8-week clinical traineeship (Famulatur) to familiarise the student with the tasks of a pharmacist. In addition, it gives the student insight into the organisation and operations as well as the legal regulations for pharmacies and introduces him or her to the terminology. The clinical traineeship is to be completed under the supervision of a pharmacist between lecture periods on a full-time basis, before the student registers for the first segment of the state examination. At least four weeks of the "Famulatur" must be completed in a public pharmacy, which should not be a branch pharmacy; the remaining part of the traineeship can be completed in a hospital pharmacy or a pharmacy in the armed forces, in the pharmaceutical industry, a pharmaceutical testing office or a comparable institution including the armed forces.

3. a 12 months' practical training is divided into:
  1. six months in a public pharmacy
  2. six months, which can alternatively be completed in a) a public pharmacy, b) a hospital pharmacy or a pharmacy in the armed forces (3 months can also be completed on the ward), c) the pharmaceutical industry, d) a university institute or other appropriate scientific institutions inclusive those of the armed forces, e) a pharmaceutical testing office or a comparable institute including those of the armed forces.
4. the pharmaceutical examination, which is to be made in three examination sections

The time limit for the course of study is 4 years. Conditions for admission are the general matriculation standard (Abitur) or the proof of qualification for enrolment at a university and the physical aptitude for exerting the profession. The acquisition of the qualification for enrolment at a university depends on the relevant law regulations of the individual "Länder".

Knowledge of Latin is not compulsory, but can be advantageous in view of the pharmaceutical and medical terminology during the studies. A practical activity (practical course) before the beginning of the studies is not required.

After the state examination has been passed, the pharmacist license (Approbation) can be applied for at the responsible authority.

Given the increasing speed of progress in medicine and pharmacy, continuous further training for pharmacists is unavoidable. Therefore the Regional Pharmacists' Chambers of the 16 German Länder, to which all pharmacists belong by operation of the law, are obliged to ensure further training of pharmacists. Further training can only be started after the licence as pharmacist has been granted. The structure of the further training results from the regulations on further training issued by the Pharmacists' Chambers on the basis of the "Heilberufsgesetze" (laws on the medical professions). These regulations on further training regulate the kind, extent and implementation of the further training. At present, further training is particularly possible in the fields of chemist's shop

pharmacy, clinical pharmacy, pharmaceutical technology, pharmaceutical analysis, medicine information and public health. A successfully completed further training entitles to bearing a specialised pharmacist designation (e.g. „Pharmacist in clinical pharmacy“).

### **Specialisation in hospital pharmacy**

With the „2. Verordnung zur Änderung der Approbationsordnung für Apotheker (2. AAppO-ÄndV)“ (2nd decree amending the admission decree for pharmacists), which has become effective on 1 October 2001, Clinical Pharmacy was established as independent 5th examination course, whose subject is the optimisation of the use of medicines on and by the patient. With this course knowledge is e.g. imparted about special pharmaceutical therapy, criteria for the evaluation of medicines, profit risk assessment of a drug therapy, therapy recommendations on the basis of concrete patient cases, health economics.

The "2. AAppO- ÄndV" aims particularly at preparing the pharmacists in their training henceforth more on informing and counselling patients and doctors. In this connection the possibility was offered to students to complete 3 months out of the 6-month practical training in a hospital pharmacy (or a pharmacy in the armed forces) on the ward of a hospital including those of the armed forces.

### **Mutual recognition of diplomas and free circulation of pharmacists**

Mutual recognition of diplomas is subject to certain conditions, which are laid down in the admission decree for pharmacists (according to §20 AAppO) and the federal decree on pharmacists (Bundesapothekerordnung). If a licence is to be granted, the applicant that has not been trained according to the regulations of the AAppO must present documents on his completed pharmaceutical education instead of the certificate. The competent authority may require the presentation of further proofs, particularly on the authenticity of the documents presented and on the activity done hitherto. Instead of the certificate, nationals of other member states of the European Communities or of the other contracting states of the Agreement on the

European Economic Area can either present a certificate of acknowledgement issued by the competent authority of the native country or the country of origin, or an extract from the penal register issued by such an authority, or, if the latter cannot be produced, an equivalent proof.

### **THE HOSPITAL PHARMACIST**

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The prospects of hospital pharmacists should be considered in direct relation with the situation of the hospital pharmacy. It is to be expected that supply by other pharmacies (public or other hospital pharmacies) will further increase particularly in the case of smaller hospitals. This presupposes that the supplying pharmacies are adequately staffed.

As regards promotion possibilities, a pharmacist can take over the representation of the chief pharmacist or the management of a hospital pharmacy. As a rule the chief pharmacist is in his position as head of the department directly subordinate to the hospital management. The remuneration for employed pharmacists consists of the basic remuneration, the residential allowance (depending on the family status), a bonus and property-creating performances. Remuneration according to the Bundes-Angestellentarifvertrag (BAT, Federal wage agreement for employees) is done by remuneration groups. A 45-year old chief pharmacist with at least five permanently subordinate pharmacists has in remuneration group I a gross income of 5116.24 euros/month (status: January 1997).

### **MEDICINES AND MEDICAL DEVICES**

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Since 1995 there exist two European licensing procedures:

- Central licensing, which is compulsory for all medicines manufactured using biotechnological procedures. Other technologically high-quality medicines can optionally be licensed centrally. Licensing is done by the European Medicines Control Agency (EMA) which has been created in 1995.
- The decentralised procedure of mutual recognition between member states is based on licensing granted in any of the EU member states, which can be extended to other states within the scope of mutual recognition.

Apart from both "European" licensing procedures, there is as before the possibility to obtain licensing of a medicine in a sole Member State through the national procedure. The national licensing authority for Germany is the Federal Institute for Medicines and Medicinal Products (BfArM). Also in the purely national licensing procedure the European directives and guidelines applicable to the other procedures prevail so that for the national procedure basically the same requirements and standards apply as for the „European" procedure. National licenses represent the same scientific standard as other licenses and can be used as basis (starting point; point of departure) for the mutual recognition procedure.

With the 10th amendment of the law on medicines, which became effective on 12 July 2000, in Germany the procedure for medicines under post-licensing was tightened up and the regulations on post-licensing were further adapted to those on the new licence of medicines, thus taking account of certain objections of the European Commission who had previously pointed to a lacking conformity of a few national regulations with Community law.

The law on medical devices (MPG), which was published in the Bundesgesetzblatt on 2 August 1994 and modified by law of 6 August 1998, transposes Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices as well as Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, into national law.

The obligation to transpose the EC Directive on in vitro diagnostic medical devices (98/79/EC) as well as the EC Directive 2000/70/EC amending Council Directive 93/42/EEC (Concerning medical devices incorporating stable derivatives of human blood) made a modification of the law on medical devices necessary.

The modification of the law on medical devices was published in the Bundesgesetzblatt on 13 December 2001 and has become effective on 01 January 2002.

The European Waste Catalogue (EWC) and a list of dangerous waste have been elaborated on the basis

of Council Directive 75/442/EEC of 15 July 1975 on waste and Council Directive 91/689/EEC of 12 December 1991 on hazardous waste. Both the catalogue and the list have been transposed into German law by the "Verordnung zur Bestimmung von besonders überwachungsbedürftigen Abfällen" (Decree defining waste that particularly requires inspection) and the "Verordnung zur Einführung des Europäischen Abfallkataloges" (Decree on the introduction of the European Waste Catalogue).

At present a draft "Regulation for transposing the European list of wastes" is under consideration, with which the Commission Decision 2001/118/EC of 16 January 2001, 2001/119/EC of 22 January 2001 and 2001/573/EC of 23 July 2001 amending Commission Decision 2000/532/EC of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1 (a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant Article 1 (4) of Council Directive 91/689/EEC on hazardous waste has to be transposed in national law.

This decree on a list of waste regulates the assignment of waste to certain waste codes and their disposal, including waste of drugs. Waste code EWC 0705 includes waste from the manufacture, formulation, supply and use of pharmaceuticals, whereas waste code EWC 1801 includes waste from natal care, diagnosis, treatment or prevention of disease in humans. Further recommendations for the disposal of waste from institutions for human medicine are given in the LAGA directive (Länderarbeitsgemeinschaft Abfall), which is presently being revised.

## **THE HOSPITAL PHARMACY PRACTICE**

### **Regulations**

As regards the medical supplies in the hospital, there are no regulations that oblige the hospital to keep an own hospital pharmacy. The hospital management therefore has the possibility:

1. to establish its own hospital pharmacy
2. to be supplied by the hospital pharmacy of another hospital

3. to conclude a supply contract with a public pharmacy.

To secure a highly qualified medicine supply also to hospitals supplied by a public pharmacy, in 1980 in conjunction with the ABDA, the Federal Association of the German Pharmacists' Organisations, the DKG has elaborated a model for an adequate contractual agreement between hospital and public pharmacy.

### **Financing**

As regards medical supplies and pricing for medicines, the hospital sector and that of panel doctors are considerably different in Germany.

In the hospital, prices are freely negotiable. As a rule they are directly negotiated with the pharmaceutical producer. Some hospitals have merged into purchasing groups. In this case the supply is done directly to the hospitals, whilst the negotiations are carried out on the basis of the better negotiation position (larger quantities, better discounts) concentrated for all hospitals merged into the purchasing group. Discounts in kind are also granted to hospitals.

As a general rule, the hospital pharmacy may only dispense medicines to inpatients and ambulant operated patients. As hospitals are more and more open to outpatient care, this sharp legal regulation is no longer considered as up-to-date by many people. A corresponding amendment of the law on pharmacies is being politically discussed for quite some time now.

The medical supply in the sector of panel doctors is characterised by a graduation of prices corresponding to the distribution channel „manufacturer - pharmaceutical wholesalers - public pharmacy". The various margins (wholesale margin, pharmacy margin) are regulated in the medicine price regulation (Arzneimittelpreisverordnung). The price is almost doubled from the factory gate to the patient. The wholesale margin varies from 17.4% (lowest price category) to 10.7% (highest price category), whereas the pharmacist's profit margin ranges between 40,5% and 23,1%. Public pharmacies must allow 5% of the amount as discount to the social health insurance funds. About

1/3 of the medicine price is sales expense. In addition, in Germany the full turnover tax amounting to 16% applies.

The share of the complete medicine requirements in the hospital budget is about 16% (status: 1998). Apart from medicines, these requirements include other items such as blood, stored blood and blood plasma, bandaging material, drugs and adjuvants, consumption material and instruments, laboratory equipment, pharmacy equipment, implants, grafts, dialysis equipment etc.

### **Hospital pharmacists' activities**

The hospital pharmacist is responsible for the pharmaceutical services in the hospital. Medical care in the hospital always includes pharmaceutical care, i.e. the provision of the inpatients with medicines, diagnostic agents, reagents, and other medical products. In the hospital the right medicine should be available to the right patient in the right composition at the right time. This presupposes close and permanent collaboration of the doctors with a pharmacist. In the hospital, pharmacists are competent partners of the doctors. Hence the hospital pharmacy staff is not only responsible for the distribution of the medicines, but they also advise the hospital doctors on effect and efficacy as well as use of medicines. It is responsible for a comprehensive information and documentation system on medicines and their risks. Only in this way diagnostics and therapy can be performed in a medically efficient and at the same time pharmaceutically faultless way.

The pharmacist secures a comprehensive stockpiling and supply of the wards and units of the hospital with medicines. On the wards he checks the perfect condition of the medicine supplies and their proper conservation. Furthermore, the pharmacist must guarantee an economically justifiable medicine supply. Therefore he collaborates on the collection and assessment of data on the use of medicines and makes recommendations for the planning, organisation and control of the use of medicines in the hospital.

In the hospital pharmacies, medicines are also manufactured in single-part production (Rezeptur)

and on a small industrial scale (Defektur). This is especially true when the required medicine is not available on the market in the speciality, quality or quantity demanded in the hospital. Exactly the possibility to take part in the development and production of medicines is attractive to many pharmacists in hospital pharmacies. Today many hospital pharmacies are already specialised pharmacies, in which a high quality production of cytostatic drugs can be achieved. Moreover, the pharmacist collaborates in the information and training of the nursing staff. He is also involved in the training and supervision of the pharmacists and pharmaceutical-technical assistants.

The hospital pharmacist must basically plan, organise and supervise the whole medicine circuit from the production, selection and requisition over the distribution and transport to the application on patients.

To reduce the large number of available medicines to a clear necessary degree for the individual hospital, most hospitals have Drug Committees. Here the hospital pharmacist collaborates as a member or executive manager of the Drug Committee on the drawing up and adjustment of lists of drugs, with due regard to medical, pharmaceutical and scientific points of view. The work in the Drug Committee is very important for the control of the use of medicines in the hospital and requires a strategic and purposive procedure, because the decisions taken in this body do not only depend on scientific knowledge. As a rule the chief hospital pharmacists chair these committees.

In some Länder the establishment of a Drug Committee in the hospital is prescribed by law ("Landeskrankenhausgesetze", hospital laws of the Länder).

## FACTS AND FIGURES

Ratio:

Hospital pharmacists / Total number of recognised pharmacists:

$1857/52221 = 1/28.1 = 3.57\%$

- Number of hospital pharmacist (1999): 1,857 (of whom 912 male, 945 female)

- Total number of recognised pharmacists (1999): 52,221 (of whom 20,480 male and 31,741 female)

Particularly the larger German hospitals keep their own hospital pharmacies. The total number of hospitals is decreasing, but more and more hospitals are supplied by other hospital pharmacies: Notwithstanding the job slashes and the austerity measures in the public sector, the number of pharmacists occupied in hospitals remained almost stable.

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## **STUDIES**

### **The pharmacists' curriculum**

To qualify as a pharmacist, students must successfully complete a five-year university degree, including 6 months of training at a community or hospital pharmacy or in the pharmaceutical industry. The resulting diploma is called "Candidata(us) Pharmaciae" (cand. Pharm.).

The Royal Danish School of Pharmacy is the only school of pharmacy in Denmark. It has restricted access according to the student's qualifications in high school.

### **Specialisation in hospital pharmacy**

There is no specialisation in hospital pharmacy. It is expected to be established in 2002. The curriculum will be in accordance with the EU guidelines for hospital pharmacy specialisation.

## **THE HOSPITAL PHARMACIST**

The pharmacists working in hospitals have no specific legal status, but are part of the distribution monopoly for drugs. The head of the pharmacy must be cand. pharm., and certain processes are to be carried out by pharmacists.

## **MEDICINES AND MEDICAL DEVICES**

The pharmacy (community and hospital) has a monopoly to sell and distribute drugs. Licenses are given by the Danish Medicines Agency.

The European classification of drugs, the ATC system, is widely used in Danish hospitals. The European Pharmacopoeia is in use including a 'DLS' supplement (Danish Medicines Standards published by the Danish Medicines Agency).

With the exception of a limited number of drugs (e.g. growth hormones), Danish hospitals do only supply outpatients with drugs until the patient can get his medicine from a community pharmacy.

The hospital drug supply is purchased through an EEC tender once a year. Therefore the prices for a

given drug differ from those in community pharmacies.

Drug policies are outlined by the hospitals' DTC. As there is no national Drug Formulary, Local Drug Formularies are in use.

The EEC directive on medical devices has been implemented in Denmark. The device covered by the legislation is therefore marked with the CE mark.

## **THE HOSPITAL PHARMACY PRACTICE**

### **Regulations**

Only the Danish counties and the Copenhagen Hospital Corporation are allowed to open hospital pharmacies. Hospital pharmacies must fulfil the provisions of the pharmacy acts. They are inspected by the Danish Medicines Agency.

### **Financing**

The budgets for the hospital pharmacies in Denmark differ from county to county, but mostly they have a global budget, covering drugs, staff and other expenses to run the pharmacy. There is no national budget.

### **Hospital pharmacists' activities**

The hospital pharmacist is responsible for the purchase, storage, and distribution of drugs. The pharmacist keeps records of the overall consumption incl. blood derivatives.

Hospital pharmacists produce drugs to GMP level (5-10% of the turn over e.g. LVP's) and reconstruct TPN, antibiotic and cytotoxic drugs.

Hospital pharmacies are in general not involved in the production, sterilisation and distribution of medical devices.

The hospital pharmacies are responsible for handling outdated drugs and drugs in form of waste.

## **THE DRUG CIRCUIT AT HOSPITAL**

To a minor degree the pharmacist is involved in packaging and distributing the drugs to single patients, according to the unit dose concept. However, clinical pharmacy where pharmacists work on a daily basis on the wards with the medication of patients, guiding nurses and doctors, is becoming more and more widespread in Denmark.

## **THE OTHER ROLES OF THE PHARMACIST IN A HOSPITAL**

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The hospital pharmacy is the drug information centre for all hospital professionals.

Hospital pharmacists are responsible for the quality control of drugs and for setting up safety procedures in the hospital pharmacy.

The pharmacists also have a role in research and development within the areas of hospital pharmacy, pharmacy services and products. They take part in clinical trials.

As a member of the DTC the hospital pharmacist is the editor of the Drug Formulary of the hospital.

Hospital pharmacists are also members of the hygiene organisations of hospitals.

## **THE RELATIONSHIPS OF THE HOSPITAL PHARMACIST**

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All hospital pharmacists work under the responsibility of the head of the pharmacy.

As regards the relation with physicians, pharmacists have the right to generic prescription.

The hospital pharmacist has the role of a consultant, and is not a formal part of the administrative hospital level.

There is no relation with insurance companies.

## **FACTS AND FIGURES**

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About 4% of all pharmacists are working in a hospital pharmacy.

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## **STUDIES**

### **The pharmacists' curriculum**

To qualify as a pharmacist, students must successfully complete a five-year university degree, including six months of practice training. Most universities have a numerus clausus: access to the studies is restricted to students with certain high school qualifications. The diploma is called: "Licenciado en Farmacia".

### **Specialisation in hospital pharmacy**

There is a specialisation in hospital pharmacy, which takes 48 months (4 years). It has been legislated in the "Real Decreto 2708/1982" of 15 October, which regulates the studies during the specialisation period and the way to obtain the specialisation diploma.

### **Mutual recognition of diplomas and free circulation of pharmacists**

Mutual recognition of diplomas and free circulation of pharmacists have been transposed into Spanish legislation by the "Real Decreto 1667/1989" of 22 December (BOE no. 4, 4/1/90), the "Real Decreto 1595/1992" of 23 December (BOE no. 34, 9/2/93) and the "Orden del Ministerio de Sanidad y Consumo" of 14 October 1991 and 16 October 1996, which regulate the conditions and homologation procedure for foreign diplomas of specialist pharmacists.

## **THE HOSPITAL PHARMACIST**

The hospital pharmacist has the same status and belongs to the same professional category as physicians. The hierarchical structure of the pharmacy department is similar to that of medical departments. The "Orden Ministerial" of 1 February 1977 establishes that the pharmacy services will be developed within the entirety of all hospital services from the functional and hierarchical points of view and that they depend on the same Hospital Board Direction.

## **MEDICINES AND MEDICAL DEVICES**

Pharmacies have a monopoly for selling drugs. Hospital pharmacies dispense medication only to inpatients but outpatients can receive drugs for hospital use.

In 1993 the Council of Europe established the European Agency for the Evaluation of Medicinal Products (EMA) and laid down the procedures for the authorisation and supervision of medicinal products. Currently, there are three procedures: the Centralised Community authorisation procedure (obligatory for biotechnology drugs and optional for new drugs), the Mutual Recognition procedure (for products already authorised in a Member State) and the National Procedure. The "Agencia Española del Medicamento", which was created in 1995, is responsible for the licensing of drugs.

The Spanish Pharmacopoeia includes particularly Spanish monographs and monographs of the European Pharmacopoeia.

Specific regulations describe the use of drugs in hospitals ("Circulares N° 11/91 y N° 12/91" of 17 Apr., "Circular N° 20/93" of 18 Nov., both from the Dirección General de Farmacia y Productos Sanitarios) dividing drugs in 3 categories: "uso hospitalario" (only in-patient), "diagnóstico hospitalario" (prescribed by hospital physician and dispensed by pharmacy shop), "con receta médica" (prescribed by any physician, acquired in pharmacy shop).

Drug prices are established by the government: PVP (customer sales price) and PVL (laboratory sales price).

Hospital pharmacists may negotiate the PVL with the laboratory, getting discount for some drugs. They prefer to buy drugs in unit dose and 'clinic packing'. Multidose packages are usually repacked by the hospital pharmacy.

The EEC directive on medical devices and implantable devices have been transposed into Spanish legislation.

## **THE HOSPITAL PHARMACY PRACTICE**

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### **Regulations**

The hospital pharmacist's role has been regulated by the "Orden Ministerial" of 1 Feb. 1977 (BOE no. 43 of 19 Feb. 1977).

The "Ley del Medicamento" (Ley 25/1990 of 20 Dec., BOE no. 306 of 22 Dec. 1990) regulates all the matters related to drugs and includes articles related to the hospital pharmacy. Every hospital with more than 100 beds must have a pharmacy department under the responsibility of a pharmacist specialised in hospital pharmacy.

### **Financing**

The global budget is on average about 8% of the hospital's general budget and does not include the pharmacist's salary.

### **Hospital pharmacists' activities**

Before validation, medical prescriptions are analysed on their adequacy or suitability to dosage, interactions, incompatibilities, side effects, etc... The hospital pharmacist must assure a safe and efficient system of drug dispensing.

The hospital pharmacist is responsible for the manufacturing of preparations that may be necessary or convenient for the hospital.

The pharmacist must guarantee full observance of the laws concerning narcotics, psychotropic substances, clinical trial medications or any other drugs that require special control. For the other products periodical controls are performed.

Most cytotoxic drugs and TPNs are prepared in the hospital pharmacy.

Not all hospital pharmacies are involved in the management of medical devices and disposables (mainly because of staff shortage). However, the pharmacist always gives advice on the selection of products before purchasing. Local regulations sometimes put the competencies of the hospital pharmacy regarding medical devices on the same level as drugs.

## **THE DRUG CIRCUIT AT HOSPITAL**

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The hospital pharmacy service receives drug supplies directly from manufacturers or from wholesalers.

Drug supplies are stored in the pharmacy service. Pharmacists can allow some drug store in wards and other hospital units, but they remain responsible for drugs.

In 1995 more than 54% of hospitals had more than 50% of beds under unit dose drug distribution, which means that this system is widespread in the country. For the rest the pharmacy can send drugs in bulk or for specific patients.

Transportation to the ward is performed by pharmacy staff.

Drugs are administered to the patient by nurses, but the 'Ley del Medicamento' stipulates that the pharmacist has to guarantee the correct administration of drugs to the patient and to develop the means for that purpose.

The pharmacist has also to guarantee the good conservation of the drugs and must control expiration dates of the drugs at the hospital. He must periodically inspect all drug deposits available at the hospital. Unopened packages can be returned to the manufacturer within six months after the expiration date.

## **THE OTHER ROLES OF THE PHARMACIST IN A HOSPITAL**

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The pharmacist belongs by law to the Drug and Therapeutic Committee (DTC) and to the Clinical Trials Committee (CTC), playing an important role in the selection of drugs for the Drug Formulary.

He also takes part in drug audits, drug evaluation studies and any activities dealing with drugs in the hospital.

The pharmacy service has a Drug Information Centre from which the pharmacist provides both active (bulletins) and passive (drug consults) information to the medical and the nursing staff as well as to the patient. He implements and participates in protocols for the good use of drugs in the hospital.

The hospital pharmacist keeps track of all blood derivative products.

The pharmacist usually takes part in the Infections and Hygiene Committee. The Spanish law stipulates that antiseptic products and disinfectants that may be used in human beings have to be registered as drugs and have to be dispensed from the hospital pharmacy.

Other roles are in the field of pharmacokinetic activities, outpatient administration of certain drugs (drugs for hospital use), educational activities (training of pharmacy students and nurses, organisation of meetings and other educational activities), clinical pharmacy and pharmaceutical care (where the pharmacist assumes responsibility for the outcomes of medication therapy, rather than merely provide functions).

### **THE RELATIONSHIPS OF THE HOSPITAL PHARMACIST**

There are several kinds of healthcare professionals working in the pharmaceutical services. They come under different authorities from the hierarchical point of view:

- nurses come under the nursing head;
- technicians come under the nursing head;
- hospital porters come under the General Services Board;
- clerks come under the Clerks Director;
- pharmacists come under the Medical Director.

As regards the relationship with physicians, the DTC usually allows the pharmacist to change the brand name of the drug, taking into account not only economic issues but also other issues that are important from the pharmaceutical point of view: packaging of the drug (unit dose forms, etc), quality of the supplier's service, information provided, etc.

There is a close relationship between the pharmacist and the nursing staff resulting in a close collaboration. The pharmacist helps the nurse to deal with problems related with drug administration, drug stability, etc...

The hospital pharmacist is sometimes a member of the Board of Directors.

There is no specific relationship between pharmacists and insurance organisations.

### **FACTS AND FIGURES**

The hospital pharmacists represent 3.67% of the total number of pharmacists. There are about 2.25 pharmacists per hospital (3.94 pharmacists in case of hospitals with more than 100 beds).

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### STUDIES

#### The pharmacists' curriculum

There are two levels of degrees in pharmacy: B.Sc.Pharm. (assistant pharmacist) and M.Sc.Pharm. (pharmacist), which can be obtained at the Helsinki and Kuopio Universities.

The Bachelor's study programme consists of 120 credits (a credit unit refers to an input of ± 40 hours work required from the student to achieve the set objectives). The programme can be completed in three years. The Master's programme consists of 200 credits. This programme can be completed in five years. Both programmes include practical training for 6 months in a community pharmacy or in a community and hospital pharmacy. A numerus clausus restricts access to both programmes.

#### Specialisation in hospital pharmacy

Specialised education in hospital pharmacy (both for assistant pharmacists and pharmacists) is offered by the Pharmaceutical Faculty at Kuopio University but is not compulsory for working in a hospital pharmacy.

#### Mutual recognition of diplomas and free circulation of pharmacists

The requirements for the pharmacist degree (M.Sc.Pharm.) are based on the directive of the Council 85/432/ETY. The diploma of an assistant pharmacist is a Nordic characteristic for pharmacy diplomas.

### THE HOSPITAL PHARMACIST

In most hospitals the hospital pharmacy or the medicine centre is one of the medical service departments. The manager of a hospital pharmacy is required to have a M.Sc. in pharmacy while the manager of a medicine centre is required to have a M.Sc. or B.Sc. in pharmacy. A manager of a hospital pharmacy or a dispensary is usually authorised by the medical director of the hospital.

### MEDICINES AND MEDICAL DEVICES

Only licensed (mainly private) community based pharmacies have a monopoly on the sale of medical

products. The pharmacies of hospitals and other medical institutions do have a monopoly on medical products within their own boundaries.

Discharged (out)patients can only receive medicines from the hospital to ensure the continuity of the therapy until these patients can get the products they need from the community pharmacy. Also special patient groups (e.g. AIDS) can obtain their medication from the hospital pharmacies.

Besides the centralised EU application procedures where EMEA is handling the applications, the National Agency for Medicine has been responsible for market authorisations since 1999.

The European Pharmacopeia, which is based on e.g. EMEA definitions, is in use in Finland. Also ATC coding is in use.

Different acts (395/87, 402/184, 583/86, 1289/93, 1143/94...) stipulate regulations concerning drugs used in hospitals.

The procurement plan for drugs in hospital pharmacies and medicine centres is prepared by asking for quotations from manufacturers and resellers and importers of drugs. Some drugs may have considerable rebates when sold to the hospitals.

Every medical device on the Finnish market must fulfil CE marking (EU directive concerning medical devices 93/42/ETY).

Also the EU directives on medical and implantable devices and on waste of drugs and protection of the environment have been implemented.

### THE HOSPITAL PHARMACY PRACTICE

#### Regulations

The general letter of the National Board of Health No. 1927 and the instruction of the National Agency for Medicines 1/1997 define the preconditions and procedures, with which the drug supply of a hospital and a health centre can be arranged. The Drug Act (395/87) refers to the production and distribution of drugs by hospitals and health centres.

## Financing

Financing varies from global budget to internal pricing (where the pharmacy charges the (internal) price of the pharmaceuticals to the clinical departments).

## Hospital pharmacists' activities

The hospital pharmacist is responsible for drug prescription and drug dispensing. Upon delivery, the life-span of the medicine, the perfect condition of the package and product number are verified. If the medicine has been ordered for an individual patient, also the dosage, interactions, non-compatibility etc. are checked.

Drug dispensing is done by the (assistant) pharmacist.

Large hospital pharmacies prepare medical products that are not commercially available (e.g. specific dosage forms and dosages for premature infants / children, dosipowders, injection solutions);

Several hospital pharmacies are involved in the reconstitution of cytotoxic drugs and some are involved in TPN reconstitution (it may also be decentralised to the wards).

Some hospital pharmacies have their own sterilisation device service or share a common device service in one of the hospitals.

## THE DRUG CIRCUIT AT HOSPITAL

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According to the Drug Act a hospital pharmacy and a medicine centre can order medicines from a medicine wholesaler, a pharmacy or a subsidiary. From a drug manufacturer only the manufacturer's own drugs can be obtained. Drugs can be imported with the permission of the Agency for Medicines.

Drugs are stored within the hospital pharmacy or medicine centre storage area. Products with large packaging may be stored separately (e.g. infusions) Some products may be stored outside the hospital pharmacy/medicine centre (medical gases), but remain under the responsibility of the hospital pharmacy / medicine centre.

Drugs are mostly distributed to cabinets on the wards, in original packages according to the ward's orders. In some large hospital pharmacies there are automated patient specific dispensing systems (ATC 212).

Transportation of medicines to the wards is done in closed containers by staff from the pharmaceutical or hospital transportation service.

Administration of drugs to the patients is the nurses' and doctors' responsibility

Pharmacists and assistant pharmacists are responsible for implementing a quick stock rotation in a pharmacy / drug stock to avoid drugs going out of date. The head nurse is responsible for the drugs of the ward and for returning expiring or out-of-date medicines to the hospital pharmacy / medicine centre

The hospital pharmacy/medicine centre delivers the medicine waste to 'Ekokem' for destruction. Ekokem is a company specialising in the treatment of hazardous waste in an environmentally sound manner, utilising the best available technologies.

## THE OTHER ROLES OF THE PHARMACIST IN A HOSPITAL

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The Pharmacy service is involved in several Hospital committees (Drug Committee, Hygiene, Infection and Parenteral Nutrition, Working Group).

The negotiating council for drugs at the hospital consists of pharmacists from hospital pharmacies and the manager of a dispensary. Pharmacists play an important part in the procurement of drugs and when deciding about the selection of basic medicines for the hospital. Hospital pharmacies and medicine centres monitor the consumption of drugs at the hospital and regularly report to their customers within the hospital.

The pharmacy service may be involved in pharmacoeconomic studies and drug expenditure monitoring (follow-up) or take part in research. Pharmacists may also be involved in clinical trials: they manage and sometimes prepare the products for clinical trials and participate actively within the medical teams.

Another task of the hospital pharmacy and medicine centre is to take care of drug information and to promote drug safety in written bulletins and as part of internal training.

The hospital pharmacist also keeps track of blood derivative products.

Other roles are in the field of educational activities (training of pharmacy students and medical workers) and clinical pharmacy (e.g. ordering of drugs, distributing drugs in ready made doses, when necessary making parenteral drugs ready for use, managing the drug cabinet and giving information on drugs).

### **THE RELATIONSHIPS OF THE HOSPITAL PHARMACIST**

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The staff of the hospital pharmacy works under supervision of the manager of the hospital pharmacy (pharmacist). The latter may delegate part of his tasks to other staff members, but is still in overall charge for drug supply. In medicine centres the head is as a rule the leading assistant pharmacist.

In his relationship with physicians, the pharmacist can make changes in the patient's medicines by using generic products. If a ward orders a drug that is not in the basic drug selection and a 100% equal product cannot be found in the hospital pharmacy / dispensary, the pharmacy staff will contact the physician / nurse.

In some large hospitals the pharmacist is part of the Board of Directors.

There is no actual co-operation with insurance organisations.

### **FACTS AND FIGURES**

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The hospital and health centres' pharmacists represent 4% of all (1193) pharmacists while 10% of the assistant pharmacists are working in hospitals and health centres.

There are on average 1.6 (assistant) hospital pharmacists per (public) hospital or health centre. Pharmaceuticals are about 5% of total hospital expenditure.

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## **STUDIES**

### **The pharmacists' curriculum**

Studying to be a pharmacist takes six years in the Faculty of Medicine at the University, resulting in a "Diplôme d'Etat de Docteur en Pharmacie". The course of study includes 6 months of training in a community pharmacy, a medical analysis laboratory or an industry, and a "Hospital/ University Year", during which students share their time (50/50) between a hospital ward or a hospital pharmacy and the University. Access to the course is restricted by a numerus clausus at the end of the first year.

### **Specialisation in hospital pharmacy**

A student succeeding in the competitive examination for "Internship" at the end of the 5th year, can specialize for four years in hospital pharmacy and thus obtain the "D.E.S. (Diplôme d'Etudes Spécialisées) in Hospital Pharmacy" after a total of 9 years' study.

### **Mutual recognition of diplomas and free circulation of pharmacists**

This is regulated by article L.514 of the Code de la Santé Publique and the Arrêté of 9 September 1996, defining the list of diplomas, certificates and titles accepted.

## **THE HOSPITAL PHARMACIST**

Having passed the competitive examination "Concours National de Practicien Hospitalier", a hospital pharmacist obtains the title of "Hospital practitioner" and the same status and salary as medical doctors. He is assisted by "attachés vacataires" and "assistants généralistes" with the basic diploma and "assistants spécialistes" with a specialisation degree in hospital pharmacy.

## **MEDICINES AND MEDICAL DEVICES**

Pharmacists have a monopoly on drugs for human use. These drugs are licensed by AFSSaPS ("Agence Française de Sécurité Sanitaire des Produits de Santé"). An increasing number of hospitals are using the ATC classification of drugs.

The European Pharmacopoeia is also in use in France together with the French Pharmacopoeia.

French hospitals only purchase drugs for hospitalised patients, except for drugs not available in community pharmacies, which can be sold to outpatients. Packaging is often different from the drug packaging available in community pharmacies (larger boxes, unit dose packaging, sometimes bulk..). Also pricing is different from that in community pharmacies; this results from consultations and bid invitations made by hospital pharmacists or purchasing groups of pharmacists to the pharmaceutical industries.

Every medical device available on the French market fulfils CE marking. The EEC directive on medical devices and implantable devices has also been implemented in the French regulations, as well as the EEC directive on waste of drugs and protection of the environment.

## **THE HOSPITAL PHARMACY PRACTICE**

### **Regulations**

To include a pharmacy within its structure, a hospital must ask for special authorisation. The licence is delivered by the prefecture after agreement by the Regional Pharmacist Inspector.

### **Financing**

The budget granted every year to a pharmacy is a part of the budget allotted to the hospital. It does not include the pharmacist's salary or any other worker's salary. It only includes drugs, medical devices and other pharmaceutical products.

### **Hospital pharmacists' activities**

Their first task concerns the ordering, purchasing and stock management for drugs and pharmaceutical products.

Also drug prescription analysis is done by pharmacists (dosage, length of treatment, drug interactions, incompatibilities, counterindications). This is not always performed extensively in French hospitals due to a lack of resources for accurate software.

"Préparateurs" or pharmacy students under the supervision of pharmacists dispense drugs in bulk to the wards or by the recommended unit dose system.

French hospitals manufacture drug preparations that are not available from the pharmaceutical industries.

Reconstitution of cytotoxic drugs, of TPN or less often of injectable drugs is mostly done within the pharmacy service, but may be decentralised to the wards. Drugs and preparations also have to be controlled before being released to the wards. The purchase, management, and dispensing of all sterile products (medical devices and disposables) is compulsorily under the responsibility of the hospital pharmacy.

The pharmacy service may be involved in pharmacoeconomic studies or take part in research, either through the various committees it is involved in, e.g. the Drug and Therapeutic Committee (DTC), or projects coming from the pharmacy itself. Pharmacists are also involved in clinical trials: they manage, and sometimes prepare products for clinical trials and participate actively within medical teams.

### **THE DRUG CIRCUIT AT HOSPITAL**

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Hospital pharmacies order from manufacturers, wholesalers, and sometimes, upon authorisation, from other hospitals for very specific products. Drugs are usually stored alphabetically within the pharmacy storage area, separated from medical devices as well as from products with large packaging i.e. infusions... Some products such as fluids for dialysis and medical gases may be stored outside the central pharmacy (but still under its responsibility).

The prescription is required at the pharmacy, and must be analysed by the pharmacist and dispensed in a patient oriented distribution with unit doses. However, in many hospitals drugs are still distributed in bulk from lists of orders from the ward, (or renewal of lists established together with the medical staff) which does not allow prescription analysis.

Transportation is performed in closed containers, by staff either from the pharmaceutical service or from the hospital transportation service.

Administration of drugs to the patient is the nurses' responsibility.

It is the pharmacist's responsibility to implement a quick stock rotation to avoid drugs going out of date. Unused drugs may be returned to the manufacturer before the expiry date if the packaging is not damaged. Out-of-date drugs are disposed of by the hospital.

### **THE OTHER ROLES OF THE PHARMACIST IN A HOSPITAL**

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The hospital pharmacist is part of and often the president of the DTC, which defines the hospital drug policy. On the basis of the decisions taken in this committee he elaborates the Drug formulary, which is the list of all the drugs (and devices) available in the hospital. He also belongs by law to the IHC, which in connection with the DTC may influence drug policy for example in antibiotherapy.

Information for good use of a drug is given through the DTC and specially its drug utilisation reviews (DUR) and evaluation (DUE), through notes or bulletins issued by the pharmacy, through oral answers to phone consultations, through advice and information given when visiting wards... In large hospitals, pharmacists are involved in the hospital Drug Information Centre.

The pharmacist is responsible for the management of stable blood derivative products and for their traceability.

In the field of hospital hygiene, the pharmacist belongs by law to the IHC. He is also consulted for the choice of disinfectants for the hospital.

Being involved in vigilance concerning drugs and medical devices and in the IHC, the pharmacist contributes to the security and protection of the environment.

Other roles are in the field of clinical activities, clinical trials, quality assurance and quality assessment, vigilance concerning drugs and medical devices, nutrition, educational activities, either for basic education or for life long training, and (in some

hospitals) bromatology. and pharmacokinetic activities.

### **THE RELATIONSHIPS OF THE HOSPITAL PHARMACIST**

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The pharmaceutical staff works under the responsibility of the pharmacist who is Chief of Department. This chief may delegate part of his responsibility to other pharmacists in his team, but he is still responsible for them.

In his relationship with physicians, the pharmacist is responsible for drug replacement. He purchases generics and other medicines under their international common denomination.

The pharmacist is only part of the administrative team in very few hospitals.

Hospital pharmacists have dealings with insurance organisations very occasionally, and on very specific points.

Many other persons such as nurses, dieticians, staff from sterilisation services, staff from computer services, staff from the hospital's technical and transportation services and staff from prisons, for the general hospitals in charge of providing treatment for prisoners...are generally in contact with the pharmacy in hospitals.

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**STUDIES**

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**The pharmacists' curriculum**

To qualify as a pharmacist, students must successfully complete a four-year university degree, followed by one year of pre-registration competence assessed training, normally in a hospital or a community pharmacy. Most hospital pharmacists study for a postgraduate qualification, for example in clinical pharmacy, to Certificate or Diploma level and some complete Masters degrees or a Doctorate.

**Specialisation in hospital pharmacy**

There is no specific specialisation degree in hospital pharmacy. However, having gained a general grounding in hospital pharmacy, many hospital pharmacists go on to specialise in a therapeutic area, such as paediatrics, oncology or surgery, or in a technical area, such as manufacture, radiopharmacy or quality assurance, or in a more managerial capacity, such as formulary control and evaluation or dispensary services.

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**THE HOSPITAL PHARMACIST**

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Typically, after registration a hospital pharmacist works for about two years at a "basic grade" level, rotating through different areas, such as medicines information, clinical pharmacy, manufacture and dispensing. Senior pharmacists supervise the training of the junior pharmacists.

An extensive pharmacy support staff, comprising pharmacy technicians and pharmacy assistants, works with the hospital pharmacists.

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**MEDICINES AND MEDICAL DEVICES**

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Medicines legislation in the UK does not require a hospital to have a pharmacist or registered pharmacy to supply medicines. This can be achieved under the authority of a doctor. However, National Health Service (NHS) policy is that not only should pharmacists be responsible for the supply of medicines, they should also ensure safe and effective systems of medicines management are in place throughout the hospital. Most NHS hospitals have their own pharmacy department, with staff

employed by the NHS, or are served by one in a neighbouring NHS hospital.

Medicines are licensed by the EMEA or Medicines Control Agency, through central or local procedures. The European Pharmacopoeia is used in the UK, and takes precedence over the British Pharmacopoeia, which is also used.

Medicines are supplied free of charge to most NHS hospital patients. An NHS prescription charge has to be paid by some patients. Medicines are increasingly supplied in original packs.

All medical devices have to be CE marked by a Notified Body, in keeping with the EU Medical Devices directives. Disposal of medicines follows national and European requirements.

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**THE HOSPITAL PHARMACY PRACTICE**

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**Regulations**

Hospital pharmacy practice is principally governed by three types of regulations:

Medicines legislation, which regulates the manufacture, distribution, import, export, sale and supply of medicinal products;

Misuse of Drugs legislation, which controls the availability of drugs liable for misuse and specifies which health care professionals can possess, supply, prescribe and administer controlled drugs;

The Pharmacy Act. Pharmacists have to be registered with the Royal Pharmaceutical Society of Great Britain or the Pharmaceutical Society of Northern Ireland and follow a professional code of practice.

**Financing**

The cost of the hospital pharmacy service and medicines is met from within the overall allocation to the NHS hospital. The Chief Pharmacist receives and manages the budget for the pharmacy service. The budget for medicines is generally delegated to clinical directorates.

### **Hospital pharmacists' activities**

Hospital pharmacists are responsible for ensuring the clinical and cost effective prescribing and use of medicines, the effective and efficient procurement of medicines, and the safe and secure supply and handling of medicines within the pharmacy and throughout the hospital.

Increasingly, pharmacists spend their time on the wards and in other patient care areas monitoring prescriptions and advising nurses and doctors on the safe use of medicines, including as part of consultant ward rounds.

Hospital pharmacists have developed their clinical activities to ensure patients receive maximum benefit from their medicines as cost effectively as possible. This is achieved both at an individual patient level (ascertaining patients on-going medication needs, advising doctors on drug choice, individualising drug therapy, counselling patients, medication help lines post-discharge) and at a strategic, organisation-wide level (development of formularies, prescribing guidelines, managing the uptake of new medicines, monitoring prescribing patterns, providing feedback to clinicians).

### **THE DRUG CIRCUIT AT HOSPITAL**

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Medication is ordered from pharmaceutical wholesalers or direct from manufacturers. In some areas, purchasing consortia buy medication for groups of hospitals. Most hospitals have a formulary that lists medicines that can be prescribed.

Medicines are usually stored alphabetically within the hospital pharmacy dispensary.

Each patient has a drug chart with his or her name and hospital number, serving three purposes. It is the nurses' administration instructions, the administration record and the instructions to pharmacy to supply medication. Medication orders are written by doctors directly onto this chart, verbal orders are not usually permitted. Medicines are usually prescribed by generic name, rather than brand name. Electronic prescribing is being introduced.

Most medicines for inpatients are supplied from general stock held by the ward. Increasingly medicines are being dispensed for individual inpatients, using original packs, labelled with full instructions, so that when the patient is ready to go home their medicines are ready too.

Medication is prepared immediately prior to administration during nurses' medication administration rounds.

Trained nurses may administer medication alone, except in the case of parenteral and controlled drugs that must be checked by a second nurse.

Self-administration schemes are being introduced in many hospitals, in which patients, where appropriate, administer their own medication from a bedside medicine cabinet.

When a patient is discharged, any medication no longer needed will usually be returned to the pharmacy department. Medication of low value and partially used liquid or topical medication will be destroyed. Other medication, where appropriate, will be returned to pharmacy stock for subsequent re-issue.

### **THE OTHER ROLES OF THE PHARMACIST IN A HOSPITAL**

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To inform clinicians on drug therapy, hospitals have a Drug and Therapeutics Committee. This is a multi-disciplinary committee, including doctors, pharmacists and nurses. It develops and monitors local prescribing policies and produces a local drug formulary. Information is collated and presented by pharmacists on new drugs, which are assessed for their clinical and cost effectiveness as compared to medicines already in the formulary.

Pharmacists are involved in ensuring appropriate storage and use of blood derived products as for any drugs.

As to hospital hygiene, hospital pharmacists work closely with medical microbiologists to develop, implement and monitor antimicrobial prescribing policies. Some hospitals also employ pharmacists

specialised in the pharmaceutical management of infectious diseases.

In the field of security and protection of the environment, pharmacists will usually be involved in developing policies on handling, disposal and spillages of drugs.

Pharmacists also have a role in the quality assurance and control of medicines manufactured, prepared, stored and dispensed in hospitals. This includes monitoring the raw materials, processes and procedures, equipment and environment, and staff used.

Experienced pharmacists are responsible for training pharmacy students, junior pharmacists and other health professionals on the prescribing and use of medicines. They also educate patients on the appropriate use of their medication.

### **THE RELATIONSHIPS OF THE HOSPITAL PHARMACIST**

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All hospitals have a Chief Pharmacist, who is responsible for the overall pharmacy service and the safe and secure handling of medicines across the organisation. Other hospital pharmacists work within a managerial framework. However, they remain professionally accountable.

As to the relationship with the physicians, generic substitution is universal in NHS hospitals, as part of prescribing policies, alongside local formularies. Pharmacists may also be given authority by doctors locally to amend prescriptions, for example switching a prescription for an intravenous antimicrobial medicine to a suitable oral formulation, where appropriate. Legal powers have been taken for certain pharmacists to prescribe in the future.

Hospital Chief Pharmacists have access to the Board of Directors and senior management on matters concerning medicines and pharmacy services.

Communication between hospital and community pharmacists is increasingly being formalised to

transmit patient medication profiles on admission and on discharge from hospital.

### **FACTS AND FIGURES**

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About 5,500 pharmacists in Great Britain (20% of practising pharmacists) work within NHS hospital pharmacies. 70% of hospital pharmacists are female. There are around 300 hospital pharmacy departments, mainly based in acute hospitals.

On average there are 18 hospital pharmacists for each main NHS hospital. NHS hospital expenditure on medicines, including medical gases, for 1999/2000, was £1,360m.

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## **STUDIES**

### **The pharmacists' curriculum**

To qualify as a pharmacist, students must successfully complete a five-year university degree at the Faculty of Pharmacy. The fifth year includes at least 6 months of practice in a community and hospital pharmacy.

Access to the studies is restricted by national examinations. Three universities in Greece have a Faculty of Pharmacy (Athens, Thessaloniki and Patras).

After the fifth year, the student has to pass the examinations organised by the Hellenic Ministry of Health in order to get the permission to exercise the profession in Greece.

This permission is required to work in a community or hospital pharmacy and for any other position in organisations under the coverage of the Hellenic Ministry of Health. It is not necessary in industry.

### **Specialisation in hospital pharmacy**

There is no specialisation in hospital pharmacy, but the universities of Athens and Patras provide postgraduate studies in Clinical Pharmacy, Pharmacokinetics, Pharmaceutical Technology, Cosmetics, Industrial Pharmacy, Compounding, Pharmaceutical Analysis, Quality Control and Radiopharmacy.

A committee is now establishing the specifications for the specialisation in accordance with the Directive / Recommendation of the European Union and the reference of the European Association of Hospital Pharmacists (EAHP).

### **Mutual recognition of diplomas and free circulation of pharmacists**

All the diplomas, certificates and titles provided by the Greek authorities are recognised by all Member States of the European Union and there is free circulation of pharmacists (they must prove their

knowledge of the language of the Member State where they intend to work).

## **THE HOSPITAL PHARMACIST**

To be able to work as a hospital pharmacist, he/she needs to have his/her bachelor degree "Diploma in Pharmacy" and the permission to exercise (from the Ministry of Health).

In the Hospital Pharmacy Department the new pharmacist (0 years of practice) gets the C grade. He/she gets the B grade after 8 years of practice (5 years in hospital -obligatory) and the A grade after 10 years of practice (8 years in hospital - obligatory). After 12 twelve years of practice (10 ten years in hospital - obligatory) he/she is granted the title of Director of Hospital Pharmacy Department.

## **MEDICINES AND MEDICAL DEVICES**

Drugs are licensed by EOF ("Greek Drug Organisation"). Greek hospitals purchase drugs for hospitalised patients, for outpatients under special pharmacotherapy - such as for cancer treatment - and for indigent patients that are under the coverage of social security. Indigent patients receive their drugs free of charge only from the hospital pharmacies.

Packaging is often different from the drug packaging available in community pharmacies (larger boxes, unit dose packaging, sometimes bulk). Also pricing is different from that in community pharmacies. It results from consultations made by the Ministry of Health and Ministry of Commerce to the pharmaceutical industries.

Every medical device available on the Greek market fulfils EC marking. The EEC directive on medical devices has also been implemented in the Greek regulations, as well as the EEC directive on waste of drugs and protection of the environment.

## **THE HOSPITAL PHARMACY PRACTICE**

### **Regulations**

To include a pharmacy within its structure, the hospital must ask for special authorisation from the local Department of Health. The licence is delivered by the prefecture after agreement by the Regional Inspector.

## Financing

The budget granted every year to the pharmacy is part of the budget allotted to the hospital. It does not include the pharmacist's salary or any other worker's salary. It only includes drugs, medical devices and other pharmaceutical products.

## Hospital pharmacists' activities

In the Hospital environment, pharmacists have the total responsibility of drugs.

The main task concerns the ordering, purchasing and stock management for drugs, pharmaceutical products and sterilised medical devices.

The pharmacists have the obligation to make drug prescription analysis, such as, dosage, length of treatment, drug interactions, incompatibilities, counterindications. This is not always performed due to lack of personnel and specialised software (both are very serious problems in Greek hospital pharmacies).

Hospital pharmacies manufacture drug preparations that are not available in pharmaceutical industries, such as creams, syrups etc. They provide and prepare TPN (in large hospitals where there are special units), reagents and chemical substances.

Reconstitution of cytotoxic drugs can be implemented within the pharmacy service, but may also be decentralised to the wards.

Drugs and preparations are controlled before being released to the wards.

The purchase, management, and dispensing of all sterile products, medical devices and disposables are obligatory under the responsibility of the hospital pharmacy.

The pharmacy department is involved in pharmaco-economic studies and in research.

## THE DRUG CIRCUIT AT HOSPITAL

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Hospital pharmacies order only from manufacturers. Drugs are usually stored alphabetically within the pharmacy storage area, separated from medical

devices and from products with large packaging i.e. infusions. Some products may be stored outside the central pharmacy (but still under its responsibility) i.e. fluids for dialysis and some medical devices.

The prescription is required at the pharmacy and must be analysed by the pharmacist and dispensed in a patient oriented distribution with unit doses. However, in many hospitals, drugs are still distributed in bulk from order lists from the ward, (or renewal of lists established together with the medical staff) which does not allow prescription analysis. The dispensing of narcotics is always patient oriented with unit doses.

Transportation is performed in closed containers, by staff either from the pharmacy department, either from the hospital transportation service. Administration of drugs to the patient is the nurses' responsibility.

It is the pharmacist's responsibility to implement a quick stock rotation to avoid drugs coming out of date. Non-used drugs may be returned to the manufacturer before the expiry date if the packaging is not damaged. Out of date drugs are destroyed by the hospital.

## THE OTHER ROLES OF THE PHARMACIST IN A HOSPITAL

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The hospital pharmacist is part of the DTC, which defines the hospital drug policy.

The pharmacist also belongs by law to the Hospital Infections Committee, which may influence the antibiotics policy in the hospital.

Information on good drug use is given through oral answers to phone consultation, or directly to patients, physicians and nurses.

The pharmacist is responsible for the management of stable blood derivative products and for their traceability.

Being involved in the vigilance of drugs, of medical devices, and in the Hospital Infections Committee,

the pharmacist contributes to the security and protection of the environment.

Other roles are in the field of clinical activities, clinical trials, vigilance concerning drugs and medical devices, nutrition, educational activities, either for basic education, or for life long training, and in some hospitals pharmacokinetic activities.

Many Hospitals in Greece have the responsibility for the local Nursing Schools. In that case the hospital pharmacists are the teachers of Clinical Pharmacology.

### **THE RELATIONSHIPS OF THE HOSPITAL PHARMACIST**

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The pharmaceutical staff works under the responsibility of the pharmacist who is Director of Department. This director may delegate part of his responsibility to other pharmacists in his team, but he is still responsible over them.

The pharmacist collaborates with the hospital physicians in terms of drug replacement, giving advice concerning the pharmacology of the drug, buying generics and working with the Drug Committee.

Many other persons such as nurses, nutritionists, staff from the sterilisation services, staff from the computer services, staff from the hospital's technical and transportation services and from the hospital administration, are in an everyday contact of the pharmacy in the Greek hospitals.

### **FACTS AND FIGURES**

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The number of pharmacists per bed is very small and the most common is 1-2 (one-two hospital pharmacist in a medium hospital with 200-400 beds).

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## **STUDIES**

### **The pharmacists' curriculum**

The B.Sc. (Pharmacy) degree is obtained at University. The available number of places at the university - currently 70 - restricts entry to the Pharmacy Degree Course. Entry is based on a points system and the number of points required varies from year to year depending on the demand for places. The 4 years' studies (B.Sc.) are followed by one year of practical training which is carried out under the supervision of a tutor pharmacist. This training may consist of one year of practical training in a community pharmacy or hospital. Or the trainee may prefer to do six months of practical training in a community pharmacy or hospital plus 6 months training in a pharmaceutical industry.

To obtain registration as a Pharmacist on the register of pharmaceutical chemists, a written examination in Pharmacy Law must be passed after the practical training. This register is kept by the Registrar of the Pharmaceutical Society of Ireland, as required by law.

### **Specialisation in hospital pharmacy**

No additional qualifications are required to practice as a hospital pharmacist.

### **Mutual recognition of diplomas and free circulation of pharmacists**

The EU Free Movement Directives have been fully transposed into Irish Law.

## **THE HOSPITAL PHARMACIST**

As the numbers of places available in hospital pharmacies is limited, interviews are competitive. Pharmacists must however generally spend three years working as a basic grade pharmacist in a hospital and five years experience is generally required before they can apply for a senior hospital pharmacist post. Additional qualifications are desirable for senior positions. Five years experience is generally required for Chief Pharmacist posts. Pharmacists may also participate in further (university) education courses while working in their

hospitals. These courses may lead to the award of third level diplomas and degrees in hospital / clinical pharmacy.

Pharmacy staff includes Chief Pharmacists, Dispensary Unit Pharmacists, Ward/ Clinical Unit Pharmacists, Compounding Unit Pharmacists, Drug Information Unit Pharmacists, Student Pharmacists, Pharmacy Technicians, Pharmacy Porter, Pharmacy Cleaner and Pharmacy Secretary /Administration staff.

## **MEDICINES AND MEDICAL DEVICES**

Prescription-only medicines for human use are confined by law as a monopoly to pharmacies where their dispensing must be under the personal supervision of a pharmacist. In the case of non-prescription medicines, only a small number of medicines may be sold by outlets other than pharmacies.

The Irish Medicines Board is the competent authority for the authorisation of medicinal products to be placed on the market. Authorisations granted centrally by the European Commission, on a recommendation of the Committee on Proprietary Medicinal Products, are also recognised in Ireland.

Very few Irish hospitals are currently using the ATC/DDD classification system recommended by WHO for carrying out drug utilisation analyses. Attempts are being made to standardise the systems being used to analyse drug consumption. The WHO ATC/DDD system is preferred by the Department of Health and Children.

The European Pharmacopoeia is the official pharmacopoeia in Ireland. The British Pharmacopoeia is also recognised. Drugs purchased in Irish hospitals tend to be for inpatient use only. There is very little outpatient dispensing. Special arrangements are made for drugs that cannot be readily obtained or administered in the community.

In general, pack sizes used in hospitals tend to be the same as those used in community pharmacies. Occasionally, larger bulk dispensing packs are

purchased for some of the more frequently used drugs that are more economical and convenient in this form. Occasionally, "hospital starter packs" may be used.

Pricing may be different from that in community pharmacies. This may arise from negotiation and/ or tendering systems operated by some hospital pharmacists or by purchasing groups made up of hospital pharmacists.

Every medical device on the Irish market is required to comply with CE marking, except for invitro diagnostic medical devices. The EU Directive on these devices has not been transposed into Irish law yet but is due to be transposed shortly.

The EU Directives on Active Implantable Medical Devices and on Medical Devices have been transposed into Irish Law and compliance is mandatory.

As regards the EEC directive on waste of drugs and protection of the environment, Hospital Administration liaise with the environmental authorities regarding the safe disposal of hospital waste.

## **THE HOSPITAL PHARMACY PRACTICE**

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### **Regulations**

No authorisation is required by law to open a hospital pharmacy, neither is there an obligation for the hospital to have a hospital pharmacy.

### **Financing**

The pharmacy department is generally allocated a proportion of the overall hospital budget. The following are ordered out of pharmacy budget: drugs, medicated and specialised dressings, IV fluids, surgical disinfectants, parental and enteral nutrition products, sip feeds and special foods, vaccines, certain anaesthetic preparations (generally not medicated gases), certain blood products e.g. immunoglobulin solutions (not albumin, FF plasma, blood, platelets etc.), needles and syringes for use in the pharmacy department. Also the pharmacy staff wages are paid for out of pharmacy budget.

Not paid for out of pharmacy budget are: re-usable medical devices, needles, syringes, simple dressings and general-purpose disinfectants, medicated gases. These are ordered by and paid for by the general supplies/purchasing department of the hospital, not by pharmacy department.

### **Hospital pharmacists' activities**

The pharmacy departments are normally open from 9.00am to 9.00pm. Outside these hours, necessary services are provided by the pharmacists on an "on-call" basis.

The first task concerns the ordering, purchasing and stock management for drugs and pharmaceutical products.

A general analysis of drug consumption is done annually on a gross basis for individual hospitals in order to determine annual budget allocation. The detail of this analysis varies from hospital to hospital. Analysis of drug consumption at individual ward level is also increasingly being carried out. Various drug classification systems are currently being used (e.g. the Intercontinental Medical Statistics (IMS), BNF, etc.) and the commercial hospital pharmacy IT package Clini-Script is the most commonly used software package. Attempts are being made to standardise the analysis of drug consumption using the WHO ATC/DDD system.

The drugs are dispensed to the wards as described under "drug circuit". Individual patient prescription dispensing /analysis concentrates on dosage, length of treatment, drug interactions, incompatibilities, and, when the diagnosis is known, counterindications are checked during daily ward reviews of patient's drug charts. This practice is not carried out at all hospitals, but depends on the size, the type and the requirements of the hospital concerned and the priority given by the hospital authorities to the establishment of a clinical ward pharmacy service.

Hospital pharmacies do also drug compounding of "specials", not available commercially in a ready made form.

Cytotoxic drug reconstitution and central intravenous antibiotic reconstitution services are provided by

many of the larger hospital pharmacy departments. The smaller hospitals tend to have a lesser requirement for these services and therefore either do not provide a re-constitution service or chose to buy these re-constituted preparations from a larger hospital which offers this service and which has a manufacturing licence.

Where possible Total Parenteral Nutrition Products (TPN) bags tend to be ordered by the pharmacy department from a commercial company licensed to provide this service. Additions to these bags may be necessary and these are carried out in the pharmacy department's compounding unit.

Every drug or preparation must be checked /controlled before being released to the wards. Pharmacy departments have standard operating procedures for quality control.

The purchase, management and dispensing of sterile products such as reusable medical devices are not the responsibility of the hospital pharmacy department. This is generally contracted out to a Central Sterilisation Services Unit. The same goes for sterilisation of reusable medical devices.

The Hospital Pharmacists' Association of Ireland organises various continuing education events for hospital pharmacists.

In addition to the formal courses (see "STUDIES"), individual hospital pharmacy departments hold journal clubs, organise continuing education lectures etc. Staff also take part in presentations/projects, committee work etc.

The pharmacy service may be involved in pharmacoeconomic studies or take part in research, either through the various committees it is involved in (i.e. DTC, Dressing Committees), or through projects initiated by the pharmacy itself. Pharmacists may also be involved in providing support for the conduct of clinical trials. In this context they may manage, and sometimes prepare the products for use in the clinical trials and participate actively within the medical teams.

In some of the larger hospitals pharmacists are becoming more involved in following the pharmacokinetic profile of administered drugs and in advising on dosage adjustments etc. This particularly occurs for drugs with low therapeutic indexes e.g. warfarin, anti-epileptics, theophylline, digoxin, aminoglycoside antibiotics.

A number of the larger hospitals have active drug information departments as part of the pharmacy services. Smaller hospital pharmacy departments provide this service on an informal basis.

### **THE DRUG CIRCUIT AT HOSPITAL**

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Hospital pharmacies order from manufacturers, wholesalers, and sometimes from other hospitals for very specific products.

Drugs are usually stored alphabetically or according to their pharmacological action, or by manufacturer, within the pharmacy storage area. Medical devices (medicated dressings, volumatics, needles, syringes) are stored separately, as well as products with large packaging i.e. infusions, foods.

The nursing staff fills out a ward requisition form, marking the items required for the wards on the basis of the medical prescriptions. Alternatively in some hospitals the pharmacist visits the ward daily and reviews the patient's drug chart together with the medicine trolley and drug cabinets. The pharmacist may also take part on ward rounds. The pharmacist then either returns to the pharmacy and dispenses the required items or transmits the order to the dispensary staff for dispensing. The required medicines are either dispensed in an individual patient pack or in a bulk pack for ward use on the medicines trolley. Health Authorities encourage the first type of dispensing. Drug dispensing is performed either directly by the ward/clinical pharmacists or, under the supervision of pharmacists, by pharmacy technicians or pharmacy students.

In some hospitals bulk supplies may be made to the wards on orders made by the ward sister or by a pharmacist/pharmacy technician. They are then delivered to the ward by a porter. Each ward would generally have a stock list and a stock level against

which the person ordering would check the ward stock. Non-stock items must be ordered separately and may require a medical consultant's endorsement.

Transportation to the ward is carried out in closed containers, either by staff from the pharmacy or by staff from the hospital transportation service.

The administration of drugs to the patient is the nurses' responsibility.

It is the pharmacist's responsibility to implement a quick stock rotation policy to avoid drugs going out of date. Unused drugs may occasionally be returned to the manufacturer before the expiry date and if the packaging is not damaged. Out of date drugs are destroyed by the hospital.

### **THE OTHER ROLES OF THE PHARMACIST IN A HOSPITAL**

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The DTC has general responsibility for hospital drug policy. The pharmacist is generally chairman of this committee. No official national formulary exists. Individual hospitals decide on their own formulary. The pharmacy department in consultation with the hospital's DTC generally draws up this list of appropriate drugs for use in their hospitals or departments.

Pharmacists contribute to protocol development through their involvement with the DTC and through their involvement with consultants and nursing staff, at ward level.

Adverse drug reactions or drug interactions reporting must be done to the Irish Medicines Board through the Adverse Drug Reaction Reporting System, which has been established nationally.

A separate unit under the supervision of a consultant haematologist is generally responsible for ordering blood and blood derivatives. The pharmacy department is not involved.

Most hospitals have an infection control committee and the hospital pharmacist would generally be on this committee.

Hospital Administration liaise with the environmental authorities regarding the safe disposal of hospital waste.

### **THE RELATIONSHIPS OF THE HOSPITAL PHARMACIST**

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Most hospital pharmacists have a good working relationship with the hospital consultants, doctors and nursing staff etc. The degree to which hospital pharmacists are available to become involved with other hospital staff depends on the hospital's resources and priorities. Most hospital managements encourage the involvement of pharmacists at ward level.

Hospital doctors are generally required as a matter of hospital policy to prescribe generically, and items are dispensed from the hospital formulary. For that reason, the substitution of branded products for generic products is not usually an issue.

Pharmacists can influence the prescribing habits of doctors through personal contact and through the pharmacist's role in protocol and formulary development. In most Irish hospitals non-formulary prescribing must be endorsed by a medical consultant.

The pharmacist is usually not part of the administrative team. The chief pharmacists will however meet with the hospital administration on a regular basis to discuss matters of mutual interest and for planning purposes.

The pharmaceutical staff work under the responsibility of the Chief Hospital Pharmacist who is head of the Department. This chief may delegate part of his responsibility to other pharmacists on his team, but he still retains overall responsibility. Each of the pharmacy units listed above may have associated with it, a unit chief, a unit deputy chief, senior, basic grade and student pharmacists working in it. The number of pharmacy staff employed will depend on the size of the hospital, its speciality and on the general hospital policy and requirements. In some of the smaller hospitals there may only be a requirement for a single pharmacist for the whole

hospital. In the latter case, the post would be advertised as a senior pharmacist post.

Junior (basic grade) pharmacists tend to be rotated between units during their first three years in hospital pharmacy practice to expose them to a wide range of practice areas. Senior pharmacists tend to specialise. Unit chief pharmacists are senior pharmacy staffs who have been assigned overall responsibility for a particular unit within the pharmacy department. This may be the dispensary, the compounding unit, the clinical unit, drug information unit etc. Deputy unit chiefs, senior and basic grade pharmacy staff report to their respective unit chief. The unit chiefs in turn reports to the Chief Hospital Pharmacist.

Hospital Pharmacists have little or no involvement with insurance companies.

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## IT - Italy

### STUDIES

#### The pharmacists' curriculum

After having completed their basic education successfully, pharmacy students are awarded a degree in pharmacy ("laurea di dottore in farmacia"), which can be obtained in one of the 26 universities with a school of pharmacy.

Except for a pharmacy degree, schools of pharmacy also offer a degree in pharmaceutical chemistry (CTF, Chimica e Tecnologia Farmaceutiche).

With the recent approval of the university reform, pharmacy and CTF degrees are included in category 14/S of "lauree specialistiche" (the highest of two levels of university degrees). The specific branch for pharmacy is called "Pharmacy and industrial pharmacy". These degrees are regulated by European Union rules and they do not require a 1st level university degree as prerequisite (Ministerial Decree [DM] of 28.11.2000).

The laurea specialistica is a 5-year programme, in which a 6-month practical training period in a community or hospital pharmacy is included. This training is performed under the supervision of the pharmacy chief, and covers at least 20 credits (one credit equals 25 hours). The remaining curriculum covers at least 198 credits.

#### Specialisation in hospital pharmacy

According to the Ministry of the University and Scientific Research Decree no. 509 (03.11.99) on teaching autonomy for universities, article 3, Italian universities offer a specialisation diploma (diploma di specializzazione) and a research doctorate to graduates with a laurea specialistica.

In the pharmacy sector, the schools of specialisation regulations follow the 06.09.95 Decree. According to this decree, the school of specialisation in hospital pharmacy is a 3-year programme. In order to be admitted to the programme, registration by the board of pharmacy is required. The programme includes

three educational branches: biology, pharmaceutical chemistry and analysis, applied technology. They should cover at least 2400 hours.

Moreover, the curriculum includes practical training at either a hospital pharmacy or a servizio farmaceutico territoriale (SFT)<sup>1</sup> of the local health authorities (LHA)<sup>2</sup>, accounting for a minimum of 400 hours/academic year.

Following their autonomy, in many universities the regular courses are combined with seminars and educational courses. These initiatives aim at approaching more in detail the topics of particular relevance for the pharmacy profession.

At present, there are 17 schools of specialisation in hospital pharmacy in Italy. Since the activation of the first school (academic year 1977-78) 1186 out of the 2100 pharmacists working in the hospital pharmacy services and SFTs have obtained a degree certificate of specialisation in hospital pharmacy.

#### **Mutual recognition of diplomas and free circulation of pharmacists**

According to the above-mentioned decree and the 85/432/EEC directive, a person graduated with a laurea specialistica degree either in pharmacy or CTF and having passed the board of pharmacy exam, is authorised to practise pharmacy. The graduate is allowed to perform the following basic activities at minimum: preparation of dosage forms; drug manufacturing and quality control; storage, conservation, and dispensation of medicinal products at the wholesale level, in community pharmacies and in hospital pharmacies; drug information, documentation and counselling. The educational background may also include other professional activities typical of pharmacy practice in different EU Member States. This will allow equal work opportunities across Europe.

As regards any other profession recognised by article 33, fifth paragraph of the Italian Constitution, the graduate in pharmacy or CTF has to pass an exam of the Board of Pharmacy in order to get registered and be authorised to practise pharmacy. This step plays a key role, since it guarantees that

services provided by practising pharmacists are of high standard and properly monitored.

#### **THE HOSPITAL PHARMACIST**

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According to decree no. 502 of 30.12.92 on health care reform and subsequent modifications and integrations, physicians, veterinarians, pharmacists (1,7% of all the health care managers), biologists, chemists, physicists and psychologists are all classified at the same position level, i.e. managers of the public health sector.

Access to these positions is regulated by a selection process typical of the public sector conditioned by the university degree in the corresponding professional profile, professional board registration and a specialisation diploma in the specific discipline.

For the hospital pharmacy field, the equipollence of different specialisation diplomas for each managerial professional profile is defined in the Ministerial Decree of 30.01.98:

Specialisation: hospital pharmacy  
Equipollent schools: pharmacology, applied pharmacology, pharmacognosy

#### **MEDICINES AND MEDICAL DEVICES**

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Drug selection for government reimbursement is made by the Committee for Medicine of the Ministry of Health (Commissione Unica del Farmaco, CUF). The criteria for selection are efficacy, safety and cost.

In public hospitals, drug management is a task of the pharmacist working in the hospital pharmacy. Almost all LHUs/Aziende Ospedaliere have a hospital pharmacy. On the other hand, in several private hospitals the pharmacy (and the pharmacist) is replaced by a drug deposit. In this case drugs are managed by other health care professionals.

On the basis of the choices made at central level by the CUF, each hospital develops its own formulary, adapting the list of available drugs to the needs and the characteristics of the hospital. The hospital formulary is a dynamic instrument where the selection of drugs is made on the basis of their clinical efficacy, safety and cost comparing the available alternatives. This comparison is made by

analysing the available medical knowledge from published clinical research. It is regularly updated in order to keep abreast of the new discoveries. The DTC Committee takes care of drug selection for use within the hospital. It is normally co-ordinated by a pharmacist and its composition is multidisciplinary. Generally, drugs are classified according to the ATC.

A copy of the current Italian Pharmacopeia has to be kept in any pharmacy by law. For substances not included in the Italian Pharmacopeia, the European Pharmacopeia serves as reference.

Production, marketing and use of medical devices with CE marking follow law no. 46 of 24.02.97, enforcing 93/42/EC directive regarding medical devices.

So far a national formulary on medical devices does not yet exist.

In a hospital, the pharmacy department is responsible for developing and keeping, most of the times, a commented list of all medical devices, similarly with what happens with drugs (hospital formulary). This commented list is an operational tool for different groups of professionals (physicians for selection for use, administrators for cost comparison, etc).

## THE HOSPITAL PHARMACY PRACTICE

### Regulations

Minimum requirements for a pharmacy (both structure and personnel) are detailed in the current law.

### Financing

Each pharmacy service has an assigned budget, covering the personnel cost, the space, the equipping, and general expenses. The budget is negotiated by the pharmacy director with the executives on the basis of a yearly operational plan. Pharmacy services are also assigned a budget for the purchase of drugs, medical devices, and all other materials they provide to the wards.

### Hospital pharmacists' activities

The hospital pharmacist first executes the basic activities of every pharmacist: drug supply, accountability and logistics. This means:

- definition of demand for pharmaceuticals and preparation of technical documentation for purchases;
- documentation, technical reporting, comparison of efficacy, safety and cost with the available alternatives on new items (e.g. pharmaceuticals, medical devices, etc.) for advice on possible purchasing;
- analysis of drug consumption data on pharmaceutical products for efficient management of supply and demand;
- control of ward drug storage, in terms of appropriateness of supply, vigilance on psychotropic drug accountability.

These activities are done in interdisciplinary collaboration (physicians, nurses and administrators).

In a clinical pharmacy, specific activities are also performed such as:

Compounding of traditional and special formulations toward a unit dose system. Under specific circumstances and in accordance with local requirements, preparation and/or manipulation of special drugs may be centralised for the whole hospital/unit and also for home care distribution (e.g., artificial nutrition, oncology treatments, pain therapies, antibiotic regimens etc.). This requires interdisciplinary collaboration with ward physicians, specialists, surgeons, dieticians, home care physicians, etc.

The pharmacoepidemiological evaluation of periodical drug use is done for drugs prescribed for specific indications and for selected populations (e.g. children, elderly, etc) and by different prescribers, drug prescription trends for high cost drugs and other therapeutic classes under specific monitoring programmes. Interdisciplinary collaboration is necessary with DTC, committee for hospital infections, and other commissions.

Normally the hospital pharmacy is responsible for the management of medical devices, although in some

cases these items are managed by the purchase office.

Investigational drugs must be sent to the pharmacy which will take care of their accountability, storage and distribution to the investigators. Public pharmacists play a central role in clinical experimentation, both before and after approval for trials.

### **THE DRUG CIRCUIT AT HOSPITAL**

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Hospital pharmacies purchase drugs and other materials to supply wards, other services and ambulatories within the hospital.

The supply requests are sent to the hospital pharmacy according to different procedures, depending on the local situations. In all hospital pharmacies a process for urgent requests has been established. In some cases, the pharmacist is on call 24-hours a day. Drug dispensing is planned on specific days and is decided with the head nurse of the ward.

For the majority of drugs there is no direct control on the appropriateness of therapy with regard to the patient profile, since the drugs are distributed as bulk supply for the ward, and not on a single patient basis. However, for a limited list of drugs (very expensive or those requiring specific patient monitoring) the prescribing physician is required to fill out an individual prescription, and the drugs are dispensed on an individual basis, after the pharmacist has checked its appropriateness.

Nurses are in charge of therapy administration on prescription by a physician. A pharmacist must be available to provide information on the correct use of drugs and on the place the available therapeutic approaches take in therapy.

Normally, patients do not have direct access to hospital pharmacies. However, in well-defined cases, this may happen, such as for particular drugs and particular groups of patients (e.g. diabetics), for distribution programmes promoted by the Ministry of Health (e.g. at present a direct distribution for Alzheimer disease is running parallel to an

epidemiological investigation co-ordinated by the Ministry of Health) or for drugs purchased abroad. In other cases, this task is performed by the SFT.

In several cases the pharmacy is also in charge of shipment of the material for home care. Shipment is performed by public employees when it is to be done within the hospital, and by an external carrier for outside the hospital. The materials have to be appropriately packed, with written documentation in order to be able to easily identify its content and the receiver. The conditions of conservation have to be met during shipment and handling.

Drugs and, separately, the other materials, are stored in proper rooms with specific characteristics, according to specific legislation. The pharmacist is responsible for this management. Technicians must be instructed in relation with their tasks. Educational and training initiatives for technicians and personnel must be documented.

Written procedures need to be defined for all operations which may influence the stability and the quality of the products, as well as for the dispensing activities (e.g. reception and storage check, storing conditions, room cleaning).

The supply quantity needs particular attention. An efficient system ensuring rotation of the supply (the drug with the closest expiration date should be dispensed first) should be implemented. Out-of-date drugs should be kept separate from the other drugs, before their disposal. Documentation on the disposal should be kept for 5 years.

### **THE OTHER ROLES OF THE PHARMACIST IN A HOSPITAL**

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The hospital pharmacist participates in hospital committees either as co-ordinator, member or person responsible for the scientific secretariat. Some examples are: DTC, Ethical Committee for clinical experimentation, Committee on Hospital Infections, Commission for home care, Committee for Medical Device Evaluation. A new law enforced in 1998 states that in each Ethical Committee a pharmacist should be appointed as an ex officio member. Depending on the specific function within the

committee, the pharmacist may be responsible for the technical examinations of the requests (e.g. introduction of a new drug in the hospital formulary, application for a clinical trial within the hospital etc). This evaluation is made possible by a detailed literature search, and the technical and research background of the pharmacists. In many cases (e.g. scientific secretariat of either a DTC or an Ethical Committee) the pharmacist is in charge of the co-ordination of the committee's activities. Interdisciplinary collaboration between hospital physicians, general practitioners and nurses is required as well links with other committees, both intra and extra hospital.

Drug Information is needed for drug formulary and medical device formulary management, and further preparation of material for public education. The task to give drug information to health care professionals within the hospital and information on drug use and therapeutics to the public outside the hospital also requires the ability to consult medical texts, drugs databases and literature databases. Drug information can also be given to a physician concerning an individual patient upon the latter's discharge. This is possibly through interdisciplinary collaboration with hospital physicians, public and general practitioners.

In collaboration with the Ministry of Health, regional pharmaceutical office and the directors of units/departments in the hospital, the hospital pharmacist is also responsible for pharmacovigilance. This includes adverse events reporting for drugs and reporting on incidents/malfunctions for medical devices as well the receipt and notification of withdrawal of drugs and medical devices from the market to the users and public authorities.

Finally the hospital pharmacist is implied in training and continuing education by giving practical training to trainees, pre- and post-graduate pharmacy students, being advisor for graduation theses and taking teaching responsibilities within schools of specialisation, and within the hospital to health practitioners.

## THE RELATIONSHIPS OF THE HOSPITAL PHARMACIST

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The hospital pharmacist carries out most of his activities in interdisciplinary collaboration, including ward physicians, specialists, surgeons, dieticians, general practitioners, nurses, administrators. He may also participate in regional commissions for drug formulary, etc.

But he works in the first place with the pharmaceutical staff, consisting of:

- Director: beyond the activities proper to the professional role, the director has the task of directing and organising. These activities need to be in line with the mission of the organisation. This may be implemented by giving rules to the personnel. The director is also responsible for the management of the pharmacy budget.
- Pharmacist manager: Pharmacists managers have the task of independently carrying out pharmaceutical care activities in their sector. Their level of responsibilities varies according to their grade. Moreover, they have tasks related to consulting, research and teaching.
- Administrative personnel: their task is to perform all administrative functions of the pharmacy service (e.g. secretarial activities, transmission of purchase orders, invoice control etc.)
- Support personnel: this category of personnel does not have any specific training in the pharmacy field. Their tasks relate to deposit management, distribution and shipping of materials to the wards, compounding, under the supervision of the pharmacist who co-ordinates and controls the work done. Moreover, the pharmacist is in charge of their continuing training.
- Laboratory technicians and registered nurses: in several pharmacy services, these professional profiles have been introduced with the following specific functions: well-defined compounding (e.g. artificial nutrition bags, oncology preparations, pain therapies, antibiotic regimens).

## LU - Luxembourg

### STUDIES

#### The pharmacists' curriculum

None of the universities in Luxembourg offer a full training programme in pharmacy. To obtain a degree in pharmacy students must go to universities in Belgium, France, Germany, Austria, Switzerland, etc. For homologation of the foreign certificates Luxembourg legislation requires a minimum study length of nine semesters.

#### Specialisation in hospital pharmacy

Specialisation in hospital pharmacy is not required to have access to the profession in Luxembourg.

### THE HOSPITAL PHARMACIST

The status of hospital pharmacist is regulated by the "règlement grand-ducal" concerning the hospital pharmacy.

### MEDICINES AND MEDICAL DEVICES

Pharmacists have a monopoly on selling drugs for human use. Drugs purchased by hospitals are for inpatient use only, with the exception of drugs that are not available in community pharmacies.

Drugs are authorised by the Luxembourg Ministry of Health.

Hospitals use the ATC classifications of drugs and the European Pharmacopoeia.

Packaging is often different from the drug packaging available in community pharmacies (larger boxes, unit dose packaging, sometimes bulk).

Also pricing is different from that in community pharmacies (because of consultation and bid invitations by hospital pharmacists to pharmaceutical companies or group purchasing).

Every medical device available on the Luxembourg market fulfils CE marking. The EEC directives on medical devices and implantable devices have been implemented in the Luxembourg regulations.

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## **THE HOSPITAL PHARMACY PRACTICE**

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### **Regulations**

The Minister of Health grants a license for hospital pharmacy on request of the hospital and after agreement by the Pharmacist Inspector.

### **Financing**

The hospital pharmacy does not have its own budget. Refunding by the health insurance is supplied per service.

### **Hospital pharmacists' activities**

The first task concerns the ordering, purchasing and stock management of drugs, medical devices and other pharmaceutical products.

Also drug prescription analysis (dosage, length of treatment, drug interactions, incompatibilities, counter-indications) is done by pharmacists, although not in all hospitals.

"Préparateurs" or pharmacy students under the supervision of pharmacists dispense drugs in bulk to the wards or by the recommended unit dose system. Only few drugs are prepared in the hospital pharmacy due to staff shortage.

Only cytotoxic drugs are reconstituted in the hospital pharmacies. Injectable drugs are not.

All drugs and preparations are controlled before being released to the wards.

Purchase, management and dispensing of all sterile products (medical devices and disposables) are obligatorily the responsibility of the hospital pharmacy.

### **THE DRUG CIRCUIT AT HOSPITAL**

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Medication is ordered from pharmaceutical wholesalers or direct from manufacturers in Belgium, France and Germany. In some areas, purchasing consortia buy medication for groups of hospitals. Most hospitals have a formulary which lists medicines that can be prescribed.

Medicines are usually stored alphabetically within the hospital pharmacy dispensary. Large packages, medical devices and other products like medical gases may be stored elsewhere under the responsibility of the hospital pharmacist.

In many hospitals, the drugs are distributed to the wards on the basis of a list, which makes it impossible to analyse the prescriptions. Dispensing is done by "préparateurs" or pharmacy students under supervision of the pharmacists. More and more hospitals start to use computerised prescriptions and nominative distribution of drugs combined with an analysis of prescriptions in order to reduce the number of wrong drug prescriptions and dispensing. Those initiatives are stimulated by government authorities.

Transport is done in closed containers by personnel of the pharmacy or transport services of the hospital. Administration of drugs to the patient is the nurses' responsibility.

The pharmacists ensure a quick stock rotation to avoid drugs going out of date. Unused drugs may be returned to the manufacturer before the expiry date if the packaging is not damaged.

### **THE OTHER ROLES OF THE PHARMACIST IN A HOSPITAL**

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The hospital pharmacist is part of and often the president of the DTC, which defines the hospital drug policy. On the basis of the decisions taken in this committee he elaborates the Drug Formulary, which is the list of all the drugs (and devices) available in the hospital. He also belongs by law to the IHC, which in connection with the DTC may influence drug policy for example in antibiotherapy.

Information for good use of a drug is given through the DTC and especially its drug utilisation reviews (DUR) and evaluation (DUE), through notes or bulletins issued by the pharmacy, through oral answers to phone consultations, through advice and information given when visiting wards...

The pharmacist is responsible for the management of stable blood derivative products.

In the field of hospital hygiene, the pharmacist belongs by law to the IHC. He is also consulted for the choice of disinfectants for the hospital.

Being involved in pharmacovigilance and vigilance concerning medical devices and by participating in the IHC, the pharmacist contributes to the security and protection of the environment.

Other roles are in the field of clinical activities, clinical trials, quality assurance and quality assessment, vigilance concerning drugs and medical devices.

### **THE RELATIONSHIPS OF THE HOSPITAL PHARMACIST**

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The pharmaceutical staff works under the responsibility of the pharmacist who is Chief of Department. This chief may delegate part of his responsibility to other pharmacists in his team, but he is still responsible for them.

The pharmacist is the reference person concerning drug information for physicians.

The pharmacist is not part of the administrative team but he is the reference person for budgeting the drugs and medical devices to be negotiated with insurance organisations.

Hospital pharmacists have dealings with insurance organisations very occasionally and on specific points.

The pharmacy is also in contact with many other persons such as nurses, dieticians, staff from sterilisation services, staff from computer services, transportation services...

### **FACTS AND FIGURES**

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About 4.3% of the 350 pharmacists are working as hospital pharmacists.

There are about 1.5 hospital pharmacists on average per hospital. The average budget for the hospital pharmacy (medical devices included) is about 20% of the average budget of a hospital.

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## NL - The Netherlands

### STUDIES

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#### The pharmacists' curriculum

Studying to be a pharmacist takes six years and results in the degree of "Apotheker" (Pharm. D.). Pharmacy can only be studied at two universities in The Netherlands: the State Universities of Utrecht and Groningen.

#### Specialisation in hospital pharmacy

After four years of specialisation in authorised hospital pharmacies, pharmacists are entitled to registration as a specialised pharmacist in the register of Hospital Pharmacists in the framework of the Dutch Health Professions Act.

### THE HOSPITAL PHARMACIST

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Hospital pharmacists are a member of the medical staff of the hospital and are employed by the hospital.

### MEDICINES AND MEDICAL DEVICES

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Pharmacists have a monopoly on drugs for human use. Drugs are licenced by the "Centraal College ter Beoordeling van geneesmiddelen". EMEA evaluations are applicable in The Netherlands.

Most hospitals use the ATC classification of drugs. A classification according to the national "Farmacotherapeutisch Kompas" (FTK, Pharmacotherapeutic Compass advising on all available drugs in the Netherlands) is also common. The European Pharmacopoeia is the standard Pharmacopoeia.

Drugs purchased in the Dutch hospitals are for the hospitalised patients only. Drugs reserved for hospital use only (e.g. cytostatic drugs) or drug formulations not readily available in community pharmacies, can be provided to outpatients.

Legislation has recently been revised allowing hospital pharmacies to sell drugs to outpatients while community pharmacists may provide drugs to hospitalised patients. A few hospital pharmacies are now collaborating with an outpatient pharmacy.

Packaging is often different from the drug packaging available in community pharmacies (larger boxes, unit dose packaging, sometimes bulk).

Pricing is also different from that in community pharmacies. It results from consultations and bid invitations made by hospital pharmacists or (regional) purchasing groups to the pharmaceutical industries.

Every medical device on the Dutch market fulfils CE marking. The EEC directives on medical devices and implantable devices have been implemented in Dutch regulations, as well as the directive on wastes of drugs and protection of the environment.

### THE HOSPITAL PHARMACY PRACTICE

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#### Regulations

To include a pharmacy within its structure, the hospital must ask for special authorisation (licence).

#### Financing

The budget allowed every year to the pharmacy is a part of the budget allotted to the hospital. It includes drugs, infusion and rinsing fluids, other pharmaceutical products and the pharmacist's and all other worker's salaries. In most hospitals the drug budget is allocated to the units within the hospital. The units then have the financial responsibility for the budget.

#### Hospital pharmacists' activities

The hospital pharmacy has the responsibility and the monopoly for the total chain from purchasing to dispensing to the individual patient.

Hospital pharmacists also analyse drug prescriptions (dosage, length of treatment, drug interactions, incompatibilities) and check for counterindications. Furthermore the hospital pharmacist acts as clinical therapy consultant to optimise individual patient therapy. Therapeutic drug monitoring and pharmacokinetic modelling is integrated into the consultancy.

Drug dispensing is performed by pharmacy technicians under the supervision of hospital pharmacists. Drugs are delivered to the wards either in bulk (drug provision replaced when used) or with a

patient oriented distribution. Almost all hospitals use a unit dose drug distribution system.

The drug preparations manufactured in hospitals are preparations that are not available from pharmaceutical suppliers, either because of specific dosage, special mixtures, or preparations with stability problems.

Drug reconstitutions are mostly implemented within the pharmacy service, but may be decentralised in the wards.

All batchwise manufactured products are prepared according to protocols, tested in the laboratory and released by a quality control pharmacist.

Most individually prepared drugs or preparations are manufactured according to predefined protocols and double-checked by technicians before release to the wards. Ad hoc preparations are prepared according to an ad hoc protocol designed by a hospital pharmacist. A final release by a hospital pharmacist is performed before release for cytotoxic drugs and after release for other preparations.

In most hospitals the hospital pharmacist is responsible for the sterile medical devices, disposables and the Central Sterilisation Departments.

The use of reusable medical devices is not encouraged. If decided upon it is only performed in predefined cases according to protocol.

The hospital pharmacist is a member of the local Medical Ethics committee. The hospital pharmacy may be involved in pharmacoeconomical, pharmacokinetic or pharmacotherapeutic studies or play its part in medical research. Hospital pharmacists are also involved in clinical trials.

### **THE DRUG CIRCUIT AT HOSPITAL**

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Hospital pharmacies order from manufacturers, wholesalers, and sometimes, after authorisation, from other hospitals for very specific products.

Drugs are usually stored alphabetically within the pharmacy storage area. Medical devices are stored separately, as well as products with large volumes i.e. infusion fluids. Some products may be stored outside the central pharmacy (but still under its responsibility) i.e. fluids for dialysis and medical gases.

Regulations require a prescription for each drug to be dispensed to the patients. The most common distribution system is the prescribing on the ward, the input of the prescription in a computerized system combined with analysis by the pharmacy technician and dispensing in a patient oriented distribution in unit dose Pharmacy technicians under the supervision of hospital pharmacists perform drug dispensing. The hospital pharmacist analyses pharmacotherapy either through the computerized medication system (most common) or on the ward.

In some hospitals the process takes place entirely on the ward. Electronic prescribing by the doctors is more and more introduced.

Drugs are transported to the wards in closed containers by staff from the pharmacy department or hospital transportation service.

Nurses administer drugs to the patient. The hospital pharmacist is responsible for the distribution process. Increasingly the hospital pharmacy supplies patient information.

It is the pharmacist's responsibility to implement a quick stock rotation to avoid drugs going out of date. Out of date drugs are destructed by the hospital.

### **THE OTHER ROLES OF THE PHARMACIST IN A HOSPITAL**

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The hospital pharmacist is part of and often the president of the Drug and Therapeutics Committee (DTC) which defines the hospital drug policy. The hospital pharmacist implements the decisions taken by the DTC in the Drug Formulary, which is the list of all drugs (and sometimes devices) available in the hospital. The pharmacist is also part of the Infection and Hygiene Committee, which, in connexion with the DTC, may decide on the drug policy for antibiotic therapy.

The hospital pharmacist provides information for efficacious drug use, through the DTC and specially its drug utilisation reviews (DUR) and drug use evaluation (DUE), through notes or bulletins issued by the pharmacy department, through oral answers to telephonic consultations and through advice and information given when visiting the wards.

In large hospitals, pharmacists are involved in the hospital Drug Information Centre.

The pharmacist is responsible for stable blood products, their management and their traceability.

As member of the "Infection and Hygiene Committee" the hospital pharmacist is consulted for the choice of disinfectants for the hospital. In most cases the hospital pharmacist is responsible for the disinfection of (fibre)scopes and the sterilisation of medical devices.

Other roles of the hospital pharmacist are in the field of clinical activities, clinical trials, quality assurance and quality assessment, vigilances concerning drugs and medical devices, parenteral nutrition, pharmacokinetic consultations and educational activities.

### **THE RELATIONSHIPS OF THE HOSPITAL PHARMACIST**

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The pharmaceutical staff works under the responsibility of the hospital pharmacist who is Head of the Pharmacy Department. Although the Head of the Department may delegate part of his responsibility to other pharmacists in his team, he remains legally responsible.

The hospital pharmacist is member of the medical staff. The pharmacist performs drug substitutions within the context of a substitution policy for non-formulary drugs. Pharmacists often buy generics and work with the International common denomination of the drugs.

The pharmacist is usually not part of the management team of the hospital, but there are frequent contacts with staff responsible for the drug budget in the hospital.

With the insurance companies the relation of the hospital Pharmacist is very occasional, and on very specific subjects.

Other persons in contact with the hospital pharmacist are the medical director, nurses, nutritionists, staff from the sterilisation department, the IT-department, technical services and transportation services of the hospital. The hospital pharmacist is regarded as a reliable and unbiased partner for all matters regarding drugs and drug use.

Contacts with community pharmacists are becoming increasingly important to ensure seamless pharmaceutical care for the health community related to the hospital.

### **FACTS AND FIGURES**

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The hospital pharmacists represent about 11% of all pharmacists. On average there are 4,5 hospital pharmacists and 22 hospital pharmacy technicians for each hospital.

The national budget for in-hospitals drugs counts for 8,75% of the national budget for drugs and for about 5% of the national budget for hospitals.

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## **PT - Portugal**

### **STUDIES**

#### **The pharmacists' curriculum**

It takes six years of university study - including a full year of practice training in a community or hospital pharmacy - to obtain the "Degree in Pharmaceutical Sciences".

The access to the studies is restricted to students with certain marks as final high school results.

#### **Specialisation in hospital pharmacy**

There is a one-year post-graduation in hospital pharmacy and a two-year master in hospital pharmacy, both at the university of Lisbon.

### **THE HOSPITAL PHARMACIST**

Pharmacists have access to the hospital pharmacy career after a three-year residence training. The title of specialist in hospital pharmacy is conferred by the Portuguese Pharmaceutical Society to all hospital pharmacists with 5 years of professional experience, after having passed an examination.

### **MEDICINES AND MEDICAL DEVICES**

The 'Formulário Hospitalar Nacional de Medicamentos' (F.H.N.M.) is used at national level as a guidance document for drug selection in hospital pharmacies. This document is edited by the Comissão do Formulário Nacional (National Formulary Commission).

Hospital pharmacies dispense medicines for both inpatients and outpatients.

Outpatient dispensing is limited to hospital prescriptions approved by the hospital's management board.

Dispensing of medicines to the public is limited to situations such as emergency cases or to charity organisations.

### **THE HOSPITAL PHARMACY PRACTICE**

The main activity of hospital pharmacists consists in dispensing medicines and blood derived products. After the hospital pharmacist has received the prescription, he interprets the dosage, interactions,

etc. A patient medication record is elaborated and kept in the pharmacy.

The hospital pharmacy prepares medicines for specific patients in small quantities when consumption/use is immediate, and produces large quantities for storage when several potential patients are expected to use them.

Sterile preparations, cytotoxic drugs and total parenteral nutrition are prepared by the hospital pharmacy if adequate facilities and technology are available (only in a few hospitals).

The hospital pharmacy is also responsible for the dispensing of drugs used in clinical trials.

### **THE DRUG CIRCUIT AT HOSPITAL**

Drugs are stored in the pharmacy under the supervision and responsibility of the pharmacist.

Dispensation of drugs to the wards is made under a medical prescription including the identification of the patient as well as the service/department and the bed number. Prescriptions must specify the generic name of the drug and its unit dose.

The majority of Portuguese hospitals adopt the unit dose distribution system. Hospital management encourages the implementation of the system whenever human resources and facilities are available.

All medicines are administered by nurses.

### **THE OTHER ROLES OF THE PHARMACIST IN A HOSPITAL**

Hospital pharmacies deliver information to physicians and nurses and participate in protocol development for the good use of drugs in the hospital.

The hospital pharmacist is member of several technical committees (DTC, Antibiotics, Infection Control, Clinical Nutrition and Oncology) and of the Ethic Committee.

The pharmacist also collaborates in the national pharmacovigilance system.

Other roles are in the field of therapeutic drug monitoring, pharmacokinetics, clinical trials, outpatient dispensing of drugs, educational activities (controlling practical training of pharmacy students and pre- and post-graduating training), clinical pharmacy and patient counselling.

### **THE RELATIONSHIPS OF THE HOSPITAL PHARMACIST**

Contact with physicians is mainly about confirmation of a prescription, changing drugs or altering posology and is made either personally or by phone and, if necessary, by a written document.

Contact with nurses mainly concerns problems connected with the administration or stability of the drug.

Other contacts are with the Purchasing Service, the Management Board, etc.

### **FACTS AND FIGURES**

There are 512 hospital pharmacists, i.e. 7 % of the total number of pharmacists. Although not established by law, it is considered appropriate that one pharmacist be assigned to 60/50 beds. A technician (paramedic) is advisable for every 40 beds.

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## **SW - Sweden**

### **STUDIES**

#### **The pharmacists' curriculum**

There are three different degrees in pharmacy: Master of Science, Bachelor of Science and 'farmacie kandidat'.

The length of academic studies in Sweden is measured in credit units. A credit unit refers to an input of approximately 40 hours work required from the student to achieve the set objectives.

The extent of the basic diploma programme in pharmacy consists of 120 credits. The education programme includes practical training for 6 months in a community pharmacy or in a community and a hospital pharmacy. The degree can be completed in three years. The degree "farmacie kandidat" is similar but does not include the pharmacy practise training.

The Master's degree programme in pharmacy consists of 200 credits. It includes practical training for 6 months. During the training period 2 weeks at a hospital pharmacy are compulsory. The Master's degree can be completed in five years.

Access to the education programmes is based on grades obtained at the gymnasium. Natural science background is required.

#### **Specialisation in hospital pharmacy**

A specialisation in hospital pharmacy was started in January 2001. It is a three-year programme with one year of theory and two years of diverse practical training. To work in a hospital pharmacy, this specialisation is not compulsory.

#### **Mutual recognition of diplomas and free circulation of pharmacists**

Only the Master's degree fulfils the requirements of the directive of the Council 85/432/ETY. The Bachelor degree is a Nordic characteristic as regards pharmacy diplomas.

## **THE HOSPITAL PHARMACIST**

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Within the hospital, the pharmacist is a specialist in the field of pharmaceutical products. Clinical pharmacy is at its beginning in Sweden. Most hospital pharmacists have leading positions in departments within the pharmacy or do research. The status of the hospital pharmacist is high but the lack of integration between pharmacy and hospital is a negative factor for recognition of the pharmacist at the hospital.

## **MEDICINES AND MEDICAL DEVICES**

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Apoteket AB, a state-owned company, has the monopoly on selling all drugs including OTC drugs and veterinary drugs to the public. Apoteket AB manages all the hospital pharmacies in Sweden but there is no monopoly in the hospital pharmacy sector. The hospital pharmacy almost always includes an outpatient section. The fact that all hospital and community pharmacies belong to the same company makes it easier to provide service to patients both when they are in hospital and afterwards when they are at home. Due to the monopoly there is only one computer system within the pharmacy service in Sweden.

In Sweden the European Pharmacopeia is used, which is e.g. based on EMEA definitions. Also ATC coding is in use.

For outpatient pharmacies, the price of drugs is negotiated between the drug company and the national social insurance board. Apoteket AB takes no part in the negotiations. The county councils and regions co-operate with Apoteket AB in order to get discounts from the pharmaceutical industry for the drugs used in the hospital.

Every medical device on the Swedish market has to fulfil the CE marking.

## **THE HOSPITAL PHARMACY PRACTICE**

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### **Financing**

Almost all major hospitals in Sweden are managed by the county councils or regions. There is a variety of financing methods for the hospital pharmacy service in the different county councils and regions. The most common method is that the pharmacy

charges the (internal, AIP) price of the pharmaceuticals and gets paid per service supplied.

### **Hospital pharmacists' activities**

The hospital pharmacist is responsible for prescription analysis (only possible for outpatient cases) and for dispensing the drugs to the wards. Packages of drugs are normally not opened although unit dose distribution is mostly encouraged by the health authorities.

Larger hospital pharmacies also prepare drugs that are not commercially available (e.g. specific dosage forms and dosages for premature infants / children, injection solutions etc.). Apoteket AB also has four centres taking care of most of the drug compounding.

The pharmacies prepare TPN, cytotoxic drugs and ambulatory pumps that are used in the hospital or in advanced Home Care. Every drug or preparation is controlled before being released to the wards.

The hospital pharmacy service is normally not involved in management of medical devices and disposables or in sterilisation of reusable medical devices and management of blood derived products.

Pharmacists participate in research projects, produce statistics on drug use and are involved in pharmacoconomics.

## **THE DRUG CIRCUIT AT HOSPITAL**

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A hospital pharmacy orders medicines from a wholesaler, another pharmacy, a drug manufacturer or the compounding units of Apoteket AB. Drugs are stored within the hospital pharmacy. Products with large packaging (e.g. infusions) may be stored separately. Some products (e.g. medical gases) may be stored outside the hospital pharmacy, but they are still under the responsibility of hospital pharmacies.

Drugs are mostly distributed from the pharmacy to cabinets on the wards, in original packages according to the ward orders. Transportation in closed containers is usually performed by staff from the hospital transportation service.

Administration to the patient is always done by nurses who have to register each dose that is administered.

The head nurse is responsible for the drugs of the ward and for returning expiring or out of date medicines to the hospital pharmacy.

The hospital pharmacy is responsible for implementing a quick stock rotation to avoid drugs going out of date.

### **THE OTHER ROLES OF THE PHARMACIST IN A HOSPITAL**

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Pharmacists play an important part in the procurement of drugs and in the selection of basic medicines for the hospital. Hospital pharmacies monitor the consumption of drugs at the hospital and regularly report to their customers within the hospital. Each ward is inspected by pharmacy staff at least once a year. All clinical trials have to pass the pharmacy.

The hospital pharmacy provides drug information and promotes drug safety.

Pharmacists participate in the work of the hygiene committees in hospitals.

The hospital pharmacy produces statistics on consumption of e.g. antibiotic drugs used in the hospital.

As regards security and protection of the environment, Apoteket AB has had its own policy for several years. The first pharmacies in Europe to be certified according to EMAS are the pharmacies in Jönköping.

Pharmacists also take part in a lot of activities to promote safe drug handling at the hospital. Other roles are in the field of educational and research activities, training of pharmacy students, clinical pharmacy (review charts, advice on stability and compatibility of parenteral drugs, drug information to patients, pharmacist member of a nutrition team), developing and maintaining good manufacturing practise and nuclear pharmacy and dialysis.

### **THE RELATIONSHIPS OF THE HOSPITAL PHARMACIST**

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The hospital pharmacy staff works under the manager of the hospital pharmacy (pharmacist). The latter may delegate part of his tasks to other pharmacists, but is still in overall charge for drug supply.

As regards the relation with physicians, hospitals should follow the confirmed basic drug selection. Basic drugs not in stock may be replaced by a 100% comparable product from the pharmacy stock. The pharmacist is not a member of the Board of Directors.

There is no actual co-operation with insurance organisations.

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**The pharmacists' curriculum**

Due to the fact that the University of Cyprus does not have a faculty of pharmacy, most pharmacists in Cyprus are holders of diplomas which they have acquired in European or American universities. There are also a substantial number of pharmacists who have graduated at a university in one of the former eastern block countries.

**Mutual recognition of diplomas and free circulation of pharmacists**

In order to register as a pharmacist in Cyprus under the current legislation the following requirements must be fulfilled:

1. Pharmacists must be Cypriot citizens or married to a Cypriot citizen or a child of a Cypriot citizen with Cyprus being their usual country of residence.
2. They must be holders of a License, Degree or Diploma in pharmacy obtained at a university in Greece, Turkey or the UK, which enables them to register as pharmacists in these countries.  
OR  
They must be holders of a License, Degree or Diploma in pharmacy from any university or school in pharmacy which has been declared an adequate qualification by the Council of Ministers.
3. They must have succeeded in the examination in forensic pharmacy.
4. They must have completed a one-year training in Cyprus in the field of pharmacy.

In the future situation (upon accession to the EU) all the relevant provisions resulting from the adaptation of directives 85/432/EEC and 85/433/EEC will apply for EU citizens.

**THE HOSPITAL PHARMACIST**

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Due to the fact that hospitals in Cyprus are government owned, hospital pharmacists are government employees working for the Pharmaceutical Services of the Ministry of Health. There is no clinical pharmacist in every hospital pharmacy, but there is a Clinical Pharmacy Sector at

central level, which is directly involved in many issues regarding drug policy at hospital level.

**MEDICINES AND MEDICAL DEVICES**

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Pharmacists have a monopoly on drugs for human use.

The Drugs Council is responsible for licensing of drugs. There is a single database for drugs which is maintained centrally at the Pharmaceutical Services without a possibility to access the database from the hospital pharmacies. Drug entries are classified by ATC codes.

Cyprus does not have its own pharmacopoeia; the British and European Pharmacopoeias are used instead.

Drugs used in hospitals are purchased centrally by the procurement department of the Pharmaceutical Services and distributed to government hospital services.

Under the current health system, drugs are charged according to the economic status of the patient, irrespective of their actual cost, at a fixed amount/drug. For private patients, the price is doubled.

**THE HOSPITAL PHARMACY PRACTICE**

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**Financing**

A budget is allocated every year to the Pharmaceutical Services. This budget, which is part of the global budget, includes the purchasing of drugs and medical devices, payment of salaries as well as other fixed or running costs of the Pharmaceutical Services.

**Hospital pharmacists' activities**

The vast majority of pharmacists working at hospital level deal with the dispensing of drugs by prescription to outpatients, by treatment charts to inpatients and on requisition to wards.

Drugs not available on the market as ready-made products are usually prepared by the pharmacy unit. Other preparations with stability problems are also reconstituted at pharmacy level before dispensing.

TPN mixtures and cytotoxic drugs are reconstituted in a dedicated unit of a hospital or at decentralised level.

For inpatient use drugs are double checked before being released to the wards.

A number of medical devices are held in stock at pharmacy level and issued on requisition to the wards.

One pharmacist per hospital pharmacy is responsible for maintaining adequate stock levels of drugs and medical devices and for organising the staff in their daily tasks.

### **THE DRUG CIRCUIT AT HOSPITAL**

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There is a central Pharmaceutical Store from which all hospital pharmacies obtain their supplies. Usually hospital pharmacies order their supplies in quantities, which are estimated to last for one month. After processing the requested drugs and/or medical devices are forwarded to the hospital pharmacy on the same day.

Drugs are usually stored in alphabetical order or by therapeutic category in dedicated stores within the pharmacy or outside the pharmacy premises.

Drugs are dispensed to wards through the issuing of a requisition. Quantities requested are usually adjusted at pharmacy level according to variable factors. Transportation to the wards is done by the hospital transportation service.

The nursing staff has the responsibility of administering the medication to the patient according to the doctor's orders.

The pharmacy uses FIFO to dispense drugs to outpatients, inpatients and wards. In the case drugs expire, a destruction certificate is issued at pharmacy level and the expired drugs are then destroyed.

### **THE OTHER ROLES OF THE PHARMACIST IN A HOSPITAL**

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There is one hospital formulary common to all hospitals. Drugs included in the formulary are

approved by the Drugs Committee, which consists among others of clinical pharmacists.

Clinical pharmacists, through the drug information and poisoning centre, provide information to doctors, nurses and the public on various issues regarding the use of drugs.

The hospital pharmacist collaborates with the physicians and recommends the most cost-effective treatment for the patient.

The hospital pharmacist also participates in clinical and educational activities.

### **THE RELATIONSHIPS OF THE HOSPITAL PHARMACIST**

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The hospital pharmacist is in frequent communication with the staff of other sections of the Pharmaceutical Services (e.g. during the procurement process).

There is a close co-operation with the nursing staff of the hospital. With physicians the relationship becomes more productive when the pharmacist is member of the treatment team.

Many other persons such as staff from the patient registration department, computer services, technical services, transportation, etc. are generally in contact with the pharmacy at the hospital.

### **FACTS AND FIGURES**

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The ratio number of physicians/number of hospital pharmacists is 7/1. There are on average 25 hospital beds per hospital pharmacist.

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**The pharmacists' curriculum**

To qualify as a pharmacist, students must successfully complete a five-year academic degree.

There is no numerus clausus at present, but access is restricted to students with an Advanced Level in Chemistry, and two subjects from Physics, Biology, Mathematics, Computer Science, Philosophy, English Language, one of which at Advanced Level and one at Intermediate Level.

The resulting diploma is 'Bachelor of Pharmacy (Hons)'.

**Specialisation in hospital pharmacy**

There is no formal specialisation in Hospital Pharmacy. The Bachelor of Pharmacy course includes a ten credit optional practice based module in clinical pharmacy during the 5th year. Nevertheless, a number of specialised areas have been identified, where further training in a foreign training centre is required. At present there is special training for cytotoxic drugs reconstitution, whilst training for TPN and injectable drugs reconstitution (CIVAS) is being developed.

**Mutual recognition of diplomas and free circulation of pharmacists**

At present, the recognition of the basic degree is on an individual basis.

**THE HOSPITAL PHARMACIST**

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Although the pharmacy department has a similar hierarchical structure to medical departments, the hospital pharmacist does not have the same status as physicians and has a lower salary.

**MEDICINES AND MEDICAL DEVICES**

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Pharmacies have a monopoly on selling and dispensing drugs. In Malta, having a comprehensive health service to all Maltese citizens, the Government supplies medicines free of charge to

inpatients at Government hospitals and a free 3-day supply on discharge.

A European licensing system has been initiated in 2001 and will be in line with EU directives by 2003.

Legislation still refers to the British Pharmacopoeia, the British Pharmaceutical Codex and Pharmacopoeia Internalis. The regulations are amended to recognise the European Pharmacopoeia as the official pharmacopoeia by 2003.

The state health care system has a national formulary, which is dynamic and encompasses a wide range of pharmaceutical products.

The sale of drugs from hospitals to outpatients is limited to drugs that are unavailable in private retail pharmacies and drugs needed urgently out of hours.

In Malta there is no Drug Price Index as yet although the Government has shown a clear intention to introduce a pricing policy in the pharmaceutical field. All Government hospital pharmacies and health centre pharmacies obtain their medical supplies from a central store within the Government Pharmaceutical Services which purchases pharmaceuticals by tender. In cases where the hospital sells medicines to outpatients, a 15 % mark-up is added to the purchasing price.

Packaging is often different from the drug packaging available in community pharmacies (hospital packs are generally used).

The Malta Standardisation Authority is in the process of legislating in order to ensure that all products on the local market are CE marked.

The Government of Malta has recently signed the Basle Convention to meet the EEC directive on wastes of drugs and protection of the environment. At present, there is no local incinerator, which reaches the required high temperatures for cytotoxic waste disposal, and cytotoxic wastes are kept in storage to be shipped for disposal.

## **THE HOSPITAL PHARMACY PRACTICE**

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### **Regulations**

To include a pharmacy within its structure, a hospital must ask for special authorisation. However, the hospital pharmacy per se does not have a licence.

### **Financing**

Although the yearly expenditure by the different hospitals is made available, there is no budget allocated specifically to hospital pharmacy for the daily running. There is a central budget within the Health Division, which provides for pharmacists' salaries and a central budget for medical devices and pharmaceutical products.

### **Hospital pharmacists' activities**

The hospital pharmacist is responsible for drug dispensing. Prescription analysis is only carried out upon request.

The quantities of drugs delivered to the ward are predetermined following consultation between pharmacists, nurses and doctors. A smaller number of drugs are delivered with a patient oriented distribution.

The drug preparations manufactured in hospitals are preparations, which are not available in pharmaceutical industries, either for specific dosage, special mixtures or for preparations with stability problems.

The hospital pharmacy exerts control on narcotics and psychotropic substances. Dispensing of certain drugs is restricted by protocol guidelines issued by the Drug and Therapeutic Committee, which is another area of control within the formulary.

Only cytotoxic drugs are reconstituted locally in two Government hospital pharmacies. TPNs are as yet not reconstituted locally and are therefore purchased ready-made. As yet there is no intravenous additive service being provided in any of the local hospitals.

Although the purchase is by the Government Pharmaceutical Services, the management and dispensing of all sterile products are not under the responsibility of the hospital pharmacy.

## **THE DRUG CIRCUIT AT HOSPITAL**

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The Government hospitals pharmacies order from the Government Pharmacy Services, who in turn receive their supplies from manufacturers or from wholesalers by tender systems. Each hospital pharmacy has an adjacent store for the storage of pharmaceuticals. The pharmacist can allow some drug store in the wards and other hospital units for which the nurses are responsible.

In many hospitals, nurses makes ward orders, except for patient specific requests for narcotic and psychotropic drugs, where a special drug ordering booklet is used which requires authorisation by the prescribing doctor.

Drug dispensing to the wards is performed by pharmacists or pharmacy technicians under the supervision of pharmacists. Narcotic drugs are dispensed by pharmacists only.

Transportation is performed in closed containers, by the hospital or pharmaceutical transport service, or even the ward staff.

Administration of drugs to the patient is the nurses' responsibility with the exception of the initial dose of an intra-venous drug, which is given by a doctor. It is the pharmacist's responsibility to implement a quick stock rotation to avoid drugs going out of date. Out of date drugs are reviewed by a board and they are then forwarded for destruction according to EEC directives.

### **THE OTHER ROLES OF THE PHARMACIST IN A HOSPITAL**

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The hospital pharmacist is the secretary of the DTC, which defines the hospital drug policy. From the decisions taken in this committee, he elaborates the Drug Formulary with drugs for both hospital and outpatient use. He is also part of the Infection Control Team and the Antibiotic Sub-committee. The pharmacist is consulted for the choice of disinfectants for the hospital.

Advice and information for drug good use is given through the DTC and its drug utilisations reviews and evaluation, by phone or when visiting wards.

The pharmacists keep track of all these products where possible to patient level

The hospital pharmacist is also responsible for the disposal of clinical wastes with particular reference to cytotoxic drug disposal.

Other roles are in the field of drug information, clinical activities, quality assurance and quality assessment, vigilance concerning drugs, educational activities and clinical pharmacy (yet not fully implemented).

### **THE RELATIONSHIPS OF THE HOSPITAL PHARMACIST**

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The pharmaceutical staff works under the responsibility of the Senior Pharmacist who may delegate part of his responsibility to other pharmacists in the team.

As regards the relationship with physicians, there is a policy by the Health Department that prescribing and dispensing within the National Health Service should be based on generic products. There are some cases however where a particular branded product may be requested for specific patients.

There is a close relationship between the pharmacist and the nursing staff resulting in a close collaboration.

The pharmacist is usually not part of the administrative team.

There is no specific relationship between pharmacists and insurance organisations.

### **FACTS AND FIGURES**

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5.6% of the 720 pharmacists are hospital pharmacists while there are 1033 physicians. There are 40 hospital pharmacists for 5 hospitals. The cost of drugs issued per hospital bed is about 5,500 Euros.

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