Part I

Introduction
1 PHARMACEUTICAL CARE, INTRODUCTION

Defining an activity like care in itself is difficult and on an international level it becomes hazardous. The concept of care is strongly influenced by national care concepts and local circumstances in health care practice.

This chapter deals with issues surrounding health systems and the definitions of pharmaceutical care. The place of pharmaceutical care within a general health system is defined and the scope on pharmacy and pharmaceutical care is used for explaining the development of different definitions. Different linguistic and cultural influences on the construct of the definition are given.

1.1 THE CHALLENGES OF DEFINING PHARMACEUTICAL CARE ON AN INTERNATIONAL LEVEL

Looking at the literature, pharmaceutical care is a way of dealing with patients and their medication. It is a concept that deals with the way people should receive and use medication and should receive instructions for the use of medicines. It also deals with responsibilities, medication surveillance, counselling and outcomes of care. In some countries the concept also deals with the way people should obtain information about disease states and lifestyle issues. In exceptional cases even purchasing medicines by a pharmacy is considered to be part of the concept.

Observations of, and communications with, researchers in the field of pharmacy practice in different countries in Europe, Australia, New Zealand, and in the USA reveal many differences in the interpretation of the concept of pharmaceutical care and its outcomes. The different interpretations sometimes prohibit the exchange and comparison of the results of pharmaceutical care and pharmacy practice research. The differences are a result of international cultural factors in pharmacy practice (see also Chapter 8), linguistic difficulties, the national and social environment in which health care is provided and different interpretations of the terms ‘managed care’ and ‘disease management’. Also different approaches towards outcomes may lead to misunderstandings. All these factors have contributed to a continuous development of the concept of pharmaceutical care internationally. The questions of how and why different definitions have developed and why the original American definition of pharmaceutical care¹ has been and perhaps should be further reshaped in other countries are discussed.

¹ A slightly adapted version of this chapter has been accepted for publication in the December 1999 issue of the International Journal for Pharmacy Practice as: van Mil JWF, McElnay J, de Jong-van den Berg LTW, Tromp ThF]. The Challenges of defining pharmaceutical care on an international level.
To be able to outline the place and function of pharmaceutical care, the terms managed care, disease management and pharmaceutical care will first be described, before identifying elements that might influence the concept and the definition of pharmaceutical care at a national level.

1.1.1 Sources of information
Initially a literature search was performed using Medline Silver Platter, from 1985 to 1993, using the keywords ‘pharmaceutical care’ as text in title and/or abstract and appropriate articles including definitions of the subject or discussions around the definition were selected. For the period between 1993 and 1999 additional searches were performed in a similar way. These latter searches did not offer important new viewpoints.

Although a large number of articles dealt with the elements, which might or might not be part of the pharmaceutical care concept, the number of articles discussing its definition is limited especially in Europe. Furthermore literature descriptions reflected the ideal situation rather than reality. Therefore the content of this chapter is also influenced by discussions with representatives of the international academic and professional pharmaceutical community, such as researchers united within the Pharmaceutical Care Network Europe Foundation (PCNE) and peers meeting during the conferences of the International Pharmaceutical Federation (FIP). The results of a questionnaire survey on international pharmacy are also used. This questionnaire was compiled in 1997 in co-operation with the community pharmacy section of FIP. Information was obtained from the pharmaceutical societies of 31 different countries (response rate was 68%, see chapter 8). Most section member countries in Asia and Eastern Europe did not reply. South Africa is not represented in the FIP community pharmacy section.

Although the results of the survey have not yet been published, one of the questions in the questionnaire specifically asked for the definition of pharmaceutical care used nationally. Other information was obtained from the Internet, especially the PharmCare discussion list Pharmweb.

1.1.2 Pharmaceutical Care, Disease Management and Managed Care
In the European world of healthcare and pharmacy, the terms managed care, disease management and pharmaceutical care often seem to be used without much distinction. From discussions with peers it appears that many activities are labelled as managed care (especially in Switzerland) or disease management (sometimes in The Netherlands or Germany), where pharmaceutical care probably would be more appropriate. In the USA, where the terminology originated, there is a much clearer distinction between those terms.
There is a major difference between these different forms of care in a sense that the drivers and the subjects of the processes differ. Managed care, disease management and professional care (e.g. pharmaceutical care) are concepts, which are initiated by groups with specific interests. Many definitions have been advanced to indicate the differences between these forms of care or care activities, but none of them seems to be appropriate. One of the confusing examples of such definitions can be found in a Dutch article by de Smet et al.³. They define managed care as a framework and disease management as a process. But others see disease management as a framework for which the processes still must be defined in the form of protocols for the health care professionals. On the other hand, during a FIP-meeting in Germany, managed care was defined as a process⁴.

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<tr>
<th>CONCEPT</th>
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<td>Pharmaceutical Care</td>
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<td>Disease management</td>
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† (Published with consent from the author)
The different parties in health care, being the patient, professionals, insurance companies and the health care industry, obviously have different approaches. The different parties have developed methods, systems and concepts. However, the role of the patient in these developments often seems to be rudimentary.

In the different concepts, systems or methods, functions are assigned to the different other parties in the field. Table 2-1 best illustrates this.

**Managed Care** is a market-driven framework for the provision of health-care, originally developed in the United States. ‘Health-care management’ could be another term for this. The Managed Care Organisation (MCO), or a large employer initiates and controls the framework through a managed care plan either offered by a Health Maintenance Organisation (HMO) or by directly hiring health care professionals though a Preferred Provider Organisation (PPO). The physician plays the central role, within a large administrative organisation. The role of the patient and his/her influence on the system is often almost absent. Pharmacists discussions on different internet platforms (the Pharmaceutical Care Discussion Group and the Pharmacy Mail Exchange), suggest that managed care’s main purpose is reducing costs and providing care to a level which is just acceptable to society.

Managed care is the principal driving force behind health care in the USA. In Europe the influence of managed care on health care systems is limited although the UK National Health System could be seen as one large HMO.

In **Disease Management** the physician is the initiator of a framework which controls the treatment of specific diseases. Often the HMO drives the physicians’ actions through a disease management programme. The role of the pharmacist and patient is usually acknowledged but the individual patient has no direct influence on the content of the care provided.

The pharmacists’ role in disease management has become increasingly clear. Munroe et al. state that pharmacists have the unique expertise that is vital to ensuring the maximum benefit of pharmacotherapy to be able to deliver improved patient outcomes and lower costs. Pharmaceutical care has some of the characteristics of disease management in the sense that attention is being paid to the patient and protocols are sometimes being used when disease specific pharmaceutical care is to be delivered. But the concept of disease management is usually only applied to groups of patients with ‘expensive’ diseases, certainly in Europe.

In **Pharmaceutical Care** the individual patient is the main subject and usually the pharmacist is the initiator and driving force of the process. Depending on the interpretation of the definition, the latter need not always be the case. By identifying, resolving, and preventing undertreatment, overtreatment or inappropriate treatment, pharmacists can prevent or reverse many adverse drug-therapy related events and also have an economic impact. These activities can be protocollised to a certain extend. Sometimes the insurers seem to be interested in the concept, but distance themselves from it. Usually the profession itself supports the development of the concept through their professional organisations.
Pharmaceutical care is a form of professional care like nursing care or medical care, and therefore the core roles of the patient and the provider are vital.

1.1.3 Defining Pharmaceutical Care
In the complex field of care, as outlined above, it is necessary to define pharmaceutical care. One can regard the activities in a (community) pharmacy as separated into supportive pharmaceutical actions, (carried out in the back-office) and clinically oriented activities (disease or case oriented). In addition to these activities pharmaceutical care, aimed at the individual patient, can be carried out at the counter or in the consultation room. Figure 1-4 shows the relationships of those activities.

Figure 1-3 Relationships between care in a health system

Figure 1-4 Relationships between care in a health system
Depending on the time and the country of origin, different definitions of pharmaceutical care are in use. In the United States, for example, the definitions have developed into their current form, starting in 1976, and since then pharmaceutical care has been often redefined. However, in the FIP questionnaire, which was evaluated at the University of Groningen, 6 out of the 30 responding countries indicated that they use the Hepler and Strand (1990) definition as their current working definition. Twelve countries did not give a definition of pharmaceutical care (including the USA) and 12 countries gave their own description or definition, which was in all cases significantly different from the Hepler and Strand definition. All definitions and descriptions have the same intent, namely care for individual patients.

A message on the PharmCare discussion list also suggests that a community level provision of pharmaceutical care is possible, especially in developing countries. In this case pharmaceutical care would focus on developing standard treatment guidelines, effective supervision of dispensing and effective use of support personnel. Although these activities are extremely useful in certain circumstances, this structural group-approach is not common and currently is not regarded as pharmaceutical care according to all published definitions.

The American definitions

Clinical pharmacists generated the first definition for pharmaceutical care in the US, not unexpectedly if we look at the history of the pharmacy profession in that country. Mikeal et al. described pharmaceutical care in 1975 as ‘The care that a given patient requires and receives which assures safe and rational drug usage’. In the following years the term pharmaceutical care has been used a number of times for all actions which are needed for compounding and dispensing medicines. Brodie et al. were the first to give a more complete definition of pharmaceutical care in 1980. They stated: ‘Pharmaceutical care includes the determination of the drug needs for a given individual and the provision not only of the drugs required but also of the necessary services (before, during or after treatment) to assure
optimally safe and effective therapy. It includes a feedback mechanism as a means of facilitating continuity of care by those who provide it\textsuperscript{13}.

In this definition for the first time a possible feedback-mechanism was suggested, a principle that Hepler later used in the work following his joint definition with Strand\textsuperscript{14}. It also placed pharmaceutical care in a sociological context in which the role of the patient and his or her needs became important.

In 1987 Hepler formulated his first definition, in which the commitment to the patient became apparent: ‘a convenantal relationship between a patient and a pharmacist in which the pharmacist performs drug-use-control functions (with appropriate knowledge and skill) governed by awareness of and commitment to the patients’ interest’\textsuperscript{15}. It is interesting to note that Hepler at the time of formulating this definition seemed to suggest that only a pharmacist could provide pharmaceutical care. This viewpoint is less clear in the widely accepted definition published in 1990, which Hepler formulated together with Strand. That definition is the current cornerstone of many parties working in the field of pharmaceutical care, in hospital as well as in community pharmacy: ‘pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes which improve a patient’s Quality of Life’\textsuperscript{1}.

Strand, in 1992, published a new definition together with Cipolle and Morley, in which the patients’ central position in the process receives even more emphasis. ‘Pharmaceutical Care is that component of pharmacy practice which entails the direct interaction of the pharmacist with the patient for the purpose of caring for that patient’s drug-related needs’\textsuperscript{16}. In her address delivered when receiving the Remington Medal in 1997, Strand redefined pharmaceutical care as: ‘A practice for which the practitioner takes responsibility for a patient’s drug therapy needs and is held accountable for this commitment’\textsuperscript{17}. It seems like Strand’s approach has become more humanistic while Hepler’s approach remains more process orientated in nature. Others, like Munroe, see pharmaceutical care as a service during which the clinical and psychosocial effects of drug therapy on a patient are systematically and continuously monitored i.e. a more clinical approach\textsuperscript{18}, which still can be recognised in the Australian interpretation of pharmaceutical care.

In summary, currently in the US there seems to be three approaches to pharmaceutical care: a process oriented one (Hepler), a humanistic one (Strand) and a clinical one (Munroe).

The Dutch definition, an example

When pharmaceutical care started to develop in The Netherlands in the beginning of the 1990s, the definition was formulated as follows: ‘Pharmaceutical care (Farmaceutische Patiëntenzorg, FPZ) is the structured, intensive care by the pharmacist for an optimal pharmacotherapy in which the patient and his condition are the primary concern. The aim is to obtain optimal Health Related Quality of Life’\textsuperscript{19}.

Some typical Dutch aspects of community pharmacy practice are inherent to this definition e.g. continuity of care, protocols or critical pathways, documentation, high quality communication with patients, providing drug information, medication surveillance and communication with other professionals. These aspects therefore are not explicit in the definition. The new aspect for Dutch pharmacy was that the care now became targeted
directly at the individual, whereas before it was more of a technical professional approach originating from clinical pharmacy.

In 1998 the WINAp, the scientific Institute for Dutch Pharmacists, redefined pharmaceutical care as ‘the care of the pharmacy team for the individual patient in the field of pharmacotherapy, aimed at improving the quality of life’. In this definition the role of the whole pharmacy team, pharmacist and assistant-pharmacists, is stressed and pharmaceutical care also became a possible activity when there was no current pharmacotherapy involved, thus including disease prevention or merely providing advice on drug related issues.

In both definitions the patient plays the central role and it is also clear that from the Dutch viewpoint pharmaceutical care is a practice philosophy solely for the pharmacy profession.

1.1.4 Language and cultural differences

Whenever someone comes up with a definition, be it for an object or a concept, words and meaning of words in a language play an important role. But the problem is not only linguistic. The framework of reference in which a definition is constructed is also important. This framework can be societal, as seen by any observer, but also professional as seen by practitioners close to the subject defined.

Language differences

As words may have slightly different meanings in different languages, translating definitions becomes a hazardous activity. The English word ‘care’ and the Dutch word ‘zorg’, as far as we can judge, have approximately the same meaning in the health care environment being personal and emotional care combined with professionalism and quality. But words like ‘soin’ (French), ‘Fürsorg’ (German), or ‘omsorg’ (Scandinavian languages)† have a different meaning, with much more emphasis on the intrinsic emotional aspect. That is why the French would rather speak about ‘suivi pharmaceutique’ (meaning a pharmaceutical follow up) and the Germans speak of ‘Betreuung’ (meaning coaching). The Scandinavian countries have not found a more suitable word and tend to use the English expression.

An essential word like the English word ‘outcome’, which is used in the definition of Hepler and Strand, cannot be translated into the Dutch ‘uitkomst’ or ‘resultaat’. It is a concept that covers both Dutch words.

The language difficulties noted above are one of the reasons why certain countries cannot adapt or translate the basic definition of Hepler and Strand.

Influence of health systems

In describing an activity like pharmaceutical care, the meaning of the words ‘pharmacy’, ‘pharmaceutical’ and ‘care’ must be interpreted with regard to the health system of the country of origin.

For the word pharmacy, an American will have the image of a shop where you can buy health related substances but also all kinds of other commodities like food, cigarettes,

† Personal information Dr. Hanne Herborg, Danmarks Apoteksforenings Kursusenjendom and Dr. Christian Berg, Norske Apotekerforening
detergents, photo equipment etc., and somewhere in the back of this store you can go with your prescription. The British will have images, which depend not only on national but also regional differences. Someone who lives in a city may have the image of, for instance, a department store with mainly beauty-related products and a counter where you can buy OTC products or present a prescription for dispensing. Someone from a village in Great Britain has the image of the place to go for prescription medicines, a limited set of other health care products and perhaps veterinary products. In The Netherlands a pharmacy is the place where you usually only go to have your prescriptions filled, and perhaps purchase self care pharmaceutical products. The only common feature of the meaning of the word ‘pharmacy’ is therefore a place where you can go to have your prescription filled and where you can buy self care products. All other features are different between the countries mentioned.

Depending on the country, community pharmacies serve anywhere between 1500-18000 patients and the generated income in some countries depends heavily on the turnover from related products, rather than drugs. Pharmaceutical Care is the concept of a patient orientated activity in this broad range of pharmacies with a variation of driving forces.

**Professional differences**

If Dutch pharmacists describe Pharmaceutical Care from a professional viewpoint, they will relate to the pharmacy practice in their country. Since in The Netherlands professional aspects like medication surveillance, keeping medication records and giving patient-information leaflets are common practice in all community pharmacies, those activities are an implicit part of the definition. In Denmark and Sweden, where keeping medication records is largely prohibited because of privacy laws, certain activities which are standard practice in Dutch pharmacies are hard to conceive and their interpretation of the same definition will therefore show a conceptual difference. In Norway keeping medication records is now common practice in community pharmacies but medication surveillance by computer is not, and the provision of patient information leaflets is restricted to ‘group’ leaflets of the type used in The Netherlands about 10 years ago.

In most western countries the licensed team-members in a pharmacy fill and dispense the prescriptions. There is, however, an amazing difference in the amounts of prescriptions the team-members handle per day. According to the results of the FIP questionnaire, each licensed team-member in a pharmacy in Luxembourg fill on average 130 prescriptions per day, in Spain 107, in the USA 70, but in The Netherlands only 32. Although it is unclear how a prescription is interpreted (the total prescription or the numbers of different medicines on it), this suggests a difference in the professional content of the work of licensed team-members (mostly pharmacists).

Another major professional difference in The Netherlands, when compared with countries world-wide, is that the assistant-pharmacist also may provide patients with prescription medicines, even when no pharmacist is on the premises. This is unthinkable in

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§ Personal information Swan Apotheke, Tromso
\[\] A Dutch assistant pharmacist receives a 3 year non-university education in preparing and dispensing medicines
other countries, where a pharmacist always must be present during opening hours and supervise the pharmacist-assistants.

Additionally a pharmacist does not always have an academic degree. In most Scandinavian countries there are two types of so-called pharmacists, but with a different background. One is the university-educated person, the other is the prescriptionist (reseptar), who has not received a full academic pharmacy education but also is called a pharmacist. In a country like Brazil there even are two kinds of pharmacists with a different university education (three or five years after highschool).

The relationships between professionals, especially the physician and pharmacist, also are very different in different countries. In the United Kingdom and the United States it is quite customary for hospital pharmacists to attend the wards-rounds, but according to the FIP questionnaire, communication in the community setting is much less well developed although there have been advances in this area. In the Dutch setting the regular pharmacotherapeutic consultation meetings or the drug-formulary committees in hospitals between pharmacists and physicians ensure a reasonable easy communication between those two professions. In Germany and Switzerland the controversies between pharmacists and doctors about dispensing rights and professional responsibilities make relationships difficult but such relationships are slowly starting to improve as a result of developing communication between the professions††.

What outcomes?

The concept of outcomes of pharmaceutical care, usually meaning final outcomes, may lead to confusion as well. The major fields of outcome in care a threefold: economic outcomes, clinical outcomes and humanistic outcomes (quality of life and satisfaction)²⁰.

The word ‘outcomes’ was deliberately not used in the Dutch definition because of conceptual difficulties, but also because there may be a potential conflict when outcomes are used in the double sense of Heplers’ definition, e.g. ‘definite outcomes which improve the patients’ Quality of Life (HRQL)’. Certain desirable outcomes in a pharmaceutical sense may sometimes conflict with that main outcome of care i.e. to obtain an optimal Health Related Quality of Life. Nevertheless the outcome might be worth pursuing. This can be easily explained by the example of benzodiazepine use in an elderly population. As an outcome in general, decreased use of benzodiazepines in the elderly would be a possible target for a pharmaceutical care intervention, because elderly people in general should preferably not use this class of drugs²¹. Although in the long term HRQL may improve as a group effect in elderly patient if benzodiazepine use is discontinued, certainly not all elderly patients will benefit this way if examined at an individual level. That also explains why in both Dutch definitions, the ‘individual patient’ is mentioned.

Additionally economic outcomes may conflict with health status or quality of life. If all three types of final outcomes are to be taken into account, which one has priority? In the Dutch definition therefore an explicit choice has been made for the field of quality of life as (final) outcome, which needs to improve under the influence of the provided care.

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1.2 CONCLUSION AND RECOMMENDATIONS

The concept of pharmaceutical care is part of health care. There are essential differences between the concepts of pharmaceutical care, disease management or managed care, although there are also some relationships. The main difference can be found in the extent of influence of the patient on the process or concept of care and the initiator of the care concept. In some countries conceptual differences are overlooked and this leads to a confusing use of the terminology. From pharmaceutical care through disease management to managed care there is a decreasing chance for the patient to influence his/her own treatment. However, pharmaceutical care can be, and often is, part of disease management while managed care uses disease management strategies to control costs.

There are different definitions and interpretations of the term ‘Pharmaceutical Care’. When defining pharmaceutical care, at least the culture, the language, and the pharmacy practice in the country of origin have to be taken into account. Even after 20 years of evolution of the definition of pharmaceutical care in different cultures, it is not absolutely clear whether pharmaceutical care is a service that could be provided by different healthcare providers who have been trained, or a practice philosophy for pharmacy. The current different approaches in the USA by Strand and Hepler illustrate that differences in opinion can even be found within one country i.e. a process approach (Hepler) versus a humanistic approach (Strand). It is therefore amazing that the Hepler and Strand definition (1990) is so often used in other countries, apparently without taking into account the existence of differences in culture, language and the professional context. It is clear from the issues raised in this chapter that authors and presenters should include their working definition of pharmaceutical care when presenting or writing about the concept. A Cochrane review in 1997 reached the same conclusion, based upon articles by Rupp et al. and Ilersich et al.23,24

Social and culturally bound activities like pharmaceutical care need rephrasing, depending on factors in the country of origin and the health care system developments over time. When literally translating definitions, one must also take conceptual language differences into account.

1.3 REFERENCES TO CHAPTER 1

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