SUMMARY

The first chapter of this dissertation deals with issues surrounding health systems and the position and definitions of pharmaceutical care. 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 of patients and professionals, 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.

Throughout this dissertation, the following working definition has been used, unless stated otherwise. ‘Pharmaceutical care is the care of the pharmacy team for the individual patient in the field of pharmacotherapy, aimed at improving the quality of life’ (the Dutch WINAp definition 1998). This definition assumes that the pharmaceutical care is provided by the pharmacy team (in the Netherlands the pharmacist and the assistant-pharmacists), and that a medication surveillance system is in place.

The concept of pharmaceutical care is, beyond any doubt, part of health care. There are essential differences between the concepts of pharmaceutical care, disease management and 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 driving force behind the care concept. However, pharmaceutical care can be, and often is, part of disease management while managed care uses disease management strategies to contain costs.

There are important conceptual differences between the descriptions or definitions of pharmaceutical care in different countries. In some countries such differences are overlooked and this leads to a confusing use of the terminology. When defining pharmaceutical care, at least the culture, the language and pharmacy practice in the country of origin have to be taken into account. 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 take conceptual language differences into account.

The long history of the profession of pharmacy in the Netherlands has been filled with many important developmental issues. As is the case in many other countries, the profession developed from the extemporaneous preparation and selling of medicines to the dispensing of medicinal products coupled with patient counselling. In the Chapter 2 of this dissertation an attempt is made to identify the forces influencing the development of the profession and convergence into pharmaceutical care, as a tool to help improve understanding of the current and future professional developments of pharmacy in The Netherlands. The same issues can probably be identified in other countries, although the pace of change may differ.
The more recent movement of Dutch community pharmacy during the last 30 years towards a pharmaceutical care model of practice is the result of many discrete influences, including:

- Development of the pharmacist-physician relationship,
- Development of the pharmacist-patient relationship,
- Advances in the education of pharmacists,
- Increased provision of information to patients,
- Improved medication surveillance and conceptualisation of clinical pharmacy,
- Development of social pharmacy;

Many of these influences were unrelated, making the development of pharmaceutical care in The Netherlands somewhat episodic and dependent on chance. The convergence of various influences into the pharmaceutical care pharmacy practice model required strong catalysts including the intellectual philosophy advocated by Hepler and Strand and the emerging demands of society for more information about medication therapy.

The events preceding the development of pharmaceutical care in the Netherlands, however, are not so surprising. Pharmacy is an open system that operates in the marketplace. As such is also sensitive to many outside influences. In the Netherlands, the pharmacy profession appears to have been reactive to the influences of government, industry, sick funds, patient-groups and automation. For instance, the pressure of the pharmaceutical industry on prescribers initiated the development of the pharmacists’ advisory activities to physicians and was later supported by the health authorities. The development of clinical pharmacy was initiated in the United States as a reaction to changes in the field of medicine, and followed up in the Netherlands as an addition to pharmacy practice based upon the pharmacotherapeutic knowledge of the Dutch pharmacists. The demand for drug information came from consumer organisations, while the university community as a result of societal pressure has initiated the development of social pharmacy.

The development of the pharmacy profession in The Netherlands obviously has depended much more on outside forces than on pressures from within the profession. It should be stressed, however, that pharmacy as a profession is not alone in this ‘forced’ evolution. Most other professions have followed a similar path of reacting to pressures from their ‘clientele’.

The existence of a front-runner role of some pharmacists must be acknowledged. Some professionals with vision, picked up early signals and tried to develop the professional activities that were required and desired by society. This takes time and especially dedication due to the many barriers that have to be overcome. The rest of the profession eventually follows their pioneering work. A proactive attitude, not only from the front-runners, but from the entire profession and professional organisations, is desirable if pharmaceutical care is to be incorporated into routine community pharmacy practice and for a further development of the profession.

With all the (international) developments involving pharmaceutical care in community pharmacy it becomes important to establish its effects. In Chapter 3 the methodology for two research projects is described. The projects (TOM in asthma patients and OMA in the elderly using 4 or more different medicines) were started in 1994 at the Department of Social Pharmacy and Pharmacoepidemiology of the University of Groningen. The design of both
projects is similar and included a reference group, which did not receive special care. Nevertheless there are some essential differences in the processes of the studies as well as in the field of the outcomes studied. The TOM project had a more clinical orientation. It concentrated on teaching good inhaler technique and asthma self-management, and on improving compliance with preventive medication. Certain definite outcomes could be monitored such as the asthma status. The OMA study was more diffuse, the process concentrated on improving compliance and understanding of medicines, and trying to decrease the use of benzodiazepines. As a result of the heterogeneous population, this study dealt with less well defined outcomes, and therefore concentrated on the quality of life and improvements in patient knowledge of medicines and diseases.

The OMA study into the effects of pharmaceutical care in the elderly was carried out between 1995 and 1997. In Chapter 4 some results of this study at the patient level are described and discussed. The provision of pharmaceutical care to elderly using four or more different medicines led to a high satisfaction amongst patients. However, no major influence was seen on knowledge or quality of life (according to the SF-36). There was no clear picture with regards to the influence on compliance with the use of diuretics, probably due to low numbers of patients at the end of the study and the short pre-study period of available drug data. No influence on the use of benzodiazepines in the intervention group could be seen. Some other outcomes, however, changed in the expected way, but not to a statistically significant degree. The picture with regard to drug-related problems was mixed. Although the pharmacists recorded a decreasing number of problems while providing care (mainly problems dealing with side effects), according to the patients at the end of the project there was no difference between the intervention and reference groups with regards to the problems with medicines they really experienced.

The TOM study was also conducted between 1995 and 1997. Some results of this project at the patient level are described in Chapter 5. In general terms the results of the TOM project are positive. In the intervention group more patients started to use peak-flow meters and became involved in self-management than in the reference group. In addition more patients were now using their reliever medication before their preventive medication if they used both. There was better asthma control in the intervention group. This finding is clearly supported by the analysis of the drug use, which shows a decrease in the amount of reliever and rescue medication (short courses of antibiotics and/or oral corticosteroids). There is also an indication that the quality of life (according to the Asthma Quality of Life Questionnaire (Junniper) improved as a result of the care provided. The knowledge about illnesses related to asthma, e.g. chronic bronchitis and emphysema, improved. Patients were satisfied with the care provided and found the regular consultations useful, certainly in the beginning of the study. The patients’ image of a pharmacist changed and after the study they had a more positive opinion of the capability of pharmacists to help them with their drug use and in coping with their disease. However, the relative high drop-out rate in the intervention group was probably an indication that asthma patients might not appreciate a 2 year long study.

Patients are not the only people involved in pharmaceutical care. The providers (in this case the pharmacists) and the patients’ GPs are also involved. In Chapter 6 the influences on
those professionals are described, based upon the opinions and experiences in the TOM and OMA study. These results are put in perspective by two additional smaller projects into the relationship between pharmacists and physicians, and into the role-division of pharmaceutical care tasks between pharmacists and assistant pharmacists in Dutch community pharmacy.

It is not surprising that the intensity of co-operation between pharmacists and GPs in the field of care depends largely on the quality of their relationship. Apart from professional aspects, personal aspects of the relationship also seem to influence the co-operation. When pharmacists provide pharmaceutical care, currently the major worry of GPs seems to be the assumed lack of knowledge of the pharmacist about diseases. However, the more pharmacists are involved in pharmaceutical care, the less they doubt their own knowledge in this field.

For both the TOM and the OMA project, in those cases where medication had to be changed, the necessity to co-operate with GPs is apparent. In general one can say that Dutch community pharmacist, with their excellent pharmacotherapeutic knowledge, perform their advisory roles towards prescribers in a corrective manner and this may provoke resistance amongst the physicians. This resistance can be recognised in the results of both studies and in other projects. One can, however, imagine forms of pharmaceutical care where this co-operation is not absolutely necessary, as long as there is no necessity to change pharmacotherapy and the pharmacist sticks to tasks in the field of pharmacoepidemiology and giving instructions for drug use. Therefore, if the relationship between pharmacists and physicians is not optimal, that should not be an excuse for pharmacists to abstain from providing any form of pharmaceutical care to their patients.

When it comes to incorporating the tasks of providing pharmaceutical care into the Dutch pharmacy organisation, according to the pharmacists, the real core of the work still should be done by the pharmacists themselves, although some side-issues and part of the patient-contact can also be delegated to the assistant pharmacist.

In the TOM and OMA studies it has been proven that the provision of pharmaceutical care has a positive influence on the outcomes of patient care. At this point of time others have also clearly established that the provision of pharmaceutical care has its value in the case of general ambulatory care, psychiatry, HIV infections, asthma, diabetes, hypertension, and hyperlipaemia. In spite of this evidence, it remains to be seen whether all pharmacists are willing to implement pharmaceutical care into their routine practice because this would imply a change in professional attitude and daily work. In Chapter 8 the result of a European survey of implementation barriers for pharmaceutical care are described.

Pharmacists in the European countries studied perceive time and money as the major barriers for the implementation of pharmaceutical care. Both issues are interrelated. From the survey it is clear that the European Pharmaceutical Associations must pay attention to remuneration issues if they would like pharmaceutical care to advance in their countries. It is also clear that they need to work continuously on a change of attitude amongst pharmacists and try to influence the opinions of other health care providers. The latter could not only be reached by public relations initiatives, but also by supporting researchers in publishing the results of their projects. Important barriers have also been identified in the
educational domain. More and/or better education of European pharmacists in the field of clinical pharmacy, communication skills, documenting skills and management skills therefore seems necessary.

In community pharmacy around the world there currently is a role for the pharmaceutical care. Especially the community pharmacy section of the International Pharmaceutical Federation (FIP) has advocated pharmaceutical care as a new role for pharmacist. In 1996 FIP itself advocated that role in its joint statement on Good Pharmacy Practice (GPP) in community and hospital practice settings, together with the World Health Organisation (WHO). Currently that new role is more obvious in some countries than in others.

How do different aspects of pharmacy practice enable or hinder the introduction of pharmaceutical care in a country and how much is actually happening? In Chapter 8 an analysis is given of the current status of pharmacy practice and the chances for the development of pharmaceutical care in different countries, based upon the results of an international questionnaire which was developed together with the community pharmacy section of FIP. From this analysis it became clear that the circumstances in the Netherlands, the USA and Japan are optimal for the provision of pharmaceutical care by community pharmacies. There is some evidence that this is also the case in eight other countries but the lack of certain key-data made a full evaluation impossible. From latter eight countries it is obvious that pharmaceutical care develops in Austria, Canada, Denmark, Great Britain, Ireland, and Norway.

In spite of less favourable circumstances in certain countries, research and implementation activities can also be found in Australia, Finland, France, Germany, Iceland, Portugal, Spain, Sweden and Switzerland. Details of those activities can also be found in chapter 9 and appendix A5.

In the last chapter of this dissertation the TOM and OMA studies are put in a health care perspective, using the Donabedian trias for the quality of healthcare, which divides health care into structure, process and outcomes. The outcomes of the study then are briefly evaluated using Kozma's ECHO model.

The TOM and OMA research projects were 'real life' studies. This implies that many research barriers had to be overcome which are inherent to pharmacy practice research. A number of such barriers are given and discussed, including process monitoring, the data quality in practice, the availability of validated instruments, the documentation, and the absence of good research models.

If such barriers are overcome, how easy is it then to establish the effect of pharmaceutical care, assuming that the process control is optimal? This largely depends on the availability of outcomes and outcome measures that can be selected for the study.

Significant changes in final clinical outcomes of care as a result of pharmaceutical care interventions usually have come from projects with clearly identifiable diseases and clinical outcomes. However, the processes that can lead up to optimising outcomes of pharmacotherapy need to be refined further. Disease specific pharmaceutical care remains a topic for requiring much further research. Protocols can be developed and tested for implementation. However, the concept of comprehensive pharmaceutical care offers the
opportunity to provide all patients with pharmaceutical care irrespective of medical standards, but based upon drug use and medication related errors. In community pharmacy practice this seems a very useful approach, because the pharmacist in most countries, including the Netherlands, often lack information on the indication for drug use. The effects on final outcomes of the comprehensive form of pharmaceutical care, without knowing the indication for drug use, are hard to establish. To be able to measure the effects of pharmaceutical care in practice, the indications for drug use should preferably be known and more and better co-operation with the treating physicians about individual patients therefore should be established.

Pharmaceutical care is here to stay. Its format may be refined further, but from many of the studies performed to date it is clear that clinical and humanistic outcomes improve and that the patients are very satisfied as well. Worthy of consideration is how important the economic outcomes should be under such circumstances. Improving care should and cannot always mean decreasing direct costs. The gain would be long-term. Policy makers often seem to forget this. Only improving clinical outcomes should not be the goal for care either, a fact often overlooked by the professionals.

Patients (or the society) will in the end always look for improved humanistic outcomes. Pharmaceutical care can, as a part of the total network of care, certainly help to improve the knowledge, quality of life and satisfaction of patients.