Fimea Develops, Assesses and Informs

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RATIONAL USE OF MEDICINES THROUGH INFORMATION AND GUIDANCE

Medicines Information Services:
Current State and the Strategy for 2020

fimea

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SUMMARY
RATIONAL USE OF MEDICINES THROUGH INFORMATION AND GUIDANCE

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Vision

Finland will have in place a multidisciplinary national network of pharmaceutical sector stakeholders to produce and disseminate evidence-based, objective and reliable information to healthcare professionals and the public.

Mission

Medicines information promotes the rational use of medicines among the population and thus maintains and improves the health of the Finnish population.

STRATEGIC GOALS AND OBJECTIVES 2012–2020:

1 To establish a multidisciplinary medicines information network in Finland.

- Establishing a national medicines information network.
- Incorporating research and follow-up in medicines information activities.
- Participating in international initiatives.

2 To ensure that healthcare professionals utilise reliable information sources and services.

- Increasing awareness of reliable information sources.
- Improving the accessibility and usability of medicines information.
- Utilising experts and existing specialist services.

3 To ensure a high level medicines expertise and multidisciplinarity in healthcare.

- Improving medicines expertise and developing training in medication counselling.
- In basic and complementary education emphasising a patient-centred attitude, a multidisciplinary approach and support for patient self-management.

4 To base medication counselling on national guidelines and local agreements.

- Harmonising the provision of medication counselling in healthcare.
- Using medicines information to support the provision of pharmacotherapy in various settings.
- Ensuring medication counselling in self-care.

5 To ensure that medicine users utilise reliable information sources and services.

- Ensuring the availability of reliable medicines information.
- Promoting the readability and usability of package leaflets.
- Producing medicines information in minority languages and for other special groups.
- Increasing the use of information and communications technology to disseminate medicines information.

6 To achieve a high level of health literacy among the general public.

- Promoting health literacy among children and adults.

INTRODUCTION

In Finland, medicines information and its dissemination have been discussed since the 1970s. Physicians have traditionally been responsible for advising patients on the use of medicines. In the 1980s, however, pharmacists were given greater responsibility for ensuring that medicine users were aware of the correct and safe use of each particular medicine. The first computer-based directions designed to increase such awareness were developed at roughly the same time. Medicines information activities have expanded considerably since then.

From a citizen and patient perspective, medicines information can be considered to be a right, and it should be an essential component of the rational use of medicines. The patient's own role and active participation in maintaining health and treating diseases have been emphasised in recent years. Medicines information activities have also striven to ensure that medicines are used effectively, safely and economically. The healthcare system is placing greater emphasis on multidisciplinary cooperation in which the patient has a central role. To ensure good collaboration, it is essential that everyone has an adequate and sound knowledge base to allow them to participate in the discussions and decision-making.

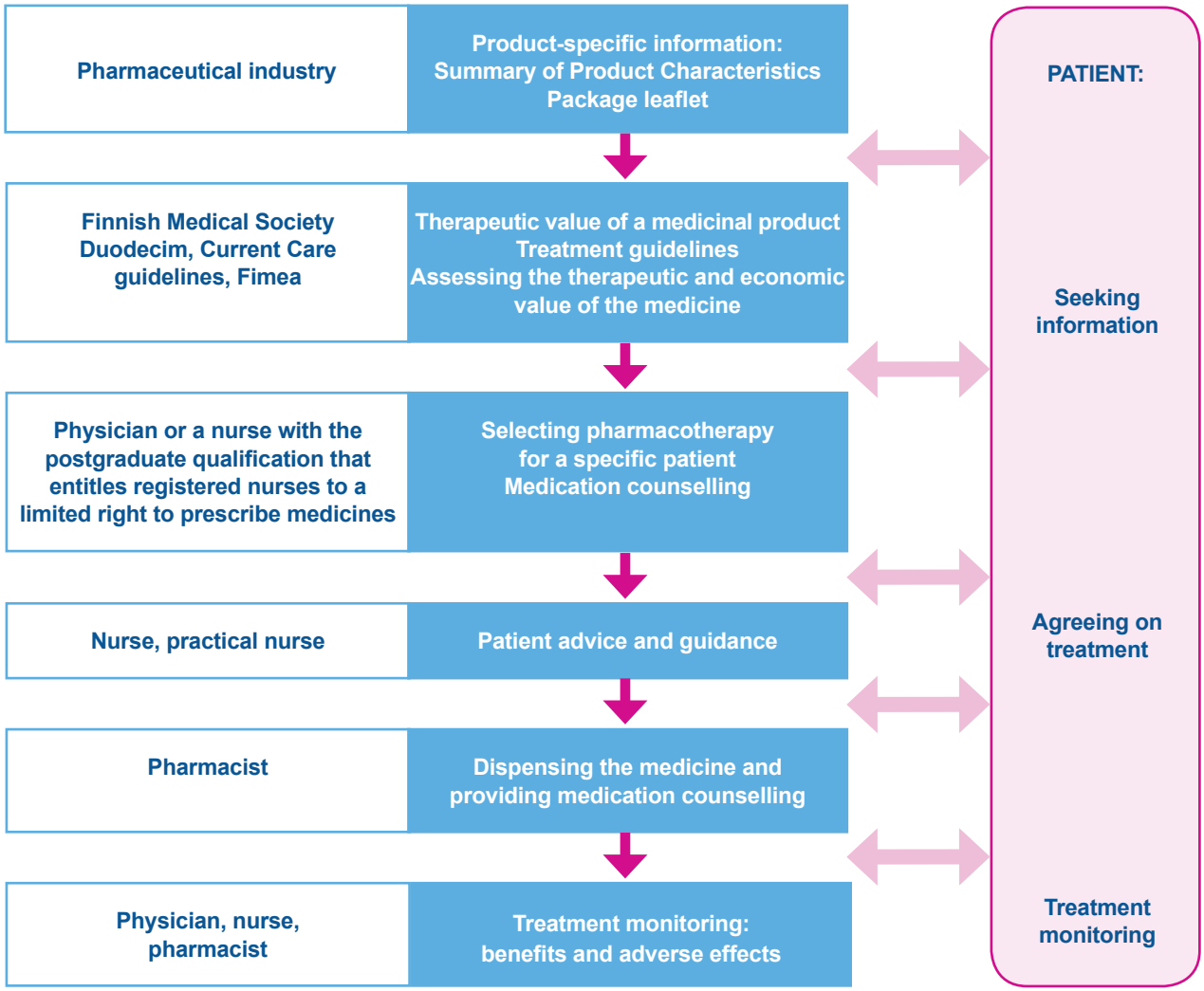
Patient access to information has increased greatly in recent years. Healthcare professionals have become more active, a variety of medication guides have gained wider usage, and the Internet and social media are becoming increasingly important information sources. The wealth of these formal and informal sources presents challenges for patients and healthcare professionals alike. It is now more important than ever to find objective and reliable information and assess existing information.

At the European level, too, medicines information has been given considerable attention in recent years. The Pharmaceutical Forum of the European Commission compiled guidelines on the quality of medicines information available to patients and on disseminating information in the various healthcare sectors. The European Parliament has witnessed at times quite heated debate on access to medicines information and on disseminating medicines information to patients. The concerns expressed have included to what extent patients' needs are being addressed and whether citizens stand on equal ground in the different EU member states. Information quality, oversight and access to objective information are matters where the opinions of stakeholders have differed to a great extent.

The dissemination of medicines information in Finland has made considerable progress over the past decades. In spite of this, the needs of patients and healthcare professionals for reliable and objective information are not always met. The Medicines Information Strategy therefore aims to address the state of medicines information activities as a whole: where are we now, where do we want to go and which goals do we wish to achieve during the next decade? Stakeholders have actively participated in compiling the Strategy, and this collaboration will continue when the new medicines information network is established. In line with its duties, Fimea will compile, evaluate and disseminate information on medicines to the public, to healthcare professionals and to others who are in need of medicines information, as determined in the Medicines Policy 2020 compiled by the Ministry of Social Affairs and Health.

Sinikka Rajaniemi
Director General
Finnish Medicines Agency Fimea

FROM MEDICINES INFORMATION TO THE RATIONAL USE OF THE MEDICINE



BACKGROUND

The Finnish Medicines Agency Fimea has the statutory duty of compiling, evaluating and disseminating information on medicines to the public, to social services and healthcare professionals and to others who need medicines information (Act on the Finnish Medicines Agency, 593/2009). It must carry out these duties in collaboration with stakeholders in the field, such as public authorities, universities, research institutions and social services and healthcare units. Fimea is also responsible for the long-term planning and coordination of medicines information activities. It has been charged with compiling a national medicines information strategy that addresses the work being performed by the existing stakeholders, while also identifying any deficiencies (Government proposal 74/2009).

This Medicines Information Strategy has been produced on the basis of discussions with stakeholders and statements received on an initial draft strategy **(Annex 1)**. Experts from the Fimea Assessment of Pharmacotherapies Process as well as from the Pharmacovigilance Unit participated in compiling the strategy. The person responsible for the Strategy compilation was Katri Hämeen-Anttila, Development Manager. The Strategy describes best practices, deficiencies and challenges with respect to current medicines information activities. Since medicines information is closely linked to many pharmaceutical functions, the Strategy provides an extensive description of the current status of medicines information activities, from ensuring adequate medicines expertise among healthcare professionals to developing health literacy among the public.

The Strategy proposes various measures and emphasises the need to establish a medicines information network in Finland. The network would recommend which proposals are to be collaboratively developed. It would also determine the goals of various interventions and the ways in which their achievement will be monitored. The network may also identify a need for completely novel interventions. The Strategy will be reassessed and updated at regular intervals.

The proposals concern very different magnitudes of scale. Some require significant additional resources to be feasible, while others can probably be carried out with existing resources by increasing collaboration and discussion. However, this requires commitment on the part of stakeholders as well as a willingness to incorporate the Strategy in their own activities. Fimea has also identified medicines information development needs related to its own activities and will seek to achieve progress on these in its future operations.

Vision

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- Promoting health literacy among children and adults.

GOAL 1.

TO ESTABLISH A MULTIDISCIPLINARY MEDICINES INFORMATION NETWORK IN FINLAND.

Establishing a national medicines information network.

A wide range of bodies produce medicines information in Finland. While this represents an important resource, it can cause duplication of work and produce information that is fragmented. One of the goals of the Medicines Policy 2020 is to increase both national and international collaboration in the production of medicines information and associated services and in the evaluation of their effectiveness (Ministry of Social Affairs and Health 2011a).

In the proposed model for a medicines information network, a Medicines Information Coordination Group appointed by Fimea will carry out development projects and monitor their progress. The group will also assess development projects launched or commissioned by stakeholders. A communications team will assist with the projects assessed. The communications team will involve communications expertise from various stakeholders and representatives of special groups such as sign language users. Development projects bring forth concrete development needs, which will be put forward at meetings titled The Medicines Information Forum – users and producers. The network will also include education and research working groups **(Figure 1)**. Fimea will be in charge of coordinating the activities of the network. Each stakeholder will decide independently on the extent to which they commit themselves to the network and participate in development projects.

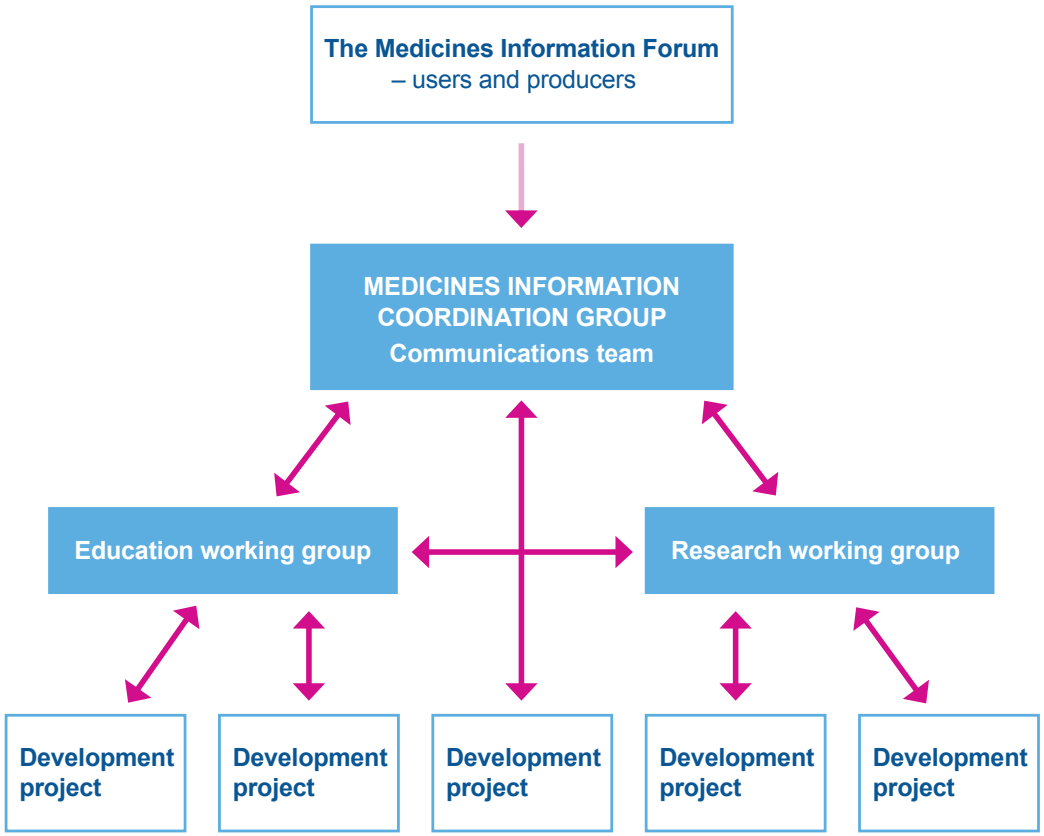


Figure 1. *The medicines information network. Current proposal.*

Medicines Information Forum – users and producers

• This biannual multidisciplinary forum will bring together the users and producers of medicines information. The forum will foster wide-ranging debate on the current status and challenges of developing medicines information and on the need for new development projects.

Medicines Information Coordination Group

• The group will consist of representatives of key medicines information stakeholders and meet at least once a year (more often at the outset). The group will:
  - promote and coordinate the development of medicines information in Finland
  - make proposals for the prioritisation of development projects presented in this strategy
  - monitor development projects and comment on their progress
  - coordinate research related to medicines information
  - promote international collaboration.

Education and research working groups

• The education working group will be a forum for teachers working at vocational institutions, polytechnics, universities and complementary education units. It will develop solutions aimed at promoting a multidisciplinary approach and medicines information activities in basic and complementary education. The needs of working life will be taken into account in its activities.
• The research working group will include stakeholders who carry out research on medicines information and promote research and collaboration in this field. The research working group will also determine the most important research areas and topics related to medicines information.

Development project committees

• An operative committee will be established for a fixed term for each development project. It can be established on the initiative of the Medicines Information Coordination Group or of a stakeholder party.

All stakeholders will fund their own participation in the network. Development projects may also apply for external funding.

Proposal:

• Establish a medicines information network in order to increase cooperation, a more systematic approach and greater multidisciplinarity in developing medicines information activities and to promote collaboration between the public and private sectors.

Incorporating research and follow-up in medicines information activities.

At the start of the network's activities, concrete existing medicines information tools and development projects designed for healthcare professionals will be collected with a view to promoting their use. Proven medicines information tools and best practices can be shared and disseminated, for example via the Innokylä InnoVillage. The Innokylä InnoVillage (www.innokyla.fi) is an innovation community for social services and healthcare stakeholders and developers. It offers, among other things, forums and online tools for the creation and introduction of new practices.

The activities of the medicines information network must be based on research and existing best practices. Activities can thus be developed in the right direction, and medicines information can be produced in a targeted manner. It is important that the research and expertise of universities and polytechnics are utilised in the network's activities. When evaluating the different aspects of medicines information, it is also necessary to assess the opportunities to utilise national studies conducted at regular intervals. For instance, the survey on Health Behaviour and Health among the Finnish Adult Population of the Finnish National Institute for Health and Welfare has in previous years contained questions on medicines information (e.g. Närhi and Helakorpi 2007).

To monitor medicines information activities, the medicines information indicators created by the Medicines Policy 2020 indicator working group will be further developed.

Proposal:

• To direct the activities of the medicines information network, the following will be assessed:
  - the need for information among healthcare professionals in the different sectors
  - the need for information among patients and medicine users
  - the effectiveness of medication counselling and guidance.

Participating in international initiatives.

The Pharmaceutical Forum of the European Commission (2005–2008) gathered together best practices and available tools in order to improve the medicines information available to patients (High Level Pharmaceutical Forum 2008). The Pharmaceutical Forum also issued recommendations on the core quality principles for medicines information to patients and the best ways of disseminating information in the different healthcare sectors. The Pharmaceutical Forum emphasises the need to share best practices among the different European Union member states. International models and tools should be assessed with regard to their applicability in Finland, and their feasibility in developing medicines information should be evaluated. The medicines information network should also take an active role in promoting Finnish best practices for the European Commission and other member states. The aim should be uniform medicines information throughout the European Union.

Proposal:

• Assess the applicability of international models and medicines information tools for use in Finland.

GOAL 2.

TO ENSURE THAT HEALTH-CARE PROFESSIONALS UTILISE RELIABLE INFORMATION SOURCES AND SERVICES.

Increasing awareness of reliable information sources.

A number of stakeholders produce medicines information in Finland, and there are numerous sources of medicines information **(Annex 2)**. There is a wealth of information on medicinal substances and products in particular. There is also plenty of information on the role of pharmacotherapies in the treatment of different medical conditions. The bodies producing and disseminating such information are, however, outnumbered by those producing information on a specific product. The most important information channels are the Current Care guidelines produced by the Finnish Medical Society Duodecim and the extensive medical database Terveysportti. It is important to increase awareness of existing sources of information and to encourage their use. One way to achieve this is by training healthcare professionals to use them. In Finland, the availability of medicines information in Swedish is much poorer than in Finnish.

Few healthcare professionals have time to gain a detailed insight into the characteristics and interactions of medicines or to study the differences between medicines with similar mechanisms of action. Assessments and summaries are essential in developing medicines information and will continue to be so in the future. New information should be incorporated into commonly used databases or portals.

In future, pharmacotherapies will be increasingly individualised, and this will increase the need for information. New medicines are an area where the need to obtain properly evaluated, up-to-date information comparing the product with other medicines and treatments is particularly great. Medicines information produced by pharmaceutical companies mainly focuses on the features of a specific product. However, pharmaceutical companies gain a substantial amount of information on their products during pharmaceutical development, research and the post-marketing surveillance of safety and effectiveness. It is important that such information is published. Companies disseminate product-specific information to healthcare professionals via medical information services, manuals, training events and other channels.

Information management during a crisis is an area that needs particular attention in Finland. There is currently no system that would allow a message to be sent to all healthcare professionals during the same day.

Proposals:

- Produce summaries of pharmacotherapies (such as the Kapseli publication series).
- Produce evaluations and summaries of the therapeutic and economic value of medicines for healthcare professionals and patients. Encourage greater utilisation of evaluated evidence.
- Improve the availability of medicines information in Swedish for healthcare professionals.
- Establish an effective information management system for crisis situations and pharmacovigilance-related information to ensure that all healthcare professionals can be contacted during the same day.

Improving the accessibility and usability of medicines information.

The amount of available medicines information is large, but its fragmented nature and poor accessibility may cause problems. Factors such as shortage of time, poor skills and the fees charged may also hamper the use of information sources. Successful pharmacotherapy and thus patient safety can be promoted by means of automatic clinical decision support systems integrated into electronic patient records systems. Novel technological approaches will also improve the accessibility and user-friendliness of medicines information in the future.

Summaries of Product Characteristics (SPCs) vary in terms of their content, and the terms used may also differ from one medicinal product to the next, for instance because of the different marketing authorisation practices employed in different countries. This affects the user-friendliness of SPCs. Harmonisation of SPC texts is ongoing in the European Union, but progress is slow.

There may also be problems in the accessibility of SPCs. It may sometimes take time before information on a specific medicine is available on the Fimea website. If a medicine has been approved via the centralised EU procedure, its SPC and package leaflet are only available on the European Medicines Agency (EMA) website.

It would also be important to compile and publish an impartial medicines information formulary based on generic names that would give suggestions for the choice of an appropriate medicine and gather together the most important general information about different medicinal substances irrespective of the SPCs used by different manufacturers. The need for such a formulary is particularly evident as new biosimilars are being launched.

Proposals:

- Ensure through basic and complementary education that healthcare professionals are aware of the various information sources and databases and are able to use them.
- Develop electronic clinical decision support systems and integrate them into existing information systems.
- Ensure easy access to SPCs. Improve the quality of SPCs in the EU.
- Produce a medicines information formulary in Finnish based on generic names.

Utilising experts and existing specialist services.

In their work, healthcare professionals encounter difficult questions related to pharmacotherapies, which they first discuss with their colleagues. The most challenging questions and problem situations for which local resources are insufficient should be presented to experts specialising in pharmacotherapy. Unfortunately, the availability of such services is restricted.

Medical specialists in Clinical Pharmacology and Pharmacotherapy are able to solve challenging patient-specific problems irrespective of where the patient is being treated. They provide consultation services to support the treatment of both inpatients and outpatients and participate in producing information on medicines and pharmacotherapy. To improve the safety of pharmacotherapy and patient safety, it is important to utilise these expert resources to the full and use them to address the most challenging problems in pharmacotherapy. There are about 30 medical specialists in Clinical Pharmacology and Pharmacotherapy in Finland.

It is also important to draw on the expertise of hospital and health centre pharmacists in the treatment provided by healthcare units. Pharmacists working in hospital pharmacies and health centre dispensaries, as well as ward pharmacists, are asked about matters relating to the pharmaceutical properties of medicines in particular. However, they also address patient-specific problems in pharmacotherapy. The expertise of ward pharmacists could be utilised more extensively for instance in providing pharmacotherapy-related training for other personnel. Ward pharmacists may also review medication, participate in patients' admission interviews and provide medication counselling. Those with a formal specialisation may also carry out comprehensive medication reviews. Ward pharmacists' services are currently available in at least 35 hospitals and health centres and on more than 200 wards. There are about 150 ward pharmacists, some of whom work in more than one ward.

Pharmacists with a formal specialisation in comprehensive medication reviews are a resource that could be utilised more widely in hospital and outpatient medicines information work **(Annex 3)**. The total number of pharmacists formally specialised for this is currently about 150.

Healthcare professionals with queries may also consult online and telephone services such as the HUS (Hospital District of Helsinki and Uusimaa) and TYKS (Turku University Hospital) Clinical Pharmacology consultation services; the National Pharmaceutical Information Centre KLIK, owned by the Pharmaceutical Information Centre and the University of Eastern Finland; the University Pharmacy information services; the HUS Poison Information Centre; and the HUS Teratology Information Service. Networking and collaboration between these institutions would reduce overlapping in the provision of services and improve the potential to utilise all stakeholders' expertise. In networking, it is important to assess resources and the distribution of tasks, e.g. how the resources of medical specialists in Clinical Pharmacology can best be used to address the most challenging problems in pharmacotherapy. It is also important to increase awareness of medicines information services. Primary care units, for instance, should be aware of who to contact if they have problems concerning medicines information.

The same medicines information services also respond to queries submitted by patients. From a population and patient perspective, it is important that medicines information services can also be contacted by e-mail and that they are active in social media, a route often used by medicine users to seek help for their problems. Providing information to the population in crisis situations, e.g. in the event of a pandemic, should also be an integral part of medicines information activities. Special groups should also be taken into consideration, particularly in crisis situations.

Proposals:

- Evaluate opportunities for networking and coordination of activities between the stakeholders currently providing medicines information services.
- Evaluate and monitor the quality of medicines information disseminated by stakeholders providing medicines information services.
- Increase awareness of and collaboration between Clinical Pharmacology and Clinical Pharmacy services.
  - Develop Clinical Pharmacology and Clinical Pharmacy services and ensure access to them everywhere in Finland, for instance by creating a network-type consultation service for healthcare professionals.
  - Shift the focus of ward pharmacy activities from medicine logistics towards clinical pharmacy: medication review and medication counselling for patients (e.g. admission interview, review of admitted patients' medication, medication counselling on discharge together with a physician and a nurse).
- Step up collaboration in producing hospital-specific internal Standard Operating Procedures (SOPs) and in disseminating these SOPs and best practices in pharmacotherapy. Opportunities to utilise guidelines and practices from other countries should also be evaluated.

GOAL 3.

TO ENSURE A HIGH LEVEL OF MEDICINES EXPERTISE AND MULTIDISCIPLINARITY IN HEALTHCARE.

Improving medicines expertise and developing training in medication counselling.

Healthcare professionals are patients' primary source of information related to medical conditions and their pharmacotherapy (Närhi 2007, Närhi and Helakorpi 2007). An adequate pharmacotherapy knowledge base is essential for all counselling. The development of pharmacotherapy-related training requires different perspectives and focuses on different aspects of pharmacotherapy depending on the group of professionals in question. The needs of working life must be taken into account in the teaching contents of both basic and complementary education. Development should particularly focus on counselling for pharmacotherapies for key public health concerns such as cardiovascular disease and diabetes. The availability of generic products (including biosimilars) means that understanding of generic information is important for all professionals involved in pharmacotherapy. This includes both the recognition of generic names instead of brand names and an understanding of potential differences between generic products. To avoid misunderstanding, medicines information should primarily be based on generic names. Professionals and patients alike may have trouble grasping the several brand names and generic products available for a single medicinal substance.

In-house training has a major impact on how medication counselling is provided in practical situations. Areas covered may include information sources, SOPs and agreed medication counselling practices applicable to the unit in question. During a professional's career, the development of professional expertise depends both on the unit in which the professional works and on his or her personal interests and opportunities to seek information (for instance, independent selection and reading of professional literature, participation in training). Some licensed healthcare professionals providing pharmacotherapy and professionals with a protected occupational title have their medicines expertise and skills evaluated according to their units' pharmacotherapy plans, for instance with practical examinations and site-specific pharmacotherapy licences repeated every 2 to 5 years (Ministry of Social Affairs and Health 2006).

Physicians are well educated in the diagnosis and treatment of medical conditions during their basic education, specialisation process and complementary education. Medical education provides teaching on patient-physician interaction, but less time is devoted to medication counselling. Physicians also need further training in the critical assessment of research evidence and in the assessment of cost-effectiveness. It is also important to ensure that, in addition to product-specific information, physicians have access to comparative, impartial information on medicines.

The basic education of pharmacists focuses on medicinal substances and their effects in humans. It also provides good skills in providing patient-centred medication counselling. Students practise their ability to apply theoretical knowledge in practical situations by means of medication counselling labs. This area is also addressed during students' traineeships at teaching pharmacies. Basic education should pay more attention to clinical pharmacy skills and increasingly focus on the practical application of theoretical knowledge. As ward pharmacy activities increase, it is important that basic education puts a stronger emphasis on skills required in hospital work.

Graduating nurses must have adequate skills to carry out pharmacotherapy-related tasks in a safe and effective manner (Sulosaari et al. 2010). In Finland, this is ensured by issuing a Medication Passport, a tool used during nurses' basic education courses. The extent and focus of medicines expertise depends on the unit in which the professional works (e.g. specialist healthcare unit, child and maternity welfare clinic, elderly care unit). Medicines expertise is playing an increasing role in the management of major public health concerns (e.g. hypertension, diabetes, heart failure, kidney failure). In addition to technical dispensing, professionals must be aware of the effects and interactions of a medicine and be able to determine the need for monitoring. Legislative reforms have extended the duties of nurses and introduced a postgraduate qualification that entitles registered nurses to a limited right to prescribe medicines (Ministry of Social Affairs and Health Decree on pharmaceutical prescriptions, 1088/2011). This demands sufficient professional experience after graduation together with additional studies, as stipulated in the Decree. The rights only apply to the nurse's duties and site of employment.

Practical nurses have a basic qualification in social services and healthcare. They can work as healthcare professionals with a protected occupational title in healthcare units as well as in social services, e.g. in home care and residential institutions, and may assist in providing and monitoring pharmacotherapy. They work close to the client and their duties allow them to monitor the success of pharmacotherapy and its effects on each individual. It is important that this group of professionals has adequate skills. Practical nurses must be able to identify the adverse and unwanted effects of medicines and refer the client for assessment by a nurse or a physician. Requirements concerning the education of social services personnel are stipulated in the Decree on qualification requirements for social welfare professionals (608/2005). Social services

legislation does not provide for the participation of social services personnel in pharmacotherapy; this area is always the responsibility of healthcare professionals. Personnel qualifications and medicines expertise vary greatly, as do the local practices employed at different sites.

Proposals:

- Develop basic and complementary education for all professional groups.
  - Develop existing syllabuses and ensure that physicians and other healthcare professionals are well prepared for reading, assessing and applying published research, treatment guidelines and assessments of the therapeutic and economic value of medicines.
  - Increase the practical application of theoretical knowledge in clinical pharmacy teaching for pharmacy students.
  - Further develop medicines expertise among nurses and ensure equal skills everywhere in Finland.
  - Further develop practical nurses' medicines expertise.

In basic and complementary education emphasising a patient-centred attitude, a multidisciplinary approach and support for patient self-management.

The National Archive of Health Information (KanTa) will emphasise the role of patients as experts in their own treatment. Everyone will be able to view their KanTa records online using the service entitled 'Viewing one's personal information'. Patients will also decide which healthcare professionals are allowed to view their records. According to the Health Care Act (30 December 2010/1326, section 24), local authorities are required to provide guidance to enhance patients' treatment adherence and self-management.

Sound medicines expertise is essential for those working to support self-management, but this on its own is not enough. All healthcare professionals must, during their basic education, acquire sufficient basic knowledge and skills to provide medication counselling and support for self-management. Professionals must be able to take into account each patient's wishes and attitudes with regard to medicine use and be able to discuss pharmacotherapies in a manner that is understandable for the individual in question. Complementary education, including specific formal qualification and specialisation programmes, must also provide knowledge and skills required in medication counselling and supporting self-management. It is important that tools such as the National Institute for Health and Welfare ROHTO network are utilised to promote healthcare professionals' medicines expertise, ability to support self-management and a multidisciplinary approach.

With regard to supporting self-management, it is important that different professionals complement and support each others' work in terms of the medication counselling they provide. This requires multidisciplinary collaboration. Professionals first develop a positive attitude towards multidisciplinary collaboration during their basic education as they have shared courses with other groups of professionals and thus learn about each others' competence. This facilitates multidisciplinary collaboration after graduation. All healthcare professionals must be aware of the importance of a multidisciplinary approach.

Healthcare professionals, particularly physicians, play an important role in ensuring that general information from other sources is put in the right perspective with regard to each patient's situation. Patients particularly wish to have balanced benefit and risk information (European Medicines Agency 2009). Medicines information is often presented on a general level, and medicine users may have trouble applying it to their individual situation, even if the information is reliable.

Proposals:

- Ensure that basic and complementary education for all groups of professionals contain multidisciplinary courses. Teaching should address at least the following areas:
  - a patient-centred approach and support for self-management
  - tailored medication counselling
  - a multidisciplinary approach
  - increasing awareness of the competence of one's own professional group among other groups of professionals.
- Consider special groups: Medicines information should be included in the basic and complementary education of sign language interpreters and interpreters working with immigrants.

GOAL 4.

TO BASE MEDICATION COUNSELLING ON NATIONAL GUIDELINES AND LOCAL AGREEMENTS.

Harmonising the provision of medication counselling in healthcare.

According to the Health Care Act (30 December 2010/1326), healthcare provision plans must include regional procedures for cooperation between the participating local authorities in health and welfare promotion and arrangements for the provision of healthcare services between the different parties involved. The plan must also include pharmaceutical services and the bodies responsible for them. The Medicines Policy 2020 also emphasises the importance of local agreements to promote collaboration in pharmaceutical services (Ministry of Social Affairs and Health 2011a). It is also a good idea to include in the plan an agreement on medicines information activities. From a medicines information perspective, the patient's arrival, transfer from one unit to another, and particularly the point of discharge are key contact points. Their smooth implementation with regard to matters such as the provision of medication counselling should be ensured and recorded in the healthcare provision plan.

Patients have a statutory right to be informed about the significance of their treatment, any alternative forms of treatment and their effects and about other factors related to their treatment that are significant when treatment decisions are made (Act on the Status and Rights of Patients, 17 August 1992/785, section 5). A physician agrees with the patient on the treatment of the condition in question, prescribes medication and provides sufficient information on the therapeutic indication and use of the medicine. Registered nurses with the postgraduate qualification that entitles them to a limited right to prescribe medicines provide medication counselling to the patients they treat. In pharmacies pharmacists instruct and advise patients on the safe and correct use of medicines while dispensing the products **(Table 1)**. Personnel providing pharmacotherapy give information and practical advice on the use of medicines at the different stages of the pharmacotherapy process (Ministry of Social Affairs and Health 2006).

To strengthen the patient's role and enhance patients' adherence, it is also important that patients are actively encouraged to ask about their medication, to report their wishes and to say which pharmacotherapy-related matters they find significant with regard to their life and quality of life. Each patient's treatment is recorded in his or her health and care plan at the local health centre (Ministry of Social Affairs and Health Decree on patient documents 298/2009; Health Care Act, 30 December 2010/1326). The health and care plan is an essential tool in monitoring the patient's treatment as a whole.

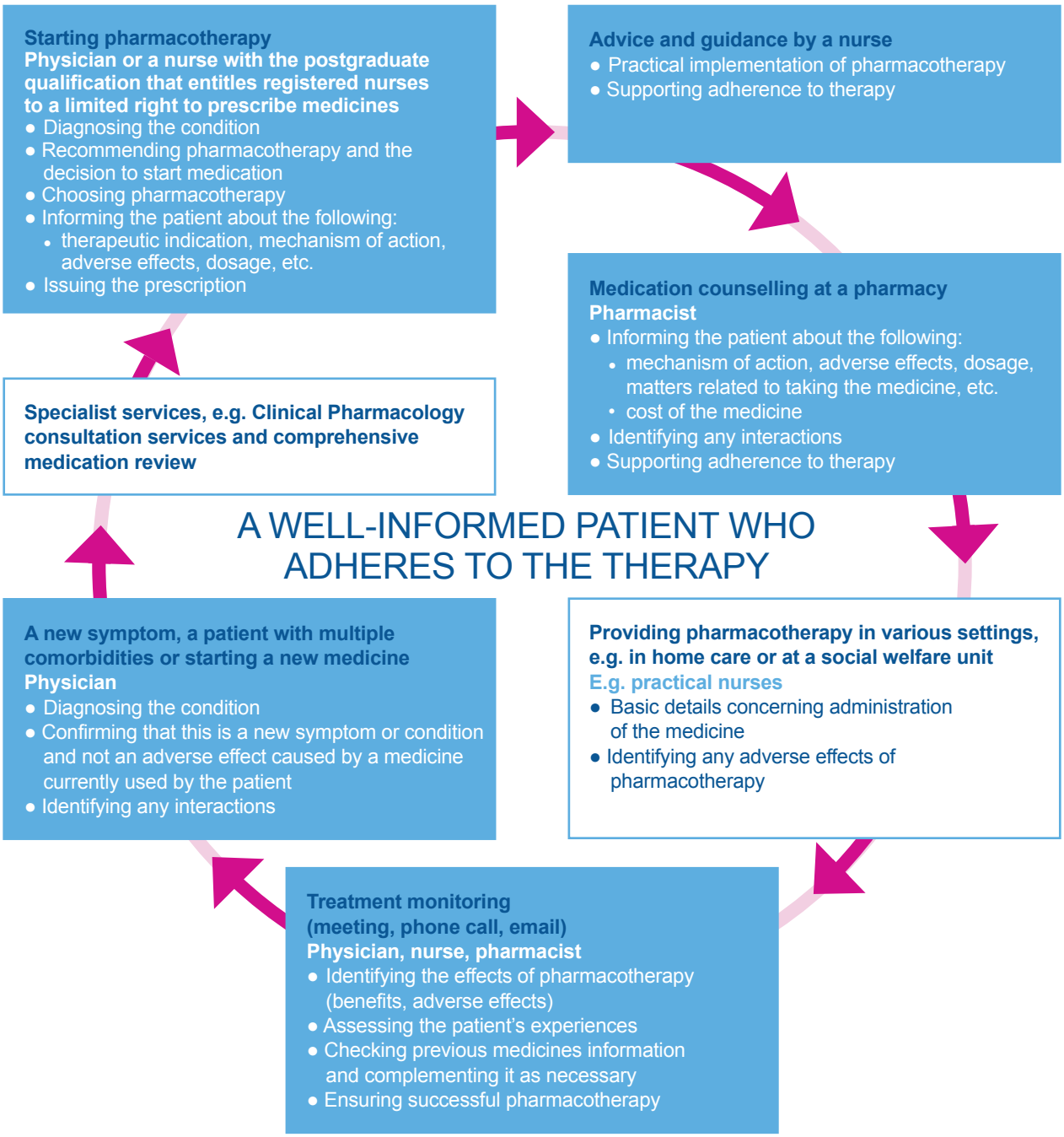
Table 1. *The statutory duties of different professional groups in disseminating medicines information*

Professional group and provision	Statutory duty
Physician Registered nurse with the postgraduate qualification that entitles them to a limited right to prescribe medicines Ministry of Social Affairs and Health Decree on pharmaceutical prescriptions, 1088/2011 sections 8, 9 and 10	• Prescribers must give the patient adequate information on the therapeutic indication and use of the medicine. • If necessary, prescribers must cooperate with the pharmaceutical personnel of the pharmacies that their patients commonly use in order to ensure that patients receive medication counselling and that their pharmacotherapy is safe, effective and cost-effective. • Prescribers must also take into consideration any guidelines concerning use.
Pharmacist Medicines Act, 10 December 2010/1112, section 57	• When supplying medicinal products from pharmacies and subsidiary pharmacies every effort must be made, through the advice and guidance of pharmaceutical personnel, to ensure that the users of the medicinal products are aware of the correct and safe use of the product. • In addition, medicinal product purchasers must be given information about the medicinal product prices and about other factors affecting their choice of medicinal product. • When supplying medicinal products from pharmacy service points and via online pharmacy services, pharmaceutical personnel must ensure that medicinal product purchasers have access to the advice and guidance of pharmaceutical personnel on the correct and safe use of medicines and to information about medicinal product prices and other factors affecting their choice of medicinal product.

Increasing patient-centredness and promoting health are central goals of the Working Health Centre programme (Ministry of Social Affairs and Health 2009). One of the main measures proposed in the programme is to develop the treatment and prevention of chronic diseases on the basis of the Chronic Care Model. According to the model, chronic disease management should move from a condition-centred approach towards holistic, systematic assessment and support for the patient (Wagner 1998). From the patient's perspective, local action is very important. It is therefore essential to develop local multidisciplinary cooperation.

At local level it is important to agree on ways to increase multidisciplinary cooperation to improve the follow-up and medication counselling of all chronic care patients. It is, for instance, important to agree on prescription renewal

TREATMENT CHAIN FOR PATIENTS WITH A CHRONIC CONDITION



practices and associated medication counselling: When should pharmacists and nurses refer a patient to a physician instead of having the prescription renewed? Public health programmes are good examples of multidisciplinary cooperation (Ministry of Social Affairs and Health 1994, Finnish Diabetes Association 2000, Finnish Heart Association 2005, Haahtela et al. 2006). Pharmacies have contributed to national public health programmes by organising their own Pharmacies' National Health Programmes: Pharmacy Asthma Programme, Pharmacy Diabetes Programme and Pharmacy Heart Programme. Thanks to public health programmes, public health expert networks have been established for primary care and pharmacies, which has significantly improved medication counselling for patients with a chronic condition. It is important to ensure that these expert bodies continue their work and further step up their collaboration.

Those with a chronic condition visit a pharmacy at least once every three months to obtain their medicines. These visits could be part of medication follow-up, which would support the first primary goal of the medicines policy, i.e. ensuring that the pharmaceutical service constitutes part of the social welfare and healthcare service systems (Ministry of Social Affairs and Health 2011a, Ministry of Social Affairs and Health 2011b). Medication counselling practices for those with a chronic condition should also be agreed locally.

Recording the medication counselling given at different stages of a patient's treatment pathway could facilitate medication follow-up and indicate any areas that have not been discussed with the patient. The Working Group on Development Needs Regarding Outpatient Pharmacy Operations suggests that quality standards for medication counselling should be defined to ensure that the statutory counselling given when dispensing a medicine is clearly distinguished from chargeable additional services (Ministry of Social Affairs and Health 2011b). Such quality standards would define the minimum requirements for medication counselling and help to harmonise practices across Finland. Quality standards should also address medication counselling for special groups. The need to document medication counselling should be considered while drafting the standards.

Proposals:

- Increase collaboration between pharmacies and healthcare units and encourage more local agreements on monitoring long-term treatments. Medication counselling practices should also be agreed on.
- Define quality and structural standards for medication counselling and assess the possibility to document and monitor medication counselling.

Using medicines information to support the provision of pharmacotherapy in various settings.

Pharmacotherapy is provided in a very wide range of settings, for instance in institutions for the disabled, child protection institutions and various residential institutions such as residential homes for the elderly (Ministry of Social Affairs and Health 2006). Medicines may also be used at nurseries and schools. The personnel providing pharmacotherapy have very different educational backgrounds, and some of them have no vocational healthcare education at all.

To ensure safe pharmacotherapy, the unit-based pharmacotherapy plans compiled for each healthcare and social services unit must be followed (Ministry of Social Affairs and Health 2006). The plans cover the planning and implementation of pharmacotherapy at the unit as a whole, as well as the ways in which any deviations are monitored and reported. In their plans, each unit must also address the way in which medication counselling is arranged, since all patients, including those in institutional care, have the right to know what medicines they are given and what their use entails. The following key aspects of patient information should be addressed in the unit-based pharmacotherapy plan:

1) supporting the patient's participation and adherence
2) providing information
3) oral and written advice and guidance
4) ensuring advice and guidance has been understood
5) reporting any deviations occurring during treatment.

Institutional care and home care mainly involve patients with chronic conditions who need long-term medication. Their prescriptions are renewed by a physician, and the unit or home care personnel pick up the medicines from the pharmacy. Those providing pharmacotherapy are thus responsible for ensuring that patients receive enough information about their medicines. Those providing pharmacotherapy must have easy access to information on medicines in real-life situations, including when no Internet connection is available (for example, in the home of an elderly patient). They must be able to obtain support for pharmacotherapy problems, for instance from the local pharmacy.

When pharmacotherapy is provided in atypical settings, such as nurseries and schools, the emphasis is on collaboration with healthcare professionals and mutual agreements. In a nursery or school setting, an employee with no basic pharmacotherapy education may agree to participate in the pharmacotherapy of, for instance, a child's chronic condition such as asthma or diabetes. In such cases, the employee must undergo additional training, permission must be obtained from the physician in charge (e.g. the school healthcare physician) and an agreement must be made between the parents, the employee providing the pharmacotherapy and the unit's management (Ministry of Social Affairs and Health 2006).

Practical nurses may also participate in providing pharmacotherapy in nurseries and schools, for instance when working as a school assistant or childcarer. Persons providing pharmacotherapy must receive adequate information, particularly about the medicines in question. The unit-based pharmacotherapy plan describes how pharmacotherapy is carried out and how the necessary skills are ensured. It addresses both the provision of pharmacotherapy for children with chronic conditions and the use of medicines given for short periods and as required, such as antibiotics and painkillers.

Proposals:

- Ensure that units have unit-based pharmacotherapy plans that also include medicines information activities.
- Ensure that persons providing pharmacotherapy have access to medicines information, for instance by:
  - developing multidisciplinary cooperation with local stakeholders such as pharmacies;
  - developing new tools and utilising new information and communication technologies (ICT) to support the provision of pharmacotherapy in social services and home care;
  - utilising the networked services of institutions providing medicines information services, listed on page 13, in social service units and in atypical settings where pharmacotherapy is provided;
  - assessing existing permit practices in atypical settings providing pharmacotherapy and using them to ensure the availability of key medicines information.

Ensuring medication counselling in self-care.

Today, patients are able to treat an increasing number of conditions or alleviate their symptoms on their own. The importance of self-care in treating symptoms and mild conditions has increased and continues to do so, for instance because of limited healthcare resources, the higher level of education among the population, an emphasis on patients taking responsibility for their treatment, and the wider range of over-the-counter (OTC) medicines available. In fact, the majority of symptoms are self-treated at home without any contacts with healthcare professionals. Appropriate self-care and self-medication mean savings for both the patient and society. According to one estimate, a 10% reduction in health centre visits achieved through self-care would result in annual public savings of € 63 million (Pappila 2008).

For the self-care patient, the pharmacy is often the only contact with the healthcare system. One of the most important functions of a pharmacy is to advise and counsel patients with regard to self-care and the need to seek medical care. Counselling concerning the use of OTC medicines is also an important part of pharmacy activities. Since April 2011, OTC medicines have also been available via pharmacy service points and online pharmacy services. According to the Medicines Act (1112/2010, section 57), when supplying medicinal products from pharmacy service points and via online pharmacy services, pharmacies must ensure that medicinal product purchasers have access to the advice and guidance of pharmaceutical personnel on the correct and safe use of medicinal products and to information about medicinal product prices and other factors affecting their choice of medicinal product.

Physicians and nurses inform patients about the importance of a healthy lifestyle, including nutrition and exercise, in the treatment of symptoms. Many pharmacies also provide guidance and support for things such as quitting smoking or losing weight. Physicians may also advise patients on how self-care affects the patient's medication as a whole if the use of certain OTC medicines or herbal medicinal products is not recommended because of a risk of interaction. Other healthcare professionals may also play a significant role in guiding self-care. Physiotherapists, for example, may have a central role in the self-care of pain associated with musculoskeletal complaints.

In order to take self-care and self-medication into account in the patient's treatment as a whole, physicians and nurses must be familiar with OTC products and the way in which pharmacies advise patients in their use. All parties involved must be aware of the treatment as a whole (including the use of OTC products and other preparations); one way to achieve this is to record the data on a medicines card. Pharmacies, health centres, child and maternity health clinics, maternity clinics and home care for the elderly should all use the same treatment guidelines and products and give the same advice (Ministry of Social Affairs and Health 2011b). Providing support for self-care requires both multidisciplinary cooperation and the appropriate tools.

In future, self-care should be increasingly incorporated into healthcare as presented in the goals of the Medicine Policy 2020 (Ministry of Social Affairs and Health 2011a). When compiling the self-care programme, collaboration between pharmaceutical and healthcare services in supporting self-care should be addressed on a national level.

Proposals:

- Support the work of professionals by producing evidence-based treatment guidelines concerning self-medication and self-care and integrate these into existing treatment guidelines wherever possible.
- Incorporate guidance for self-care and self-medication into the national self-care programme.
- Assess and monitor the quality of medicines information and medication counselling available from online pharmacy services and pharmacy service points.

GOAL 5.

TO ENSURE THAT MEDICINE USERS UTILISE RELIABLE INFORMATION SOURCES AND SERVICES.

Ensuring the availability of reliable medicines information.

The role of medicine users and patients has changed and is still changing from passive to active. Many sources of information are available for patients and the general public **(Table 2)**. Participation in treatment decisions requires reliable and unbiased information, and the dissemination of such information to those needing medicines needs to be further improved. For instance, it is important to support patient organisations as they work to disseminate medicines information and to cooperate with these organisations to produce targeted information for specific patient groups.

Proposal:

- Increase collaboration between patient organisations and other stakeholders in this field to improve medicines information.

Table 2. *Examples of patients' sources of information*

Party producing or disseminating information	Information source
Physicians, nurses	Medication counselling, patient guidance
Pharmacies, pharmacists	Medication counselling, customer magazine Terveydeksi!
Finnish Medical Society Duodecim	Terveyskirjasto.fi website Patient versions of the Current Care guidelines
National Pharmaceutical Information Centre KLIK	Telephone, online and e-mail services
University Pharmacy information services	Telephone, online and e-mail services
Poison Information Centre Teratological Information Service	Telephone services
Finnish Medicines Agency Fimea	Package leaflets List of interchangeable medicinal products
Pharmaceutical Information Centre	Kodin Lääkeopas book Lääkeinfo.fi
Finnish Generic Pharmaceuticals Association	Lääkeohje.fi
Pharmaceutical industry	Package leaflets, patient information guides
Social Insurance Institution of Finland	Information on reimbursement, Medicinal Products Database
Patient organisations	Magazines Information and educational events Peer support education

Promoting the readability and usability of package leaflets.

Package leaflets are an important source of medicines information for patients (Närhi 2007, Närhi and Helakorpi 2007). They must comply with the SPC, and information necessary for product use must be presented in a specific order (Finnish Medicines Agency 2010, Directive 2001/83/EC of the European Parliament and of the Council). Patients from the target group must give their opinions to ensure the leaflet is readable, clear and user-friendly. The Fimea Normative Guideline 1/2010 provides detailed instructions on compiling the labelling and package leaflet for a medicinal product. Although instructions are given, leaflet usability may be poor. There may also be differences in the package leaflets of medicinal products with the same active substance, which is confusing for the patient. In July 2011, EMA revised its package leaflet compilation instructions (European Medicines Agency 2011). In future, the benefits of the medicine must be better presented, and information on its suitability for children must also be provided.

The European Union is currently preparing a Directive as regards information to the general public on medicinal products subject to medical prescription that will clarify the role of the pharmaceutical industry in direct patient communication about prescription-only medicines (European Commission 2008/0256 [COD]). The proposals reviewed by the Commission retain the current ban on advertising prescription-only medicines and emphasise patient rights, benefits and safety. According to the proposals, patients may only be given certain information on prescription-only medicines, e.g. labelling and package leaflet information, prices, information on clinical trials and instructions for use. The proposals also restrict available communication channels and set out the quality requirements that the information must meet.

Proposal:

- Further enhance package leaflet readability and contents in the EU.

Producing medicines information in minority languages and for other special groups.

The Act on the Status and Rights of Patients (17 August 1992/785, section 3) notes that the mother tongue, individual needs and the culture of the patient must be taken into account as far as possible in the patient's care. In Finland, medicines information in Swedish can be obtained from package leaflets available via the Fimea FimeaWeb service, the Lääkeinfo.fi online service of the Pharmaceutical Information Centre and the Lääkeohje.fi online service of the Finnish Generic Pharmaceuticals Association. Patient versions of Current Care guidelines are also being translated into Swedish. To meet the rights of immigrants and others to obtain medication counselling in their mother tongue, both tools for healthcare professionals and material for patients are required. Pictograms might be one such tool. English-language material may

also be useful. Major immigrant languages include Russian, Estonian, English, Somali, Arabic and Vietnamese.

Very few sources of medicines information are available for special groups. Package leaflets are available for the visually impaired in mp3 audio file format at the Lääkeinfo.fi online service of the Pharmaceutical Information Centre. However, not all those with visual impairment are able to use computers and search information independently online. Medicines information must therefore also be available in other formats suitable for the visually impaired, such as large print, Braille and audio recordings. Particular attention should be given to the accessibility of websites containing medicines information. Medicines information should also be provided for sign language users, for instance by translating material into sign language and making it available online.

Proposals:
- Produce medicines information in Swedish.
- Produce medicines information for special groups (immigrants, deaf and hard of hearing, visually impaired, elderly, children, patients with public health problems).

Increasing the use of information and communications technology to disseminate medicines information.

The importance of ICT in disseminating medicines information will increase in the future. This is both a challenge and an opportunity for the healthcare system. New technological innovations may help patients to use medicines in daily life (e.g. reminders, technologically advanced packaging) and also help in providing patients with medicines information specific to their needs. Electronic healthcare services provide electronic information transfers, for instance between patients and healthcare service providers. The range of available applications is large and extends from electronic patient records systems and appointments systems to telemedical services and portable patient monitoring devices. The development of ICT technologies will encourage patients and medicine users to take greater responsibility for their own treatment.

There is plenty of reliable medicines information for patients online, an example being the Terveyskirjasto.fi health library site maintained by the Finnish Medical Society Duodecim. However, not all online information is reliable or unbiased. Online discussion forums in particular contain plenty of discussions on current matters related to medicines. They are often based on individual experiences, and the writers may not have understood the fact that pharmacotherapies are tailored individually. Pharmaceutical companies display on their websites information and patient information leaflets concerning their proprietary products. To help people find and identify reliable medicines information, reliable medicines information sources that meet predefined criteria could be collected on a single site through which patients could also report adverse effects. A quality label would be another option.

The Ministry of Finance eServices and eAdministration project (SADe) involves plans for a project to gather general social affairs and health information and make it available to citizens and local authorities. The aim is to use such general information to compile a shared knowledge base available on the websites of local authorities and accessible to everyone, particularly the customer advisors of local authorities. This would support citizens in their use of electronic services and communications. Information would be produced by e.g. organisations in the Ministry of Social Affairs and Health administrative sector, each organisation being responsible for covering its own sphere of competence. Patient-specific information in the National Archive of Health Information's ePrescription system should also be linked to general information on the medicines currently used by the patient.

Patients use the Internet for a number of purposes, not just to seek factual information. They also look for peer support and treatment experiences by other medicine users (Pohjanoksa-Mäntylä 2010). Healthcare service providers should take this into account, for instance by providing discussion forums in which healthcare professionals are present to ensure the information is reliable.

Proposals:
- Incorporate general medicines information for citizens into other social affairs and healthcare information in the SADe project.
- Link general medicines information, including information on medicines currently used by the patient, to patient-specific information in the National Archive of Health Information's ePrescription system.
- Create a list of links to reliable sources of medicines information or establish a quality label.
- Develop and promote the visibility and participation of healthcare professionals in social media.

GOAL 6.

TO ACHIEVE A HIGH LEVEL OF HEALTH LITERACY AMONG THE GENERAL PUBLIC.

Promoting health literacy among children and adults.

A large amount of medicines information is currently available to the public. However, it is not easy to assess whether the information is reliable and unbiased. Promoting health literacy among the public has therefore been considered to be a challenge both internationally (High Level Pharmaceutical Forum 2008) and in Finland (Ministry of Social Affairs and Health 2011a). In addition to improving the population's skills to seek information and assess its reliability, greater self-confidence and skills are required when making health and lifestyle decisions (Nutbeam 1998, Paakkari and Paakkari 2012). It is therefore important to encourage clients and patients to seek information and discuss their medication with healthcare professionals. A number of tools have been developed to help in assessing the reliability of medicines information. These include the DARTS checklist (Närhi et al. 2008), the use of which should be promoted. The dissemination of information on falsified medicines and the risks of medicines ordered online should also be continued, for instance by means of population-level campaigns such as those required by the Falsified Medicines Directive (Directive 2011/62/EC of the European Parliament and of the Council).

Population-level campaigns may also be used to increase awareness of the correct use of medicines. The campaign could include the following, which are relevant for both medicine and medication safety:

- The difference between medicines and other products, e.g. nutritional supplements.
- Individual differences in how people react to medicines.
- Potential differences between generic preparations.

The campaign should address different target groups (different messages and communication media are required to reach both young people and the elderly) and special groups such as the visually impaired and the deaf. In addition to increasing awareness, promoting local cooperation between healthcare stakeholders should be an important goal. To be worthwhile, the campaign should therefore take the form of multidisciplinary collaboration between a number of stakeholders to achieve wide visibility.

The development of health literacy skills should start in childhood. School health education allows educators to reach the entire cohort of Finnish children of a specific age. According to the national Core Curriculum, medicines education, i.e. education on the appropriate use of medicines, should be included in environmental and natural sciences in primary school and in health education in lower secondary school (Finnish National Board of Education 2004). However, teachers may be unfamiliar with matters related to medicines and may need training to be able to deliver teaching consistent with the Core Curriculum. Teaching may also be organised jointly by inviting a school health nurse or pharmacist to give medicines education lessons during health education classes. The Core Curriculum contains a large amount of material for the number of hours available, and medicines education is a small part of health education. Health education currently focuses on warning against medicine abuse, which may result in children starting to fear medicines. In future, it is important to motivate and advise teachers to talk about the appropriate use of medicines as such and avoid linking the matter to abuse issues. The medicines education web pages compiled by the University of Eastern Finland School of Pharmacy can be used in teaching as a supplement to coursebooks. It is important that these pages are maintained and updated.

Proposals:

- Promote the use of the DARTS checklist, developed to help assess whether medicines information is reliable, among the public and in school teaching.
- Carry out a multidisciplinary population-level campaign on the safe and appropriate use of medicines.
- Update medicines information webpages to produce a generic source of medicines information for the general public.
- Ensure that the appropriate use of medicines and medicines information literacy continue to be included in the Core Curriculum for basic education.
  - Create national medicines education guidelines for schools in which the appropriate use of medicines is integrated into a wider educational context.
  - Encourage medicines education collaboration between schools and the healthcare system and develop guidelines and material to support healthcare professionals giving medicines education lessons.
  - Ensure teaching material is provided for special groups such as sign language users.

Fimea's participation in the development of the medicines information proposals

Fimea has examined the proposals in the Medicines Information Strategy that are clearly within its scope of activities or that it could consider carrying out subject to further investigations **(Table 3)**.

Table 3. *Fimea's participation in the development of the medicines information proposals*

Proposal	Fimea's contribution
Establish a medicines information network in order to increase cooperation, a more systematic approach and greater multidisciplinarity in developing medicines information activities and to promote collaboration between the public and private sectors.	Fimea will coordinate the activities of the medicines information network.
Produce summaries of pharmacotherapies (such as the Kapseli publication series).	Fimea will assess the need to compile new Kapseli publications and update past issues together with the Social Insurance Institution. Fimea will publish summaries of new approved medicines in its publication Sic!
Produce evaluations and summaries of the therapeutic and economic value of medicines for healthcare professionals and patients. Encourage greater utilisation of evaluated evidence.	Fimea will produce evaluations of the therapeutic and economic value of medicines in collaboration with other stakeholders, based on agreed guidelines.
Improve the availability of medicines information in Swedish for healthcare professionals.	Fimea will also produce medicines information in Swedish.
Establish an effective information management system for crisis situations and pharmacovigilance-related information to ensure that all healthcare professionals can be contacted during the same day.	Fimea will increase collaboration with other stakeholders with regard to providing information in crisis situations.
Ensure easy access to SPCs. Improve the quality of SPCs in the EU.	Fimea will participate in improving SPC quality in the EU. Fimea will develop its website to allow easy access to SPCs (including those for products approved via the centralised procedure) based on the brand name or generic name in Finnish.
Evaluate opportunities for networking and coordination of activities between the stakeholders currently providing medicines information services.	If necessary, Fimea will coordinate the evaluations.
Evaluate and monitor the quality of medicines information disseminated by stakeholders providing medicines information services.	Fimea will produce an evaluation of the quality of medicines information disseminated by stakeholders providing medicines information services.
Increase awareness of and collaboration between Clinical Pharmacology and Clinical Pharmacy services. • Develop Clinical Pharmacology and Clinical Pharmacy services and ensure access to them everywhere in Finland, for instance by creating a network-type consultation service for healthcare professionals. • Shift the focus of ward pharmacy activities from medicine logistics towards clinical pharmacy: medication review and medication counselling for patients (e.g. admission interview, review of admitted patients' medication, medication counselling on discharge together with a physician and a nurse).	Fimea will address the need to develop clinical pharmacology, clinical pharmacy and ward pharmacy activities in a collaborative project to create national guidelines for multidisciplinary work.
Define quality and structural standards for medication counselling and assess the possibility to document and monitor medication counselling.	Fimea will establish a working group and coordinate its activities.
Incorporate guidance for self-care and self-medication into the national self-care programme.	Fimea will participate in compiling a self-care programme including ways to ensure medication counselling in self-care and self-medication.
Assess and monitor the quality of medicines information and medication counselling available from online pharmacy services and pharmacy service points.	Fimea will monitor the quality of medicines information and medication counselling as part of its pharmacy inspections. It will also carry out a more extensive review.
Increase collaboration between patient organisations and other stakeholders in this field to improve medicines information.	Fimea will increase collaboration with patient organisations.
Further enhance package leaflet readability and contents in the EU.	Fimea will participate in improving package leaflet quality in the EU.
Create a list of links to reliable sources of medicines information or establish a quality label.	Fimea will assess the opportunities to evaluate reliable sources of medicines information. This assessment will then be used to decide whether Fimea will maintain a website or a list of links to reliable sources of information.

Table 3 continuing. *Fimea's participation in the development of the medicines information proposals*

Promote the use of the DARTS checklist, developed to help assess whether medicines information is reliable, among the public and in school teaching.	Fimea will utilise the checklist and promote its use wherever possible, for instance via campaigns intended for the general public.
Carry out a multidisciplinary population-level campaign concerning the appropriate use of medicines.	Fimea will participate in carrying out a multidisciplinary population-level campaign, if relevant.
Update medicines information webpages to produce a generic source of medicines information for the general public. Incorporate general medicines information for citizens, produced by Fimea, in other general social affairs and healthcare information in the SADe project.	Ownership and control of webpages produced by the University of Eastern Finland School of Pharmacy will be transferred to Fimea. In connection with this, Fimea will update the website and transform it into a source of generic medicines information for the general public. The site contents will be used in the SADe project in the form of general medicines information.
Create national medicines education guidelines for schools in which the appropriate use of medicines is integrated into a wider educational context. • Encourage medicines education collaboration between schools and the healthcare system and develop guidelines and material to support healthcare professionals giving medicines education lessons.	Fimea will be one of the partners in a research project by the University of Eastern Finland School of Applied Educational Science and Teacher Education and the School of Pharmacy. The project will seek to produce recommendations on how to integrate information on the appropriate use of medicines into a wider educational context in primary and secondary schools.

ANNEXES

ANNEX 1. Organisations that participated in preparing the Medicines Information Strategy

Public administration
Association of Finnish Local and Regional Authorities
Finnish Medicines Agency Fimea
Ministry of Social Affairs and Health
Social Insurance Institution of Finland

Trade and professional unions and organisations
Association of Finnish Pharmacies
Finnish Medical Association
Finnish Nurses Association
Finnish Pharmacists' Association
Finnish Union of Practical Nurses
Finnish Pharmacists' Society
Union of Health and Social Care Professionals Tehy

Scientific societies
Finnish Medical Society Duodecim
Finnish Society of Clinical Pharmacology
Finnish Society of Clinical Pharmacy

Pharmaceutical industry organisations
Finnish Generic Pharmaceutical Association
Pharma Industry Finland

University pharmacies
University of Eastern Finland Pharmacy
University Pharmacy

Universities, polytechnics, vocational institutions and complementary education units
Pharmaceutical Learning Centre
Savonia University of Applied Sciences
Savo Vocational College
Turku University of Applied Sciences
University of Eastern Finland, Aducate Centre for Training and Development
University of Eastern Finland, Faculty of Health Sciences
University of Helsinki, Faculty of Medicine
University of Helsinki, Faculty of Pharmacy
University of Helsinki, Palmenia Centre for Continuing Education
University of Tampere, School of Medicine
University of Turku, Faculty of Medicine
Åbo Akademi, Unit of Pharmaceutical Sciences

Hospitals, hospital pharmacies and dispensaries
City of Lahti social and health services, hospital pharmacy
HUS Pharmacy
Kuopio University Hospital
Kuopio University Hospital, hospital pharmacy
Varkaus Hospital, dispensary

Companies offering pharmaceutical services
DRA Consulting Oy
Farenta Oy
Pro Dosis Oy

Companies producing medicines information
Pharmaceutical Information Centre

Patient associations and organisations
Allergy and Asthma Federation
Association of Voluntary Health, Social and Welfare Organisations
Finnish Association of the Deaf
Finnish Diabetes Association
Finnish Federation of the Visually Impaired
Finnish Heart Association
Finnish Kidney and Liver Association
Finnish Migraine Association
Finnish Osteoporosis Association
Finnish Rheumatism Association
Pääkaupunkiseudun Osteoporoosiyhdistys
('Metropolitan Area Osteoporosis Association')
Suomen Nivelyhdistys ('Finnish Joint Association')
Suomen Potilasliitto ('Finnish Patient Association')
Thyroid Foundation of Finland

Student associations and organisations
Tehyn opiskelijayhdistys ry
('Students' Association of the Union of Health and Social Care Professionals Tehy')
Finnish Pharmaceutical Students' Association FiPSA
Finnish Medical Students' Association
Sairaanhoitajaliiton opiskelijajärjestö
('Students' Association of the Finnish Nurses Association')

ANNEX 2. Examples of medicines information sources for healthcare professionals

Party producing or disseminating information	Information source
Authorities	
Social Insurance Institution of Finland	Statistics on the use of medicines reimbursed from health insurance funds Kapseli publications (together with Fimea) Medicinal Products Database
Finnish Medicines Agency Fimea	SPCs and package leaflets Medicine consumption statistics Medicines classification (ATC-DDD) Database of medication for the elderly Database on medicinal products available for compassionate use List of interchangeable medicinal products The journal Sic! Drug information from Fimea Pharmacovigilance-related information Other publications and publication series, including the Kapseli publications in collaboration with the Social Insurance Institution
Public and professional bodies	
Finnish Medical Society Duodecim	The Terveysportti portal and its specialised databases: • Duodecim Lääketietokanta medicines database • SFINX • Renbase • Gravbase, Lactbase • Herbalbase • Lääkkeen vaikutus laboratoriotutkimuksiin (Drug Laboratory Effects) database • Physicians' and nurses' databases Current Care guidelines Evidence-Based Medicine electronic Decision Support (EBMeDS) system
Poison Information Centre Teratology Information Service	Telephone services
Hospital pharmacies	Solving problems related to pharmacotherapies Instructions concerning pharmacotherapies Information on medicines consumption, new guidelines, product defects etc.
Hospital districts	Instructions concerning pharmacotherapies
Association of Finnish Pharmacies	The Tietotippa, Salvia and Salko databases
Clinical Pharmacology units at university hospitals and universities	Solving challenging patient-specific problems in university hospitals (consultation service) Producing information on pharmacotherapies, e.g. coursebooks
Organisations and associations in different fields	Scientific publications (e.g. Duodecim Medical Journal) Professional publications (e.g. the Lääkeinfo pages in the Finnish Medical Journal) National guidelines compiled by specialist societies
Private stakeholders	
National Pharmaceutical Information Centre KLIK	Telephone, online and e-mail services, documented reply database
Pharmaceutical Information Centre	Pharmaca Fennica® Medicines lists
Pharmaceutical companies	Information on specific medicinal substances and products SPC and package leaflet Medical information services
University Pharmacy	University Pharmacy HELP texts, information services

ANNEX 3. Multidisciplinary collaboration methods in monitoring self-management and long-term treatment (Ministry of Social Affairs and Health 2011b, Peura et al. 2007)

Type of collaboration	Contents	Responsibilities
Medication assessment	• Assessment of an individual patient's medication, the need for it and its appropriateness as part of a normal patient examination and treatment planning.	• A physician makes an assessment. • Other healthcare professionals assist the physician, if necessary.
Prescription renewal	• In the guidelines for prescription renewal (Lahnajärvi 2006), the emphasis is on treatment follow-up: 1) submitting a prescription for renewal, 2) receiving and preparing the prescription, 3) checking the renewal, 4) producing the prescription, 5) signing the prescription, 6) recording prescription renewals and 7) picking up the prescription. • Renewal practices are discussed in meetings to review particular problem areas such as: - medicines not renewed without an appointment - patients with chronic conditions and polypharmacy - centrally acting substances and other medicines with abuse potential - medicine abusers.	• A nurse (at appointments) or a pharmacist (at a pharmacy) receives the prescription, asks when the patient last had a medical check-up and when the next one is due, and asks the patient's opinion about the effectiveness and use of the medicine and any problems associated with it. The nurse or pharmacist also prepares the prescription for renewal. • The physician treating the patient or renewing the prescription or a nurse prepares the renewal entries or, if necessary, issues a new prescription form by hand or on computer. • Before renewal, the physician treating the patient or renewing the prescription checks whether a renewal is required and reviews the duration of the therapy and any interactions. The physician signs the renewal entries and puts a stamp on the prescription. • A clinic assistant enters any manually renewed prescriptions in patient records. Computer prescriptions are entered automatically. • A nurse (at appointments) or a pharmacist (at a pharmacy) gives the prescription and any associated messages to the client.
Electronic prescription renewal (National Archive of Health Information, 2011) • The use of electronic prescriptions is based on a centralised national database known as the Prescription Centre. • For each electronic prescription, the Prescription Centre records data on who has viewed, changed or otherwise processed the prescription or cancelled it and the time when this took place (Act on Electronic Prescriptions, 61/2007).	• The patient or a person acting on the patient's behalf may request to have the electronic prescription renewed by phone, by visiting a healthcare unit or during other contacts with a healthcare unit or pharmacy. • Renewal requests may also be submitted via an electronic health service requiring reliable identification. • The pharmacy sends the renewal request to the Prescription Centre, which transfers the request automatically to the healthcare unit indicated by the patient. • A prescription may only be renewed if no more than 16 months have passed since the original prescription was issued. • Prescriptions with refills and those for narcotics or centrally acting substances may also be renewed. • Patients cannot determine which physician in the organisation will receive and process the renewal request. • The Prescription Centre considers a renewal request to have expired if it has not been processed at a healthcare unit within 8 days of the renewal request being submitted to the patient records system. • If a renewal request expires, a new renewal request may be submitted for the same prescription. • Healthcare units cannot be requested to renew a rejected prescription. • If a patient wishes, the results of a renewal request may be sent by SMS. • The renewal request may also contain a message to the physician. • If a patient's prescription is not renewed for therapy-related reasons and the patient has not requested an SMS notification, the healthcare unit must inform the patient that the request was rejected by some other means, e.g. by phone or mail.	• Each healthcare unit lists the employees who have the right to receive renewal requests. • The right to process renewal requests in the patient records system may also be given to a person who is not a healthcare professional. • Those processing renewal requests must have an authentication card issued by a healthcare authenticator to log on to the patient records system. • A renewal request may also be received by a physician who did not issue the original prescription. • The physician who received the renewal request has the right to download the prescription from the Prescription Centre without the separate consent of the patient. • A physician may either approve, reject or return the renewal request. 1) To approve it, the physician issues a new prescription on the basis of the old one and sends it to the Prescription Centre. 2) If a physician does not renew the prescription, he or she records in the system that the request was rejected. 3) If the renewal request is not to be renewed by the organisation in question and it is being processed by a physician, the physician may return it in the same way as those processing renewal requests do.

ANNEX 3 continuing. Multidisciplinary collaboration methods in monitoring self-management and long-term treatment (Ministry of Social Affairs and Health 2011b, Peura et al. 2007)

Medication review	• A healthcare professional checks that the dosage and administration times of the patient's medication are consistent with accepted treatment practice. The same person also checks for any overlaps and incompatibilities. • This review is part of the normal dispensing of medicines in pharmacies and distribution on wards or in connection with home nursing. • Pharmacies also perform the review when dispensing OTC medicines. • A medication review does not involve an assessment of therapeutic indications or the need for pharmacotherapy.	• A healthcare professional (a physician, nurse, pharmacist) checks that the dosage and administration times of the patient's medication are consistent with treatment guidelines. The same person also checks for any overlaps and incompatibilities. • The physician treating the patient decides on any changes to the patient's medication and is responsible for the patient's pharmacotherapy and its follow-up.
Dose dispensing	• The patient's medication is reviewed, and the list of medicines being used is updated. • The medicines are divided into doses either manually or by machine. • A check is then made to ensure that the medicines have been divided correctly. • The medicines are dispensed to the patient in unit dose bags.	• A pharmacist reviews the patient's medication. • A physician decides on any medication changes recommended by a pharmacist. • The pharmacy is responsible for ensuring that the contents of the order and the contents of the medicine doses dispensed to the patient are correct. • A pharmacist is responsible for updating the patient's medicine list and giving it to the patient. • If necessary, home care or home nursing personnel administer the medicines to the patient.
Comprehensive medication review	• To perform a comprehensive medication review, sufficient background details (age, sex, conditions and their treatment, previous medication, current status, nutrition, exercise, smoking, alcohol) are obtained from the following sources: - interview with the patient (if necessary, relatives or nursing personnel) - patient records - laboratory records. • In a comprehensive medication review, the need and therapeutic indications for pharmacotherapy are assessed, as are any adverse effects, interactions, the effects of age on pharmacotherapy, inappropriate or symptomatic medication, medication overlaps, dosages and administration times and the reimbursement status and economic aspects of pharmacotherapy. • The information collected is analysed, and the problem being addressed is solved. • After the comprehensive medication review, a written report is compiled. This contains a list of the observations made and recommendations for the physician treating the patient. • When the report is submitted, its contents are discussed with the patient and, if necessary, a physician or other persons or units treating the patient. • Further measures and their effects on follow-up are assessed.	• Comprehensive medication reviews are performed by a pharmacist with the necessary formal qualifications. • The physician treating the patient decides on any changes to the patient's medication and is responsible for the patient's pharmacotherapy and its follow-up. • Nursing professionals participate in the medication review and in medication follow-up as required and are involved in a multidisciplinary treatment team. • Multidisciplinary consultation and collaboration are arranged during all stages of the process.

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