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MEDICINES POLICY 2020

Towards efficient, safe, rational and cost-effective use of medicines

MINISTRY OF SOCIAL AFFAIRS AND HEALTH
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SUMMARY

■ The document Medicines Policy 2020 reports on the joint objectives of the social welfare and healthcare authorities and stakeholders in the field of medicines by the year 2020.

1. Pharmaceutical service is a part of the social welfare and healthcare service system

Social welfare and healthcare services must be increasingly developed to respond to the needs of the clients. The chief objective of pharmaceutical service is to enable an efficient, safe, rational and cost-effective pharmacotherapy for all those in need of it. Interprofessional cooperation and agreeing on joint policies and goals regionally and locally are prerequisites for securing systematic and sustained operations. The utilisation of information systems available in social welfare and healthcare and their compatibility should be enhanced. The goal is to deliver all prescriptions electronically.

2. Pharmaceutical service is of high quality, efficient and cost- effective

A good availability and a professionally operating distribution of medicinal products must be secured for citizens under all circumstances. The funding systems must underpin such pharmacotherapy or services that promote the maintenance of the population's working and functional capacity as well as independent coping. The expenses of medicinal products must be evaluated as a part of the total healthcare expenditures. The medicine reimbursement system must support cost-effective treatments in order to curb the expenditure. The know-how and practices of the advisory committees on medicines, hospital pharmacies and medicine dispensaries in establishing a basic formulary of medicinal products, in purchases of medicinal products and competitive tendering needs to be developed.

3. Rational pharmacotherapy and good medication safety enhance the wellbeing of the population, improve public health and decrease the healthcare expenditures

The clients' own role and responsibility in healthcare and medical treatment should be increased in particular in the treatment of long-term diseases and symptoms that they can easily treat themselves. Successful pharmacotherapy should be improved by guidance provided for instance by pharmacists, dispensers and other healthcare professionals. Treatments following the national Current Care Guidelines must be promoted. The access of healthcare professionals, the population and users of medicines to reliable and evidence-based information on medicinal products must be ensured. The consumers' and patients' critical literacy in health information should be promoted.

4. Pharmaceutical research enhances health, wellbeing and employment

Successful pharmaceutical research enhances the population's health, wellbeing and employment, and therefore innovations and their utilisation in the field of medicines ought to be promoted. The assessment of the therapeutic and economic value of medicinal products must be increased, and optimally uniform methods based on similar criteria and evidence should be used in this work. The methods of assessing the therapeutic and economic value must be utilised to a greater extent in the decision-making concerning the reimbursement status of medicinal products.

5. Veterinary pharmaceutical service safeguards public health and promotes the wellbeing of people and animals

An appropriate use of veterinary medicinal products secures the safety of consumers. The regional and national access to veterinary medicinal products must be secured, and their imports and distribution must be safe. The monitoring of the consumption and use of antimicrobial agents should be developed, and adequate systems must be created for the use, dispensing and prescribing of veterinary medicinal products.

Key words: **health care, health policy, health services, medicinal products, pharmaceutical service, pharmacotherapy, social services**

PREFACE

Medicines policy is a part of the social welfare and health policy. The present Medicines Policy 2020 document includes the medicines policy objectives for the coming decade and sharpens the focus of the social welfare and healthcare strategy.

The medicines policy outline has been drawn in collaboration with the stakeholders of the pharmaceutical branch. All phases of the medicine life are here represented: from research to patients.

The work started in early 2010. The steering and preparatory groups as well as various subgroups elaborated on the best ways to provide the Finns with necessary pharmacotherapies, also in the future.

The process towards the Medicines Policy 2020 document was very positive and successful. Sitting around one table, the participants weighed the strengths and weaknesses, threats and possibilities of the current pharmaceutical sector, looking for means to further improve it. In addition to the joint outlines, we learned to collaborate in a more efficient way.

The strategy of the Ministry of Social Affairs and Health was under preparation at the same time. According to the new strategy, our objective is a socially sustainable society where individuals are treated equally, ensuring each and everyone's inclusion and promoting their health and functional capacity. The medicines policy shares these objectives. Successful pharmacotherapy is an important tool in the treatment of diseases, and good pharmaceutical services must be equally available to all.

Having now completed the Medicines Policy 2020 document we are happy to continue the co-operation. The implementation of the outlines on a national and international level will call for good interaction and open communication between the stakeholders in the branch. The government programme sets the framework for the implementation of the medicines policy but the document also includes several objectives specific to the branch, best implemented in day-to-day practical work. Medicines Policy 2020 is a positive start to a sustainable and solid practical co-operation.

Kari Välimäki
Permanent Secretary

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FOREWORD

The main objective of the pharmaceutical service is to provide efficient, safe, rational and cost-effective pharmacotherapies to those who need them. The objective can be reached by developing the current system towards a better match with the customer needs.

Medicines Policy 2020 is a document reporting on the joint medicine policy perspectives of the social welfare and healthcare authorities and the branch stakeholders for the coming decade. The policy outlines are crystallised in the form of five main objectives:

The main medicines policy objectives for 2020 defined by the working group:

1. The pharmaceutical service constitutes a part of the social welfare and healthcare service system.
2. The pharmaceutical service is of high quality, efficient and cost-effective.
3. Rational pharmacotherapies and good medication safety promote people's wellbeing and public health, decreasing the healthcare expenditure.
4. Pharmaceutical research has a positive impact on health, wellbeing and employment.
5. Veterinary pharmaceutical services safeguard public health and promote the wellbeing of humans and animals.

The Medicines Policy 2020 document presents the agreed actions for the attainment of the main objectives as well as the parties that are responsible and co-operate for their implementation. The advantages pursued through the actions are also presented. The final part of the document defines a follow-up plan for the attainment of the objectives and measurement of the outcomes.

The Appendices to the document contain numerical data about the pharmaceutical branch as well as definitions of terms and abbreviations used and the co-operation parties involved.

1 PHARMACEUTICAL SERVICE CONSTITUTES PART OF SOCIAL WELFARE AND HEALTHCARE SERVICE SYSTEMS

Medicines and vaccines play an essential role for healthcare and medical care. A well working social welfare and healthcare service system benefits from pharmaceutical services, and vice versa. Well-functioning services and satisfied customers and patients are shared objectives.

The core values of medicines policy are responsibility, effectiveness, quality, equality and justice as well as economy defined as cost-effectiveness. The respect of human dignity and customer-orientation aim at the promotion of people's health and their working and functional capacity under all circumstances. Other aims include sustainable development, transparent systems and systematic operation according to plan.

The logistic chain in the pharmaceutical services includes the pharmaceutical industry, pharmaceutical wholesalers, outpatient and hospital pharmacies and medicine dispensaries. The pharmaceutical industry is in charge of pharmaceutical research and development as well as production. Universities, university hospitals and various research institutes, also those run by the authorities, engage in research focused on medicines and the pharmaceutical service. The pharmaceutical industry and wholesalers are responsible for pharmaceutical imports while the wholesalers are in charge of the stocking and distribution of medicines. The retail distribution of medicines takes place through outpatient and hospital pharmacies and medicine dispensaries and, to a limited extent, through retail grocery trade in the case of nicotine replacement therapy products. The Institute for Health and Welfare as well as hospital pharmacies and medicine dispensaries are in charge of the distribution of vaccines included in the general vaccination programme. The medicines reimbursement system plays a central role for the operation of the pharmaceutical service.

The provisions related to medicines and vaccine control are harmonised with the EU regulations, and from the control function perspective, Finland constitutes a part of the control network of the EU Member States. The decisions influencing the Finnish pharmaceutical service are increasingly made on the international arenas. The EU medicines legislation (Medicines Directive[1] and Regulation[2]) regulate the pharmaceutical marketing authorisations, distribution and control at the community level. Pharmaceutical distribution, medicine reimbursement systems and vaccine programmes fall within the national competence. The main provisions on the pharmaceutical service are

1 Directive 2001/83/EC of the European Parliament and of the Council

2 Regulation (EC) No 726/2004 of the European Parliament and of the Council

included in the Medicines Act[3] and the provisions laid down on the basis of it, while those on the tasks of pharmaceutical service operators are included in the Act on Health Care Professionals.[4] The medicines reimbursement system is defined in the Health Insurance Act[5]. The Act on the Status and Rights of Patients[6] contains the respective healthcare-related provisions while the ones focusing on the social welfare clients are contained in the Act on the Status and Rights of Social Welfare Clients[7]. There is also specific legislation on medication of animals.

Administration and supervision of the social welfare and healthcare services

The Ministry of Social Affairs and Health is responsible for the administrative development of the pharmaceutical service, the preparation of the medicines legislation and the medicines policy. The Finnish Medicines Agency Fimea is in charge of the authorisation and control functions related to the pharmaceutical branch as well as for the medicine safety issues. Moreover, Fimea engages in research focusing on pharmaceutical-epidemiological, medicines policy and pharmacoeconomical aspects, forwarding pharmaceutical information to improve the effectiveness of the pharmaceutical service and pharmacotherapies. The Pharmaceuticals Pricing Board is the responsible authority for the decisions on medicine prices and reimbursability. The National Supervisory Authority for Welfare and Health Valvira guides and supervises the operation of healthcare organisations and professionals. It also covers certain functions related to the guidance and supervision of social welfare services. The Social Insurance Institution is in charge of the basic social security of the residents of Finland, including medicine reimbursements. Moreover, the Social Insurance Institution does research focused on the medicines reimbursement system and the use of medicines. The National Institute for Health and Welfare THL is an expert institution under the administration of the Ministry of Social Affairs and Health. The Institute's responsibilities include the vaccination programme.

3 Medicines Act 395/1987

4 Act on Health Care Professionals (559/1994)

5 Health Insurance Act 1224/2004

6 Act on the Status and Rights of Patients 785/1992

7 Act on the Status and Rights of Social Welfare Clients 812/2000

1.1 PHARMACEUTICAL SERVICE OPERATIONS ARE CUSTOMER-ORIENTED

The pharmaceutical service must be developed to meet the customer needs. Customer orientation also means that the patients are encouraged to take responsibility for their own care.

The nationally agreed care recommendations, such as the Current Care Guidelines, promote the proper use of medicines. The regional agreement procedure encompasses the municipal healthcare organisation plans, defined in the Health Care Act, and the plans are based on the regional population's health follow-up data and service needs. They also include agreements on municipal co-operation, objectives and responsible bodies for the promotion of health and wellbeing as well as the organisation of healthcare services between the various actors. From the perspective of pharmaceutical service, it is particularly important to agree on the local practical actions to promote co-operation.

Interprofessional co-operation between various healthcare professionals lays the foundations for a smooth client-oriented service whole that transcends any administrative and organisational boundaries. The patients' well-functioning care pathways and successful medication can be promoted through the development of interprofessional and inter-organisational co-operation models.

A high level of basic training of the healthcare professionals that meets the needs of practical work life as well as their systematic further education are tools for keeping up the level of competence needed in healthcare. We must ensure that the level of professional competence remains high in the future.

Well-working information systems – including the e-prescription – will facilitate the effectiveness and overall cost-effectiveness analyses, thereby improving patient safety. Patient records, including the medication data, are already now mostly in digital form. However, the problems in the transfer of data between patient record systems as well as the internal usability problems in the systems weaken their feasibility potential. Compatible information systems would support the continuity of care and comprehensive monitoring of its outcomes. As a consequence, the care pathway would not be interrupted when the patient moves from primary healthcare to specialised medical care, or a social welfare client moves from an institution to the non-institutional care sector. Comprehensive recording of medication data is a prerequisite for the monitoring of care outcomes on the national, regional and local levels.

Actions

1. Develop smooth, client-oriented and cost-effective operational models in social welfare and healthcare both regionally and locally in view of the implementation and monitoring of pharmacotherapies.

   Responsible parties: Ministry of Social Affairs and Health, National Institute for Health and Welfare

   Co-operation parties: Fimea, Valvira, Social Insurance Institution, Regional State Administrative Agencies, professional organisations, Finnish Medical Society Duodecim, municipalities, hospital districts, social welfare and healthcare units, hospital pharmacies, medicine dispensaries, pharmacies, pharmaceutical industry, pharmaceutical wholesalers.

2. Agree on the joint pharmaceutical service objectives to ensure systematic and sustained operations.

   Responsible parties: Ministry of Social Affairs and Health, National Institute for Health and Welfare, Fimea, Valvira, Social Insurance Institution

   Co-operation parties: All pharmaceutical branch stakeholders

3. Strengthen interprofessional operational models in the implementation of the patient's pharmacotherapy and consultation, both in outpatient and inpatient care.

   Responsible parties: Fimea, National Institute for Health and Welfare

   Co-operation parties: Social welfare and healthcare units, pharmacies, hospital pharmacies, medicine dispensaries, Association of Finnish Pharmacies, University Pharmacy, professional organisations, universities

4. Strengthen co-operation between the Ministry of Social Affairs and Health on the one hand and the Ministry of Education and Culture on the other hand to develop basic, continuing and on-site education. More efficient co-operation in training between the authorities and the training units.

   Responsible parties: Ministry of Social Affairs and Health, Ministry of Education and Culture

   Co-operation parties: Fimea, universities, universities of applied sciences, secondary level vocational institutes

5. Develop information systems used in social welfare and healthcare, related to the pharmaceutical service, improving their mutual compatibility and usability.

   Responsible parties: Ministry of Social Affairs and Health, Social Insurance Institution

   Co-operation parties: Fimea, National Institute for Health and Welfare, hospital districts, information system providers

6. Introduce e-prescriptions, with the aim of all prescriptions issued in digital form.

   Responsible parties: Ministry of Social Affairs and Health, Fimea, Social Insurance Institution

   Co-operation parties: Association of Finnish Pharmacies, University Pharmacy, professional organisations, social welfare and healthcare units, pharmacies, hospital pharmacies, medicine dispensaries

Aims of actions:

- improved operational models, planned action and improved co-operation makes the entire healthcare system more efficient and more client-oriented
- the pharmacotherapy objectives are increasingly attained
- increased co-operation in the training of healthcare professionals improves staff competence
- better monitoring of treatments improves the pharmacotherapy outcomes
- the exchange of information can be improved through well-functioning electronic systems

2 PHARMACEUTICAL SERVICE IS OF HIGH QUALITY, EFFICIENT AND COST-EFFECTIVE

2.1 ENSURE ACCESS TO MEDICINES AND FUNCTIONING OF PHARMACEUTICAL SERVICE IN ALL CONDITIONS

The access to medicines and a professionally operating pharmaceutical distribution system must be guaranteed to the population. The medicines selection must ensure the rational and efficient pharmacotherapy of patients. The challenge is to warrant the availability of novel medicines and those rarely needed by a small group of patients as well as to guarantee the existence of a comprehensive distribution network throughout Finland, the remote areas included.

The access to and availability of medicines depends on the functioning of the pharmaceutical industry, wholesalers, pharmacies, hospital pharmacies and medicine dispensary systems as well as on the predictability of the factors influencing the pharmaceutical market.

From the perspective of the current distribution system, the essential factors influencing the access to medicines include the comprehensiveness of the pharmacy network and the quality of its operation as well as the coverage and delivery times of the wholesaler operations. The pharmacies must also participate in the monitoring of patient care, and their operations will be increasingly concentrated on health-promoting pharmaceutical service functions.

Hospital pharmacies and medicine dispensaries operate as a part of the public healthcare system. Cost-effectiveness appraisals must be performed as an integral element of the pharmaceutical service.

Imported medicines play an important role in pharmaceutical service, and therefore the access to medicines under emergency circumstances must be ensured through the obligatory and emergency stockpiling arrangements for medicines and vaccines, implemented by the pharmaceutical industry, hospitals, healthcare centres, the State, the National Institute for Health and Welfare and the National Emergency Supply Agency as well as by maintaining the conditions for national pharmaceutical production.

Actions

1. Develop the pharmaceutical distribution and stockpiling systems to ensure that patients have rational, safe and effective pharmacotherapies on a nation-wide scale.

   Responsible parties: Ministry of Social Affairs and Health, Fimea

   Co-operation parties: Association of Finnish Pharmacies, University Pharmacy, pharmaceutical wholesalers, pharmaceutical industry, pharmacies, hospital pharmacies, medicine dispensaries, professional organisations

2. Develop the obligatory and emergency stockpiling functions in a cost-effective manner to guarantee the security of supply.

   Responsible parties: Ministry of Social Affairs and Health, Fimea, National Emergency Supply Agency

   Co-operation parties: National Institute for Health and Welfare, hospital pharmacies, medicine dispensaries, pharmaceutical wholesalers, pharmaceutical industry

3. Enhance the competence and practices of pharmaceutical advisory committees and hospital pharmacies and medicine dispensaries in relation to the basic medicine formulary, medicine procurements and competitive bidding.

   Responsible parties: Hospital districts, municipalities, hospital pharmacies, pharmaceutical industry

   Co-operation parties: Ministry of Social Affairs and Health, Fimea

Aims of actions:

- patients receive the necessary medication under all circumstances
- the practices of outpatient and institutional pharmaceutical service will improve through developed processes
- ensured competitive conditions will maintain a well-functioning pharmaceutical service

2.2 FINANCING SYSTEMS PROMOTE MATERIALISATION OF ECONOMICALLY MOST ADVANTAGEOUS PHARMACOTHERAPIES AND EFFICIENT UTILISATION OF LIMITED RESOURCES

Financing systems also influence the choice of pharmacotherapies. Today, pharmacotherapies are mainly funded through two separate channels. The medicines used in public healthcare are included in the treatment costs paid by the patient's municipality of residence or the joint municipal board. The public healthcare sector also pays for the vaccines included in the national vaccination programme. The outpatient medicines prescribed by a doctor are partly reimbursed by the national health insurance while the patients pay the whole price of the self-care medicines they buy without a prescription. The current two-tier financing system may in some cases lead to partial optimisation of the treatment.

The financing systems must support pharmacotherapies and services which promote the maintenance of working and functional capacity and independent coping of the population. The financing systems must be evaluated and developed so that they allow for a rational and effective pharmacotherapy for the patients. It is indispensable to use the resources efficiently to ensure the availability of services but this objective must not constitute any risk for patient or medicine safety.

In 2008, the medicines and medicinal consumer goods accounted for about 14% of the overall healthcare expenditure (Appendix 2). In 2009, the total sales of medicines at retail prices, taxes included, were about 2.6 billion euro, 1.3% less than in 2008 (Appendix 3). The health insurance reimbursements on medicines were about 1.2 billion euro in 2009 (Appendix 3).

Medicine costs must be seen as a part of the overall healthcare expenditure. According to the report[8] by the expert group at the National Institute for Health and Welfare focusing on the multi-tier financing of social welfare and healthcare services, there are no solid arguments to separate the financing of the outpatient medicines from the rest of the healthcare system. Medicine financing responsibility could be in the same "basket" with the other forms of treatment and operation in the healthcare system. However, in the context of the current municipal structure, it is not rational to decentralise pharmacotherapy financing to the municipal level. Decentralisation would require considerably stronger organisations to shoulder the financing responsibility. Any possible new system should operate on the basis of nationally uniform medicine reimbursement criteria.

8 Expert group of the National Institute for Health and Welfare: *Sosiaali- ja terveydenhuollon monikanavaisen rahoituksen edut, haitat ja kehittämistarpeet*, 17.11.2010

Actions

1. Consider need to reform the financing of the pharmaceutical service (outpatient and institutional care) in the overall context of the social welfare and healthcare reform.

   Responsible parties: Ministry of Social Affairs and Health, National Institute for Health and Welfare

   Co-operation parties: Fimea, Social Insurance Institution, hospital districts, municipalities, pharmaceutical industry

Aims of actions:

- there are less financing-related problems, such as partial optimisation
- medical grounds are emphasised in the choice of patients' therapy options

2.3 MEDICINE REIMBURSEMENT SYSTEM IS UNAMBIGUOUS AND DECISION-MAKING SYSTEM TRANSPARENT

The core objective of pharmaceutical service is to guarantee high quality, reasonable prices and cost-effective pharmacotherapies. To keep costs in control, the medicines reimbursement system must promote cost-effective therapies. The share of patient and customer co-payments of the healthcare expenditure must remain reasonable.

The current medicine reimbursement system is complicated and causes much administrative work. The future individual pharmacotherapies will make the system even more complex. The reimbursement system must be simplified, and the new IT possibilities must be exploited to an increasing extent. The implementation of the system must be in proportion to the targets set or advantages gained.

The regulation of medicine reimbursements and prices is extensively used by various countries as one means of controlling the medicine expenditure. A well-functioning regulation system ensures the availability of reasonably-priced and necessary medicines, and supports and promotes the competition on the pharmaceutical market.

Significant cost savings are generated when the pharmaceutical market competition and use of generics are promoted. An unambiguous and transparent decision-making system helps to improve the functioning of the reimbursement and price regulation system. The openness and transparency criteria apply to both the authorities and the companies.

The reference price system has been an efficient means to curb the costs of medicines that have been on the market for a long time as well as to promote price competition. The system must be further developed, taking the experience gained by various stakeholders and patients into consideration.

Actions

1. Ensure the reasonableness of the co-payment burden carried by the patients in need of medicines through a joint payment ceiling for the social welfare and healthcare systems.

   Responsible parties: Ministry of Social Affairs and Health, National Institute for Health and Welfare, Social Insurance Institution

   Co-operation parties: Municipalities

2. Develop the decision-making process focusing on reimbursement and price regulation:
   - by implementing an electronic application procedure and utilising other web-based services
   - by analysing the need for new operational models and procedures in price regulation
   - by analysing the operational models and evaluation criteria of the pharmacotherapy price regulation, in use for a long time

   Responsible parties: Ministry of Social Affairs and Health

   Co-operation parties: Fimea, Social Insurance Institution, pharmaceutical industry

3. Examine the possibilities to decrease the administrative work caused by the medicines reimbursement system.

   Responsible parties: Ministry of Social Affairs and Health

   Co-operation parties: Social Insurance Institution, patient organisations, pharmacies

4. Develop the reference price system on the basis of the experiences gained to date.

   Responsible parties: Ministry of Social Affairs and Health

   Co-operation parties: Fimea, Social Insurance Institution, pharmaceutical branch stakeholders

Aims of actions:

- the processes related to medicine reimbursements and price regulation improve
- the transparency throughout the process increases
- developed decision-making processes reduce the administrative work

3 RATIONAL PHARMACOTHERAPY AND GOOD MEDICATION SAFETY IMPROVE PEOPLE'S WELLBEING AND PUBLIC HEALTH, DECREASING HEALTHCARE EXPENDITURE

3.1 MEDICINE USERS ARE ENCOURAGED TO ASSUME RESPONSIBILITY FOR TREATMENT OF THEIR DISEASES

The patients' and customers' role must be enhanced, especially in the treatment of chronic diseases and easily manageable symptoms. The patients or their representatives must be involved and agree on the objectives and implementation of the therapy. The task of pharmaceutical service is to support the responsibility and involvement of the medicine user in the pharmacotherapy. Moreover, the advice given by the healthcare professionals, pharmacists and dispensers in particular, is instrumental for the proper use of self-care medicines. Promotion of health and prevention of diseases are also among the pharmaceutical service objectives.

Pharmacotherapies do not always materialise as instructed. Irrational or downright erroneous use of medicines may weaken the outcome of the pharmacotherapy, cause significant adverse health effects and increase the use and cost of healthcare services. The attainment of pharmacotherapy objectives can be promoted, for example, by using tools such as the patient-specific medication plans, medicine cards, comprehensive medication reviews (CMR) or dose dispensing.

Actions

1. Support the patients in the attainment of therapy objectives.

   Responsible parties: Social welfare and healthcare units, pharmacies

   Co-operation parties: Patients, municipalities, patient organisations, Social Insurance Institution

2. Promote and enhance ways to improve the success of pharmacotherapies.

   Responsible parties: Social welfare and healthcare units, pharmacies, hospital pharmacies, patients

   Co-operation parties: Municipalities, professional organisations, Ministry of Social Affairs and Health, Fimea, National Institute for Health and

Welfare, Valvira, Social Insurance Institution, patient organisations, pharmaceutical industry

3. Promote the good outcome of self-care and self-management through the advice provided by pharmacists, dispensers and other healthcare professionals.

   Responsible parties: Association of Finnish Pharmacies, University Pharmacy, pharmacies

   Co-operation parties: Fimea, professional organisations

4. Develop ways to integrate safe self-care into the healthcare whole.

   Responsible parties: Fimea, National Institute for Health and Welfare, Association of Finnish Pharmacies, University Pharmacy, pharmacies

   Co-operation parties: Ministry of Social Affairs and Health, pharmaceutical industry, universities

Aims of actions:

- the patients' treatment adherence improves
- systematic planning improves treatment safety

3.2 INCREASE PRODUCTION OF RELIABLE INFORMATION ON RATIONAL PHARMACOTHERAPIES DISSEMINATED TO HEALTHCARE PROFESSIONALS AND MEDICINE USERS

Reliable and evidence-based pharmaceutical information accessible to healthcare professionals, the general public and medicine users constitutes the basis for the rational use of medicines. For healthcare professionals, the most important channels of information on pharmacotherapies are the Current Care guidelines as well as the *Terveysportti* database and related specialised databases, such as the ones on medicine interactions and prices.

The general public and the medicine users obtain pharmaceutical information from different sources. Abundant pharmaceutical information is available in the Internet but the quality of the information varies. The organisation of pharmaceutical information in the web-based pharmacy operations is a new challenge. We must also remember that not everybody uses computers or other means of ITC.

Proper advice on the use of medicines is particularly necessary to the patients with long-term pharmacotherapies. There is insufficient reliable

pharmaceutical information, with a balanced presentation of the medicine efficacy and safety vis-à-vis other available therapy options. The threats include the unnecessary increase in medicine use, improper use of the medicines and medicalisation.

Actions

1. Strengthen basic, further and continuing education on pharmacotherapies, information sources and patient advice functions targeted at pharmaceutical and healthcare professionals.

   Responsible parties: Ministry of Education and Culture, universities, universities of applied sciences, social welfare and healthcare units, training organisations, secondary level vocational institutions

   Co-operation parties: Ministry of Social Affairs and Health, Fimea, professional organisations, pharmacies, hospital pharmacies, medicine dispensaries, professional organisations

2. Support measures to provide social welfare, healthcare and pharmaceutical points of operation and those involved in the practical pharmacotherapy of patients with proper, necessary and updated pharmaceutical information sources and to ensure that there is competence to use these sources.

   Responsible parties: Social welfare and healthcare units, Association of Finnish Pharmacies, University Pharmacy, Duodecim, pharmacies, hospital pharmacies, medicine dispensaries

   Co-operation parties: Ministry of Social Affairs and Health, Fimea, National Institute for Health and Welfare, Social Insurance Institution, universities, universities of applied sciences, professional organisations, secondary level vocational institutes

3. Ensure that healthcare professionals, the general public and medicine users have access to reliable and evidence-based pharmaceutical information.

   Responsible party: Fimea

   Co-operation parties: Ministry of Social Affairs and Health, National Institute for Health and Welfare, Social Insurance Institution, universities, universities of applied sciences, Association of Finnish Pharmacies, University Pharmacy, social welfare and healthcare units, pharmacies, hospital pharmacies, medicine dispensaries, Duodecim, professional organisations, secondary level vocational institutions, pharmaceutical industry, patient organisations

4. Strengthen national and international research and development geared towards the production of pharmaceutical information and services, including their effectiveness analyses.

   Responsible parties: Fimea, universities, universities of applied sciences

   Co-operation parties: Ministry of Social Affairs and Health, National Institute for Health and Welfare, Social Insurance Institution

5. Promote health information literacy and critical analysis skills among consumers and patients.

   Responsible parties: Universities, schools, adult education centres, pharmacies

   Co-operation parties: Fimea, social welfare and healthcare units

Aims of actions:

- healthcare professionals and medicine users have better information on medicinal products and their use
- high-quality and updated pharmaceutical information may decrease the number of adverse interactions of medicines used by a patient
- co-operation promotes the R&D on medicines, and the research outcome can be used to improve the quality and effectiveness of pharmaceutical services
- consumers and patients are more competent in assessing the quality of the information obtained

3.3 PROMOTE EFFICIENT, SAFE, RATIONAL AND COST-EFFECTIVE USE AND PRESCRIPTION OF MEDICINES

In addition to the prescription of medicines, the other factors influencing the appropriateness of pharmacotherapies include the regular recording and assessment of therapy outcomes and adverse effects, as well as the transfer of the information between the healthcare units participating in the care of the patient. Pharmacotherapies should not be unnecessarily used instead of non-medicinal forms of therapy, such as healthy habits and life changes.

The training for a rational prescription practice, already started during medical and pharmaceutical studies, should be further developed. The objective is to apply electronic tools and operational models in medicine prescriptions, shown to be useful and cost-effective in practical work or through other evidence-based means.

In particular, the patients with several simultaneous medicines, older persons and other special groups should have medication plans and their pharmacotherapies and their needs should be assessed on a regular basis. The systems supporting rational prescription practices should be further developed and introduced.

Actions

1. Consider pharmacotherapies as an element of the patient's comprehensive care, remembering the appropriate preventive medications and non-medicinal forms of therapy.

   Responsible parties: Social welfare and healthcare units, pharmacies

   Co-operation parties: Social Insurance Institution, Association of Finnish Pharmacies, University Pharmacy, professional organisations

2. Promote comparative evaluations and financing of pharmacotherapies and non-medicinal forms of therapy.

   Responsible parties: Ministry of Social Affairs and Health, Fimea, universities, National Institute for Health and Welfare, Social Insurance Institution

   Co-operation parties: Social welfare and healthcare units, Social Insurance Institution, pharmaceutical industry, research funding parties

3. Promote therapies complying with the national Current Care guidelines and guarantee the resources for the development and maintenance of the support systems.

   Responsible parties: Ministry of Social Affairs and Health, Fimea, National Institute for Health and Welfare, Social Insurance Institution, Duodecim, healthcare units, pharmacies, hospital pharmacies

   Co-operation parties: Professional organisations

4. Draft instructions on the contents and needs of comprehensive medication reviews (CMRs), defining the tasks of various professional groups in this process.

   Responsible parties: Fimea, National Institute for Health and Welfare

   Co-operation parties: Duodecim, professional organisations, universities

5. Enhance the quality of pharmacotherapies by increasing the expertise in clinical pharmacology and ward-based pharmacy activities in hospitals, and by utilising unit-specific pharmacotherapy plans.

   Responsible parties: Healthcare units, hospital pharmacies, universities

Aims of actions:

- increase in therapy effectiveness, decrease in the number of adverse reactions caused by medicines and improved therapy outcomes
- rational pharmacotherapy brings cost savings by decreasing the need of health services and unnecessary use of medicines

3.4 IMPROVED MEDICATION SAFETY PROMOTES PUBLIC HEALTH

Marketing authorisation practices and subsequent supervision are central tools to ensure drug safety. These processes have been harmonised in the European Union. In Finland, Fimea is responsible for this area.

The Finnish system works well as concerns notifications of product defects and subsequent reactive steps. The dissemination of counterfeit medicines through international Internet-based trade and illegal importation constitute new threats in this respect.

Medication safety refers to the safety in relation to the use of medicines. The term covers the principles and operations of the social welfare and healthcare units, geared at ensuring the safety of pharmacotherapies and protecting the patient from harm. Medication safety is threatened by factors such as minimal participation by the patients in their own care and lack of pharmacotherapy coordination. Pharmacotherapy plans made at points of care, reports on dangerous and adverse effects as well as security-enhancing databases can promote medication safety.

Actions

1. Strengthen and develop co-operation in the supervision, monitoring and guidance of drug safety and medication safety issues.

   Responsible parties: Ministry of Social Affairs and Health, National Institute for Health and Welfare, Fimea, Valvira

   Co-operation parties: Social welfare and healthcare units, pharmacies, hospital pharmacies, medicine dispensaries, professional organisations, universities, pharmaceutical industry, pharmaceutical wholesalers

2. Intensify national and international co-operation between the authorities to recognise counterfeit medicines and solve related crime

   Responsible parties: Fimea, Valvira, Customs, Police, pharmaceutical industry

   Co-operation parties: Ministry of Social Affairs and Health, Social Insurance Institution

3. Increase the general public's awareness of counterfeit medicines and risks related to medicines acquired through the Internet.

   Responsible parties: Fimea, National Institute for Health and Welfare, pharmaceutical industry, pharmacies, hospital pharmacies

   Co-operation parties: Ministry of Social Affairs and Health, healthcare units, professional organisations, pharmaceutical wholesalers, patient organisations

4. Enhance medication safety research to recognise risk medicines and processes, also using the related registers.

   Co-operation parties: Fimea, National Institute for Health and Welfare, Social Insurance Institution, universities, university hospitals

Aims of actions:

- good drug safety and medication safety
- improved public awareness of counterfeit medicines

4 PHARMACEUTICAL RESEARCH IMPROVES HEALTH, WELLBEING AND EMPLOYMENT RATES

4.1 PROMOTE GENERATION AND EXPLOITATION OF PHARMACEUTICAL INNOVATIONS

Finland is the venue of high-quality biomedical and clinical research, and we have sufficient competence in industrial pharmaceutical development and thus the conditions to generate new pharmaceutical innovations.

The areas requiring development include the healthcare permit processes and contractual negotiations related to research as well as the opportunities granted to researchers to participate in pharmaceutical development work. Enhanced exploitation of the outcomes obtained in basic research would improve patentability opportunities and thus also the exploitation of pharmaceutical innovations. More comprehensive and more sustained pharmaceutical risk funding would promote business opportunities. Pharmaceutical development creates new jobs not only in the pharmaceutical companies but also in related service companies and in the healthcare sector.

Pharmaceutical development calls for active national and international co-operation and networking among the experts of various disciplines as well as among the various pharmaceutical stakeholders. We should anticipate the changes in healthcare resulting from pharmaceutical development. The participation in the pharmaceutical development on the EU level will provide the research institutes and companies excellent opportunities to this anticipatory work and international networking. For the pharmaceutical branch, it is important that Finland is involved and influencing the EU medicines policy and legislation.

Actions

1. Strengthen the co-operation between basic research and clinical trials of medicines.

   Co-operation parties: Ministry of Social Affairs and Health, Ministry of Education and Culture, Fimea, National Institute for Health and Welfare, National Committee on Medical Research Ethics TUKIJA, universities, universities of applies sciences, healthcare units, Academy of Finland, university hospitals, pharmaceutical industry, professional organisations

2. Provide healthcare professionals with better opportunities to engage in clinical trials of medicines.

   Co-operation parties: Ministry of Social Affairs and Health, Ministry of Education and Culture, Fimea, National Institute for Health and Welfare, universities, universities of applies sciences, healthcare units, Academy of Finland, university hospitals

3. Simplify the administrative processes related to contracts and permits related to pharmaceutical research and, if necessary, revise the respective legislation.

   Responsible party: Ministry of Social Affairs and Health

   Co-operation parties: Fimea, National Institute for Health and Welfare, Valvira, National Committee on Medical Research Ethics TUKIJA

4. The Ministry of Social Affairs and Health will work in closer co-operation with the Ministry of Education and Culture and the Ministry of Employment and the Economy to develop the research operations.

   Responsible parties: Ministry of Social Affairs and Health, Ministry of Education and Culture, Ministry of Employment and the Economy

   Co-operation parties: universities

5. Promote national and international co-operation and networking in pharmaceutical research and development among hospital districts, research schools, universities, companies and authorities.

   Responsible parties: Fimea, Finnish Funding Agency for Technology and Innovation TEKES

   Co-operation parties: Ministry of Social Affairs and Health, Ministry of Employment and the Economy, National Institute for Health and Welfare, universities, universities of applies sciences, Finnish Innovation Fund SITRA, pharmaceutical industry, Academy of Finland, hospital districts, professional organisation

Aims of actions:

- more pharmaceutical research is done and the related practices become less complicated
- new jobs in this sector are generated in Finland
- in the long run, the number of Finnish pharmaceutical innovations may grow

4.2 PROMOTE RATIONAL PHARMACOTHERAPIES THROUGH EVALUATIONS OF THERAPEUTIC AND ECONOMIC VALUE OF MEDICINES

The information on the therapeutic and economic value of medicines and vaccines, in other words, their cost-effectiveness, is the foundation for their rational use. To become reimbursable, novel medicines must be accompanied with a health economic evaluation. Health economic studies are usually performed at the early stages of medicine development. At that point, there is not yet any experience on the impacts of the medicine on the population level.

Today, the requirements and resources for cost-effectiveness appraisals of outpatient medicines on the one hand and the hospital medicines on the other hand are different. The Pharmaceuticals Pricing Board has been appraising reimbursable outpatient medicines since 1998, while the limited resources available to hospitals have been allocated to uses other than the medications assessments. In both sectors, the limited number of experts and the lack of effectiveness data influence the development of evaluations and the possibility to estimate the respective costs. To accumulate versatile and updated research and evaluation data on medicines, it is indispensable that researchers have access to registers containing the information on all prescribed and dispensed medicines as well as on the integrated care pathways and therapy outcomes.

More cooperation between the organisations and researchers in the sector is needed to develop the operations. According to the respective legislation, the Fimea responsibilities include both the pharmacoeconomic research and the cost-effectiveness evaluations, in other words, the evaluations of the therapeutic and economic value of pharmacotherapies. Moreover, Fimea should build up cooperation in these sectors. At the request of the Pharmaceuticals Pricing Board, Fimea can also perform evaluations related to the medicine reimbursement and price decisions.

Actions

1. Promote the training of experts in pharmaceutical epidemiology and health economics in collaboration with the authorities, universities and other educational institutions.

   Responsible parties: Ministry of Education and Culture, universities, universities of applied sciences

   Co-operation parties: Ministry of Social Affairs and Health, Fimea, Ministry of Employment and the Economy, National Institute for Health and Welfare

2. Ensure that the evaluations on the therapeutic and economic value of medicines are performed using uniform, evidence-based procedures based on as equal criteria as possible.

   Responsible parties: Fimea, Social Insurance Institution

   Co-operation parties: Ministry of Social Affairs and Health, National Institute for Health and Welfare, Duodecim, pharmaceutical industry

3. Increase national and international co-operation in the cost-effective evaluations of medicines.

   Responsible parties: Fimea, Social Insurance Institution

   Co-operation parties: Ministry of Social Affairs and Health, National Institute for Health and Welfare, pharmaceutical industry, universities

4. Make increased use of evaluations of the therapeutic and economic value of medicines in the decision-making related to the reimbursement status of a medicinal product. Promote the use of evaluation data in all medicine-related decision-making.

   Responsible parties: Ministry of Social Affairs and Health, Fimea, National Institute for Health and Welfare, Social Insurance Institution

   Co-operation parties: pharmaceutical industry

5. Create a comprehensive prescription database, accumulating the information on all dispensed prescription-only medicines. Make sure that the social welfare and healthcare registers can be utilised in the research on medicines.

   Responsible parties: Fimea

   Co-operation parties: Social Insurance Institution, pharmacies, hospital districts, hospital pharmacies, medicine dispensaries

Aims of actions:

- information on cost-effectiveness helps to allocate the resources to rational therapies
- improved national and international co-operation improves evaluation processes and promotes the exchange of information
- increased information on medicine use helps to identify the areas requiring new resources

5 VETERINARY SERVICE SAFEGUARDS PUBLIC HEALTH AND PROMOTES WELLBEING OF HUMANS AND ANIMALS

5.1 RATIONAL USE OF VETERINARY MEDICINES GUARANTEES CONSUMER SAFETY

The use of veterinary medicines must be rational to ensure public health and consumer safety. Controlled use of antimicrobial medicines requires particular attention. Animal wellbeing will influence the quality of animal-based foodstuffs, the cost-effectiveness of animal production and the wellbeing of humans.

The regional and national availability of veterinary medicines must be ensured, and their imports and distribution must be safe. The Finnish veterinary medicine market is small, and therefore the number and selection of medicines with marketing authorisations are not sufficient to cover all indications. The availability of several veterinary medicines and vaccines is ensured through special permits. Difficulties in the access to vaccines may lead to the spreading of animal diseases. In case of production disturbances, the small selection of generic medicines may have a significant negative impact on the availability of the medicines. The consequences would include considerable problems in animal wellbeing, not to mention economic losses.

The medication of production animals must always take place with due attention to food safety. The safety of pharmaceutical residues has been evaluated, and the medicines have appropriate safety periods which must be followed. A national monitoring programme follows pharmaceutical residues in foodstuffs comprehensively and systematically.

Contrary to many European countries, Finland is free from many common animal diseases, and we must maintain this situation. The inspection of imported vaccine batches and their high quality ensure that pathogenic substances do not spread in the country in the form of vaccine impurities. If vaccines are not available, we risk having serious animal disease epidemics that may also lead to lower productivity. Some vaccines also provide the animals with protection against zoonotic pathogens that may be dangerous to humans.

The use of veterinary medicines must be based on reliable information. The production and dissemination of reliable and evidence-based information on veterinary medicines will promote the correct and safe use of the medicines in question.

Actions

1. Promote animal health and wellbeing through better veterinary healthcare and medicine, improved living conditions of animals and more active controls. Emphasise preventive animal healthcare instead of mere treatment of diseases.

   Responsible parties: Ministry of Agriculture and Forestry, Evira

   Co-operation parties: Fimea, Ministry of Social Affairs and Health, universities, food industry

2. Improve nation-wide availability of veterinary medicines and their sufficiently comprehensive selection. Ensure the availability of animal vaccines during epidemics.

   Responsible parties: Fimea, Ministry of Social Affairs and Health, pharmaceutical industry, pharmaceutical wholesalers, pharmacies

   Co-operation parties: Ministry of Agriculture and Forestry, Evira, universities

3. Communicate actively on the appropriate use of veterinary medicines through channels close to the users. Information on the risks of illegal importation and Internet trade.

   Responsible parties: Fimea, Evira

   Co-operation parties: Ministry of Agriculture and Forestry, universities, professional organisations, pharmacies, pharmaceutical industry

4. Develop monitoring systems focusing on the consumption and use of antimicrobials used on animals, creating sufficient systems to accumulate information on the use, dispensing and prescription of veterinary medicines for different indications, broken down by animal species. Promoted compliance with antimicrobial recommendations.

   Responsible parties: Fimea, Ministry of Agriculture and Forestry, Evira

   Co-operation parties: Ministry of Social Affairs and Health, universities, professional organisations, pharmacies, pharmaceutical industry

5. Promote sensitivity monitoring of microbes isolated from animals, launching permanent publications that report on the antimicrobial resistance situation related to both human and animal medicine.

   Responsible parties: Evira, National Institute for Health and Welfare, Ministry of Agriculture and Forestry

   Co-operation parties: Fimea, Ministry of Social Affairs and Health, universities

6. Promote co-operation between pharmaceutical experts and enhance animal medication contents in the basic education of various professional groups.

   Responsible parties: Ministry of Agriculture and Forestry, Fimea, Evira

   Co-operation parties: Ministry of Social Affairs and Health, universities, professional organisations

7. Draft a national strategy for producing reliable and understandable veterinary medicine information.

   Responsible parties: Fimea, Ministry of Social Affairs and Health

   Co-operation parties: Fimea, Ministry of Social Affairs and Health, Ministry of Agriculture and Forestry, Evira, universities, professional organisations, pharmaceutical industry

Aims of actions:

- the access to veterinary medicines improves and their use becomes increasingly rational
- food safety remains at a good level
- the use of antimicrobials is more appropriate
- information on the proper use of veterinary medicines is more accessible to the authorities and medicine users
- the development of preventive healthcare of productive animals enhances the profitability of agriculture

6 FOLLOW-UP PLAN FOCUSING ON IMPLEMENTATION OF PROPOSED MEDICINES POLICY 2020 ACTIONS

The Medicines Policy document outlines the respective decision-making until the year 2020. The Ministry of Social Affairs and Health will lead the work for the attainment of medicines policy objectives. The strategic steering takes place through the performance agreements between the Ministry and the agencies under its umbrella. However, to reach the objectives, all pharmaceutical branch stakeholders need to collaborate.

6.1 PRACTICAL ACTIONS AND EVALUATION OF IMPACTS

The definition of the practical actions under the medicines policy outlines and the respective evaluation are continuous processes. This work takes place in collaboration with the stakeholders in the pharmaceutical branch.

The objectives and the need for measures will be revised at regular intervals. Two monitoring groups will be established for the purpose:

a) Medicines Group constituted by the pharmaceutical authorities (Ministry of Social Affairs and Health, Fimea, Social Insurance Institution, National Institute for Health and Welfare, Valvira, Finnish Food Safety Authority Evira, and Ministry of Agriculture and Forestry), meeting once a year.
b) Pharmaceutical Forum constituted by the pharmaceutical branch stakeholders, meeting every two years.

The Ministry of Social Affairs and Health will convene the monitoring groups. Using specifically developed indicators, the Finnish Medicines Agency FIMEA and, if necessary, the other agencies will gather information on the success of the medicines policy actions and attainment of objectives for the monitoring groups.

The impacts of the actions can be evaluated from many perspectives, including that of the individual patient, society or the pharmaceutical branch stakeholders. The Medicines Policy 2020 document lists the advantages that the actions are expected to generate, mostly for the customers and the patients. In the future, the evaluations will be extended and the potential advantages, disadvantages and cost effects will be analysed more profoundly and from other angles. As far as possible, the evaluation tools will be evidence-based meters.

6.2 TIMETABLE

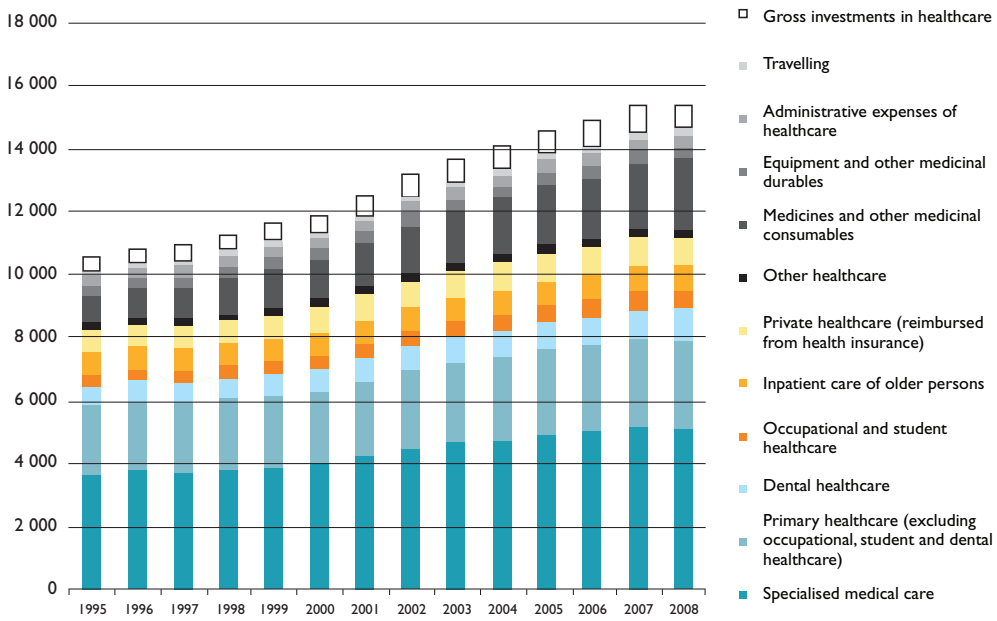
The preparations for the Medicines Policy 2020 started in January 2010.

The development of the practical actions under the medicines policy outlines as well as the impact indicators started in late 2010. At this stage, two benchmark points for the revision of the actions will be set. The first one is the meeting of the Medicines Group, constituted by the pharmaceutical sector authorities, in the autumn of 2011. At this venue, the medicines policy objectives and actions will be revised as per the publication of the new Government programme.

The Pharmaceutical Forum constituted by the stakeholders is the second benchmark point. The Forum will be convened in 2012, and it will analyse the implementation and measuring of the medicines policy from the perspective of the stakeholders. The Medicines Group will also convene in 2012, and the future benchmark points and practical actions will be agreed upon in these meetings.

APPENDIX 1

Healthcare expenditure in 1995-2008 at 2008 prices, in millions euro



Source: National Institute for Health and Welfare 2010

Central figures on medicine sales and reimbursements in 2009

	2004		2005		2006		2007		2008		2009	
	in millions euro	change from the previous year %	in millions euro	change from the previous year %	in millions euro	change from the previous year %	in millions euro	change from the previous year %	in millions euro	change from the previous year %	in millions euro	change from the previous year %
Overall sales of medicines	2 288	7,1	2 435	6,4	2 362	-1,6	2 500	5,9	2 664	6,5	2 608	-2,1
sales of outpatient prescription medicines (retail prices, including taxes)	1 685	7,7	1 756	4,2	1 744	-0,2	1 817	4,2	1 935	6,5	1 893	-2,2
sales of outpatient self-care medicines (retail prices, including taxes)	278	3,0	319	14,5	238	-18,5	275	15,5	290	5,5	301	3,8
hospital sales (recommended wholesale prices)	325	7,8	360	11,0	379	5,4	408	7,5	438	7,5	414	-5,5

Source: Finnish Medicines Agency Fimea, Social Insurance Institution

APPENDIX 3

Organisations involved in the preparation of the Medicines Policy 2020

Ministry of Social Affairs and Health Finnish Medicines Agency Fimea

National Supervisory Authority for Welfare and Health Valvira

Social Insurance Institution Ministry of Social Affairs and Health/ Pharmaceuticals Pricing Board

Ministry of Social Affairs and Health/Insurance Department

Ministry of Agriculture and Forestry Finnish Food Safety Authority Evira

Hospital pharmacies

Hospital districts

Co-operation organisation of the social welfare and health organisations YTY

Association of Finnish Pharmacies

The Finnish Pharmacists' Association

Suomen Proviisoriyhdistys (Finnish Association of Senior Pharmacists)

Association of Finnish Local and Regional Authorities

Finnish Medical Association

Finnish Dental Association

Finnish Veterinary Association

The Finnish Union of Practical Nurses SuPer

Union of Health and Social Care Professionals Tehy

Pharmacy wholesalers

University of Helsinki

University of Eastern Finland

University of Turku

University of Tampere

Åbo Akademi University

Pharma Industry Finland PIF

Finnish Generic Pharmaceutical Industry

Federation of Finnish Patients

Finnish Medical Society Duodecim

Helsinki University Pharmacy

APPENDIX 4

Abbreviations used in the Medicines Policy 2020 document

Abbreviation	**Definition**
EU	European Union
Evira	Finnish Food Safety Authority
Fimea	Finnish Medicines Agency
CMR	comprehensive medication review
Rohto	Centre for Pharmacotherapy Development Rohto
SFL	Finnish Pharmacy Federation
SITRA	Finnish Innovation Fund SITRA
Stakes	National Research and Development Centre for Welfare and Health
TEKES	Finnish Funding Agency for Technology and Innovation
TUKIJA	National Committee on Medical Research Ethics
Valvira	National Supervisory Authority for Welfare and Health

APPENDIX 5

Definitions used in the Medicines Policy 2020 document

1) Pharmaceutical service (Pharmaceutical sector)

Pharmaceutical service
A whole to ensure the availability of efficient, safe and reasonably priced medicines. The elements included are pharmaceutical development and production, imports, wholesale and retail distribution of pharmaceuticals, prescription of medicines, research on the use of medicines and pharmaceutical service research, medicines reimbursement system, pharmaceutical service administration, obligatory stockpiling and security of supply. Pharmaceutical service comprises both outpatient/non-institutional and inpatient care.

2) Patient safety, medicine/drug safety and medication safety

Patient safety
Principles and actions of the healthcare units and organisations, with the purpose of ensuring the safety of the care and protect the patient from any harm; from the patient's point of view: that the care does not cause any significant adverse effect; comprises both the safety of the care, medication safety and safety of the devices as a part of the care quality (Source: National Research and Development Centre for Welfare and Health Stakes and Centre for Pharmaceutical Development Rohto, 2006

Safe medication
Safe medication comprises drug safety and medication safety (Fimea administrative regulation 7/2007, Stakes and Rohto 2006).

Drug/medicine safety
The term mostly comprises the safety of the medicine seen as a product: the knowledge and evaluation of the medicine's pharmacological properties and effects, its high-quality manufacturing process as well as the information on the package and other product information. The efficacy and safety of medicines is evaluated through the marketing authorisation procedure. The concern for adverse reactions (ADR) also continues after the marketing authorisation has been granted (so-called subsequent supervision, in other words pharmacovigilance) (Source: Stakes and Rohto 2006).

Medication safety
The safety in relation to the use of medicines. The term covers the principles and operations of the social welfare and healthcare units, geared at ensuring the safety of pharmacotherapies and protecting the patient from harm.

Medication safety comprises actions to prevent, avoid and rectify adverse events related to the use of medicines (Source: Stakes and Rohto 2006).

User safety
Prevention of harm caused to humans by handling or dosage of veterinary medicines.

3) Rational pharmacotherapy, monitoring of drug treatment, comprehensive medication review CMR as well as rational self-medication

Rational pharmacotherapy
Rational pharmacotherapy is efficient, safe, cost-effective and purposeful pharmacotherapy (WHO).

Monitoring of drug treatment
Part of the medication process, see medication process.

Drug utilisation/regimen review/Medication review
Review of an individual patient's medication by a health care professional (physician, nurse, senior pharmacist, pharmacist) checking the medicine dosage and administration times against the approved clinical practice, detecting eventual overlapping or incompatible medications. Performed as an element of normal doctor's appointment, dispensing of the medicine at the pharmacy or distribution at a hospital ward or in home care. The pharmacy also makes reviews for self-care medicines. Does not include the evaluation of medication need or indication (Adapted from Peura et al 2007).

Medication assessment/review
As a part of the normal patient examination and treatment planning process, a review of an individual patient's medication, its need and rationality, made by a physician and assisted by other healthcare professionals, if necessary.

Comprehensive medication assessment, comprehensive medication review (CMR), medication therapy management service
The solution of an individual patient's medication problems, initiated by the attending physician in collaboration with clinical experts and/or an interprofessional group. In addition to the assessment by the attending physician, CMR can include a thorough analysis of the medication whole and proposed actions, performed by a clinical pharmacologist, specially trained senior pharmacist or pharmacist or other specially trained healthcare professional (Adapted from Peura et al. 2007).

Self-medication
Self-medication based on self-care medicines (see also item 5).

4) Integrated care pathway, individual treatment pathway, pharmacotherapy process, unit-based and individual pharmacotherapy plan, interprofessional collaboration and ward pharmacy

[Disease based] integrated care pathway, pathway of care, clinical pathway, seamless care
Organisation-oriented, planned and individually implemented, regionally agreed whole of treatment processed targeted at the same client/patient and their particular symptoms. Based on the agreements between the organisations on the arrangement of the treatment of a particular disease (Source: Norback et al. 2010)

Individual treatment pathway
The individual treatment pathways (also 'care pathway') refer to inter-organisational planned and individually implemented whole of treatment processes targeted at the same client's particular symptoms. The individual treatment pathways require that one unit is responsible for the guidance and monitoring of the services provided to the client (Source: Norback et al. 2010).

Pharmacotherapy process
A patient's pharmacotherapy process is an operative chain comprising the assessment of medication need, the choice and dispensing of the medicine, its dosage and administration, the patient's motivation, advice and commitment to the pharmacotherapy, organisation of the treatment follow-up and the evaluation of the outcome, as well as ensuring the informing of the patient and the organisations and persons involved in the treatment. A patient-specific pharmacotherapy plan is part of the pharmacotherapy process.

Unit-based pharmacotherapy plan, unit-based medicines management plan
Performed in line with the instructions issued by the Ministry of Social Affairs and Health, a plan on the implementation of pharmacotherapies in public and private social welfare and healthcare units. The management of the social welfare or healthcare unit is in charge of organising the drafting, implementation and follow-up of the pharmacotherapy plan. The hospital pharmacy or medicine dispensary responsible for the pharmaceutical service in the unit will participate in the drafting of the pharmacotherapy plan (STM 2006, Fimea administrative regulation 7/2007).

Individual pharmacotherapy plan
Part of a patient's treatment plan. Regularly updated and included in the patient records, a summary on the medicines used by the patient, their indications, treatment objectives, medicine dosage as well as treatment follow-up and duration. This plan constitutes the basis for individual pharmacotherapy, decreasing the erroneous use of medicines.

Interprofessional collaboration
In interprofessional collaboration, various professional groups coordinate their action in the best interest of the patient, also understanding the tasks and responsibilities of other professional groups in the treatment of the patient as well as the importance of exchange of information between the professional groups (Source: Zwarenstein et al. 2009).

Ward pharmacy
Ward pharmacy is the pharmaceutical service work performed by the pharmaceutical staff at the wards (Fimea administrative regulation 7/2007).

5) Customer-orientation, treatment adherence, concordance, self-management, self-care

Customer oriented services, patient oriented services
The organisation's approach in the planning and implementation of its operations from the customer/patient perspective.

Compliance
The patient follows the medical instructions without necessarily having a deeper insight of them (WHO 2003). In veterinary medicine, this means that the medication administered by the owner takes place according to the veterinarian's instructions.

Adherence
Responsible and active self-care by the patient, in a way complying with the state of health and in collaboration with the healthcare professionals (Kyngäs 1995).

Concordance
Joint understanding on the treatment as a result of a negotiation between the patient and the healthcare professional. In order to improve the conditions for rational pharmacotherapy, the negotiation also addresses the patient's wishes, beliefs and underlying knowledge.

Self-management
An operational model promoting adherence to treatment where the patient is directed to take individual responsibility for their care. This includes actions to maintain and promote health and follow-up and treatment of the symptoms of the disease, geared to manage the impact of the disease on the patient's operating capacity, emotions and social life.

Self-care
The individual's voluntary operation targeted at maintained health. Rational use of self-care medicines is part of self-care. In animals, the veterinary self-care medicines are used rationally and with caution to maintain their health.

6) Efficacy, effectiveness, cost-effectiveness (efficiency) and incremental cost-effectiveness ratio (ICER)

Efficacy
The effect of the treatment under ideal circumstances, observed in closely monitored test conditions on selected patients. The proof of efficacy is one of the preconditions for the granting of the marketing authorisation for a medicinal product. Reply to the question: can the treatment work?

Effectiveness
The impact of the treatment obtained at the population level, in normal conditions and on unselected group of patients. Reply to the question: will the treatment work in practice?

Cost-effectiveness (= efficiency)
The relation between the effectiveness of the treatment and the resources (costs) incurred for administering it. Reply to the question: is the treatment economically feasible?

Incremental cost-effectiveness ratio ICER
ICER shows how many more monetary units must be paid for each extra unit of benefits (such as avoided harm, additional life year, quality-adjusted life year QALY. Sources: Gold et al. 1996, Drummond et al. 2005, Sintonen and Pekurinen 2006, Mäkelä et al. 2007).

7) Pharmaceutical research
At all levels and areas of pharmaceutical or veterinary pharmaceutical service, operations targeted at the development of medicines and the investigation of their properties or impacts, the advantages gained or adverse effects caused by them.

Clinical research
Experimental research and trials on humans, mostly targeted at demonstrating the efficacy and safety of a medicine or other form of therapy.

Basic research
Research comprises basic research and applied research. The main purpose of basic research is to increment general knowledge, thereby understanding the links between various variables.

8) Pharmaceutical information

Pharmaceutical (drug/medicines) information
Information about medicines and pharmacotherapies, available to consumers and healthcare professionals through various information channels, either face-to-face or through written or electronic services (telephone, Internet, TV and radio). Pharmaceutical information is produced by the authorities, healthcare professionals, the pharmaceutical industry and patient organisations. The basis of medicine-specific information is the summary of product characteristics, SPC) adopted together with the marketing authorisation, as well as the package leaflet based on it. (Sources: Directive 2001/83/EC, Pohjanoksa-Mäntylä 2010, Salonen 2010).

Patient/medication counselling
A discussion between the client/patient and the healthcare professional where the professional, taking the client's personal needs and situation into consideration, supports his or her coping with the pharmacotherapy (Sources: USP 1997, Hakkarainen and Airaksinen 2001)

9) Veterinary service
Animal healthcare and treatment of animal diseases as well as other veterinary assistance, meat and milk inspection, health-related control and inspection of the production of animal-based foodstuffs and animal husbandry, fighting and prevention of veterinary diseases as well as animal protection (Veterinary Service Act 685/1990).