Final report

Rational Pharmacotherapy Action Plan

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Rational Pharmacotherapy Action Plan

Final report

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Abstract

On 18 January 2016, the Ministry of Social Affairs and Health appointed a steering group to draw up a rational pharmacotherapy action plan to implement a policy item outlined in Prime Minister Sipilä's Government Programme. The action plan outlines objectives for promoting rational pharmacotherapy. The following objectives were set for national implementation, services organisers and providers, healthcare and social welfare professionals, and medicine users:

- Pharmacotherapy and pharmaceutical services will be managed by knowledge at national and regional levels and in service units.
- Service organisers will be in charge of pharmacotherapy and pharmaceutical services as a whole.
- Pharmacotherapy will be managed as a whole – objective for healthcare and social welfare service units.
- Healthcare and social welfare professionals will implement rational pharmacotherapy.
- Medicine users will use pharmaceuticals rationally and as agreed.

The objectives to be achieved by 2022 include the following points:
Steering will be based on national policies. Regions will have effective structures to ensure multidisciplinary cooperation between various stakeholders and steering of pharmacotherapy. Electronic systems to support decision-making and reliable sources of information on medicines will be in place widely. Medicine users will receive increasing support in taking responsibility for carrying out their own pharmacotherapy in an appropriate manner, within the limits of their own resources and possibilities.

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Tiivistelmä

Sosiaali- ja terveysministeriö asetti 18.1.2016 ohjausryhmän laatimaan rationaalisen lääkehoidon toimeenpano-ohjelman pääministeri Sipilän hallitusohjelman kirjauksen toteuttamiseksi.

Toimeenpano-ohjelmassa linjataan tavoitteita rationaalisen lääkehoidon edistämiseksi kansalliseen toimeenpanoon, palveluiden järjestäjille, palveluiden tuottajille, sosiaali- ja terveydenhuollon ammattilaisille ja lääkkeiden käyttäjille seuraavasti:

- Lääkehoitoa ja lääkehuoltoa johdetaan tiedolla kansallisesti, alueellisesti ja palveluyksiköissä
- Palveluiden järjestäjät vastaavat lääkehoidon ja lääkehuollon kokonaisuudesta
- Lääkehoidon kokonaisuus on hallittua - tavoite sosiaali- ja terveydenhuollon palveluyksiköille
- Sosiaali- ja terveydenhuollon ammattilaiset toteuttavat rationaalista lääkehoitoa
- Lääkkeiden käyttäjät käyttävät lääkkeitä järkevästi ja yhdessä sovitun mukaisesti

Vuoteen 2022 mennessä tavoitteina on esimerkiksi, että ohjauksen perustana käytetään kansallisia linjauksia. Alueilla on toimivat rakenteet eri toimijoiden välisen moniammatillisen yhteistyön ja lääkehoitojen ohjauksen varmistamiseen. Sähköiset päätöksenteontukijärjestelmät ja luotettavat lääkeinformaatiolähteet ovat laajassa käytössä. Lääkkeen käyttäjiä tuetaan yhä enemmän ottamaan vastuuta oman lääkehoitonsa asianmukaisesta toteuttamisesta, kuitenkin omien voimavarojensa ja mahdollisuuksiensa mukaisesti.

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Referat

Social- och hälsovårdsministeriet tillsatte den 18 januari 2016 en styrgrupp för att utarbeta ett genomförandeprogram för rationell läkemedelsbehandling i syfte att genomföra skrivningen i statsminister Juha Sipiläs regeringsprogram.

I genomförandeprogrammet fastställs mål för att läkemedelsbehandling ska genomföras nationellt, för de som ordnar tjänster, tjänsteproducenter, yrkesutbildade personer inom social- och hälsovården och användare av läkemedel enligt följande:

- Läkemedelsbehandlingen och läkemedelsförsörjningen leds med hjälp av data nationellt, regionalt och inom serviceenheterna
- De som ordnar tjänsterna ansvarar för den övergripande läkemedelsbehandlingen och läkemedelsförsörjningen
- Den övergripande läkemedelsbehandlingen är kontrollerad – ett mål för tjänsteenheterna inom social- och hälsovården
- Yrkesutbildade personer inom social- och hälsovården genomför rationell läkemedelsbehandling
- Användare av läkemedel använder läkemedel på ett rationellt sätt och i enlighet med vad man kommit överens om.

Till exempel ett mål fram till 2022 är att nationella riktlinjer används som grund för styrningen. I regionerna finns fungerande strukturer för att säkerställa multiprofessionellt samarbete mellan olika aktörer och styrningen av läkemedelsbehandlingar. Elektroniska beslutsstödssystem och tillförlitliga källor för läkemedelsinformation används i stor utsträckning. Användarna av läkemedel ges alltmer stöd för att ta de ska ta ansvar så att den egna läkemedelsbehandlingen genomförs ändamålsenligt, dock i enlighet med de egna resurserna och möjligheterna.

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Contents

TO THE READER

Prime Minister Sipilä's Government Programme states as follows: "The Government will implement a rational pharmacotherapy implementation programme aimed at improving the implementation of comprehensive patient care, improving people's functional capacity, and creating conditions for cost-effective pharmacotherapy from the perspectives of the patient and society."

On 18 January 2016, the Ministry of Social Affairs and Health appointed a steering group for the Rational Pharmacotherapy Action Plan to implement the policy outlined in the Government Programme. The assignment of the steering group was to prepare the Action Plan, drawing on existing projects to enhance a rational approach towards pharmacotherapy, and to determine objectives for promoting rational pharmacotherapy. Five working groups were set up under the auspices of the steering group. Their operations and compositions are described in Appendices 1 and 2, respectively. Each working group included a designated contact for data management. In addition, an ad hoc working group on data management was set up for the spring of 2017 to take stock of existing projects relating to data management and digital service models, with a view to ensuring that these were paying attention to aspects relevant to rational pharmacotherapy.

The key objectives of the Action Plan are related to the safety, quality, effectiveness and cost-effectiveness of pharmacotherapy. A further purpose of the Action Plan is to promote the Government Programme's objectives of narrowing disparities in health and wellbeing and managing costs.

This final report describes the Rational Pharmacotherapy Action Plan and its objectives to be achieved by 2022. At the same time as the final report, the working groups are also publishing their own reports, which focus on different themes and are referenced in this final report.

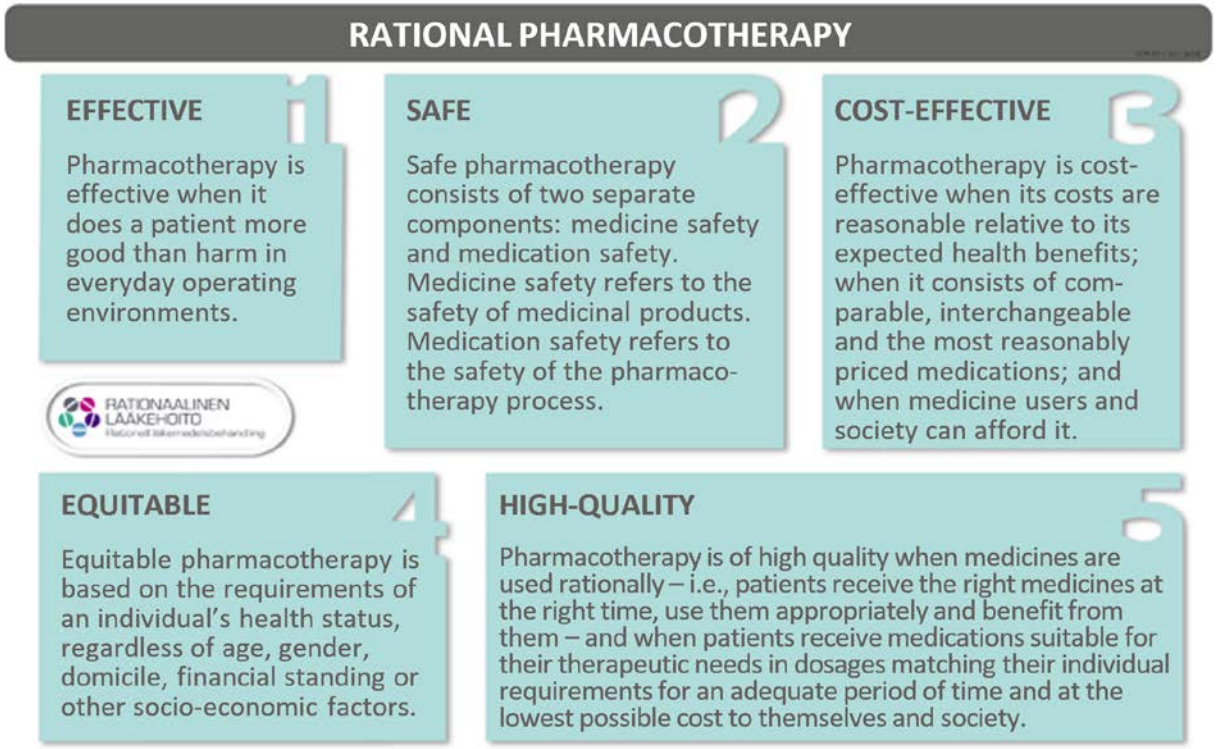
The Action Plan identifies the following key themes relating to the use of medicines:

1. Promoting rational pharmacotherapy by means of comprehensive medication management;
2. Effective pharmaceutical services in new health and social services structures;
3. Assessing therapeutic and economic value and tapping into the data resources available in health and social services;
4. Promoting research conducted in support of rational pharmacotherapy;
5. Advancing pharmaceutical innovation activities.

The policies relating to these themes are discussed in Chapters 1–5, divided into objectives for national implementation, services organisers, services providers, healthcare and social welfare professionals, and medicine users. Each of the policies outlined in chapter titles is followed by reasoning as to why it was considered important to highlight as part of the Rational Pharmacotherapy Action Plan. After that, there is an overview of objectives and vision for the future, ending with the objectives set out for 2022. Each chapter also describes the studies commissioned in the course of preparing the Rational Pharmacotherapy Action Plan and makes references to working group reports, which open up their activities in further detail. This report does not specify any parties responsible for the measures, because responsibilities for many of the measures may be assigned to several parties and specifying responsibilities may be difficult due to changes in operating environments. The hope is for the parties operating in the pharmaceutical sector to feel ownership of the objectives and to reflect on the means available to them to achieve these objectives in their own operations.

The work carried out as part of the Rational Pharmacotherapy Action Plan is based on the policies outlined in the Medicines Policy 2020, which states that “rational pharmacotherapy and good medication safety enhance the wellbeing of the population, improve public health and decrease the healthcare expenditures” (Ministry of Social Affairs and Health 2011). In addition to the policies outlined in the Medicines Policy 2020, other resources used in drafting the Action Plan include existing research data and the policies outlined by working groups dealing with development of pharmacy activities and other pharmaceutical services.

The Rational Pharmacotherapy Action Plan was drawn up in a situation where forthcoming health and social services structures and legislation governing the organisation of services were only being drafted. Nevertheless, it was expedient also to explore promotion of rational pharmacotherapy in future health and social services structures, rather than limiting the analysis to the current situation.


RATIONAL PHARMACOTHERAPY
EFFECTIVE
Pharmacotherapy is effective when it does a patient more good than harm in everyday operating environments.
SAFE
Safe pharmacotherapy consists of two separate components: medicine safety and medication safety. Medicine safety refers to the safety of medicinal products. Medication safety refers to the safety of the pharmaco-therapy process.
COST-EFFECTIVE
Pharmacotherapy is cost-effective when its costs are reasonable relative to its expected health benefits; when it consists of com-parable, interchangeable and the most reasonably priced medications; and when medicine users and society can afford it.
RATIONAALINEN LÄÄKEHOITO
EQUITABLE
Equitable pharmacotherapy is based on the requirements of an individual's health status, regardless of age, gender, domicile, financial standing or other socio-economic factors.
HIGH-QUALITY
Pharmacotherapy is of high quality when medicines are used rationally – i.e., patients receive the right medicines at the right time, use them appropriately and benefit from them – and when patients receive medications suitable for their therapeutic needs in dosages matching their individual requirements for an adequate period of time and at the lowest possible cost to themselves and society.

BACKGROUND

In recent years, the value of pharmaceutical sales has increased by about two to three per cent per year. Finnish patients and healthcare services have access to a wide and modern variety of medicines, while Finnish healthcare and social welfare services, pharmaceutical services included, are of the highest level in international terms. While the rational use of medicines makes it possible to improve people's functional and working capacity, use of pharmaceuticals also involves problems. It has been estimated that adverse patient safety events, with a significant proportion relating to medication, result in the death of 700–1,700 hospital patients per year in Finland (Pasternack 2006). Furthermore, it is known that only about 50% of drug therapies are carried out as prescribed by the doctor (WHO 2003).

According to a study published by the National Audit Office (2017), for frequent users of primary healthcare services there are deficiencies in the organisation of the services provided and the procedures in place. Smoother exchange and more efficient use of client data, complete with integration of patient record systems, would serve the quality and management of medications as a whole when identifying the group of frequent service users and planning their clinical pathways. These clients' individual therapies should be planned, implemented and monitored in a coordinated, evidence-based, performance-oriented and multidisciplinary manner, involving the individuals in the process. From the perspective of comprehensive medication management, special attention should be paid to clients with multiple illnesses and medications and high medicine costs.

Since the 1990s, the growth in medicine costs has mainly been curbed by means relating to medicine prices and users' co-payments. The underlying reasons for the growing costs include the fact that new pharmaceuticals enter the market at constantly increasing prices. Consequently, it is necessary to identify measures to safeguard Finnish patients' equal rights to access safe, efficient and reasonably priced medications, while ensuring the sustainability of public healthcare systems. The most recent amendments to the medicine reimbursement system entered into force at the beginning of 2017. As a result of these changes, rational pharmacotherapy shall be promoted through measures targeted at prescribing and dispensing medicines.

Rational pharmacotherapy is safe, effective, cost-effective, equitable and of high quality. The core contents of the objectives specified in the Rational Pharmacotherapy Action Plan are explained in Figure 1 below, with special focus on the patient perspective. The prerequisites of successful pharmacotherapy will improve when patients participate in the planning and implementation of their own pharmacotherapy as partners, when the regimen of medications is jointly agreed, and when patients

receive support in the use of medicines. Rational pharmacotherapy and pharmaceutical services form a coordinated whole, where management is based on knowledge.

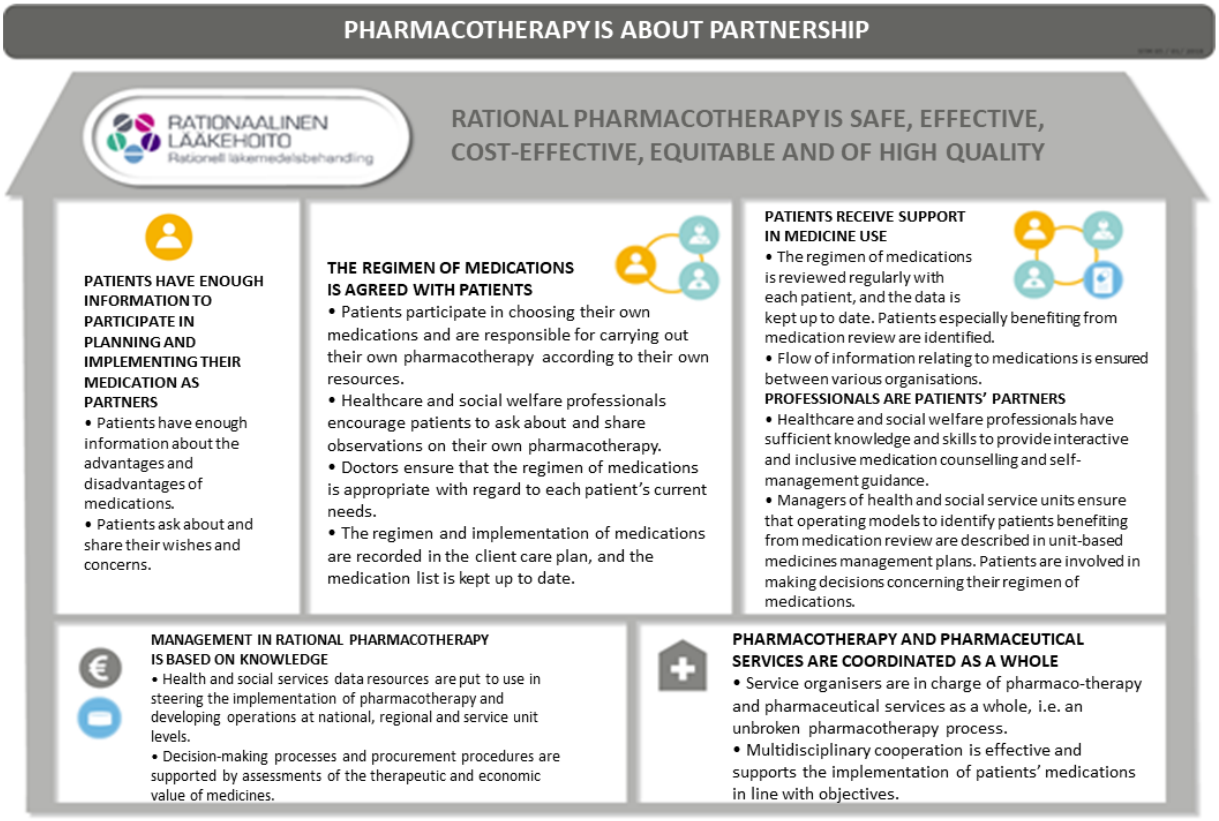


Figure 1. Objectives of the Rational Pharmacotherapy Action Plan viewed from the patient perspective.

1 Pharmacotherapy and pharmaceutical services will be managed by knowledge at national and regional levels and in service units

Objective for steering bodies (central government, service organiser, service provider)

'Management by knowledge' refers to making use of expertise and the best information available when steering and making decisions on pharmacotherapy and pharmaceutical services. The planned health and social services reform will reinforce national steering mechanisms. At the same time, the legislation currently being drafted specifies that the service organiser is responsible for ensuring that service providers cooperate with each other to guarantee clients' access to integrated services. It is therefore necessary to establish the types of information the steering bodies will require and how to collect and make use of this information in an efficient manner. Furthermore, it is necessary to decide the best way to refine and make use of the information accumulated in the data resources of health and social services as part of steering and making decisions relating to pharmaceutical services and pharmacotherapy.

Pharmacotherapy and pharmaceutical services will be steered centrally at a national level based on up-to-date information and shared objectives. The existing registers and statistics will form the foundation for steering as well as monitoring the use of medicines. The decisions made by various organisations and healthcare professionals at the different stages of the pharmacotherapy process will be based on up-to-date care recommendations, the medicine reimbursement system, the range of national healthcare services, national objectives for steering pharmacotherapy, and monitoring of care outcomes. Equitability between individuals in terms of access to medicines will be safeguarded by means of evidence-based national policies and regional guidelines. Operating models implemented in healthcare and social welfare service units will have been agreed at a national level, also involving medicine users in the process, in order to bring medication data up to date, to identify medicine users benefiting from medication review, to target medication review services appropriately, and to promote a multidisciplinary cooperation culture responsive to the needs of medicine users.

The data resources of health and social services and their quality improvement will be ensured at a national level as the health and social services structures are reformed. The health and social services data resources refer to healthcare registers, patient record systems, data accumulated in biobanks and in the National Archive for Health Information (Kanta services), etc. National bodies, service organisers and service providers will possess sufficient expertise and competence to apply and make use of the accumulated data as part of steering rational pharmacotherapy and developing their own operations. The aim is to put these data resources to better use as part of management, decision-making, allocation of resources and steering of medicine use and pharmaceutical services. The indicators created in support of the health and social services reform, including the KUVA indicators and the Information Package for Pharmaceutical Services prepared by the Ministry of Social Affairs and Health and the Finnish Innovation Fund Sitra, will supplement existing sources of information, providing information on the use and costs of health and social services, etc.

The national feedback systems and research and development (R&D) projects relating to medicines and use of medicines will produce information, facilitating the development of procedures used in service units and by various professionals within healthcare and social welfare services. R&D activities will provide information required in steering pharmacotherapy and pharmaceutical services, while research will also be utilised as part of steering and decision-making processes. Cooperation between researchers and decision-makers will increase. Cooperation between researchers will reduce overlapping work, while implementation of more extensive collaborative research projects will be enabled as a result of funding allocated to research into rational pharmacotherapy.

The infrastructure and systems of health and social services data resources will be in place, enabling the production of real-world evidence (RWE) on pharmacotherapies and pharmaceutical services to meet the needs of decision-makers. Furthermore, efforts will be made to promote the fulfilment of the significant research and innovation potential relating to health and social services data resources, which may open up possibilities for increasing pharmaceutical research in Finland. The aim is to improve access to health and social services data resources for R&D purposes, with due consideration for the data protection of individuals. The required patient data will have been recorded in a comprehensive, high-quality and consistent format, enabling nationwide utilisation of such data.

National assessments of the therapeutic and economic value of medicines will steer the use of new hospital medicines in particular. Such assessments will support decision-making, procurement procedures and determination of the real prices payable for medicines and related procedures. Additional evidence on the costs, consumption and outcomes of the assessed medicines, allocation of their use and

therapy processes will be regularly collected from health and social services data resources. Furthermore, there will be policies in place to determine who will collect such additional evidence and how it will be utilised in policies relating to the use of medications and, as far as possible, in procurement procedures.

In 2014, the Government published its Health Sector Growth Strategy for Research and Innovation Activities. The strategy includes key recommendations for measures in order to develop research and innovation activities systematically while also increasing investments and generating economic growth in the health sector. To support its implementation, a Roadmap for the Growth Strategy for Health Sector Research and Innovation Activities was published in 2016.

The pharmaceutical industry and pharmaceutical innovations form a key part of the Growth Strategy and the Roadmap. Pharmaceutical development and, in particular, clinical trials will increase pharmaceutical competencies and resources in healthcare. Pharmaceutical R&D activities will be focused on areas that offer competitive conditions. Agility, the high quality of information derived from healthcare services and networking abilities will be further consolidated in support of pharmaceutical research. Information on the prevalence and treatment of disease, care outcomes and their contributing factors will not only be collected and put to use in healthcare development, steering and management processes, but also in pharmaceutical development. Finnish pharmaceutical research will be supported using the best identified means, in order to improve possibilities for research conducted in pursuit of pharmaceutical innovations, as well as for manufacturing and commercialisation. This is expected to create new jobs and increase pharmaceutical exports and foreign investments in Finland.

OBJECTIVES TO BE ACHIEVED BY 2022

- Steering will be based on national policies, evidence-based care recommendations and other jointly agreed objectives. National operating models will have been drawn up in order to bring medication data up to date, to identify medicine users benefiting from medication review, and to target medication reviews.
- The existing data resources will be put to active use in steering the implementation of pharmacotherapy and in operational development at national, regional and service unit levels. Competencies will be sufficient to make use of information.
- The data accumulated in health and social services data resources will be nationally comprehensive, of high quality, in a usable format and easily accessible in support of management by knowledge.

- R&D activities relating to rational pharmacotherapy will have been integrated as part of the health and social services system, while research information will be utilised when steering the operations.
- Decision-making processes and procurement procedures will be supported by national assessments of the therapeutic and economic value of medicines.

REPORTS AND STUDIES INCLUDED IN THE ACTION PLAN

Pelkonen L, Rannanheimo P, Anttila V-J, Komulainen J, Koskinen H, Leipälä J, ym. Miten lääkkeiden hoidollisen ja taloudellisen arvon arviointi tulisi järjestää Suomen sosiaali- ja terveydenhuollossa? Rationaalisen lääkehoidon toimeenpano-ohjelman asiantuntijaryhmän selvitys. Sosiaali- ja terveysministeriön raportteja ja muistioita 2017:31.

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[*Palva E. Preliminary report: National Pharmaceutical Development Centre. Reports and Memorandums of the Ministry of Social Affairs and Health 2017:15.*]

Available in Finnish at: http://urn.fi/URN:ISBN:978-952-00-3865-6

2 Service organisers will be in charge of pharmacotherapy and pharmaceutical services as a whole

Objective for service organisers

The health and social services reform currently being prepared intends to transfer the responsibility for organising health and social services to new counties, simplify multisource financing of health and social services, and enable patients to choose service providers from the public, private and third sectors. Pharmaceutical services offer medicines and services to all parties involved in health and social services and contribute to enabling the implementation of integrated care pathways and rational pharmacotherapy. The Rational Pharmacotherapy Action Plan focused special attention on hospital pharmacy activities and the rational pharmacotherapy process in the forthcoming health and social services structures.

In the future health and social services structures, service organisers will be responsible for ensuring that citizens will receive the healthcare and social welfare services that they require. Pharmacotherapy is part of this whole: in other words, service organisers will be in charge of pharmacotherapy and pharmaceutical services as a whole, coordinating medication safety and medicines information, and monitoring the safety of pharmacotherapy and the effectiveness of pharmaceutical services. Furthermore, services will be adapted to meet the needs of each client by creating an integrated whole known as a care pathway, which covers timely access to pharmacotherapy and comprehensive medication management. Service organisers will thus ensure an unbroken pharmacotherapy process for the residents of their respective regions. The role of pharmaceutical services is to contribute to enabling the implementation of rational pharmacotherapy. Each service organiser will possess sufficient pharmaceutical competencies within its organisation to be capable of planning and managing pharmaceutical services as a whole, while also understanding the pharmacotherapy processes in place in provider organisations. Patients' representatives will be involved in planning pharmacotherapy processes.

Service organisers will contribute to ensuring the sufficient availability of community pharmacy services. Community pharmacies will operate as part of the healthcare and social welfare service chain and individual clients' care pathways. When dispensing

medicines, pharmacies will verify that pharmacotherapy is appropriate, while providing support for use of medicines and monitoring of pharmacotherapy.

OBJECTIVES TO BE ACHIEVED BY 2022

- Regions will have effective structures in place to ensure multidisciplinary cooperation between various stakeholders and steering of pharmacotherapy.
- Pharmaceutical services will operate on the basis of knowledge, while operations across organisational boundaries will be managed and coordinated as a whole.
- Regional steering systems to improve the quality of pharmacotherapy will be in place and put to use. Efforts will be made to monitor and develop the safety of pharmacotherapy and the effectiveness of pharmaceutical services.
- Service organisers will ensure that the principles of rational pharmacotherapy are being realised in healthcare and social welfare services as a whole.

REPORTS AND STUDIES INCLUDED IN THE ACTION PLAN

Lääkehuolto sote-toimintaympäristössä. Työryhmän raportti. Sosiaali- ja terveysministeriön raportteja ja muistioita 6/2018.

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3 Pharmacotherapy will be managed as a whole

Objective for healthcare and social welfare service units

There is plenty of research data available on problems in the rational use of medicines. Key challenges for implementing rational pharmacotherapy include comprehensive medication management and the lack of up-to-date information on individual patients' medications within healthcare and social welfare services. The situation will be improved through digital solutions, in particular the national medication list included in Kanta services. In addition, it is necessary to put new operating models into efficient use at the levels of teamwork, organisations and structures. Being in charge of providing adequate resources and defining responsibilities, each organisation's managerial staff play a key role in introducing operating models that promote rational pharmacotherapy. The Rational Pharmacotherapy Action Plan places a special emphasis on the role of the management in healthcare and social welfare service units, because the national operating models geared towards bringing medication data up to date, identifying medicine users benefiting from medication review and targeting medication reviews will be integrated as part of the operations of service units.

Multidisciplinary and cross-organisational cooperation aims to manage medications as a whole at different stages of the pharmacotherapy process and as part of individual patients' integrated care pathways. Various national operating models, specified at regional and organisational levels, will ensure a rational approach towards pharmacotherapy, including medication safety, at all stages of the pharmacotherapy process. Channels for communication and information sharing between different professionals and organisations will be in place at different phases of the service chain. Close cooperation between healthcare and social welfare services is particularly necessary in cases where patients cannot afford to pay for the medications that they need, require especially expensive medications, or have high total need for healthcare and social welfare services.

The management of healthcare and social welfare service units will ensure that the units are equipped with secure electronic tools that support professionals in their work at different stages of the pharmacotherapy process. The management of service units will further ensure that up-to-date data included in electronic decision support systems is taken into account as part of making decisions on and monitoring pharmacotherapy. Healthcare and social welfare professionals will take care of updating and documenting data relating to medications and its transfer between

different organisations, where this is not done via Kanta services. Improved coordination of prescription practices and pharmacotherapy will prevent problems identified in pharmacotherapy.

The managerial staff of healthcare and social welfare service units will be responsible for ensuring that their own unit-based medicines management plan describes the operating models geared towards bringing medication data up to date, identifying patients benefiting from medication review, targeting the most demanding medication review services appropriately, and promoting a multidisciplinary cooperation culture responsive to the needs of medicine users. Multidisciplinary cooperation across organisational boundaries will make it possible to identify and solve pre-existing pharmacotherapy problems. Pharmacotherapy will be carried out in keeping with the operating models described in unit-based medicines management plans. Multidisciplinary cooperation will be put to more coordinated use in bringing medication data up to date and in reviewing and monitoring medication. Patients' representatives will be involved in planning the deployment of the operating models at a regional level.

Client care plans and up-to-date medication lists will be widely in place at a national level. The national medication list will be based on national information system services, which are used to retrieve, record and store patient data and to ensure consistent nationwide operating models and principles for handling patient records. The medication list is based on the idea that all data on medication is stored in a single location accessible to all bodies and individuals involved in the pharmacotherapy process. The medication list can be viewed in an identical format by everyone (except for any information subject to refusals of disclosure), and all involved may update the data. One of the biggest obstacles to implementation of rational pharmacotherapy has been the lack of up-to-date information on individual patients' medication within healthcare and social welfare services. With the introduction of the national medication list, it will become easier for healthcare professionals to check the medication as a whole and carry out medication reviews in multidisciplinary cooperation. Instead of requiring specific maintenance, the medication list will be updated whenever structured medication data is stored in national information system services, regardless of the organisation that originally produced the data. Medicine users will also receive support in recording their over-the-counter (OTC) medicines and other medicinal products available without prescription in the My Kanta Pages service, making information on their use available to all healthcare and social welfare professionals. Patient record systems and their various in-built decision support systems and electronic databases will support the implementation of safe pharmacotherapy.

A self-supervision plan will be in place in each service unit providing healthcare and social welfare services, including the unit's pharmacotherapy plan. The service unit's management will be responsible for conducting medication safety audits as part of self-supervision. The safety of pharmacotherapy processes and practices in place in housing and home care services should be verified regularly in a manner at least equivalent to institutional settings.

Professionals must possess sufficient knowledge and skills to carry out pharmacotherapy appropriately, to monitor and assess its effects, to provide medicine users with medication and self-management counselling, and to use digital tools in support of their own work. The level of training in pharmacotherapy provided for different healthcare and social welfare professionals will match the duties of each professional group, while being consistent in different training units and multidisciplinary throughout the country.

Implementing the principles of rational pharmacotherapy requires strategic management of the competencies and development of service units, and understanding of safety and security culture. Any deviations relating to pharmacotherapy should be identified, reported and analysed. Healthcare and social welfare professionals will develop in their work and change their operating methods with support from their own service unit's operational development and the in-house training provided. Professionals' self-motivated continuing training will not be enough on its own to guarantee development of pharmacotherapy competencies and operating methods in service units. This also requires long-term training courses and research (Government Proposal 15/2017 for the Act on Organising Health and Social Services, section 16, section 39).

OBJECTIVES TO BE ACHIEVED BY 2022

- The national operating models geared towards bringing medication data up to date, identifying medicine users benefiting from medication review, and targeting medication reviews will be widely used in healthcare and social welfare service units.
- Cooperation between healthcare and social welfare service units and pharmacies will be effective. Effective digital channels that function well will be in place for communication between different professionals and organisations.
- Electronic decision support systems and reliable sources of medicines information will be widely in place and used to manage and prevent medication risks. Service units will ensure that the opportunities brought about by digitalisation are available to healthcare and social welfare

professionals and that they possess sufficient competencies to make use of these.
- Multidisciplinary cooperation responsive to patient needs will be put to more coordinated use in reviewing and monitoring medication.
- Pharmacotherapeutic competencies and medication safety will be included in basic, advanced and continuing training in healthcare and social services at a level suited to the duties of each professional group.
- Patients' medications and care outcomes will be recorded consistently in healthcare and social welfare service units. Special attention will be paid to diseases of significance to public health and the economy.

REPORTS AND STUDIES INCLUDED IN THE ACTION PLAN

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4 Healthcare and social welfare professionals will implement rational pharmacotherapy

Objective for healthcare and social welfare professionals

Prescribers of medicines play a key role in ensuring rational pharmacotherapy: is pharmacotherapy safe, effective, cost-effective, equitable and of high quality for every medicine user? Doctors are responsible for planning medications as a whole, involving medicine users in the process, as well as for agreeing on the monitoring and self-management of medications with users. Other healthcare professionals participate in supporting medicine users in managing and monitoring their medications. The Rational Pharmacotherapy Action Plan places an emphasis on partnership, multidisciplinary cooperation, recording the objectives and monitoring of pharmacotherapy agreed with individual medicine users in their client care plans, and the personal responsibility of each healthcare professional for updating the medication lists.

Doctors will ensure that medications and their effectiveness are reviewed regularly as a whole, especially when it comes to frequent users of services or medications, and that medications are managed as a whole and carried out so as to avoid any unnecessary costs in terms of both patients and society. Pharmacotherapy that is planned, implemented and monitored well forms part of comprehensive patient care.

Together with each patient, doctors will ensure that medications as a whole are appropriate with regard to the patient's current needs, characteristics and possibilities. The choice of medicine will be primarily based on research evidence validating the efficacy and safety of the medicine, care guidelines or approved clinical practice. The medicines prescribed are cost-effective. Doctors receive feedback on their prescription practices.

Doctors will ensure that the regimen of medications and the plan for the implementation of care agreed with each patient are recorded in the client care plan, that the medicine list is up to date, and that information on the regimen of medications is forwarded as required. The monitoring and self-management of medications will be agreed with the patient.

Pharmacists will support the implementation of safe and cost-effective pharmacotherapy through counselling when dispensing medicines, while also

monitoring the appropriate implementation of medications and referring medicine users to see a doctor as required. Where necessary, pharmacists will participate in multidisciplinary medication reviews and support patients with rational self-medication. The healthcare professionals involved in treating individual patients will support medicine users to ensure that they know how and why they are using the prescribed medicines, while also taking medicine users' individual wishes into account. They will also monitor the achievement of the objectives of pharmacotherapy together with the medicine users, while encouraging users to play an active role in managing their own therapy and to provide information on any effects of their medications that they may observe. Cooperation between different professionals and individual medicine users will be smooth.

Each professional's pharmacotherapeutic competencies will correspond to their duties in the pharmacotherapy process. Continuing professional development will maintain pharmacotherapeutic competencies and, consequently, medication safety. Healthcare and social welfare professionals will possess sufficient knowledge and skills to provide medicine users with medication and self-management counselling and to use digital tools.

OBJECTIVES TO BE ACHIEVED BY 2022

- Doctors will agree with each medicine user on the regimen of medications, implementation and monitoring of pharmacotherapy, and on recording these in the client care plan as part of other care.
- Healthcare professionals responsible for treating patients will monitor the achievement of the objectives of pharmacotherapy together with medicine users, making use of the opportunities provided by digitalisation. Other healthcare professionals and pharmacists will support and monitor the implementation of pharmacotherapy together with medicine users.
- The medications in use will be cost-effective from the perspectives of both medicine users and society.
- Every medicine user, especially frequent service users with multiple illnesses and medications, will be provided with an up-to-date client care plan and medication list drawn up and maintained together with a healthcare professional.
- Healthcare and social welfare professionals will also possess competencies required to make use of electronic decision support systems and medicines information.

REPORTS AND STUDIES INCLUDED IN THE ACTION PLAN

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5 Medicine users will use pharmaceuticals rationally and as agreed

Objective for medicine users and their family and friends

Medicine users must have a clear understanding of their medications as a whole and of why and how medicines are used. For this purpose, they need medicines information and support from healthcare and social welfare professionals. The Rational Pharmacotherapy Action Plan places an emphasis on partnership between medicine users and healthcare and social welfare professionals and medicine users' own responsibility for implementing their pharmacotherapy. An up-to-date medication list is a tool that helps a medicine user manage the whole and discuss with healthcare and social welfare professionals.

Medicine users will agree with their attending physicians on the regimen of medications, implementation and monitoring of therapy, and on recording these in their personal client care plan. Medicine users will be responsible for carrying out their own pharmacotherapy in an appropriate manner and for achieving its objectives, within the limits of their own resources (Figure 2). If a medicine user is unable to take responsibility for their own regimen of medications, the responsibility will be assigned to an individual, such as a family member or friend, whose identity is known to the healthcare and social welfare service units involved in treating the user.

Figure 2. Tasks of patients and healthcare and social welfare professionals in community care settings at different stages of the pharmacotherapy process. The pharmacotherapy process and, accordingly, the tasks involved will be different when pharmacotherapy is carried out in settings such as healthcare or social welfare service units.

Medicine users will use pharmaceuticals as agreed. Medicine users will bear their own share of responsibility for avoiding unnecessary costs and medicine wastage by means such as only buying the amount of medicine that they require and understanding that they must not hand over their medicines to others, consequently contributing to medication safety, cost-effectiveness and ecological considerations. Medicine users will participate in keeping their own medication list up to date. They may ask whether their medication list is up to date while seeing healthcare professionals, for example, and inform professionals of any over-the-counter (OTC) medicines, food supplements or other medicinal products that they may use.

Medicine users will actively share their individual wishes and concerns relating to pharmacotherapy with healthcare and social welfare professionals. They will also actively ask about any aspects of their pharmacotherapy that may remain unclear and obtain reliable information on medicines while visiting healthcare and social welfare service units or pharmacies. Subject to each medicine user's consent, all their medication data will be accessible to everyone involved in pharmacotherapy.

New digital service channels and applications will support medicine users in implementing and monitoring rational pharmacotherapy. Citizens will have access to electronic services and be able to produce information for themselves and for use by professionals. The national My Kanta Pages service at omakanta.fi allows citizens to view their own electronic prescriptions, dispensing events, and summaries of their patient records. In the future, they will also be able to add their own entries relating to pharmacotherapy, for example, to the service. Reliable sources of information and client-oriented digital services will support rational pharmacotherapy. Online pharmacy services will be smooth to use. Where required, the national digital self-management pathway will lead to reliable online pharmacy services.

OBJECTIVES TO BE ACHIEVED BY 2022

- Medicine users will be increasingly supported in assuming responsibility for carrying out their own pharmacotherapy in an appropriate manner, within the limits of their own resources and possibilities.
- Medicine users or their family and friends will agree with the attending physician on the regimen of medications, and on the implementation and monitoring of medications.
- National medication lists will be widely used. Medicine users (or family members or friends in charge of pharmacotherapy) will update the national register with details of their own medication data, such as use of over-the-counter (OTC) medicines.

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Appendix 1: Descriptions of working group operations

1. Working group for prescription, dispensation and use of medicines

The working group on prescribing medicines carried out preparatory work in support of implementing rational pharmacotherapy, especially from the perspective of rationalising the practices relating to prescription of medicines. The key areas identified for improvement included curbing medicine costs, promoting medication safety through means such as enhancing access to up-to-date medication data and comprehensive medication management, and steering and supporting pharmacotherapy decisions made by prescribers. The working group already carried out measures aiming to bring solutions to most of these areas while planning the implementation of the Action Plan (2016–2017).

Actions:

- participating in drafting legislative amendments;
- promoting the uptake of biosimilars, with primary responsibility for drawing up and implementing a plan on biosimilars to promote the introduction of biosimilars;
- preparing a communication campaign for healthcare professionals, especially drawing up a poster entitled ‘Elements of rational pharmacotherapy’;
- carrying out preparatory work to increase feedback for prescribers.

The working group for dispensing medicines focused on promoting the introduction of biosimilars, reducing unnecessary medicine purchases and medicine wastage, and improving comprehensive medication management.

Actions:

- The working group participated in drafting up a plan to promote the introduction of biosimilars, a multidisciplinary operating model and informative guidance for pharmacies.
- As part of updating Administrative Regulation No. 2/2016 issued by the Finnish Medicines Agency (Fimea) on dispensing medicines, the group specified provisions on indicating the remaining amounts of medicines on prescriptions and on small medicine packaging to be dispensed at the beginning of long-term pharmacotherapy, etc. At the same time, the Administrative Regulation was revised to align with the amendments to

Decree 1088/2010 issued by the Ministry of Social Affairs and Health on the prescription of medicines, which entered into force at the same time.
- A sub-group of the working group began deliberations on the criteria for reviewing medications, which would refer patients to medication review services in a targeted manner (a register-based model built on a screening tool).
- Furthermore, the sub-group drew up a proposal for more efficient monitoring of the success of pharmacotherapy through development of cooperation and communication between pharmacies and physicians.

The working group for the use of medicines concentrated on supporting patients and medicine users in implementing rational pharmacotherapy and managing medications as a whole as well as on providing information on biosimilars.

Actions:

- promoting the use of client care plans and up-to-date medication lists as part of a public awareness campaign named ‘Suitable Medicine’ included in the Rational Pharmacotherapy Action Plan;
- providing information for patient groups using biopharmaceuticals and biosimilars at a seminar entitled ‘Biosimilars – for me?’ held on 17 May 2017, as well as in articles appearing in magazines published by patient organisations.

Report by the working group for prescribing, dispensing and use of medicines:

Rationaalinen lääkkeen määrääminen, toimittaminen ja käyttö nykyisissä ja tulevissa sote-rakenteissa. Työryhmän raportti. Sosiaali- ja terveysministeriön raportteja ja muistioita 12/2018.

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2. Working group for pharmaceutical services structures as part of the health and social services reform

The working group’s work was affected by incomplete legislation on the health and social services reform. Within the working group’s term, it was challenging to implement the assignment recorded in the interim report of the Rational Pharmacotherapy Action Plan, namely, how to make financing structures and responsibilities, citizens’ freedom of choice in services and digital service models

support rational pharmacotherapy in the best possible way. It was not possible to go through the details of legislative amendments governing pharmaceutical services at a concrete level. Instead, the working group's work provided context, focusing on identifying current problems and alternative solutions. In its work, the group concentrated on hospital pharmacy activities and on defining the rational pharmacotherapy process.

Report by the working group for the pharmaceutical services structures as part of the health and social services reform:

Lääkehuolto sote-toimintaympäristössä. Työryhmän raportti. Sosiaali- ja terveysministeriön raportteja ja muistioita 6/2018.

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Available in Finnish at: http://urn.fi/URN:ISBN:978-952-00-3903-5

3. Working group for assessment of the therapeutic and economic value of medicines

The working group was tasked with finding out how assessment of the therapeutic and economic value of medicines should be organised in Finland in the future.

Actions:

The working group's output was a report, which aimed to:

1. collect the points to consider when planning assessment of the therapeutic and economic value of medicines;
2. describe the current status of assessment of the therapeutic and economic value of medicines in Finland;
3. identify the primary areas for improvement in the current system;
4. propose national objectives for health technology assessments of pharmaceuticals;
5. propose a national model for health technology assessments of pharmaceuticals;
6. estimate the resources and financing required for health technology assessments of pharmaceuticals;
7. determine any further aspects relating to health technology assessments of pharmaceuticals that may need to be studied.

Objectives 4 to 6 concern health technology assessments of pharmaceuticals used in public healthcare services. In this context, a medicine used in public healthcare refers to cases where a medicine is primarily intended for use in hospitals operating within the public healthcare sector or is primarily purchased in Finland by hospitals, or where the use or reconstitution of a medicine generally requires hospital conditions. The definition also covers medications for generally hazardous and notifiable communicable diseases.

Report by the working group for assessment of the therapeutic and economic value of medicines

Pelkonen L, Rannanheimo P, Anttila V-J, Komulainen J, Koskinen H, Leipälä J, ym. Miten lääkkeiden hoidollisen ja taloudellisen arvon arviointi tulisi järjestää Suomen sosiaali- ja terveydenhuollossa? Rationaalisen lääkehoidon toimeenpano-ohjelman asiantuntijaryhmän selvitys. Sosiaali- ja terveysministeriön raportteja ja muistioita 2017:31.

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4. Working group for research into rational pharmacotherapy

The working group on research explored the current status of and preconditions for research relating to rational pharmacotherapy, while also outlining some research themes for the future. Furthermore, the group supported the work of the other working groups of the Rational Pharmacotherapy Action Plan by compiling and communicating research data to inform their work.

Actions:

- organising two research seminars on rational pharmacotherapy, on 23 November 2016 and 22 November 2017;
- drawing up a research strategy for rational pharmacotherapy with the aid of extensive cooperation with stakeholders;
- putting together and launching a research network for rational pharmacotherapy;

- producing compilations of domestic and international research to meet the information needs identified by the other working groups of the Rational Pharmacotherapy Action Plan.

Research strategy for rational pharmacotherapy:

Tutkimustieto hyötykäyttöön: Rationaalisen lääkehoidon tutkimusstrategia 2018–2022. Sosiaali- ja terveysministeriön raportteja ja muistioita 7/2018.

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5. Working group for pharmaceutical innovations

Pharmaceutical development requires special expertise in several disciplines and understanding of pharmaceutical development processes and legislative frameworks. This is why the commercial potential of findings made in Finnish universities is often left untapped. The pharmaceutical innovation working group deliberated on both the opportunities for and challenges to success with a view to promoting the utilisation of pharmaceutical innovations in Finland.

The pharmaceutical innovations working group started operations in November 2016 by organising a discussion meeting entitled ‘Pharmaceutical research as part of the Health Sector Growth Strategy for Research and Innovation Activities’. Its actual work commenced in January 2017. As part of the Rational Pharmacotherapy Action Plan, the Ministry of Social Affairs and Health commissioned a preliminary study on the establishment of a National Pharmaceutical Development Centre as part of implementing the Roadmap for the Health Sector Growth Strategy for Research and Innovation Activities in early 2017 (Esiselvitys: Kansallinen lääkekehityskeskus [*Preliminary study: National Pharmaceutical Development Centre*], by Erkki Palva). In June 2017, the Ministry of Economic Affairs and Employment and the Ministry of Social Affairs and Health organised a seminar relating to the Growth Strategy, focusing on creating an innovation environment for pharmaceutical development.

As a result of the discussions, it was deemed necessary to continue considering the establishment of a National Pharmaceutical Development Centre to support pharmaceutical development activities. In its report, the working group outlines its vision for the National Pharmaceutical Development Centre.

Report by the pharmaceutical innovation working group:

Kansallinen lääkekehityskeskus. Lääkeinnovaatiot työryhmän raportti. Sosiaali- ja terveysministeriön raportteja ja muistioita 5/2018.

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6. Ad hoc working group for data management

As part of working on the Rational Pharmacotherapy Action Plan, each working group involved in drawing up the Action Plan familiarised itself with ongoing data management projects from the perspective of its own theme and identified the data required to promote rational pharmacotherapy. In February, an ad hoc working group was set up to work on data management, aiming to collect details of the data requirements of rational pharmacotherapy. The ad hoc working group compiled an overview of national ICT service packages for health and social services and examined it from the perspective of pharmacotherapy. The data management needs of the Action Plan were prioritised on the basis of national objectives and project priorities. The working group focused its work on the following two themes: data management at the level of 1) individuals and 2) providers. The first theme deals with a project to develop an up-to-date national medication list, the possibilities of medicine users to enter their own medication data into the My Kanta Pages service and use a digital care pathway, as well as the possibilities of citizens and healthcare professionals to recognise problems in pharmacotherapy. The latter theme explores how to produce indicators for pharmacotherapy and pharmaceutical services to meet steering and supervision needs and to assess the effectiveness of new medicines, for example. In addition, the working group compiled areas for improvement relating to the functionalities of various systems. The purpose of its work was to ensure that the existing projects pay attention to aspects relevant to the Rational Pharmacotherapy Action Plan.

Report by the ad hoc working group for data management:

Rationaalisen lääkehoidon tiedonhallinnan kehittäminen. Työryhmän raportti. Sosiaali- ja terveysministeriön raportteja ja muistioita 11/2018.

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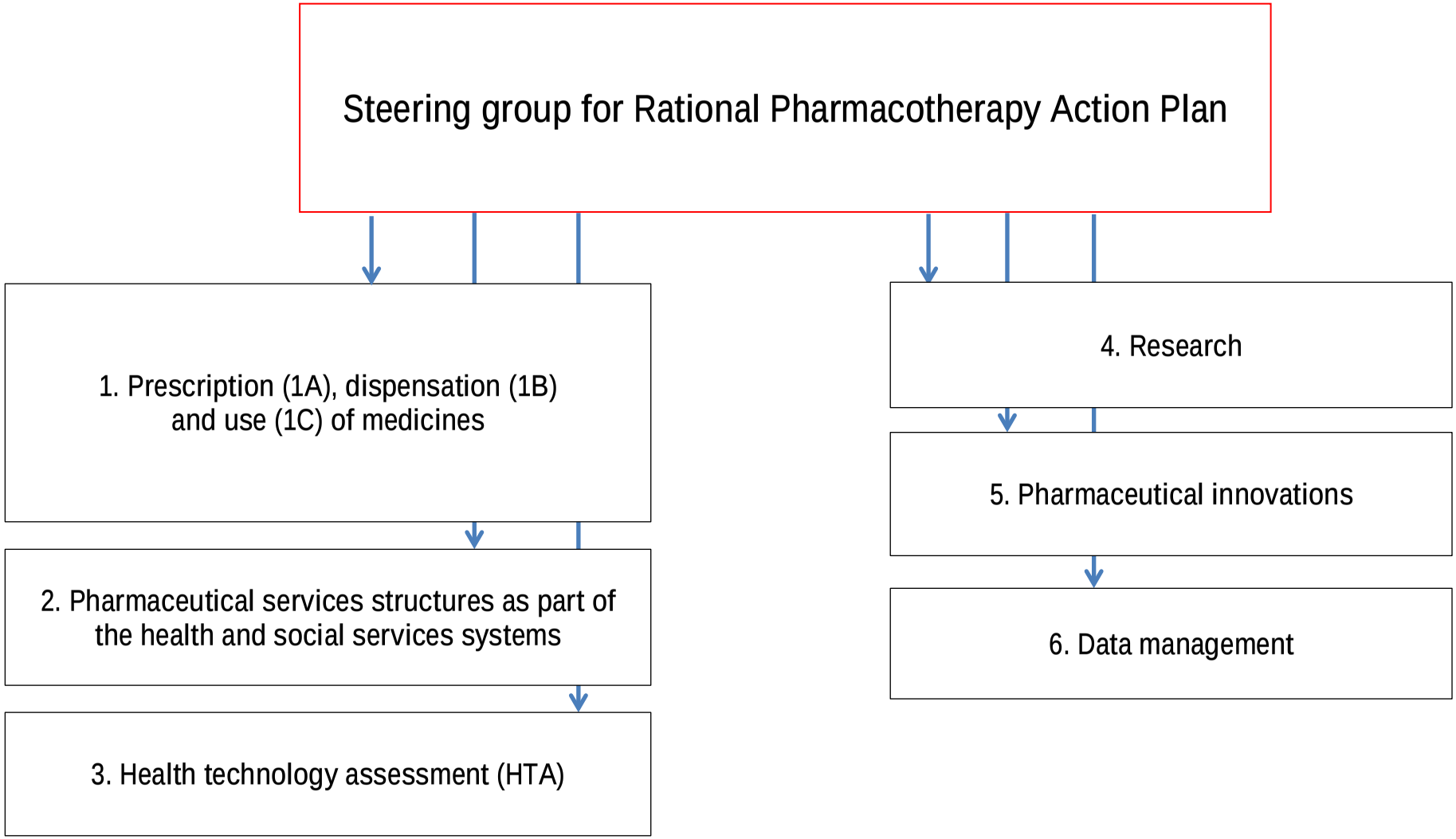
Appendix 2: Rational Pharmacotherapy Action Plan, organisation of work



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