National Pharmaceutical Strategy

Action Plan 2014

REGERINGSKANSLIET
Government Offices of Sweden

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Foreword

Medicines are an integral part of health and medical care. The challenges that exist in healthcare also apply to medicines. Some of these challenges are concerned with limited resources, unequal access to treatments and actions not always producing desirable results. Other important aspects of medicines and the use of medicines are research, patient safety and environmental impact. For the third consecutive year a large number of actors in the pharmaceutical area have agreed to focus on some areas where collaboration, resources and efficient working practices are particularly important to enable the challenges described in the pharmaceutical field to be met. The outcome is the 2014 National Pharmaceutical Strategy.

The National Pharmaceutical Strategy has been successively developed, both in terms of content and with regard to procedures, but a great deal still remains to be done. Several important participants have been added and have contributed to creating greater breadth on issues that need to be analysed and deeper knowledge on how problems should be addressed.

The action plan for 2014 contains several new features that require commitment and deeper collaboration between authorities, the healthcare system and organisations. Before work on the National Pharmaceutical Strategy had assumed its present-day form with action plans, working groups and evaluations, there was already a clear picture that close cooperation between the parties was crucial to attain good results. It is apparent from the follow-up of the strategy that there is a consensus that work on the strategy has come to fulfil an important collaborative function in the pharmaceutical field, in particular by creating the possibility of dialogue between affected actors.

The horizon scanning in the strategy shows that there is a continued need to strengthen the patient perspective, to intensify work relating to children and medicines, to continue to focus on quality aspects in pharmacies and to strengthen efforts to control antibiotic resistance. The analysis also illustrates the ambition to attain a coherent national process of introduction for new innovative medicines, as well as the need to reduce the scope for fraudulent prescribing of narcotic medicines. The results of the horizon scanning are reflected in the 2014 action plan, which in particular highlights and prioritises these areas. The endeavour to realise this common vision of correct use of medicines to the benefit of patient and society is driven by the ambitious and persistent efforts made under the National Pharmaceutical Strategy.

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Introduction

A number of actors involved in the National Pharmaceutical Strategy have been working on the vision of Correct Use of Medicines to the Benefit of Patient and Society since the autumn of 2011.

Extensive efforts have been made under the National Pharmaceutical Strategy and its 2011–2013 action plan, together enabling Sweden to come a step closer to putting the goals of the strategy into effect:

- world-class medical results
- equality of care
- cost-effective use of medicines
- attractiveness for innovation of products and services
- minimal environmental impact

The work on the national environmental strategy is directed by a high-level group chaired by the Ministry of Health and Social Affairs and with representatives from the Swedish Association of Local Authorities and Regions, the Medical Products Agency, the Swedish Institute for Infectious Disease Control (from 1 January 2014 the Public Health Agency of Sweden), the National Board of Health and Welfare, the Dental and Pharmaceutical Benefits Agency, the Swedish Council on Health Technology Assessment, the Health and Social Care Inspectorate, the Swedish Medical Association, the Swedish Association of Health Professionals, the Swedish Association of the Pharmaceutical Industry, the Swedish Pharmacy Association, Apotekens Service AB (from 1 January 2014 the Swedish eHealth Agency), Region Västra Götaland, Region Skåne and Västmanland County Council. The high-level group decides annually on an updated action plan containing clear and relevant activities aimed at putting the strategy's goals into practice.

In 2011 the Government commissioned the Centre for Rational Use of Medicines (CBL) at the Medical Products Agency to coordinate and follow up the work on the National Pharmaceutical Strategy. The remit involves the CBL secretariat coordinating work on the action plan, gathering information on ongoing activities under the strategy and passing on information about the NPS to those affected through collaboration with actors within the strategy. Follow-up of the strategy takes place at both action level and goal level.

To obtain broad understanding and endorsement among those affected in the pharmaceutical field, an advisory board known as the CBL Council has been set up. The CBL Council consists of 26 members, and annually presents horizon scanning which serves as the basis for the annual audit of the action plan.

It is apparent from the year's horizon scanning that there is a consensus that the work on the strategy has come to fulfil an important collaborative function in the pharmaceutical field, in particular through a possibility of dialogue between affected actors being created. The horizon scanning also shows that there continues to be a need to strengthen the patient perspective, that work on paediatric use of medicines needs to be stepped up, that the newly started activities concerning pharmacies need to continue and that the role of the nurse should be strengthened. The significance of the work under the strategy being pursued in the long term is also highlighted.

The actors within the National Pharmaceutical Strategy have persistently pursued highly ambitious work in the various activities and on the indicators during the year. In addition, the work on the CBL Council and in the expert and high-level groups has been highly significant. New members have been added to the expert group, the high-level group and the CBL Council, which has contributed to an enhanced and broader knowledge and ideas base for work on the strategy. The new actors in the expert and high-level groups are Apotekens Service AB, the Health and Social Care Inspectorate and the Swedish Association of Health Professionals. The pensioners' organisations, Apotekens Service AB, the Health and Social Care Inspectorate and the Swedish Association of Health Professionals have been attached to the CBL Council.

Follow-up

The need to follow up the strategy at the level of both action and goals was already emphasised at the time when the National Pharmaceutical Strategy was devised. The 2011–2012 action plan was principally followed up at the level of action.

The high-level group decided in 2012 to instruct the expert group to review existing indicators and propose continued development of the follow-up under the National Pharmaceutical Strategy. Work during the year was directed and coordinated by the CBL secretariat at the Medical Products Agency.

The remit includes clarifying how goals and indicators under the NPS inter-relate, proposing the development of existing indicators, making suggestions for new indicators and proposing ways of enhancing the follow-up methodology.

There are five overarching goals in the NPS at present. Several different ongoing activities and strategies in Sweden are working towards these goals, and some of these activities appear in the NPS. In addition, the seven action areas in the NPS, with their underlying activities, are aimed in some cases at attaining several of the strategy's goals.

A follow-up of the goals of the NPS therefore gauges the combined effort to attain the goals, within and outside the NPS. The effect of each individual action or activity on the goals is therefore difficult to measure.

Four 'indicator groups' have been added with the primary task of clarifying and developing the above. The groups are classified as follows:

1. World-class medical results and patient safety and Equality of care,
2. Cost-effectiveness,
3. Attractiveness for innovation and
4. Environment.

The high-level group has decided on continued work relating to follow-up of the National Pharmaceutical Strategy, preferably by continuing to develop and strengthen collaboration between affected parties, both within and outside the NPS.

Changes to the action plan in 2012–13

As last year, work is principally focused on concluding the activities that have been started. The action plan contained 34 activities in the 2013 version. Three activities were completed in 2012 and seven have been completed in 2013. The fact that the activities are deemed to have been concluded does not, however, automatically mean that they are implemented and evaluated for example in the healthcare system. A particular part having been concluded merely means that the actors responsible have carried out what is described in the text. In a number of cases further actions still need to be taken before the activity has been fully accomplished. In the longer term this may also mean that the activity can be resumed in the strategy, but in a later part of the implementation process.

The 2014 action plan contains four new activities. The new activities are aimed among other things at improving knowledge support when medicines are prescribed

for children, reducing the development of antibiotic-resistant bacteria and reducing the scope for fraudulent prescribing of narcotic preparations. In two cases actions that have already started are changed and broadened. The issue of starter packs as an instrument for greater concern for the environment is placed in 7.1 and purchasing of antibiotics on the Internet is placed in 4.1.

Completed activities in 2012

2.1. Create the necessary basis for effective medication reviews and medication reconciliation in healthcare transitions

It was stated in the action plan for 2011 that the necessary conditions were to be created for effective medication reviews and medication reconciliation in healthcare transitions and that these measures should be evaluated. In view of the fact that the National Board of Health and Welfare's revised regulations and general guidelines (SOSFS 2012:9) on medication reviews entered into force in 2012 and that guidance on the regulations and general guidelines had been prepared, point 2.1 was omitted from the 2013 action plan. The second element of point 2.1, "evaluate the effect of these measures" remains in the action plan for 2014. What effects medication reviews and medication reconciliation have should be investigated in the longer term, when the online service has been in operation for a time.

3.1. Draw up national guidelines on how elderly and multimorbid patients are to be treated

The National Board of Health and Welfare in 2012 draw up a guide, firstly on how account should generally be taken of the sickest elderly in application of the national guidelines for different disease groups and secondly for the situations in which the sickest elderly should be differentiated in individual recommendations. With this in mind, the activity was omitted from the 2013 action plan.

4.4. Develop the local Strama groups in the county councils

It was stated in the 2011 agreement between central government and the Swedish Association of Local Authorities and Regions (SALAR) on improved patient safety that the county council concerned would set up a local Strama group. The Swedish Institute for Infectious Disease Control's follow-up of the agreement showed that all the county councils had fulfilled this part of the agreement. This remit has been completed and the activity was omitted from the 2013 action plan.

Completed activities in 2013

1.3. Make electronic cancellation of e-prescriptions possible

Apotekens Service AB has made it possible to cancel e-prescriptions since 2011. The cancellation function has been introduced for those county councils that have the patient record system SYSTeam CROSS, at present five. In addition, the cancellation function has been introduced into the patient record system Melior, but the function has not yet been implemented in the county councils. Being able, as a prescriber, to alter, discontinue and cancel historic, but active prescriptions will also be possible when the patient record systems are integrated with the national prescription database (NOD). In consideration of the fact that it is now possible for several county councils to cancel e-prescriptions, and that other county councils intend to wait for NOD to obtain the cancellation service, this activity can be concluded.

1.4. Create national multi-dose register

The aim of this activity was to make it possible for all actors in the multi-dose-dispensing market to have access to data on multi-dose prescriptions. In the spring of 2013, Apotekens Service AB put new assortment and supply services (SOL) into production for the healthcare system and new multi-dose actors.

In future Apoteket AB will switch over to the systems that have been developed by Apotekens Service AB, but during a transition period the healthcare system, in contact with Apoteket AB, will use the previously developed assortment and supply services (IOR). A strategic group has been formed with the aim of identifying and planning to improve the functions and performance of information for the multi-dose service. The group's remit includes ensuring that the agreed timetable is respected and that necessary measures are taken. This activity can therefore be concluded.

1.7. Develop service for increased patient involvement through feedback of outcomes of treatment and non-conformance management

The aim of this activity was to be able to feed back the patient's own experience of pharmaceutical treatment and in so doing achieve greater participation by patients in their own care and treatment. The healthcare provider takes responsibility for data relating to its activities, but the individual concerned has full access to the data – wherever, however and whenever. Making the patient

more involved in and knowledgeable about his or her own treatment leads to more effective and safer treatment, better compliance, less discarding of medication and more satisfied patients. To be able to monitor cost-effectiveness in everyday clinical practice there is a need for patient-reported data on quality of life. The Centre for eHealth in Sweden (CeHis) is running the project My Health Services, which is aimed at creating the necessary conditions for the population to gain access to more good-quality e-services in the area of health and medical care. A 'service contract for form management' has been developed in My Health Services which is a basic technical component controlling how information is to be conveyed between different systems. The technical foundation has therefore been laid for being able to exchange information between healthcare providers and patients through forms and questionnaires in a secure manner. The form service is ready for implementation in the autumn of 2013. This activity can therefore be concluded.

2.2. Evaluate whether multi-dose services can contribute to greater compliance and improved patient safety and how the service can be used and refined

The Medical Products Agency has investigated the issue of multi-dose services and reported the remit to the Government Offices. The Medical Products Agency proposes that a working group be appointed to investigate what quality requirements should be set for the multi-dose services. The county councils' assessment is that it is too early to investigate the quality requirements ahead of future procurements. In those county councils that changed supplier in the summer of 2013 the service is still undergoing fine-tuning, and in the remaining county councils changes of supplier are in progress during the autumn. An evaluation of whether multi-dose services improve patient safety should not be made until 2015 at the earliest. The activity can therefore be omitted from the action plan and if necessary can be resumed in the 2015 action plan.

2.4. Develop labelling of pharmaceutical packs to reduce the risk of confusion

The Medical Products Agency and the Network for Patient Safety have developed documentation proposing various parameters for change on pharmaceutical packs in order to improve labelling and consequently also reduce the risk of confusion and incorrect use. This work has been focused on inpatient medicines. Test procurement of safe packs will take place under the auspices of the county councils in the ELIS project (Efficiency Improvement of Drug Procurement in Collaboration). The procurement will take account of the new principles for the design of drug packaging drawn up by the Medical Products Agency and others. Work on the test procurements and their evaluation is proceeding under activity 5.3, Assess the county councils' procurements of requisitioned medicines and how the process can be made more efficient.

6.2. Develop national model for development of introduction protocol and introduce coordinated assessment of medicines in clinical reality

The remit was reported to the Government Offices in November 2013. The activity can be terminated and incorporated into the process on the orderly introduction of new medicines.

7.3. Investigate what further measures can be taken at national level to reduce the discarding of medicines or in other ways to limit the environmental impact of the use of medicines

The purpose of the activity is to contribute to making it possible for the discarding of medicines to be further reduced and to the pharmaceutical residues that arise in the handling of medicines and in the consumption of medicines being dealt with in an environmentally sound way. All the objectives of the inquiry have been met. The activity has been implemented and can therefore be concluded.

Activities that partially acquire changed content or a new authority or organisation with main responsibility in 2014

6.3. Improve follow-up of pharmaceutical dosing

The Swedish eHealth Agency is taking over main responsibility from the Ministry of Health and Social Affairs.

6.4. Make follow-up of requisitioned medicines possible at individual level

The Swedish Association of Local Authorities and Regions is taking over main responsibility from the National Board of Health and Welfare.

6.5. Make it possible for the county councils, the National Board of Health and Welfare and the Dental and Pharmaceutical Benefits Agency to follow up prescribing of medicines at prescriber level

The National Board of Health and Welfare is taking over main responsibility from the Ministry of Health and Social Affairs.

General organisational changes

Swedish eHealth Agency

Apotekens Service AB underwent conversion during the year to become a government agency with effect from 1 January 2014. On 7 February 2013 the Government made a decision to appoint an inquiry chair with the task of preparing and implementing the formation of the new Agency for Health and Care Infrastructure (S 2013:03). On 23 October 2013 the Government decided that the Agency for Health and Care Infrastructure would change name and be known as the Swedish eHealth Agency (see Government Bill New Name for Agency for Health and Care Infrastructure, Govt Bill 2013/14:24).

Public Health Agency of Sweden

On 1 January 2014 the new Public Health Agency of Sweden was established in accordance with the considerations stated in the Government Bill A More Collective Agency Structure in the Field of Public Health (Govt Bill 2012/13:116). This agency is taking over the tasks of the National Institute of Public Health and the Swedish Institute for Infectious Disease Control, as well as certain tasks of the National Board of Health and Welfare. This merger improves the prospects for more efficient knowledge-based work in the area of public health. On 21 March 2013 the Government made a decision to appoint an inquiry chair with the task of preparing and implementing the formation of the Public Health Agency of Sweden (Terms of Reference 2013:33).

New activities in 2014 (see also description under each activity)

Reduce the scope for fraudulent prescribing and manipulation of special prescriptions – 1.8

Fraudulent prescribing or manipulation of prescriptions poses a serious threat to patient safety. This activity is aimed at reducing over-prescribing of narcotic medicines and other special medicines in healthcare and dentistry and at improving efficiency in supervision of the prescribing of special medicines. One aspect of this work is attempting to reduce the manipulation and forging of prescriptions.

Knowledge support in medication prescriptions for children – 3.5

This activity entails a preliminary study being performed to investigate the prospects of providing prescribing support in the drug treatment of children. The activity takes place in the light of half of all medicines given to children in hospitals being off-label, i.e. not being approved for children. This means that there is a lack of adequate information in the approval of the medicine for paediatric dosage, suitable methods of administration for children and what side effects and effects they have when given to children. There is therefore a great need for prescribing support in paediatric medicine.

Carry out studies for optimal utilisation of existing antibiotics – 4.6

We find ourselves in a situation where access to new antibiotics is very limited, while demand is continuing to increase. However, it takes a long time to develop antibiotics with new mechanisms of action. Doctors are increasingly often forced to use existing antibiotics in diagnoses for which they have not been tested. It is therefore extremely important to identify and test in a structured way all the options for new uses for those antibiotics that are already in use. The activity in 4.6 entails carrying out studies to identify how use of existing antibiotics can be optimised in order to preserve the possibility of effective treatment with antibiotics.

Staggered approval and introduction of new medicines – 6.6

A concern that has attracted international attention is the continous increase of development times for new medicines and consequently a prolongation of time before patients gain access to medicines that are important for them. There is growing international involvement in initiatives to find approaches to mitigate this problem by various forms of staggered approval processes, for example adaptive licensing, which could enable patients to gain access to medicines more quickly provided adequate safety monitoring can be ensured. This project activity entails studying various international initiatives for staggered approval of new medicines and evaluating the potential benefits and drawbacks of the process. If the benefits outweigh the drawbacks, relevant authorities should propose a plan that contributes to the development of the concept.

Action plan 2014

1 Create a better and safer prescribing process and lay the foundation for generic prescribing through nationally coordinated IT support

1.1. Make electronic reporting of drug side effects possible

Main responsibility: Medical Products Agency

Investigation into making electronic reporting of adverse drug reactions from the whole healthcare system possible. Includes further development with regard to feedback of side-effect reports to the health service and discussion with the pharmaceutical industry to examine how this change can improve the companies' work on pharmacovigilance.

Objective

Reporting of drug side effects is crucial in order to discover deficiencies in the management of medicines and to increase drug safety. All side-effect reports from the healthcare system are currently sent to the Medical Products Agency, ether on a paper form or using an online form. There is a need for more flexible and user-friendly reporting, for example directly from within patient record systems, to motivate and encourage greater reporting of side effects and feedback of knowledge for improved patient safety.

Autumn 2013

The Medical Products Agency has a Government remit to develop and make available a system that enables electronic reporting of side effects for the whole healthcare system. An interim report on the remit was presented on 30 November 2013, and a final report is due on 1 October 2014. As part of this activity in the NPS, a consultative letter has been sent to the strategy council of CeHis, on which all the county councils and regions are represented. During the autumn a decision was made on how user-friendly reporting of side effects from the healthcare system and feedback to the healthcare system is to be designed.

Work in 2014 and timetable

Work on making electronic reporting of side effects possible is continuing in accordance with the Medical Products Agency's remit from the Government, and the final report is due to be submitted on 1 October 2014. The healthcare system then needs to be responsible for implementing the changes necessary to be able to send electronic side-effect reports directly from patient record systems. The work therefore includes greater consultation between the Medical Products Agency and the healthcare system to ease implementation.

1.2. Make generic prescribing possible

Main responsibility: Medical Products Agency

Investigation on the design, technical platform and funding of a future register of substances. Evaluation of what changes in legislation may become relevant and what adaptation of IT systems will need to take place to make generic prescribing possible.

Objective

All medicines contain at least one active substance. It is the active substance that means that the medicine has an effect on the disease or symptom of disease it is intended to treat. The first approved medicine containing a particular active substance is known as an original medicinal product. When the patent has run out and the data protection period has expired, equivalent products can be manufactured, known as generic medicines. The generic medicine contains the same active substance in the same amount as the original medicine and is usually deemed to be equivalent from the point of view of efficacy and safety, but is sold under a different name. Generic prescribing means that the prescriber specifies the generic name when prescribing instead of the brand name of the product. This means that the prescriber does not choose a particular product to prescribe but that any product containing a particular substance is to be supplied. The pharmacies themselves therefore choose which product will be dispensed to the patient. The advantage of generic prescribing is that it makes the prescriber's work easier and in certain respects can improve patient safety, for example due to a reduced risk of the patient taking two drugs at the same time which have the same active ingredient but are sold under different product names.

The objective is to investigate how it can be made possible for generic prescribing to be done in a way that is safe for patients. The investigation includes analysing what statutory changes are required, what substances could be subject to generic prescribing, estimating the cost of designing relevant IT systems and of necessary training efforts and devising a plan for the introduction of voluntary generic prescribing.

Status in autumn 2013

The Medical Products Agency, on behalf of the Government, has investigated the conditions that need to be met for generic prescribing to be introduced. The final report was received in November 2012.

One conclusion drawn is that such prescribing requires time for preparations by those affected. The proposal is for the majority of existing medicines to be deemed possible to prescribe generically. Prescriber support, prescription-dispensing systems and a national infrastructure that can manage generic prescribing alongside traditional product prescribing are required. The Medical Products Agency proposes that pharmacies be required to add to the pharmacy label clear information on what active substance a dispensed medicine contains. The proposal means that legislative amendments have to be implemented.

Under the remit, the costs of the proposed IT structure have been analysed and estimated at around SEK 200 million beyond the costs of incorporating NOD/Pascal into healthcare systems. The greatest costs are associated with adapting NOD and patient record systems/prescribing tools for generic prescribing.

As the Medical Products Agency proposes that generic prescribing only be allowed to take place through updated electronic systems, generic prescribing should be introduced in conjunction with the medication modules of patient record systems being integrated with NOD. One reason for this is to ensure that the prescriber has access to updated information on what substances may be specified or prescribed and to make it easier for structured introduction of generic prescribing to be introduced. Another reason is that it is not possible to enhance and develop the present-day e-prescription format to make the adjustments needed to manage generic prescribing. It will therefore be essential to implement the changed communication interfaces in and with NOD to enable the changes needed for generic prescribing to be introduced in the healthcare system.

Work in 2014 and timetable

The report from the Medical Products Agency on voluntary generic prescribing has been discussed at the Government Offices. The reports that exist in this area have sufficiently clarified the benefits of introducing generic prescribing from the point of view of cost-effectiveness. It ought to be possible, for instance, to set the costs of implementation against any estimated benefit in a patient and prescriber perspective. Experience from other countries that have introduced generic prescribing, such as Finland, should be closely analysed. The Government intends to task the Medical Products Agency with investigating and clarifying the gains in introducing generic prescribing in relation to other measures aimed intended to bring about improvements with regard to patient safety.

1.3. Make electronic cancellation of e-prescriptions possible (completed in 2013)

Main responsibility: County councils

Objective

The objective behind the cancellation of e-prescriptions is to improve patient safety in such a way that it is not possible to fill out-of-date prescriptions or prescriptions with out-of-date information, for example changed dosage, at pharmacies.

Status in autumn 2013

Apotekens Service AB has made it possible to cancel e-prescriptions since 2011. The cancellation function has been introduced for those county councils that have the patient record system SYSTeam CROSS, at present five. In addition, the cancellation function has been introduced into Melior, but the function has not yet been implemented in the county councils.

Being able, as a prescriber, to alter, discontinue and cancel historic, but active prescriptions will also be possible when the patient record systems are integrated with NOD. This applies both what prescribers themselves have created but also to the prescriptions and orders of other prescribers. The design of the cancellation and amendment function in NOD will create traceability in a logical flow with what are referred to as prescription chains. Each new decision must be linked to a responsible prescriber, which becomes clear if each decision or amendment is viewed as a new prescription. Another reason is that, under the Patient Data Act, amending someone else's patient record notes is not permitted. On the other hand, it is obviously permissible to discontinue a treatment someone else has started or to alter a dosage someone else has prescribed. It becomes easier to show that the Patient Data Act is complied with if discontinuations and alterations are regarded as new prescriptions replacing the previous ones. Prescriptions that belong together are instead linked by being given a common ID that holds them together in a logical "prescription chain".

Work in 2014 and timetable

It is now possible for the county councils to place orders with their IT suppliers for adjustments that make cancellation of e-prescriptions possible. Whether this takes place and at what paces is a priority for each individual county council. The county councils' prioritisation is also affected by the ordering of integration of patient record systems with NOD.

In consideration of the fact that it is now possible for several county councils to cancel e-prescriptions, and that other county councils intend to wait for NOD, the activity can be concluded.

1.4. Create national multi-dose register (completed in 2013)

Main responsibility: Apotekens Service AB

Completion of IT platform for national dose registers and transfers of information from the multi-dose registers.

Objective

Make it possible for all actors in the multi-dose-dispensing market to have access to data on multi-dose prescriptions.

Autumn 2013

In the spring of 2013, Apotekens Service AB put new assortment and supply services (SOL) into production for the healthcare system and the new multi-dose actors. In future Apoteket AB will switch over to the systems that have been developed by Apotekens Service AB, but during a transition period the healthcare system, in contact with Apoteket AB, will use the previously developed assortment and supply services (IOR). In June 2013 Svensk dos took over the multi-dose dispensing service from Apoteket AB for Region Skåne. Apotekstjänst took over the multi-dose dispensing service in Halland and Västra Götaland. A total of around 60 000 multi-dose patients have consequently been transferred from Apoteket AB to new suppliers. During the autumn of 2013, Apotekstjänst is due to take over multi-dose dispensing for seven county councils, known as the 'Seven-Leaf Clover'. The planned start date is October 2013. In conjunction with this it is also appropriate to develop a new assortment and supply system that enables a multi-dose actor to manage different multi-dose assortments.

Work in 2014 and timetable

A strategic group has been formed with the aim of identifying and planning to improve the functions and performance of information for the multi-dose service. The group's remit includes ensuring that the agreed timetable is respected and that necessary measures are taken. This activity can therefore be concluded.

1.5. Create and implement a prescription database with a combined list of medicines under current legislation

Main responsibility: Swedish Association of Local Authorities and Regions

Objective

Medicines create great benefit for patients and society. But the use of medicines is not devoid of problems. Side effects, unsuitable drug combinations, incorrect dosing, inadequate compliance with prescriptions, unintentional duplicate medication and other incorrect use of medicines can lead to health problems. One way of increasing opportunities to predict and avoid medication-related problems would be for patients themselves, the healthcare system and pharmacies to have a collective and common picture of which medicines an individual patients has been recommended and why. There is no such collective picture at present. Instead, the information is spread between various medication lists and registers. For example, there is information about prescribed medicines in medication list in various patient record systems, valid prescriptions in the prescription register and information about collected medicines in the National Prescribed Drug Register. These registers and lists commonly show different pictures of reality, and they additionally have different rules regarding who has access to the information. Nor is it certain that any of the lists coincide with the patient's own picture.

This is the background to the need for and creation of a national, combined list of medication. For prescribers, the combined medication list will form part of coherent record-keeping. It will therefore be one of the essential requirements for effective decision support in prescribing, together with other information about the patient, the latest findings about medicinal products and national and local recommendations and guidelines. From the point of view of the patient, the combined medication list will be a more usable form of support to memory than the present-day lists of prescriptions and collected medicines. In the longer term the list will also be a point of departure for interactive contact with the healthcare system on issues regarding the patient's own medication.

The combined medication list will be saved and stored in NOD. Access for the healthcare system to the combined medication list in NOD is governed by the provisions of the Patient Data Act, which entails requirements for the healthcare provider to have implemented security services (SITHS, HSA), the patient being given information on the significance of the combined medication list and consent being obtained from the patient for access to the combined list.

Autumn 2013

The objective is to launch the NOD database in the autumn of 2013. A pilot study will then be performed with a number of selected prescribers. The purpose of the pilot study is firstly to test the technical communication paths and the service contracts, and secondly to gain experience regarding how access to the patient's combined medication list affects procedures, processes and how information should be presented and shown.

Service contract descriptions (specifications for how IT support, for example patient record systems, integrate with NOD) can now be viewed at www.cehis.se. There are also a large number of FAQs with activity-related questions and answers.

An agreement has been drawn up between CeHis and the county councils to clarify their responsibilities and roles in work on the integration of healthcare systems into NOD. The cooperation contract is also a declaration of intent showing the ambitions of the county council concerned to plan and carry out integration.

Signing of the cooperation contract by 30 September 2013 is one of the basic requirements for the county councils to receive funding for improved use of medicines in the 2013 agreement on coherent health and social care for the sickest elderly. The aggregate amount is SEK 300 million. All the authorities responsible for medical care have signed the cooperation contract. There will be a need to enhance technology, systems and operational activities to integrate the medication module of patient record systems into NOD. This means that the work needs to be pursued both within the county council concerned and jointly within the customer groups for patient record systems. Work is in progress at CeHis to develop and adapt the county council-wide infrastructure, service contracts and database structure of NOD.

Work in 2014 and timetable

The county councils plan to establish in 2014 what requirements should be set for technical and process-related changes to enable the medication modules of the patient record systems to be integrated with NOD. Testing of NOD is planned in 2015 so that the database can be introduced in 2016.

1.6. Establish a coherent system for discussion and decision on the development of national basic systems for prescribing support

Main responsibility: Ministry of Health and Social Affairs

Developed under National eHealth.

Objective

Adequate prescribing support for healthcare professionals is one of several important requirements to aid efforts towards achieving more effective and safer care. Several initiatives have also been taken to improve support with regard to prescriptions, but further action needs to be taken.

Status in autumn 2013

Project 1: National source for reason for prescribing
The National Board of Health and Welfare presented its final report on its remit to develop a national source for reason for prescribing to the Government on 1 July 2013. The final report can be downloaded at: www.socialstyrelsen.se/publikationer2013/2013-6-32

In accordance with its remit, the National Board of Health and Welfare has developed a coding system for reasons for prescribing and purpose texts for three ATC groups and has clarified the terminology in the area. The Board has also drawn up proposals for introduction into healthcare, operation and administration of the source and further enhancement of the coding system.

On behalf of the National Board of Health and Welfare, CeHis has adapted NOD to the structured storage of data on reason for prescribing and has devised an executable prototype in the user interface of the Pascal prescribing tool which can demonstrate possible use of the coding system.

The coding system consists of a database containing medicines, reasons for prescribing and purpose texts for ATC groups C (cardiovascular system), J (antiinfectives) and N (nervous system). A total of just under 500 reasons for prescribing have been developed. Both reason for prescribing and purpose texts have been quality-reviewed by medical specialists appointed by the Swedish Society of Medicine. The database contains links to both medicinal products and substances (through substitutability groups). The coding system has an open structure, which means that it can be supplemented for example by other reasons for prescribing and links to non-pharmacological prescribing. It is not locked to use in Pascal and NOD and can be used by other actors, for example patient record system suppliers or suppliers of decision support systems. The system in its present form is designed to support a prescribing process based on the prescriber first choosing a medicine and then documenting one or more reasons for prescribing and purpose texts for the drug prescription given. It is then to be possible to choose reason for prescribing freely from the entire lexicon.

The overarching terms (for example indication, reason for prescribing, purpose of treatment) defined in the remit were published in the National Board of Health and Welfare's term bank in July.

In its final report, the National Board of Health and Welfare recommends that the Government should instruct the organisation appointed to take responsibility for the content-related administration to:

- complete the coding system with respect to medicines and approved indications (all ATC groups),
- establish guidelines and requirements for use of the coding system paying particular attention to the aspects of information security and patient safety, privacy and user benefit,
- in consultation with representatives of the healthcare system and specialist associations, examine what further development of the content of the coding system (with respect to reasons for prescribing without approved indication and reasons for prescribing that do not concern drug treatments) is necessary to achieve the aim of creating benefit for both

patients and prescribers and reduce the risk of incorrect use of the coding system,
- in consultation with representatives of the healthcare system and specialist associations, examine such enhanced and expanded contents of the coding system should be administered and
- in consultation with affected organisations investigate how different systems that handle indications and reasons for prescribing can be harmonised.

The National Board of Health and Welfare proposes in the final report that overarching responsibility for the contents of the coding system be placed with itself, and that the future Swedish eHealth Agency be given responsibility for technical administration.

Work in 2014 and timetable

The National Board of Health and Welfare intends to continue the work on a national source for reason for prescribing in 2014 in accordance with the proposals submitted in the final report in July 2013 provided the Government gives the authority a new remit and associated funding.

Project 2: Introduction of national prescription database (NOD) and the prescribing tool Pascal

See section 1.5.

Project 3: Evaluation of electronic dispensing support (EDS)

EDS provides pharmacists in pharmacies with access to electronic expert support that automatically checks all electronic prescriptions prior to dispensing. As a result, medication clashes, duplicate prescriptions, risks due to age etc. can be discovered. It provides greater safety for the patient and improved use of medication Apotekens Service AB is working on continued development and adaptation and support for the use of EDS. The project is proceeding as intended and is aimed at making EDS accessible for prescribed-dose medicines and at making the system more user-friendly. Apotekens Service AB has also started a project to introduce a Swedish medication list The Medical Products Agency evaluated the functions of EDS in 2012 and has deemed it to have interesting potential as expert support in both pharmacies and medical care.

Apotekens Service AB underwent a transformation during the year to become a government agency with effect from 1 January 2014. On 7 February 2013 the Government made a decision on terms of reference (S 2013:03) to appoint an inquiry chair tasked with preparing and implementing the formation of a new government agency (the Public Health Agency of Sweden). The committee's remit includes commenting on how effective and appropriate the company's operation is with regard to orientation, organisation and financial management, ahead of the transfer of the operation to the new agency. The organising committee has proposed that EDS and other knowledge support be investigated. The final report is to be delivered by 31 December 2013.

Work in 2014 and timetable

A number of issues linked to the new authority will need to be the object of in-depth investigation in 2014, including EDS.

1.7. Develop service for increased patient involvement through feedback of outcomes of treatment and non-conformance management (completed in 2013)

Main responsibility: Swedish Association of Local Authorities and Regions

Objective

The aim of the activity is to be able to supply the patient's own experience of pharmaceutical treatment and therefore achieve greater participation by patients in their own care and treatment.

The aim is for each individual to be able to obtain all data about himself or herself and to actively assist. The individual has to be able to access his or her data, including information on medication, in a number of different ways depending on what suits the person best. It is also self-evident that access through mobile platforms should be possible. The healthcare provider takes responsibility for data relating to its activities, but the individual concerned has full access to the data – wherever, however and whenever. The individual can combine them with his or her own data on his or her own health and decide who to share the data with. Making the patient more involved in and knowledgeable about his or her own treatment leads to more effective and safer treatment, better compliance, less discarding of medication and more satisfied patients. This is also of great importance from the point of view of the pharmaceutical companies. To be able to monitor cost-effectiveness in everyday clinical practice there is a need for patient-reported data on quality of life.

Status in autumn 2013

CeHis is running the project My Health Services, which is aimed at creating the necessary basis for the population to gain access to more good-quality e-services in the area of health and medical care. This may apply for example to accessing My Care Contacts by mobile and tablet, seeing one's referral status, booking blood tests and receiving results direct in one's account.

A 'service contract' for form management has been developed in the My Health Services project. The service

contract is a basic technical component which controls how information is to be conveyed between different systems. A service contract can, for example, link My Care Contacts to a form service or a questionnaire tool and consequently control the transfer of information in a standardised way. The intention is for it to be possible for the solution to be used for example for health declarations or follow-ups of treatment. The technical basis has therefore been laid for being able to exchange information between healthcare providers and patients through forms and questionnaires in a secure manner. The next step is to link a form service to the service contract.

Work in 2014 and timetable

The form service is ready for implementation in the autumn of 2013. This activity can therefore be concluded.

1.8. Reduce the scope for fraudulent prescribing and manipulation of special prescriptions (new activity in 2014)

Main responsibility: Medical Products Agency and National Board of Health and Welfare

Objective

There is information from various quarters to indicate that narcotic medicines are being misused to an ever increasing extent. The issue of fraudulent prescribing or manipulation of prescriptions has been highlighted in recent years in several National Board of Health and Welfare reports, for example "Over-subscribing of narcotic medicines – A review in three supervisory regions, "Prescribing of CNS-stimulating medicines in ADHD" and "Survey of drug-assisted treatment in opiate dependence". It is evident from cases previously handled by the agency in this area that the problem can be largely linked to the use of paper prescriptions. This applies in particular to the 'special prescription form', which is used for prescribing narcotics, among other medicines. Examples of manipulation are the dispensing label affixed to the prescription at the time of dispensing being torn off so that it looks as though the prescription has not been filled. It also happens that patients change the volume of prescribed medicines stated by the prescriber on the form. Another example is prescription forms being stolen or being offered for sale with the doctor's signature.

The proportion of paper prescriptions has steadily declined following the introduction of electronic prescriptions in Sweden, and today is only around ten per cent of all prescriptions issued. Most publicly funded doctors have access to e-prescriptions (both ordinary e-prescriptions and e-prescriptions for special medicines) through prescription modules in patient record systems. Doctors who do not have access to a medicines module- for example private doctors, have the option of using what is known as a prescription block online, with associated decision support. In 2014 it will also be possible for the online application Pascal primary care to be offered free of charge to prescribers who do not have a patient record system, or who do not have a medicines module in their patient record system.

In view of the fact that it is becoming ever easier to prescribe electronically, the Medical Products Agency will examine whether it is possible to reduce or phase out the use of printed prescription forms for special medicines. Increased electronic prescribing of these medicines would improve safety for patients and prescribers, as well as reducing leakage to misusers.

Work in 2014 and timetable

The Government intends to task the Medical Products Agency and the National Board of Health and Welfare with studying whether and how it is possible to reduce or completely phase out the use of printed prescription forms for special medicines. The aim is to reduce manipulation and forging of prescriptions and consequently improve safety for patients and prescribers.

2 Increase consensus and understanding of prescribed treatment

2.1. Create the necessary basis for effective medication reviews and medication reconciliation in healthcare transitions and evaluate the effect of these measures on compliance with prescribed treatment

Main responsibility: National Board of Health and Welfare (partly completed in 2012)

Developed under the Government initiative for the sickest elderly.

In view of the fact that the first element of the activity had been implemented, this part was omitted from the Action Plan 2013. The second element, "evaluate the effect of these measures", remains.

Objective

Inadequate consensus and understanding of prescribed treatment is a common problem today, particularly with regard to pharmaceutical treatment of the elderly. The deficiencies cause great suffering for care recipients and lead to costs in the healthcare system that could be avoided with more structured management of medication. Medication reviews and medication reconciliation can be effective tools in improving patient safety in long-term pharmaceutical treatment. Systematic medication reviews can, among other things, prevent care recipients, in particular elderly patients who are treated with several different drugs, taking medicines that are unsuitable for the elderly, interact adversely or give rise to side effects. It may also mean that patients become more involved in their treatment, resulting in better compliance and less discarding of medication.

Autumn 2013

On 1 September 2012 the National Board of Health and Welfare's revised regulations and general guidelines (SOSFS 2001:1) on medication reviews came into effect. Under the new regulations, a simple medication review is to be offered to all individuals over the age of 75 who are prescribed five or more medicines. Guidance on the relevant chapter of the regulations has since been published. Online training on medication reviews for the elderly was also launched on 1 October 2013. Whoever has carried out the training has to have knowledge of what is included in a simple medication review and in-depth medication review and how and when they are to be carried out.

Work in 2014 and timetable

The National Board of Health and Welfare is currently examining how it can develop ways of measuring and following up the effects of the measures mentioned above. The Board already measures the running total of medication reviews conducted for elderly patients over the age of 65 as an indicator for Open Comparisons and has started to develop this yardstick further and adapt it to the group aged 75 and over. Another option is to repeat the study "Elderly patients with regular medication – number of medicines as a risk marker", which can be regarded as a type of baseline measurement. Other types of follow-up are also being studied, such as the possibility of conducting user surveys.

2.2. Evaluate whether multi-dose services can contribute to greater compliance and improved patient safety and how the service can be used and refined (completed in 2013)

Main responsibility: Medical Products Agency

Developed under the Government initiative for the sickest elderly.

Objective

The service is used at present for multi-dose drug dispensing to around 185,000 individuals in Sweden. The total cost of medication for the individuals who use the service today is around SEK 2.1 billion. Multi-dose drug dispensing means that medication is packed in sachets containing the medicines to be taken on a single occasion. This service is used in particular by elderly people who are taking many medicines and may find it difficult to cope with different packs of medication.

Autumn 2013

The Medical Products Agency has investigated how multi-dose services work in Sweden and abroad. The remit was reported to the Ministry of Health and Social Affairs in February 2013. To summarise, the outcome of the investigation shows that there is some support for compliance with prescribing being improved with dose sachets.

The outcome with regard to patient safety is more complex as register studies indicate that the multi-dose service may mean that fewer changes are made to the prescribing of medicines. Patients and healthcare

professionals experience benefits in the form of reduced duplicate medication and simplified handling of medicines for affected patients. At the same time, a number of deficiencies and needs for improvement are identified.

A number of proposals for refining the multi-dose service have been made by many stakeholders during the course of the investigation, for instance on usability and impact on compliance and patient safety. This investigation has only addressed the system provided by Apoteket AB, i.e. ApoDos, as this has to date been the only system on the market. Now that the market is being opened up to more actors in the multi-dose market, the need for a basis for setting requirements and quality criteria for the service are increasing. The Medical Products Agency is therefore proposing that a broadly composed grouping of stakeholders and actors be established to agree on future quality criteria for use of the multi-dose service in a re-regulated market. Account should be taken in this work of the outcome of other ongoing activities, such as the Pharmaceutical and Pharmacy Inquiry (Terms of Reference S2011:07) and the Medical Products Agency's Government remit to draw up regulations aimed at making it possible to apply the rules for medical devices to IT support systems in healthcare.

The Medical Products Agency has evaluated whether multi-dose services can contribute to greater compliance and improved patient safety, and has submitted proposals on how this work should continue. This activity can therefore be concluded.

2.3. Carry out skill-enhancing training efforts for home help service staff

Main responsibility: Swedish Association of Local Authorities and Regions

Development of interactive online training targeted specifically at home help service staff on use of medication in elderly people.

Objective

Home help service staffs meet patients in their everyday lives in the home environment. Home help service staff can be given knowledge and increased understanding of the often complex care needs and medication-related problems of elderly patients/service users through continued training on the drug treatment of the elderly. They can consequently represent an even more important resource in the medical and social care of the ageing patient.

Autumn 2013

A preliminary study has been performed in 2013 to analyse and ascertain what need there is among home help service staff for skill-enhancing training in the area of the use of medicines. The analysis has been carried out in collaboration with pharmacists employed in county councils and R&D units. An inventory of needs has been compiled through questionnaires and in-depth interviews with medically responsible nurses (MAS) and heads of units in the municipalities. The outcome of the 2013 preliminary study forms the basis for decisions on the orientation of skill-enhancing training for home help service staff.

Work in 2014 and timetable

The target group of home help service staff will be broadened to cover both help service staff and care staff in special housing. The two groups of staff have similar needs for knowledge of medicines.

A project will be carried out under the 'agreement on the elderly' between November 2013 and December 2014. The objectives for the project are to:

- provide e-training for home help service staff in basic knowledge of medicines and interactive knowledge control,
- provide and collate existing knowledge and know-how based on used materials, methods and examples of best practice, and
- quality-assure training material, knowledge surveys, educational tips and make the material openly available on an electronic platform.

2.4. Develop labelling of pharmaceutical packs to reduce the risk of confusion (completed in 2013)

Main responsibility: Medical Products Agency

Work aimed at improving patient safety through the design of pharmaceutical packs which are used in emergency care and inpatient care and confusion between which poses serious risks to patient safety.

Objective

Alongside drug side effects, incorrect pharmaceutical treatment due to packs being confused accounts for a proportion of medication-related medical injuries. It is estimated that confusion between medicines leads to 6,000 medical injuries annually. Clearer and more uniform labelling can reduce the risk of confusion occurring. The Medical Products Agency is studying possible ways of improving the labelling of pharmaceutical packs with the aim of reducing the risk of confusion and incorrect use. The aim of the project is to find a functioning "template" for how best to design the labelling of pharmaceutical packs.

Status in autumn 2013

The Medical Products Agency and the Network for Patient Safety have developed documentation describing various parameters proposed for change on pharmaceutical packs in order to improve labelling and consequently also reduce the risk of confusion and incorrect use. The work has focused on inpatient medicines that have been particularly problematic from the point of view of confusion: electrolyte solutions and cephalosporins (antibiotics). A smaller digital pilot study has been carried out by Linnaeus University. Test procurement of safe packs will take place through the auspices of the county councils under the ELIS project (Efficiency Improvement of Drug Procurement in Collaboration). Work on specifying requirements for procurements has started. The procurement will take account of the new principles for the design of drug packaging drawn up by the Medical Products Agency and others.

In view of the fact that the Medical Products Agency has devised criteria for altered design of drug packaging used in acute medical care and inpatient care and where confusion may pose serious risks to safety, this activity can be concluded. Work on the test procurements and their evaluation is proceeding under activity 5.3, Assess the county councils' procurements of requisitioned medicines and how the process can be made more efficient.

The potential for improvement that exists for drug packaging other than that under discussion now must be pursued through long-term European cooperation. This work will, however, be carried out under the authority's basic remit and not as an activity in the NPS.

2.5. Indicators of good patient safety in pharmacies (new activity in 2013)

Main responsibility: National Board of Health and Welfare and Medical Products Agency

The development of pharmacy indicators to be used in the follow-up of pharmacys' activities.

Objective

Indicators make it possible to follow up activities in pharmacies and ensure that clients are offered good care, i.e. care that is knowledge-based, appropriate, safe, patient-focused, effective, equal and delivered within reasonable time.

Autumn 2013

The Government has instructed the National Board of Health and Welfare and the Medical Products Agency, in collaboration with the Swedish Pharmacy Association and the Swedish Association of Local Authorities and Regions, to develop national indicators for pharmacy operation that is safe for patients This work is to be based on the Swedish version of the WHO standard for Good Pharmacy Practice (GPP), which provides an foundation for pharmaceutical, quality-related and ethical issues.

The pharmacy indicators are to provide the general public with a basis on which to make comparisons of the quality and safety of different pharmacies. The indicators are to cover all pharmacy operations (multi-dose dispensing, hospital and community pharmacies).

An analysis based on a literature review, study visit and discussion with partners of relevance to the remit relating to indicators used in other countries is in progress. An interim report on this analysis was presented verbally at the Ministry of Health and Social Affairs on 8 November 2013.

Work in 2014

Work aimed at identifying relevant and appropriate indicators based on the analysis and discussions with the consultation partners will continue. A final report will be delivered to the Ministry of Health and Social Affairs by 19 June 2014.

2.6. Structured discussion of medication in pharmacy (new activity in 2013)

Main responsibility: Medical Products Agency

Implementation of trial activity with structured discussions on medication in pharmacies for a limited group of patients.

Objective

Poor compliance with prescriptions for medication causes unnecessary suffering among patients and costs society large amount of money. Deliberate non-compliance accounts for the largest share. The whole care chain needs to be involved in the work so that the patient receives the right medication and uses the medication in the right way. Various actions probably need to be combined to increase the involvement, knowledge and motivation of patients, such as medication reviews and motivating discussions in pharmacies. The expertise available at the pharmacy should be put to better use in this respect.

Autumn 2013

The Government initiated a trial with structured discussion of medication in pharmacies in 2013, with the Medical Products Agency having main responsibility and the Swedish Pharmacy Association and Swedish Medical Association as co-actors. The remit states that the trial is to be designed for a limited group of patients and be designed so that doctors refer patients for discussions on

medication and pharmacies provide feedback to referring doctors. An evaluation is to be made based on cost and benefit. The National Board of Health and Welfare regulations on medication reviews are to be respected when the project is planned.

The Medical Products Agency is due to submit a written final report on the remit to the Ministry of Health and Social Affairs by 15 December 2014. This final report is to contain an integrated assessment of the trial activity involving structured discussions on medication. Particular emphasis is to be put on patient benefit in relation to the cost of the activity. The Medical Products Agency's integrated assessment is also to address the need for amendments to existing legislation, in particular provisions on coherent keeping of records in the Patient Data Act (2008:355) as a result of expanded activity involving structured discussions on medication in pharmacies. This also includes clarifying the distribution of rules between the medical and pharmaceutical professions and the principles underpinning referral.

Analysis has been carried out and comprises a literature review and study visits to the United Kingdom, the Netherlands, Norway, Denmark and Sweden. In addition, consultative meetings have been held with 17 different actors of significance to implementation of the remit. A written interim report based on the analysis was delivered to the Ministry of Health and Social Affairs on 27 September 2013. This interim report summarises under what conditions it should be possible to achieve positive effects on compliance with prescribed treatment, such as skilled staff, time and resources for the pharmacies to offer the service, space set aside at the pharmacy where the discussions can take place and cooperation between prescribers and pharmacies.

Work in 2014 and timetable

Based on the analysis, a pilot project will be designed with the aim of testing the usability and feasibility of a model for initiating, implementing and following up structured discussions in Swedish community pharmacies. The final report is expected to be ready in December 2014.

3 Develop knowledge about and guidelines for medicines and the use of medicines for those patients in whom this is most neglected

3.1. Draw up national guidelines on how elderly and multimorbid patients are to be treated (completed in 2012)

Main responsibility: National Board of Health and Welfare

In view of the fact that national guidelines on how elderly and multimorbid patients are to be treated and guidance on application of these guidelines have been drawn up, this activity was omitted from the action plan for 2013.

3.2. Expand knowledge of paediatric medicines and their use

Main responsibility: Medical Products Agency

Increase knowledge of paediatric medicines and foster safer handling of medicines in paediatric care. Implementation of a preliminary study that includes analysis of existing guidelines (national and international) and studies in the area. The preliminary study is also to contain an inventory of further special national guidelines to be developed for children.

Objective

A Swedish study in 2008 on prescriptions for children in hospital showed that children received an average of 3.8 prescriptions for medication each. Almost half of all prescribing was made up of medicines insufficiently documented for children. Newborn infants, in particular premature infants, and young children were the age group receiving the highest proportion of prescriptions of insufficiently documented medication (70%) The work is aimed at increasing knowledge on medication for children and its use in the long term and on a broad front and at fostering safer handling of medication in paediatric medicine.

Autumn 2013

The work on the Government remit "Expand knowledge of paediatric medicines and their use" is progressing in accordance with the programme proposal drawn up.

Work in 2014 and timetable

The Medical Products Agency has held a meeting on orphan medicines focused on unequal pharmaceutical treatment in rare diseases. Discussions are taking place in the run-up to 2014 with paediatricians on continued work with orphan medicines, which should cover both reduced geographical inequality with regard to access to treatment and improved follow-up of efficacy and safety in the treatment of certain rare diseases.

As a result of the collaboration between child and adolescent psychiatry, two further expert meetings are planned in 2014 to draw up treatment recommendations in the area of mental ill-health. Adolescents' need for safe and effective contraception will be elucidated at an expert meeting as part of treatment recommendations for contraception.

By gathering and analysing questions concerning the use of medication by children, put by the general public to the Public Medicines Information (Läkemedelsupplysningen), the Medicinal Products Agency intends to shed light on carers' concerns and uncertainties on medicines for children in a consumer perspective. A report is planned during the spring of 2014.

A baseline study of reports of drug side effects in children to the Medical Products Agency has been carried out and will form the basis for efforts to raise the level of drug safety in children. Work is also in progress on compiling a national drug safety report from the Medical Products Agency in which the paediatric perspective on side effects will be highlighted.

Paediatric medicine has special needs for prescribing support. Work is under way in the Medical Products Agency aimed at drawing up statutory instruments for prescribing support. Such statutory instruments are to clarify, for example, ownership, quality assurance and administration. To enable these to be applied as well as possible, guidelines should probably be drawn up in collaboration with the health service.

The Medical Products Agency is also taking part in the development of national and Nordic networks and to support clinical research concerning medicines for children.

3.3. Strengthen doctors' knowledge of medicines and use of medicines during specialist training in medication-intensive specialties

Main responsibility: National Board of Health and Welfare

Develop a concept for basic specialist courses (SK courses) for doctors undergoing specialist training focused on medicines and use of medicines.

Objective

One reason why medical injury occurs in the healthcare system is incorrect use of medicines. Crucial knowledge of medicines and use of medicines is lacking today among several professional groups in health and medical care. For patient safety reasons it is therefore important to endeavour to ensure a safer prescribing process. The initiative for SK courses is aimed at developing knowledge on medicines and use of medicines for groups of patients in which this is most neglected. To support continued training for doctors in order to improve doctors' knowledge of medicines and use of medicines.

This activity is part of a greater initiative and is included in the remit of the National Board of Health and Welfare to arrange basic specialist courses (SK courses), for which IPULS was formerly responsible, from 2013 onwards.

Status in autumn 2013

During the spring of 2013 medication-related skills targets transcending specialties, aimed at all the specialties were identified by the expert group. The expert

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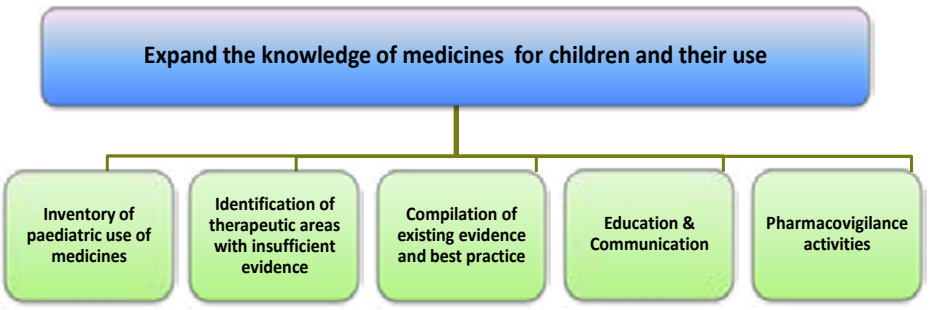

group based its identification on the analysis of needs made with four focus groups: patients, pharmacists, nurses and licensed doctor undergoing specialist medical training (ST) and specialists. These skill targets transcending specialists have since been discussed by three reference groups: the ST Council, the Medical Products Agency and the Swedish Junior Doctors' Association (SYLF). In the autumn of 2013 the project is conducting a view of the skill targets, which is then to be quality-audited by various groups and experts.

Cooperation is taking place during the autumn of 2013 with the project Course subjects during ST to develop skill targets in medicines specific to different specialties. The expert group of each specialty compiles specific skill targets related to the area of medicines. A summary of this work is expected to be ready in February 2014. Based on this summary it is to be identified whether there is a need to work in more detail on certain specialties.

To optimise cost-effectiveness and time-effectiveness, collaboration will as far as possible take place with internal and external products and with authorities, organisations and other training actors related to medicines (for example item 3.4 in the National Pharmaceutical Strategy: Online training for intern pre-registration physicians on pharmaceutical treatment of the elderly and 3.2: Expand knowledge of paediatric medicines and their use).

Work in 2014 and timetable

Work is continuing according to the project planning and in 2014 will led to:

1. completion of the specialty-specific skill targets in medicines and compilation of an inventory of existing training efforts meeting these targets and
2. preparation of training efforts meeting the specialty-transcending and specialty-specific skill targets in medicines. This many mean procurement of existing training efforts, development of factual knowledge, increased use of decision support in healthcare and developing an approach and conduct in relation to pharmaceutical issues.

3.4. Development web-based continuing professional development module to strengthen the knowledge of intern pre-registration physicians (AT-läkare) on the elderly and medicines (new activity in 2013)

Main responsibility: National Board of Health and Welfare

The Government intends to instruct the National Board of Health and Welfare to initiate a preliminary study on what needs to be done to strengthen knowledge among intern pre-registration physicians (AT-läkare) of medicines and use of medicines among the elderly through an online continuing training module. The remit includes presenting proposals for content, training goals and timetable for the launch of various parts of the training.

Objective

The prescribing of medicines to individuals over the age of 75 has increased by nearly 70% over the past 20 years. Several studies have shown that irrational and potentially unsuitable treatment occurs with certain medicines, for instance antipsychotics, anticholinergics, long-acting sedatives and hypnotics. Ignorance of the special considerations that are needed in the pharmaceutical treatment of elderly patients is one reason why unsuitable treatment occurs. The National Board of Health and Welfare report Indicators of Good Drug Therapy in the Elderly describes the problems caused by incorrect use of medicines, including impaired cognitive capacity and increased risk of falls. Up to 30% of acute admissions of elderly people to hospitals today are due to the extensive use of medicines and the side effects these cause in the elderly. To reduce the incidence of medication-related medical injuries, it is crucial to increase and spread knowledge of the use of medication in the elderly.

Status in autumn 2013

The National Board of Health and Welfare, together with experts and on the basis of evidence, is developing the content and methodology of continuing training in accordance with the needs of the target group and is analysing recipient structures in the county councils (existing platforms for e-learning modules). The training is divided into modules successively launched in 2013 and 2014.

The authority reported the results of the preliminary study conducted under the remit in June 2013. The Board proposes four overarching areas of skill targets in the online training for intern pre-registration physicians on drug treatment of the elderly. These areas are:

- the responsibility of the doctor,
- clinical pharmacology focused on elderly patients,
- communication and documentation and
- decision support and information sources.

The Board further proposes that the online training for intern pre-registration doctors should be based on patient cases and structured so that it follows the division of pre-registration internship into blocks, i.e. that the selection of patient cases in training should relate to internal medicine, general medicine, psychiatry and surgical specialties. In addition patient cases, the training should offer theoretical specialisation corresponding to identified skill targets and opportunities for self-testing. The National Board of Health and Welfare

intends in the autumn of 2013 to start expanding the training model related to the internal medicine block.

During the autumn discussion with the county councils will also be extended to how the online training is to be published, through the county councils' own teaching platforms or through a central platform. The National Board of Health and Welfare is due to submit a report to the Ministry of Health and Social Affairs in December 2013. The final report is to contain the first of several envisaged training modules but also an implementation and administration plan. These are to include:

- a timetable for launching remaining training modules,
- a cost analysis for operation and administration and
- a plan for follow-up, evaluation and updating.

Work in 2014 and timetable

In the spring of 2014 the National Board of Health and Welfare is to evaluate the first training module in cooperation with several pilot county councils and develop remaining training modules based on the results of the evaluation. Another three online continuing training modules are due to be completed in 2014. The modules are being launched in pilot county councils for broad launch in the autumn of 2014. Continued discussions are being held together with responsible organisations and authorities on operation and updating (administration) of the online training in the short and long terms.

3.5. Knowledge support in drug prescribing for children (new activity in 2014)

Main responsibility: Swedish Association of Local Authorities and Regions

Objective

Half of all medicines given to children in hospitals are off-label, i.e. they are not approved for children. This means that there is a lack of adequate information in the approval of the medicine for paediatric dosage, suitable methods of administration for children and what side effects and effects they have when given to children. The fact that the medicines concerned are not approved for children does not, however, mean that there is no information at all about them. Experience-based knowledge of the pharmaceutical treatment of children exists in the medical profession, in international literature, international databases and information portals. This knowledge has been gathered together for a few years in a database, ePed, at the Astrid Lindgren Children's Hospital. This database is used as administrative support in generating instructions on paediatric medicines. Paediatric hospitals can then share their local instructions through a web server, including those generated by ePed, to jointly arrive at best practice. The purpose of the data is for children to receive safe and effective pharmacotherapy.

Work in 2014 and timetable

Between January and June 2014 SALAR through CeHis, in collaboration with the Medical Products Agency and the National Board of Health and Welfare, is to carry out a preliminary study to investigate the prospects for national information and instruction support for pharmacotherapy for children and present proposals for necessary conditions and an organisational structure to make available and administer such a source of knowledge for all the county councils. This preliminary study is to include evaluating and reviewing the ePed database at the Astrid Lindgren Children's Hospital any other existing knowledge sources that could be used for this purpose. It is also to include an investigation into opportunities for development, administration, responsibility and follow-up. The functionality and administration of the database in relation to other sources of knowledge are also to be assessed. The work also encompasses proposing how the information in the database is to be made available via patient record systems and as a separate web solution. The preliminary study is to be carried out as a project with an interdisciplinary project group comprising people with operational, computational, technical and legal expertise.

4 Reduce development and spread of antibiotic resistance through a combination of local and global actions

4.1. Continue to foster rational use of antibiotics and reduced antibiotic resistance nationally and develop cooperation between all actors concerned

Main responsibility: Ministry of Health and Social Affairs

Continuing efforts in the area are necessary for the relatively good situation with regard to resistance in Sweden not to worsen. In addition, cooperation between all affected sectors needs to be developed, for instance, between the human and veterinary sides.

Objective

According to the European Centre for Disease Prevention and Control (ECDC) around 25 000 people die every year in Europe because of infections with resistant bacteria. Compared with many other countries in Europe, the antibiotic resistance situation in Sweden is good. Unless changes take place at the European and global levels, the threat may, however, become great for all countries. To improve patient safety, the Government has signed an agreement with the Swedish Association of Local Authorities and Regions on a performance-based payment model aimed at leading to more restrained use of antibiotics.

Status in autumn 2013

The work taking place under the 2013 Government and SALAR patient safety agreement is continuing. The follow-up of the agreement by the Swedish Institute for Infectious Disease Control shows that all the county councils reduced their prescribing of antibiotics over the period from 1 October 2012 to 30 September 2013 compared with the previous survey period. Altogether, prescribing has decreased by nine per cent across the country as a whole. In addition, all the county councils have worked towards increased compliance with local treatment recommendations and have attained the target of at least 50% of care units in primary care having provided their prescribers with an overview of their personal prescribing of antibiotics.

The Swedish Institute for Infectious Disease Control has been tasked with developing, testing and validating a model for health-economic calculations regarding antibiotic resistance to make it easier to assess the consequences for society in the form of morbidity, mortality and expenditure. An interim report concerning an enhanced calculation model was presented to the Ministry of Health and Social Affairs on 31 October 2013.

The Swedish Institute for Infectious Disease Control has reported several Government remits during the year. In the report "National communication initiative – antibiotics", the Swedish Institute for Infectious Disease Control proposes a national communication concept extending several years into the future and aimed at doctors, patients and the general public at various meeting places and in various formats. This report is under discussion at the Government Offices. In addition, the Swedish Institute for Infectious Disease Control and the Medical Products Agency have worked on the development of treatment recommendations for common infections in primary care.

The remit of the National Board of Health and Welfare and the Swedish Board of Agriculture to coordinate efforts against antibiotic resistance and healthcare-related infections, develop a cross-cutting action plan and an overarching communication strategy is proceeding according to plan.

Work in 2014 and timetable

The patient safety initiative is multi-annual and continues until 2014. The National Board of Health and Welfare's remit to develop a national collaborative function and action plan runs until 2017. The Public Health Agency of Sweden and the Medical Products Agency intend to take the initiative for an analysis of trade in antibiotics that takes place without prescription on the Internet. Who buys online, to what extent and what products are bought are some of the issues that should be investigated. The next step is to adopt a position on how any problems are to be addressed.

4.2. Promote an action plan for the development of antibiotics at EU level

Main responsibility: Ministry of Health and Social Affairs

Efforts made in this area must be set in a European and global context as the problem of resistance cannot be solved nationally. Sweden must therefore press for all EU Member States to take the measures necessary for the resistance situation to improve, both within the EU and globally. Unless changes take place at the European and global levels, the threat may become severe for all

countries. Sweden primarily prioritises efforts at EU level that involve incentives for the development of new and effective antibiotics.

Objective

Sweden is to press for the Member States of the EU and the European Commission to take measures to encourage the development of new and effective antibiotics, of both a regulatory and financial nature. Sweden is to lend particularly active support to the Commission in work towards developing a framework with industry that defines purpose, undertakings, priorities and types of activity for public-private partnership in the long term. In addition, Sweden is to actively support the work of the Commission on mobilising resources, within the framework of the Innovative Medicines Initiative with the aim of supporting research and development on antibiotic resistance. Through the work in Joint Programming – "The microbial challenge – a new threat to human health", Sweden is also to foster cooperation between the Member States in this area.

Sweden is to press in particular for a strategy to be devised at EU level on how a framework for a new global/regional/national system could be designed with regard to controlled distribution and use (CDU) of new future antibiotics.

Status in autumn 2013

ReAct has been tasked with continuing with working with the EU to lay the foundation for new systems for controlled distribution and use of new antibiotics.

Those affected are continuing to actively monitor the area and influence the European Commission to take measures under its action programme. There is continuous cooperation with the Ministry for Rural Affairs to follow up what measures are taken in the veterinary field under the Commission's action plan.

Work in 2014 and timetable

Work is taking place internally in the Government Offices to ensure long-term international work on these issues. Work with the EU will continue in 2014. This work includes reviewing how the role of the new Public Health Agency of Sweden in the area can be developed.

4.3. Promote increased efforts towards rational use of antibiotics and reduced antibiotic resistance globally

Main responsibility: Ministry of Health and Social Affairs

Efforts made in this area must be set in a European and global context as the problem of resistance cannot be solved nationally. Sweden must therefore act at the global level to ensure that improvements are attained in the area. The Swedish priority is primarily for WHO to shoulder global leadership with a view to achieving rational use of antibiotics. Particular priority is given in the bilateral cooperation to work with India and China, which is carried out by the Swedish Institute for Infectious Disease Control.

Objective

Sweden is to press for WHO to draw up a plan for work on antibiotic resistance that includes an appropriate organisational structure and distribution of responsibilities. Since 2012 Sweden has had an expert in antibiotic resistance seconded to WHO in Geneva as part of the prioritisation of this area.

Status in autumn 2013

ReAct has been tasked with continuing work on activities linked to the Government's global strategy for efforts to control antibiotic resistance in accordance with the Government's WHO strategy.

In May 2013 Sweden, together with the United Kingdom, organised a seminar on antibiotic resistance as a side-event to the World Health Assembly (WHA). The event was attended by the Minister for Health and Social Affairs Göran Hägglund, the Director-General of the National Board of Health and Welfare Lars-Erik Holm and the Chief Medical Officer of the United Kingdom Dame Sally Davies, as well as representatives of WHO and some other countries. The event attracted a large attendance and become the catalyst for continued initiatives in WHO. The issue will addressed at the WHO Executive Board meeting in Geneva as preparation for discussion at WHA 2014.

As a result of the event, Sweden now cooperates actively with the United Kingdom on issues concerning antibiotic resistance.

The cooperation with India and China is continuing.

Work in 2014 and timetable

Work is taking place at the Government Offices to ensure long-term international work on the issues. Sweden intends to continue lobbying WHO. Sweden will cooperate with other countries to develop a strategy for how the issue is to be addressed at the WHO Executive Board meeting in January 2014 and then at WHA in May 2014. A number of activities may become topical, such as high-level meetings with representatives of WHO and other bilateral and multilateral meetings. The special cooperation with the United Kingdom will continue. Bilateral cooperation with China and India is also continuing.

4.4. Develop the local Strama groups (the Swedish strategic programme against antibiotic resistance) in the county councils (completed in 2012)

Main responsibility: County councils

All the county councils have fulfilled the Patient Safety Agreement with regard to the Strama groups. This remit has thus been completed and was therefore omitted from the action plan for 2013.

4.5. Introduce performance-based payment for reduced prescribing of antibiotics through greater compliance with treatment recommendations

Main responsibility: County councils

Developed under the Patient Safety Agreement.

Objective

Sweden is among the countries with the lowest consumption of antibiotics and the lowest incidence of resistance. However, the general situation regarding the spread of resistance is steadily worsening. However, a steady deterioration is taking place in the general situation regarding the development of resistance. The initiative includes measures to reduce the prescribing of antibiotics and consequently the development of resistance in the country. Performance-based payments are made to those county councils that reduce their prescribing of antibiotics in accordance with the agreement.

Status in autumn 2013

All the county councils are now reducing their prescribing of antibiotics, and prescribing declined for the country as a whole by 9% over the survey period from 1 October 2012 to 30 September 2013 compared with the previous period. All but four of the county councils reduced heir prescribing by more than 5% over the period. In addition, all the county councils have worked towards increased compliance with local treatment recommendations and have attained the target of at least 50% of care units in primary care having provided their prescribers with an overview of their personal prescribing of antibiotics.

Work in 2014 and timetable

The patient safety initiative is multi-annual and continues until 2014.

4.6. Carry out studies for optimal utilisation of existing antibiotics (new activity in 2014)

Main responsibility: Public Health Agency of Sweden

We find ourselves in a situation where access to new antibiotics is very limited, while demand is continuing to increase. Initiatives have been taken at EU level to support the development of new antibiotics. However, it takes a long time to develop antibiotics with new mechanisms of action. Doctors are increasingly often forced to use existing antibiotics in diagnoses for which they have not been tested. It is therefore extremely important to identify and test in a structured way all the options for new uses for those antibiotics that are already in use.

Objective

Carry out studies to identify how use of existing antibiotics can be optimised in order to preserve the possibility of effective treatment with antibiotics. New knowledge from pharmacodynamic experimental in vitro studies have shown that combinations of antibiotics may be effective against multiresistant bacteria despite the products each alone lacking efficacy. Certain older antibiotic substances against which low resistance development has taken place are now used for infections despite there being no studies or trials for their use.

The length of the period of treatment can probably be reduced for some diagnoses. New knowledge therefore needs to be obtained to rationalise and quality-assure the use of antibiotics in the treatment of common infections and to find effective treatment for critically ill patients with difficult-to-treat infections caused by multiresistant bacteria. New indications for old preparations and opportunities for new dosage regimens and combination treatments must be studied to identify new treatment alternatives.

Status in autumn 2013

The Swedish Institute for Infectious Disease Control (from 1 January 2014 the Public Health Agency of Sweden) has a remit to work towards preserving the possibility of using antibiotics effectively in bacterial infections. An important strategy to attain this is to counteract increasing antibiotic resistance through rational use of existing antibiotics in the treatment of infectious diseases. This also includes identifying and optimising any new uses for existing antibiotics.

Work in 2014 and timetable

The Public Health Agency of Sweden has been given responsibility for evaluating existing antibiotics from new angles to study whether further efficacy can be obtained from them and optimised so that the possibility of effective treatment with antibiotics is preserved. In collaboration with the county councils, SALAR and if appropriate other affected actors, it is intended that proposals will be formulated for ways of coordinating and implementing studies. This includes both primary care and inpatient care and research institutions.

5 Develop a long-term sustainable pricing, prioritisation and financing model for all medicines

5.1. Review pricing and handling of original medicines without generic competition etc.

Main responsibility: Ministry of Health and Social Affairs

On 16 June 2011 the Government adopted terms of reference for an inquiry which is to review certain issues of pricing, availability and market conditions in the area of medicines and pharmacies (the Pharmaceutical and Pharmacy Inquiry (S 2011:07). On 22 September 2011 the Government decided to give the inquiry additional terms of reference under which the inquiry is to carry out a review of original medicines without generic competition and propose a long-term sustainable pricing model.

Objective

The purpose of the review to assess ways of developing the pricing of original medicines without competition in the pharmaceutical benefits scheme and propose a long-term sustainable model for this group of medicines. The proposed model is to be able to address the growing challenges in the area of medicines and is also to be able to correct high prices for certain groups of original medicines without generic competition. A basic requirement for a future pricing model is that it should create the necessary basis for good cost control and that prices of medicines in Sweden should be below or on a par with prices in other comparable countries, such as Norway, the United Kingdom and Denmark. A future pricing model is also to ensure good access to effective medicines that create the necessary basis for modern healthcare and comply with Section 2 of the Health and Medical Services Act on the goals of health and medical services. This necessitates the research-based pharmaceutical industry also continuing to be well placed to research and develop new medicines.

Status in autumn 2013

The remit was reported in October 2012 in the form of the interim report Price, access, service – continued development of the pharmaceutical and pharmacy market (SOU 2012:75). Work on drawing up a proposal to be referred to the Council on Legislation has begun.

Work in 2014 and timetable

It is planned that a Government Bill will be presented to the Government in the spring of 2014.

5.2. Investigate long-term handling of primary-care medicines not included in the pharmaceutical benefits scheme

Main responsibility: Swedish Association of Local Authorities and Regions and Swedish eHealth Agency

Preparation of procedures so that county councils, in exceptional cases, can supply medicines not included in the pharmaceutical benefits scheme to a defined group of patients where the treatment is clearly cost-effective. The county councils and Apotekens Service AB are together developing a long-term solution for handling invoicing and statistics files relating to the county councils' payment for medicines not included in the pharmaceutical benefits scheme.

Objective

The county councils subsidise medicines in primary care outside ordinary invoicing procedures for the pharmaceutical benefits scheme. Examples of these are contraceptives for young people, medicines protecting against infection and medicines for certain patients in psychiatry. However, antiinfectives account for vast majority. This may also involve medicines which are not covered by the pharmaceutical benefits scheme but which the county councils for various reasons may wish to subsidise at individual or group level. The procedure is administratively extensive both for county councils and for pharmacy actors, and modified routines are needed, for instance for improved follow-up.

Status in autumn 2013

There is a common target scenario today of being able to handle all costs of primary-care medicines wholly or partially paid for by the county councils through a single common procedure. The technical conditions to be met to enable the county councils' handling of reimbursement costs for primary-care medicines outside the pharmaceutical benefits scheme to e integrated with the handling of costs within the benefits scheme are being investigated by Apotekens Service AB, but it has not been possible to prioritise them.

The interim solution for pharmacy actors and county councils agreed upon by SALAR and the Swedish Pharmacy Association does not work optimally. The solution is based on the pharmacy actors voluntarily supplying sales statistics to a server at Apotekens Service AB, from

where the county council concerned can download them. There is no functioning way at present of ensuing that the statistics are supplied and how large any losses of data are. SALAR has therefore discontinued the procedure with effect from 2014.

Work in 2014 and timetable

The Pharmaceutical and Pharmacy Inquiry has been given a remit to review certain issues concerning antiinfectives. It is noted in the terms of reference that the statistics describing the costs of the pharmaceutical benefits scheme do not include the costs of antiinfectives, which makes it difficult to obtain a coherent picture of the costs to society of medicines issued on prescription. In view of this situation, the inquiry has been tasked with presenting proposals for how the public institutions can obtain a coherent picture of the costs to society of prescription medicines. Managing the payment flows for different types of reimbursement in the pharmaceutical area in a standardised way offers many advantages. In light of the conclusions reached by the inquiry, there may be grounds for analysing whether other medicines, for examples medicines with county council reimbursement and medicines for asylum-seekers, could be managed in a similar way.

5.3. Assess the county councils' procurements of requisitioned medicines and how the process can be made more efficient

Main responsibility: Swedish Association of Local Authorities and Regions

Investigation of limits within which the county councils can procure hospital medicines and how the process can be made more efficient.

Objective

County councils and regions have long experience of procuring medicines and already cooperate in the area today. Experience shows that increased coordination, either through regular joint procurement under the Public Procurement Act or through other strategic cooperation, can result in lower costs in use. The overarching aim through further collaboration is to bring about greater benefit for patients and the public. An opportunity is provided through exchange of experience, information and knowledge, the development of joint support functions (e.g. a price database), joint specification of requirements and combined medical, pharmaceutical and procurement law expertise, to assess and test different forms of procurement, to define what products are suitable for joint procurement and which are best procured locally or regionally.

Status in autumn 2013

Sub-project ELIS/Procurement: The intention in this sub-project has been to test, learn and gain experience of coordinated procurement, and the selection of procurement areas has been based on this perspective. Procurement is in progress for vaccines in the national childhood vaccination programme as well as cephalosporins and electrolytes in non-confusable packs. Framework contracts in these two procurements are planned in 2013. Preparation is in progress for procurement number two of childhood vaccines, radiological contrast agents and cytostatic drugs.

Sub-project ELIS/Price database: The price database for medicines is read and is being implemented in the SALAR computer environment with administrative and service contracts.

Sub-project ELIS/Negotiation: The sub-project has the overarching aim of proposing how common, possible and effective strategies for negotiation and drawing up collaboration contracts can be implemented. The sub-project has been divided into two parts. Part I is mainly concerned with surveying, description of the current situation and analysis/follow-up of the activities that county councils have carried out and plan to carry out. Part II is concerned with horizon scanning and proposals for forms of collaboration for a future county council-side strategy on negotiation and collaboration agreements with regard to conditions for the use of medicines.

Work in 2014 and timetable

No decisions have been taken on the county councils' continued cooperation in 2014 with efficiency improvement in drug procurements. The intention is, however, to further enhance this cooperation. Several of the proposals from the ELIS project are close or depend on county council-wide processes, which means that a combined assessment needs to be made in which account is taken of development in the area concerned.

5.4. Carry out trial activity where the Dental and Pharmaceutical Benefits Agency assesses selected inpatient medicines

Main responsibility: Dental and Pharmaceutical Benefits Agency

The Dental and Pharmaceutical Benefits Agency (TLV) is carrying out trial activity for two years in which it is assessing the cost-effectiveness of selected inpatient medicines under a special government remit.

Objective

The purpose of the health-economic assessments includes:

- a better basis for clinical decisions and procurement of medicines
- better utilisation of existing resources for appraisal of knowledge by the assessments being made by a national agency and not by all the responsible authorities.

Status in autumn 2013

TLV has so far completed ten knowledge bases during the year and plans to complete a total of around 10–13 knowledge bases in 2013. Collaboration with the project's stakeholders is continuing. The Swedish Agency for Health and Care Services Analysis evaluated the project during the spring and presented a first interim report in August 2013. TLV presented the Agency's combined experiences and assessments in an interim report in September 2013.

Work in 2014 and timetable

The clinical medicines project has been extended to December 2014. The Swedish Agency for Health and Care Services Analysis is due to present its final report on its remit on 30 April 2014. TLV's development activity includes the views of the Swedish Agency for Health and Care Services Analysis, more highly developed and close cooperation with the county councils and giving the county councils fast and usable data for decisions in the procurement of clinical medicines.

6 Establish a process for orderly and effective introduction and expand follow-up of the use and effects of medicines

6.1. Establish a process between authorities, county councils and industry on the managed introduction of new medicines

Main responsibility: Swedish Association of Local Authorities and Regions

Establishment of a process between authorities, county councils and industry concerning managed introduction, including horizon scanning and forecasting the information on decisions on authorisation, subsidisation and national guidelines, communication and dialogue with medical experts and prescribers concerned.

This is based on previous experience introduction in the county councils.

Objective

Introduction of a new medicine and the time until it is used can be unnecessarily long today. In addition, use may become uneven across the country and follow-up may be deficient. The goal is structured introduction of new medicines with coordinated decisions from affected actors. In the case of primary-care medicines, there should be a decision on whether they are included in the pharmaceutical benefits scheme within a very short time after marketing authorisation. There should be a health-economic assessment for inpatient medicines. There should also be a decision by the county councils that the medicine is to be used, together with guidelines on how it is to be used as well as its price – which may necessitate negotiation or procurement, depending on the medicine concerned. There should also be a plan for follow-up and tools for this. To attain this there is a need for significant coordination between actors and for it to be possible for the processes to be integrated and started before a medicine has been formally authorised. If these goals are to be attained, changes to various statutory instruments are needed.

Status in autumn 2013

To carry out activity 6.1, the project managed introduction in collaboration (OtIS) was set up in 2013.

Since the project started in the spring, two steering group meetings, three project group meetings and 15 project secretariat meetings have been held. A county council representatives group has been appointed in which all the county councils are represented. The representatives are tasked with providing feedback on the work of the project and acting as ambassadors for the project in their own county councils. Two workshops have been carried out with this group. Individual meetings have been held with selected directors of healthcare services and all the county council representatives to analyse local structures and needs.

Various working groups in the project are now working on specific sub-projects: horizon scanning, generic introduction process, the "NLT group" (new drug

therapies) of the future, ethics, law, follow-up etc., which are being presented during the autumn. The project intends during the autumn to present and, it is hoped, gain acceptance for and start a new "NLT group" to deal with both medicinal products and medical devices. The organisation relating to this is further based partly on the work done under NPS 5.3 and the sub-project of negotiation within the ELIS project.

Meetings have been held under OtIS with NPS 6.2, the Ministry of Health and Social Affairs, the Swedish Pharmacy Association and Swedish Association of the Pharmaceutical Industry (LIF). On 29 May a first meeting was held in the Forum for Horizon Scanning, with representatives of authorities, county councils and industry. Another meeting of this forum will be held during the project period. Representatives of the project have also taken part in public meetings and debates, for instance in Almedalen. A study trip to the Scottish Medicines Consortium (SMC) in Scotland has been made with directors of healthcare services and representatives of the project group. During the autumn, in addition to meetings in the project organisation an ethics seminar on orphan medicines is planned together with the Swedish National Council on Medical Ethics (SMER) and a number of eminent individuals at various public meetings, for example an IHE seminar, the prioritisation conference and the Annual Meeting of the Swedish Medical Association.

OtIS has, among other things:

- drawn up proposals for a combined generic process for managed introduction in collaboration with the county councils,
- reviewed the existing process for horizon scanning and added clearer formers of communication with the county councils in conjunction with the preparation of assessment reports and drafted proposals for a process for identifying medicines relevant for nationally organised introduction,
- devised criteria for the selection of and selected pilot medicines,
- devised proposals for generic introduction and follow-up protocol,
- investigated and worked on proposals for a new NT/NLT function,
- proposed an order of priority for the preparation of health-economic documentation,
- drawn up documentation for a common communication platform for the project and
- assisted with and presented the project in a number of contexts.

Work in 2014 and timetable

The OTIS project is still at an initial stage and needs to be extended to enable it to start being applied in everyday clinical practice in the county councils. The project also needs to be linked more clearly than today with the work in progress with regard to access to individual data for requisitioned medicines. A balance is to be aimed for in this work between national need and operational benefit. SALAR is also be responsible for work on the organisational structures being developed and improved, in collaboration with the county councils. This may, for example mean that work on managed introduction has to be coordinated with the county council-wide work taking place in the area of negotiation. The procurements and follow-ups forming part of this work are to be included. Work on the organisational structures also includes SALAR, together with the county councils, having to develop the collaboration that has been initiated by TLV.

The project endeavours to be able to meet the following overarching objectives at the end of 2014:

1. An online communication platform is to be in place. The purpose of the platform is to support information on managed introduction to different target groups.
2. The pilot project that has been started is to be developed with respect to follow-up of introduction in the county councils. Experience on follow-up from activity 6.2, managed introduction, in the NPS is to be evaluated and implemented under the joint process for managed introduction.
3. At least three pharmaceutical substances are to be tested in live operation in the national introductory process in 2014. In collaboration with CeHis/Inera, the project is to promote planning for follow-up of the new pharmaceutical substances covering use of medicines in both primary and inpatient care.

6.2. Develop national model for development of introduction protocol and introduce coordinated assessment of medicines in clinical reality (completed in 2013)

Main responsibility: Medical Products Agency

The original objective was implementation of pilot projects in which an introduction protocol for selected medicines is designed making it possible to systematically study what effects and side effects the new medicine has in everyday clinical practice and to what extent approved indications, decisions by the Dental and Pharmaceutical Benefits Agency on limited reimbursement and the recommendations of the pharmaceutical committees are followed. With experience from the pilot projects, more general conclusions and recommendations for the design of an introduction protocol and coordinated follow-up of newly introduced medicines are developed.

Objective

In the spring of 2013 the Medical Products Agency was given a changed remit, as follows.

"The Medical Products Agency is to evaluate the ongoing pilot projects in which various models for introduction and follow-up are applied with the aim of systematically studying effects and side effects of medicines in everyday clinical practice. The Medical Products Agency is also to identify and evaluate projects in which various models for follow-up are applied in the following areas:

- medicines and limitation of benefits,
- orphan medicines and
- at least one medicine that can be followed via quality registers".

Under the evaluation, the Medical Products Agency is also to study the extent to which compliance with the approved indication, decisions on limited reimbursement from TLV and the recommendations of the pharmaceutical committees can be followed up. The evaluation includes developing general conclusions and recommendations for the design of an introduction protocol and coordinated follow-up of newly introduced medicines.

The appropriation directions also stipulate that final reporting on the remit is to be presented to the Ministry of Health and Social Affairs on 15 November 2013.

Status in autumn 2013

In the light of the Government remit, the projects have revised their planning.

The pilot projects concerned submitted further data during the spring, and analysis of the data is currently in progress. A contract for a cost-benefit analysis of the different variants of managed introduction and structured follow-up represented in 6.2 has been signed with Karolinska Institutet. There is also agreement with NEPI Network for Pharmaceutical Epidemiology to produce data on the degree of compliance with various decisions and recommendations.

The project continuously collaborates with 6.1, for instance through participation in working groups and steering committees.

The project ends on 15 November 2013. Some supplementary data may be added. A follow-up activity in the form of a symposium at the National Convention of the Swedish Society of Medicine is planned for 5 December 2013.

6.3. Improve follow-up of pharmaceutical dosing

Main responsibility: Swedish eHealth Agency

Making available of data on dosage and dosing intervals in numeric form or as a "prescribed daily dose" (PDD) calculated by Apotekens Service AB. This item also includes integration of information on dosage into the quantity of information supplied to the National Board of Health and Welfare and the county councils in the monthly transfer of data.

Objective

The overarching aim in adding dosage and dosing intervals in numeric form or a prescribed daily dose (PDD) calculated by Apotekens Service AB to the data supplied to the National Board of Health and Welfare and the county councils is to improve the quality of drug prescribing and prescribing.

Status in autumn 2013

A meeting was held on 8 April 2013 with representatives of Apotekens Service AB, the National Board of Health and Welfare and the Ministry of Health and Social Affairs. It was noted at the meeting that PDD should ideally be calculated on the basis of a structured dosage, i.e. that information on drug dosing is always transferred according to a defined structured pattern. This would facilitate automated treatment in several respects, and generally represent a major advance in quality. Despite the question of structured dosing having been known for a long time, it has not come about. Those present at the meeting judged structured dosing to be the best way of attaining the overarching goal, but considered that it would not come about in the immediate future.

An alternative solution for introducing PDD into the national pharmaceutical statistics might be to make use of the dose text interpreter that exists at Apotekens Service AB and is used by electronic expert support (EES). The dose text interpreter would be applied to the dosage text reported by the pharmacies. It should correspond to the text printed on the pharmacy label, i.e. the prescriber's instruction which has been reviewed and, if necessary, clarified by the dispensing pharmacist. Those present were in agreement that use of the dose text interpreter to calculate PDD would not mean that the motive to work towards structured dosage would be significantly reduced in the long term.

The preliminary assessment is that there is interest in working on the dose text interpreter solution pending structured dosing. It is also possible that direct feedback of PDD to the county councils increases the pressure to standardise the writing of dosages, with the aim of obtaining better quality in the information given. Those present at the meeting were in agreement that the dose text interpreter ought to be administered by Apotekens Service AB, or more likely the future Swedish eHealth Agency. PDD would then be dressed in raw data files and statistical systems which are delivered.

Following the meeting, the National Board of Health and Welfare presented a memorandum to the Ministry of

Health and Social Affairs which contains proposals on designing the making available of particulars of dosage (in the form of calculated PDD) and the number of iterations that can form the basis for a remit to Apotekens Service AB/Swedish eHealth Agency. In view of the ongoing authority reorganisation it has not been possible to issue new remits for Apotekens Service AB at this stage.

Work in 2014 and timetable

The Swedish eHealth Agency should be given a remit to carry out a preliminary study aimed at analysing the prospects of adding to information supplied to the National Board of Health and Welfare and the county councils. In the first stage the prospects of introducing a dose text interpreter should be investigated. In the second stage the prospects of introducing structured dosage should be investigated.

6.4. Make follow-up of requisitioned medicines possible at individual level

Main responsibility: Swedish Association of Local Authorities and Regions

Investigation into how individual data on requisitioned medicines can be made available from various patient record systems or the pharmaceutical modules linked to them. Investigation into how individual data on requisitioned medicines can be integrated into the National Board of Health and Welfare's Prescribed Drug Register and used for example for epidemiological studies, research and preparation of statistics in the area of healthcare.

Objective

To be able to provide a complete picture of the pharmaceutical treatment of the population it is crucial, in addition to following up prescribed medicines collected from pharmacies, also to be able to follow up the treatment given to patients in wards and outpatient clinics at hospitals. This data will make more comprehensive follow-up studies possible with the aim of strengthening knowledge on and experience of use of medicines and ultimately enabling the individual patient to receive the best and safest possible care and treatment.

Status in autumn 2013

In the spring of 2012 the National Board of Health and Welfare published a preliminary study to establish what must be investigated to enable individual data for requisitioned medicines to be made available from the various patient record systems. In the autumn of the same year the authority was given a new Government remit to:

- rate alternative health data registers for the integration of individual-based data in terms of both legal and practical aspects,
- define indicators of desired quality of reported data including coverage in the register, in order to ensure dependability for follow-up studies or statistical data and
- present different ways of aggregating stored pharmaceutical data (e.g. complex dosage regimens).

The report referred to above was sent to the Ministry of Health and Social Affairs at the end of April 2013 and published at the beginning of May: www.socialstyrelsen.se/publikationer2013/2013-4-24

As part of an agreement between central government and the Swedish Association of Local Authorities and Regions, CeHis has investigated the conditions to be met for the county councils to extract information on requisitioned medicines from their patient record systems for transfer to a national register. This study is based on the proposals in the National Board of Health and Welfare's two reports. This work shows that the operational, technical, cost and legal conditions vary widely in different parts of the country. The report identifies around twenty different activities of varying scope that must be carried out in the short and long terms by a number of actors: county councils, CeHis, the Ministry of Health and Social Affairs and the National Board of Health and Welfare.

Work in 2014 and timetable

SALA via CeHis/Inera is to carry out a project that evaluates practical extraction trials with the aim of making information transfer at individual level on requisitioned medicines from patient record systems to the Swedish Prescribed Drug Register at the National Board of Health and Welfare possible in the long term.

Consultation is to take place with the National Board of Health and Welfare and the Swedish eHealth Agency on the long-term management of data that have been extracted from the patient record systems concerning prescriptions in inpatient care and how care data in the future can be structured in a more uniform way regardless of type of patient record. Under this consultation exercise, the affected parties are to evaluate the patient record extraction trials that have been started in Stockholm County Council.

6.5. Make it possible for the county councils, the National Board of Health and Welfare and the Dental and Pharmaceutical Benefits Agency to follow up prescribing of medicines at prescriber level

Main responsibility: National Board of Health and Welfare

Follow-up of why the data on prescriber code on prescriptions is not transferred to the Prescribed Drug Register or to the county councils' individually based pharmaceutical data, followed by suitable measures to make this possible.

Objective

The overarching purpose of adding a prescriber code to data supplied to the National Board of Health and Welfare and the county councils is to improve the quality in follow-up of prescribing and in the long term to improve the quality of prescribing.

Status in autumn 2013

Apotekens Service AB has argued that an amendment is required to Section 16 of the Prescription Registers Act (1996:1156) so that prescriber code can be released to the National Board of Health and Welfare and the county councils. Amendments are also required in Sections 6 and 18 of the Prescription Registers Act (1996:1156) for the release of prescriber code to TLV to be possible.

Work in 2014 and timetable

The focus is on the National Board of Health and Welfare being given a remit to investigate how it can handle prescriber codes under the regulations governing use of the Swedish Prescribed Drug Register. The National Board of Health and Welfare is also to examine, in consultation with the county councils (SALAR) and TLV whether legislation needs to be amended to make it possible for these three actors to follow up drug prescribing at prescriber level.

6.6. Staggered approval and introduction of new medicines (new activity in 2014)

Main responsibility: Medical Products Agency

To encourage the desired development of new medicines, the concept of staggered approval (adaptive licensing) has been developed. The objective with this concept in the EU is to link existing options in the regulatory EU system to approve medicines for patient populations with the greatest unmet medical need relatively early, based on limited data, together with national systems for financial compensation and managed introduction. The concept entails systematic follow-up of efficacy and safety for individual patients. The intention is partly to generate further information on the initially approved indication, but also create a basis for expansion of indications. The idea is that this follow-up should take place in such a way that it does not just meet the needs seen by regulatory authorities and industry but also satisfies the needs expressed by Health Technology Assessment/payment authorities, the healthcare system and patients.

Adaptive licensing is thus intended to address problems that are felt to inhibit drug development today. It makes medical sense that drug development initially focuses on patients with the greatest unmet medical need. The clarity that various stakeholders wish to see creates predictability, which is important to the willingness of the industry to invest. Coordination of follow-up requirements improves the possibility of documenting and assessing the medicine in real world clinical practice and creates a further basis for the assessment of cost-effectiveness.

From a national perspective, a link to managed introduction provides an opportunity for society/the health service/patients to more quickly gain an understandingof the value of the medicine in relation to alternative treatments in the Swedish healthcare system. This will provide a better foundation for pricing and decisions on reimbursement.

Managed introduction and structured follow-up with well developed monitoring routines, for example quality registers, is also an opportunity for innovation and clinical research.

A process is probably required whereby adaptive licensing is linked to the possibility of subsequent price adjustment based on increased knowledge of cost-effectiveness.

Objective

To provide a plan that contributes to enable the concept of adaptive licensing to be furtherprogressed and is compatible with the European regulatory system and adapted to Swedish conditions for managed introduction.

Activity plan for 2014 and timetable

The Government intends to give the Medical Products Agency a remit, in consultation with TLV and SALAR to, study various international initiatives for adaptive licensing of new medicines, the potential benefits and drawbacks of the process. If the benefits outweigh the drawbacks, involved authorities, primarily the Medical Products Agency and TLV, should propose a plan that contributes to the development of the concept and is compatible with development within the European regulatory system.

As a second step, it should be analysed how adaptive licensing of new medicines may affect the process for managed introduction of medicines, or alternatively what line of action Sweden should pursue in the development of adaptive licensing to optimize the concept in relation to the Swedish conditions for managed introduction.

7 Reduce the impact of medicines on the environment locally and globally

7.1. Investigate whether environmental aspects should be considered in the reimbursement of medicines

Main responsibility: Ministry of Health and Social Affairs

Review of the prospects for taking greater account of environmental considerations under the national pharmaceutical benefits scheme.

Objective

Pharmaceuticals often contain several active substances which may potentially have an environmental impact. The environmental risk assessments that have been carried out show that the present-day use of medicines does not cause a risk of acute toxicity to aquatic organisms, but may pose a risk of long-term effects and cause pollution of drinking water. There are still significant gaps in knowledge of what effects pharmaceutical residues have, for example in the form of contamination of drinking water, and what effects on human health this can lead to in the longer term.

The Dental and Pharmaceutical Benefits Agency (TLV) has not taken account of environmental concerns when deciding whether a medicine is to be included in the pharmaceutical benefits scheme. To enable TLV to do this, there needs to be adequate knowledge of the impact of medicines on the environment, ways of quantifying the costs of negative environmental effects and a system of environmental classification in which medicines are assessed on the basis of common criteria.

Status in autumn 2013

On 14 June 2012 the Government appointed an inquiry chair to conduct a review of certain issues related to pricing, availability and market conditions in the area of medicines and pharmacies.

The Government then broadened the inquiry's remit on 22 September 2012 to also include reviewing whether environmental aspects should be considered in the reimbursement of medicines. The remit includes analysing and examining whether TLV should take account of environmental aspects in pharmaceutical benefit decisions for all medicines, describe what practical conditions must be met for TLV to take account of environmental aspects in pharmaceutical benefit decisions and shed light on how consideration of environmental aspects in decisions on pharmaceutical benefits would affect the costs of medicines.

The inquiry's proposals were presented in April 2013 in the report Compensation in pharmaceutical injuries and environmental concerns in the pharmaceutical benefits scheme (SOU 2013:23).

Work in 2014 and timetable

The report has been circulated for comment and is now under discussion in the Government Offices. It has been noted in the report Compensation in pharmaceutical injuries and environmental concerns in the pharmaceutical benefits scheme (SOU 2013:23) that there are several conceivable measures that would increase the use of starter packs to reduce discarding. One way is to increase the use of starter packs in first-time use of medicines for long-term treatment. These aspects will be considered in the continued discussion of the matter within the Government Offices.

7.2. Encourage voluntary checking of emissions from pharmaceutical factories

Main responsibility: Swedish Association of the Pharmaceutical Industry (LIF)

Introduction of voluntary ecolabelling of pharmaceutical products.

Objective

The project is aimed at encouraging voluntary control emissions and discharges from pharmaceutical factories by introducing voluntary environmental assessment of medicines. A model that assesses the whole product and not just the active substance like the present-day environmental classification system at www.fass.se is becoming an important tool in the internal environmental activity of the pharmaceutical companies. The environmental assessment can additionally be used in connection with public procurement and in the reimbursement and substitution system, provided the rules are amended so that environmental considerations can be included in the reimbursement and substitution system.

The project consists of sub-projects as follows:

- preparation of a Swedish model for environmental assessment of medicines,

- preparation of a model for environmental consideration in the Swedish reimbursement and substitution system,
- training on the environmental assessment model for employees of the pharmaceutical companies and
- the establishment of an organisation that can administer the environmental assessments.

Status in autumn 2013

LIF, in cooperation with the Swedish stakeholder group, as well as a grouping consisting of the international environmental experts of the pharmaceutical industry, has prepared the proposal for an environmental assessment model. This proposal was submitted to the Ministry of Health and Social Affairs on 30 June 2013. In accordance with the recommendations contained in the second interim report of the Pharmaceutical and Pharmacy Inquiry (point 7.1), the assessment model focuses on environmental aspects. In accordance with the inquiry's recommendations, the model is adapted to enable assessments to be made in the substitution system.

Continued development will take place in close collaboration with the Medical Products Agency and TLV, for which the inquiry proposes key roles in the continued process for a formal decision on the environmental assessment model and in the design of a system to take account of the environment in the substitution system.

Work in 2014 and timetable

The model for environmental assessment of medicinal products which LIF submitted to the Ministry of Health and Social Affairs on 30 June 2013 needs be fleshed out in greater detail, and this will be done in 2014. In conjunction with this work, an e-training programme describing the model will be prepared. Alongside this, LIF intends to work together with affected authorities in 2014 to enable the other two sub-projects, preparation of a model for consideration of the environment in the Swedish system of reimbursement and substitution and the establishment of an organisation that can administer the environmental assessments to be concluded.

7.3. Investigate what further measures can be taken at national level to reduce the discarding of medicines or in other ways to limit the environmental impact of the use of medicines (completed in 2013)

Main responsibility: Medical Products Agency

Investigation into the causes of discarding and proposals for measures to reduce the discarding of medicines. Implementation of joint information efforts to encourage patients to return leftover medicines.

Objective

The purpose of the remit is to contribute to making it possible for the discarding of medicines to be further reduced and to the pharmaceutical residues arising in the handling of medicines and in the consumption of medicines being disposed of in an environmentally sound way. The inquiry has had the four objectives of:

- investigating the causes of discarding,
- presenting proposals for further measures to reduce the discarding of medicines,
- presenting proposals for measures which in some other way limit the environmental impact of the use of medicines, i.e. which ensure that the pharmaceutical waste that arises in the handling and consumption of medicines does not contribute to water, soil or air pollution, and
- conducting a joint information campaign to encourage patients to return leftover medicines in order to increase the collection rate.

Status in autumn 2013

The joint information campaign to increase the return of leftover medicines to pharmacies concluded with a follow-up SIFO opinion survey at the end of April 2012, in which around 75% of the public said that they returned leftover medicines to pharmacies. This is a somewhat higher proportion than in the SIFO survey in 2011, but the target in the national pharmaceutical strategy of 80% was not reached.

New information and data gathered through questionnaires and enquiries to wholesalers, pharmacy actors, the grocery trade, county councils/regions and municipalities have been collated together with other study results.

All the objectives of the inquiry have been met. With regard to proposed measures to reduce discarding of medicines or the environmental consequences of discarded medicines, the proposals are limited to those deemed to be most crucial from the perspective of society and to have good prospects of being implemented. The inquiry additionally describes proposals already made and the outcome of these proposals.

The remit has been reported and can be concluded.

7.4. Endeavour to make it possible for consideration to be given to the environment in the production and use of medicines

Main responsibility: Government Offices

On 9 June 2011 the Government took a decision to task the All-Party Committee on Environmental Objectives

(M 2010:4) with developing proposals for a strategy for Swedish work in the EU and internationally on a non-toxic environment. The strategy also has to encompass the impact of medicines on the environment.

Objective

Emissions and discharges from pharmaceutical production plants in Sweden are very limited as they often have their own wastewater treatment. Swedish pharmaceutical production is also closely regulated and controlled. Sweden today has limited production of medicines, and the principal challenge in our local environment is therefore posed by the consequences of the consumption of medicines. The trend in recent years has, however, been for pharmaceutical companies in Sweden to outsource more and more of their production to low-cost countries where either the environmental requirements in manufacturing are substantially less stringent than in Sweden or where the authorities have limited opportunities to monitor compliance with the national environmental requirements. A large proportion of production takes place in countries such as China and India.

Status in autumn 2013

On 31 October 2013 the Government took a decision on a milestone target for increased environmental consideration in EU pharmaceutical legislation and internationally. The milestone target for increased environmental consideration in EU pharmaceutical legislation and internationally is that by 2020 decisions have been made in the European Union or internationally which mean that existing and possible new rules on medicinal products for human and veterinary use weigh in environmental aspects to a greater extent.

In November 2013 the Government adopted the Bill On the way to a non-toxic everyday environment – platform for chemicals policy (Government Bill 2013/14:39). The Bill describes that issues the Government intends to address in this area in the period up to 2020. The test requirements for medicines should, for example, be tightened and the environmental risk assessments made in connection with an application for marketing authorisation of medicines should be improved. To enable environmental considerations to be taken into account in the authorisation of medicinal products, the Government, like many referral bodies, considers there to be a need for an amendment to the directive on medicinal products for human use (2001/83/EC) so that environmental risks in use can be factored into the risk/benefit assessment according to clear criteria. There is a need for an in-depth analysis of how the legislation on this issue could be formulated in practice so that this is made possible. Consideration should be given to regulating minimum requirements for production conditions for the sale of products on the EU market. To enable it to be established how Sweden is to continue to pursue these issues in the EU, the Government considers that the consequences of greater concern for the environment must undergo further analysis.

Work in 2014 and timetable

In 2014 Sweden will initiate lobbying of the European Commission to persuade it, within the framework of development of the Community's strategic approach to the pollution of water with pharmaceutical substances, to commence work on the decisions identified by this milestone target. Sweden is to press in particular for the Commission to identify and investigate the consequences of different alternative actions with regard to concern for the environment in the assessment of the benefit and risks of medicinal products. The Government intends at the same time to instruct the Medical Products Agency, together with other affected agencies, to carry out a more in-depth analysis in this area. As part of this analysis, further attention should be paid for example to issues relating to access to medicines, cost-effectiveness, the costs to society of medicinal products and effects on the development of new medicines, as well as the costs of damage to the environment. An in-depth analysis of this kind is necessary to establish how Sweden is to pursue the issue further in the EU and internationally.

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