Report No. 18 to the Storting (2004–2005)

On course towards more correct use of medicine

Medicinal Product Policy

1 Introduction

1.2 Summary

The chief goal of medicinal product policy is correct use of medicinal products:

Correct diagnosis – correct prescription – correct use

A more precise formulation of the goals is:

– Medicinal products shall be used correctly, in both medical and economic terms.

– Patients shall have secure access to effective medicinal products, regardless of their ability to pay for them

– Medicinal products shall have the lowest possible price

All parts of medicinal product policy must be designed to serve these goals. The better the use of medicines, the better will be the health of the population as a whole. This will also result in more effective utilization of the community's resources. Medicinal products are a major input factor of the health service, but are nevertheless only one of a number of instruments used for treatment of patients. Use of medicinal products must therefore be considered in the light of the best treatment for the patient concerned. The aim that the public shall have secure access to medicinal products regardless of their ability to pay for them entails that medicine costs are to a great extent covered by public funds.

The present Report to the Storting concerns how the authorities' measures in the area of medicinal products may be planned in order to improve the current use of medicine.

The Report is divided into four main parts:

1. Prescription and use of medicinal products
2. The pharmacies and the supply of medicines
3. Medicine costs
4. Reimbursement schemes

Medicinal product policy embraces a broad sphere of activity, and issues in a given subarea are often affected by other subareas. It is therefore important that the various chapters are viewed within the context of the whole Report.

Chapter 2 describes the sale of medicinal products, specific market conditions and the players involved in the path taken by medicinal products on their way to the patients.

Chapter 3 describes the challenges that must be dealt with in order to achieve the best possible use of medicines. The purpose of all treatment with medicinal products is that the patient's benefit from the medicinal product shall be greater than the risk of adverse reactions. This requires correct diagnosis, correct choice of treatment and correct use. A correct prioritization of medicine costs will provide more health for each krone spent and a better national health service. In order that the community

shall avoid tying up resources that might have been better used elsewhere, the costs associated with treatment with medicinal products must be commensurate with the benefit.

PART I Prescription and use

Chapter 4 describes the current use of medicine and the communication between health professionals, pharmacists and patients. The chapter also discusses the need for changes and instruments enabling improved follow-up of patients' use of medicine. Studies indicate a likelihood that one out of five patients could improve their use of medicinal products.

The results for patients of inexpedient use of medicine include lack of efficacy, adverse reactions, poorer coping with illness, reduced quality of life and increased mortality. The consequences for the community are more hospitalization, unnecessary treatment and increased sickness absenteeism.

There is a potential for improvement of the communication between the authorities, health professionals and patients. Studies indicate that medical practitioners, patients and pharmacies all often have an inadequate record of the medicinal products that an individual patient has been prescribed and actually uses at any given time. Information concerning medicinal products prescribed to patients is found in different patient files instead of being collected in a single location. The authorities must provide information to health professionals concerning the handling of medicinal products and to patients concerning correct use of medicine. Appropriate measures include sharing valuable experience gained in local projects with municipalities, health institutions and appropriate health professionals throughout the country. This would make it possible to gather a collection of detailed examples for emulation. The public information provided to patients concerning the properties of medicinal products shall also be improved. The Ministry proposes that a pilot project be set up involving the use of the pharmacies' prescription data in order to create a collective survey of patients' use of medicine based on voluntary consent.

Quality improvement measures in the nursing and care sector and the introduction of electronic prescriptions may reduce the risk of wrong medication. An example of this is the measures strengthening interaction between the various levels of the health service. Better utilization of pharmacists' competence can be achieved by involving them to a greater extent in multiprofessional cooperation on the patient's use of medicine. Examples of this are participation in treatment teams in hospital wards and review of the patient's total use of medicine in cooperation with a medical practitioner. In order to gain more experience, the Ministry proposes several different pilot projects. The advantages associated with mechanical packaging of medicinal products in individual doses are so great that the health service should make greater use of it. The authorities will communicate the advantages of multidose packaging more clearly.

Chapter 5 concerns the need for producer-independent information about medicinal products. Access to balanced information on the characteristics of medicinal products is a requirement for correct decisions concerning treatment of patients and correct priorities for the authorities. The information provided by the industry helps to raise awareness and enhance competence concerning individual medicinal products, and is

an important information channel. However, such information and activities is influenced by the desire to promote the sale of the company's own products. There is therefore a risk that such information does not present a sufficiently balanced view. Public information must help to balance the information provided by the pharmaceutical industry. The authorities must improve their efficiency in this area. In selected areas, guides to correct treatment with medicinal products have been issued, but these are not well coordinated, and are rarely provided during the introductory phase of a medicinal product, when new treatment patterns are formed. Investments by the public authorities in producer-independent medicinal product information are limited compared with the information activities of the industry. It is therefore necessary to make effective use of public information channels, to focus on relevant issues and to provide timely information inspiring the confidence of the recipients.

There is a need for information concerning medicinal products both from the authorities and from specialist institutions that are independent of both the pharmaceutical industry and the authorities. The organization of this information work is to be mainly carried out by three institutions: the Norwegian Knowledge Centre for the Health Service, the Norwegian Medicines Agency and the Norwegian Directorate for Health and Social Affairs. The Knowledge Centre is professionally autonomous in relation to both the industry and the authorities, and is therefore to be allocated the role of independent specialist institution for information concerning medicinal products on the basis of knowledge summaries in the area of medicinal products. The Norwegian Medicines Agency is to be responsible for preparing and disseminating the authorities' information concerning technically and economically correct use of medicinal products. This shall include information on the use of new medicinal products, adverse reactions and reimbursement conditions. Development of national professional guidelines for whole areas of disease, including use of medicinal products, is the responsibility of the Norwegian Directorate for Health and Social Affairs.

The Ministry will focus on peer guidance for general practitioners, and implement measures to ensure that they are provided with lists of their own prescriptions by the *Reseptregisteret* (Norwegian Register of Prescriptions). The communication facility, the Norwegian National Health Network is an important instrument for updating information on medicinal products so that this is available on the medical practitioner's workstation when making a choice of therapy. Prescription support is in process of development at the website *Helsebiblioteket* (the Health Library), but is also part of a public project for introduction of electronic prescriptions. The *Norsk legemiddelhåndbok* (Norwegian Pharmaceuticals Handbook) for health professionals is a therapy-oriented, producer and authorities-independent widely used reference book on medicinal products and treatment. It is also available in a web version. The Ministry will finance and continue production of the book. The Ministry will request the Norwegian Medicines Agency to prepare guidelines to ensure the greatest possible transparency in the work of the pharmaceutical authorities on approval and follow-up of medicinal products. Documentation of the positive and negative effects of medicinal products should be available to everyone who wishes access to it.

Chapter 6 concerns how the authorities can help to strengthen confidence in, and the quality of, medical practitioners' prescription practice. It is important that the selection of medicinal products is made in a manner that provides patients and the community with the best possible health provision for the available funds. The

medicinal products must have sufficient efficacy, and the costs must bear a reasonable relation to the efficacy. If this goal is to be achieved, it is necessary for medical practitioners to have a balanced view of the qualities of each medicinal product. It would be inappropriate if ties should occur between medical practitioners and the pharmaceutical industry, entailing that prescription be carried out on the basis of an unbalanced view of the individual medicinal product, or that no regard should be paid to the costs.

The health enterprises, the Norwegian Medical Association and the Norwegian Association of Pharmaceutical Manufacturers have increased the stringency of their guidelines in order to achieve greater transparency concerning, and confidence in, the interaction between the industry and the medical practitioners. Greater transparency concerning the influencing of medical practitioners can be achieved by publishing decisions concerning breaches of the advertising regulations and by issuing extended reports of the industry's information in connection with the launching of new medicinal products. The Ministry will propose regulations specifying the Health Personnel Act's prohibition of benefits likely to affect the services improperly provided by health personnel. Control of the pharmaceutical companies' advertising will be intensified. Moreover, an investigation will be made into other possible sanctions against prescribers than withdrawal of their right to prescribe at the expense of the National Insurance. A review of training measures aimed at medical practitioners will result in proposals for measures to encourage correct prescription of medicines and increased knowledge and understanding of the rules for public financing of medicinal products.

Chapter 7 discusses research into medicinal products. In the area of medicinal products, the state should focus its research investments on knowledge of particular interest to patients and society, which is currently not paid regard to by the industry. This applies firstly to a systematic follow-up of medicinal products while they are in use. There is a need for more research on prescription and use of medicinal products. Further consideration will be given to the organization and financing of such research.

The reimbursement conditions for each individual medicinal product must be developed in line with new knowledge. For this work, the authorities need studies comparing newer and often dearer medicinal products with the most commonly used alternatives. The burden of proof that a new medicinal product will give added value in relation to existing therapy and that any such added value justifies a higher price must in principle lie with the rightholder of the medicinal product. However, insufficient studies addressing this need are carried out by the pharmaceutical industry itself, and there is therefore a need for studies under the auspices of the public authorities. Without such documentation, the community risks paying more for new medicinal products without this resulting in improved health for patients. The Ministry will consider the organization and financing of such studies to be of significance to the assessment of reimbursement conditions. A fee imposed on the pharmaceutical industry's sale of subsidized "blue prescription" medicines would be a potential source of financing that must be considered. Such research would enable Norway to lead the way in this area. Since other countries have an equivalent need for this type of information, international cooperation would be relevant.

PART II Pharmacies and the supply of medicines

Chapter 8 considers the Pharmacies Act. A new Pharmacies Act entered into force on 1 March 2001. In 2003 and 2004, at the request of the Ministry of Health and Care Services, ECON Analyse AS carried out an evaluation of whether the objectives of the Pharmacies Act had been met. The evaluation concluded that the objectives associated with greater availability, service and rationalization of the pharmacy trade had been met. However, the Pharmacies Act has had no clear effect on retail prices. Since the new Pharmacies Act entered into force, the number of pharmacies has increased from 397 to over 530. This increase has primarily affected the central area of eastern Norway and other densely populated areas. Rural municipalities have not lost pharmacies. Moreover, the majority of pharmacies have introduced self-service and direct dispensing of prescriptions. This has resulted in a reduction of queues at pharmacies and an improvement in service. The evaluation provides no clear indication of whether there has been a reduction in the professional quality of the pharmacies' services during the last three years.

ECON points out that the Pharmacies Act has resulted in considerable changes in the structure of the pharmacy market. Three large pharmacy chains, each integrated with its own wholesaler, count for a collective market share of approximately 85 per cent. There are also a number of independent pharmacies and state-owned hospital pharmacies. The pharmacy chains have gained greater power to negotiate with manufacturers in the generic pharmaceutical market. The rules for the sale of medicinal products must be designed in such a way that the advantages reaped by the pharmacy chains and wholesalers are shared by consumers and the National Insurance. Although the market is dominated by three major players, the Ministry will aim to ensure genuine competition between pharmacies. Efficiency gains in the chain of distribution should also benefit the consumers and the National Insurance regardless of the market structure.

The authorities will assess specific services offered by the pharmacies against other instruments for attaining the objectives in the various areas of the health sector. There is reason to clarify the limitations set by pharmacy legislation for pharmacy services. The Ministry will review pharmacy legislation in detail after this Report has been submitted and considered by the Storting.

Chapter 9 assesses pharmacy provision and the pharmacies' role as guarantors of availability. Pharmacy provision in rural areas shall be maintained. The operating support funded by the pharmacies will be the most important instrument for achieving this. The easing of operational requirements for pharmacies in rural areas will be further assessed.

Chapter 10 concerns dispatch of medicinal products. In connection with the preparation of new requirements regarding dispatch of medicinal products, the Ministry will propose permitting dispatch from pharmacies to consumers throughout the country.

Chapter 11 gives an account of the securing of the availability of medicinal products. The supply of pharmaceuticals functions well in Norway. The Ministry views it as appropriate that the Norwegian Directorate for Health and Social Affairs continues its work on strengthening pharmaceutical supply contingency plans.

PART III Costs and price regulation

Price regulation of medicinal products is dealt with in *chapter 12*. The regulation of the pharmacies' maximum retail price and purchase price will be maintained. No maximum purchase prices will be imposed on wholesalers. The Ministry regards the current level of pharmacy markups as sufficiently high. If justified by a total assessment of the framework conditions of the pharmacies and pharmacy chains, markups should be adjusted. Particular emphasis must be placed on the underlying growth of the pharmaceutical market, changes in framework conditions initiated by the authorities and the position of the independent pharmacies. The Ministry will consider making gradual changes in the various components of the markups, emphasizing flat increases in relation to percentage increases.

Chapter 13 discusses other instruments that may help to reduce costs. The Ministry will encourage medical practitioners to write the name of the active substance on prescriptions instead of the brand name. Imposing a sharing of economic responsibility on medical practitioners by means of individual medicine budgets has been discussed, but the Ministry does not regard this as an appropriate measure in Norway.

PART IV Reimbursement schemes

Chapter 14 sets out the background and aims of the reimbursement schemes. *Chapter 15* describes the rules for prior-approved reimbursement (the "blue prescription" scheme).

The Norwegian Medicines Agency can currently grant prior-approved reimbursement if the additional costs do not exceed a bagatelle limit of NOK 5 million. This gives the agency the authority to grant reimbursement for medicinal products that satisfy the technical requirements. In the view of the Ministry, it would be fundamentally inappropriate for reimbursement of medicinal products not to be subjected to prioritization on a par with other measures or areas of focus within the various areas of expenditure in the fiscal budget. There is no basis for assigning medicinal products special priority in relation to other treatment provision, which may also be socially beneficial and cost effective. The bagatelle limit provides a reasonable balance between the regard for effective administrative procedures and the regard for correct priorities. The Ministry therefore proposes retention of the current bagatelle limit.

The diseases entitling reimbursement are listed in the regulations. Following the introduction of a bagatelle limit, the requirement regarding inclusion in the disease list is regarded as an unnecessary threshold for inclusion of new medicinal products. The Ministry therefore proposes that the list not be used in the future as an inclusion criterion for medicinal products eligible for "blue prescriptions". The disease categories and medicinal product groups listed in the regulations must nevertheless continue to be decisive for patients' rights and for what medical practitioners may prescribe at the expense of the National Insurance. The Ministry will therefore propose that the Ministry be assigned a general authority to make the amendments to the disease categories and medicinal product groups listed in the regulations that are necessitated by each inclusion of a medicinal product.

In order to target reimbursement at the patients who gain satisfactory benefit from the treatment, the Norwegian Medicines Agency shall prepare the most concrete and controllable reimbursement conditions possible for medicinal products on "blue

prescriptions", which are eligible for reimbursement. These conditions must be kept continuously up-to-date, so that they accord as closely as possible with available knowledge concerning efficacy, adverse reactions and price. Precise reimbursement conditions that are well communicated are important for effective control. The National Insurance Administration has revealed many breaches of the rules for research on medicinal products financed by "blue prescriptions". Control of correct prescription will therefore be intensified. The control must be balanced by an increased focus on information to medical practitioners. Information and control can be automated to a much greater extent by enabling medical practitioners to confirm electronically that the conditions for reimbursement are satisfied. The Ministry will develop a system for electronic confirmation, so that in future the prescriber will be able to take greater responsibility for prior-approved reimbursement.

Chapter 16 deals with the topic of reimbursement on individual application. There will always be a need for an application-based reimbursement scheme. Such a scheme is necessary in order to cover individual needs that fall outside the general conditions. It is also appropriate in cases where prescription is difficult to control within a prior-approved reimbursement scheme. However, there are weaknesses in such a scheme. Medicinal products designed for a limited patient group, that can be associated with clear reimbursement conditions, can be transferred from the application-based individual reimbursement scheme to prior-approved reimbursement in order to simplify the reimbursement system. However, this must be combined with information to medical practitioners concerning correct prescription and prescription control. Changes in the prescription pattern must also be followed up and controlled. Transfer of medicinal products to prior-approved reimbursement must be carried out gradually with evaluation of the medical practitioners' compliance. If the evaluation carried out after any stage indicates poor compliance, it will be possible to halt the transfer until the causes are identified and compliance is assured. Increased prescription outside the conditions constitutes grounds for returning to individual reimbursement.

It is currently a general requirement that a patient must have been examined by a specialist before individual reimbursement for a medicinal product can be applied for. The Ministry does not wish for a general phasing out of the requirement regarding specialist prescription, but proposes that this be assessed for each individual medicinal product. Both technical needs and the potential number of applications to the National Insurance Administration shall be taken into account in the assessment. A phasing out of the specialist requirement for specific medicinal products must be followed up by information and control measures.

Chapter 17 discusses the special assistance scheme. Specific conditions must be satisfied in order that the cost of a medicinal product shall be reimbursed. As opposed to the remainder of the benefit system, the special assistance scheme does not require that a medicinal product shall satisfy technical criteria for reimbursement. All costs associated with medicinal products subject to medical prescription may be reimbursed with the exception of a limited patient's charge. The scheme includes a number of medicinal products eligible for full reimbursement without any patient's charge. These include analgesics for cancer patients in the terminal phase. The scheme also allows assistance to be granted for medicinal products that are not found eligible for reimbursement. This applies to approximately one-quarter of the costs.

The Ministry will propose that all medicinal products are simultaneously withdrawn from the special assistance scheme, and that those that are eligible for reimbursement (including analgesics) are transferred to the prior-approved reimbursement scheme and the application-based individual reimbursement scheme. This will provide the same or rather more favourable patient's charges in the "blue prescription" scheme. At the same time, patients will have to pay the full price for medicinal products that are not found eligible for reimbursement.

Chapter 18 discusses reimbursement of analgesics. There is a need for a long-term solution for reimbursement of analgesics. In the view of the Ministry, the cost of analgesics should be granted prior-approved reimbursement, if the technical requirements are satisfied. This is in accordance with the proposal to transfer medicinal products from the special assistance scheme to ordinary reimbursement.

Finally, patient's charges are discussed in *chapter 19.* The Ministry proposes no amendments to the rules for patient's charges, but will continuously assess amount thresholds in connection with the annual fiscal budgets.

Box 1.1 Measures

The most important measures submitted in the Report are:

- Providing systematic information to municipalities and health professionals able to promote more correct use of medicine.
- Establishing an interface with the patient organizations in order to communicate regular information concerning new medicinal products, effects, adverse reactions and reimbursement status.
- Starting pilot projects for review of patients' use of medicine in hospitals, nursing homes and old people's homes, home nursing and pharmacies.
- Establishing a pilot project to survey consumers' use of medicine on the basis of prescription data already recorded by some pharmacies.
- The Norwegian Knowledge Centre for the Health Service (the Knowledge Centre) is to be assigned the role of a professionally autonomous institution for information on medicinal products on the basis of knowledge summaries in the area of medicinal products.
- The Norwegian Medicines Agency is to strengthen its work on preparing and disseminating the authorities' information on technically and economically correct use of medicinal products, including use of new medicinal products, information on adverse reactions and reimbursement status.
- The Norwegian Directorate for Health and Social Affairs is to continue its work on developing and disseminating professional guidelines for areas of disease where medicinal products are appropriate.
- Developing electronic prescription support through the electronic prescription project and the Internet-based information portal *Helsebiblioteket* (the Health Library).

- Proposing full state financing of the production of *Norsk legemiddelhåndbok* (Norwegian Pharmaceuticals Handbook), and continue this as a producer-independent and authorities-independent service.
- Drafting regulations specifying the Health Personnel Act's prohibition of improper interaction, inter alia, with the pharmaceutical industry.
- Preparing a strategy for public supervision of marketing.
- Reviewing possible training measures, with a view to implementing measures promoting correct prescription of medicinal products and increased knowledge of the rules for public financing of medicinal products.
- Investigating the organization and financing of research into prescription of medicinal products with a view to development of research activities.
- Investigating the organization and financing of studies significant to the assessment of reimbursement conditions, including the need for a fee imposed on the pharmaceutical industry's sale of subsidized "blue prescription" medicines.
- Maintaining pharmacy provision in municipalities where there is currently a single pharmacy.
- Continuing operating support as a main instrument for ensuring pharmacy provision in rural areas.
- Setting out requirements regarding guidance in connection with the dispatch of medicinal products and extend the right to dispatch products beyond the cachment area of a pharmacy. Continuing to regulate the pharmacies' maximum purchase price and retail price.
- The Ministry will consider making gradual changes in markup rates so that the price of a medicinal product will have less significance for the pharmacies' markup.
- Proposing removal of inclusion in the disease list as a requirement for inclusion of medicinal products in "blue prescriptions".
- Retaining the current bagatelle limit for inclusion of medicinal products in the prior-approved reimbursement scheme.
- Preparing reimbursement conditions as concrete and controllable as possible for medicinal products granted prior-approved reimbursement.
- Continuously assessing the reimbursement status of medicinal products in major areas of therapy and take the initiative to establish Nordic cooperation in this area.
- Developing a system for electronic confirmation of reimbursement conditions in connection with the introduction of electronic prescriptions.
- Implementing an arrangement involving preferred medicinal products when there is a medical basis for selecting one or more cheaper medicinal products rather than other medicinal products.
- Continuing the control methods developed by the National Insurance Service, and implementing a control system for medicinal products for which the cost is reimbursed.

– Gradually transferring medicinal products from individual reimbursement to the prior-approved reimbursement scheme where appropriate, reversing such changes if they generate a growth in costs.

– Removal of medicinal products from the special assistance scheme.

– Collectively transferring medicinal products eligible for reimbursement from the special assistance scheme to the ordinary reimbursement system.

– Assessing the specialist requirement in connection with applications for reimbursement for each specific medicinal product.

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3 The principal goals of medicinal product policy

3.1 The main goals

The Ministry of Health and Care Services has the following main goals in the area of medicinal products, cf. Proposition No. 1 to the Storting (2004–2005) programme category 10.50:

– The public shall have access to safe and effective medicinal products regardless of the ability to pay for them

– Medicinal products shall be used correctly, both technically and economically

– Medicinal products shall be priced as low as possible

Access to medicinal products and low prices for medicinal products are conditions for correct use of medicinal products on an equal footing with good prescription practice and follow-up of patients. However, it is the actual use of the medicinal products that is finally decisive for the patient's health and for satisfactory resource allocation. Correct use of medicinal products is therefore the principal goal of the Ministry's medicinal product policy.

3.2 Correct use of medicine

The purpose of all treatment with medicinal products is improvement of the patient's health. In order that this shall be possible, three conditions must be satisfied. Firstly, the medical practitioner must make the correct diagnosis on the basis of satisfactory criteria. Secondly, the medical practitioner must choose the correct treatment, based either on medicinal products, another form of treatment or a combination of these. Thirdly, the patient must comply with the treatment prescribed by the medical practitioner.

Diagnosis

Correct diagnosis is the fundamental condition for correct use of medicine. It is in the diagnosis phase that the need for treatment and the treatment goals are determined. The date for the onset of treatment is often decided by standard criteria. If there are insufficient criteria for a diagnosis, the result may be either overtreatment or undertreatment in relation to the patient's actual needs. An example of such criteria is the treatment of high cholesterol for reduction of the risk of cardiovascular disease. Treatment with medicinal products is started at far lower levels of cholesterol than was the case 20 years ago. The background for this development is the experience that has been gained of the efficacy and adverse reactions in association with medicinal products. This change entails the treatment of a much greater number of people. Those who hold the view that this recommended limit has now been set too low, may maintain that the diagnostic criteria result in overconsumption.

Prescription

When the diagnosis has been made, the medical practitioner, in consultation with the patient, shall decide which treatment shall be given. The benefit of treatment with a medicinal product must be weighed against the risk entailed by the treatment. Medicinal products are an important input factor in the treatment of diseases and disorders, but should not be used if other methods of treatment are better. In order that a medicinal product shall be able to act on the parts of the body affected by a disease, it is often necessary to subject the whole organism to the effects of the medicinal product. This may give rise to adverse reactions of varying severity.

The degree of risk of adverse reactions that a patient is willing to accept in relation to the benefit will depend on the severity of his or her condition. If the medicinal product helps to save the patient's life, the severity of the adverse reactions may be of secondary importance. New medicinal products constitute a particular challenge because there is usually no adequate documentation of the relation between benefit and risk at an early stage following the launching of a product. As experience is gradually gained from further studies and reports on adverse reactions, the medical practitioner is able to make more secure judgments on how the medicinal product should be used. Medicinal products for treatment of high cholesterol have long shown good efficacy with few adverse reactions. On the other hand, experience of a widely used medicinal product for analgesic treatment in connection with osteoarthritis and rheumatoid arthritis showed that the risk-benefit relation was so poor that the medicinal product was withdrawn from the market in autumn 2004.

When treating a disease, it is often possible to choose between several medicinal products with somewhat varying efficacy and safety. Patients as well as medical practitioners and other health professionals must therefore have as correct as possible a picture of the risk-benefit relation of a medicinal product.

This picture must be based on balanced information. The impression of a medicinal product can vary considerably, depending on whether emphasis is placed on its positive or negative qualities. The pharmaceutical industry has a legitimate interest in emphasizing the positive aspects of the medicinal products, which results in a necessity for other sources of information.

Use

Considerable attention is devoted to measures for promoting correct prescription of medicinal products, and this is a precondition for sufficiently effective treatment with medicinal products. However, it is not sufficient to focus solely on the prescription itself. The patient's actual benefit from treatment with medicinal products depends finally on how the patient uses the medicinal products. The likelihood of attaining the treatment goals is greatest if the patient uses the correct medicinal product, in the correct dose and at the correct time. Guidance of the patient, the physical availability of the medicinal products, reimbursement of the costs associated with necessary medicinal products and follow-up by health professionals are all decisive for achieving this. Many consider that it is important to listen to the patient's own views on what is meant by correct use of medicine. This is also consistent with the patients right of consultation. Patients are more motivated to adhere to a treatment regimen when they understand and accept the diagnosis, are in agreement on the treatment and

have been given the opportunity to discuss their worries. High quality of medicine handling is also important in the nursing and care sector at all stages from the medical practitioner's prescription to the patient's use of the medicinal product.

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Resources

Medical and technological potential

The health gap

The community's resources

Time

Figure 3.1 The health gap

Patient and community

All stakeholders in medicinal product policy share the goal of attaining the best possible health for the population. However, since the various players have different roles, there are also differing views as to what is meant by "best possible". There is general agreement that patients must use the medicinal products dispensed to them in the best possible way. The goal is clear and there are many means of achieving it. However, there may be different objectives associated with the diagnosis and the choice of medicinal product. What is perceived as best for the individual patient and what is considered best for all patients as a group or for the community as a whole are not always the same.

Treatment sufficient for achievement of the treatment goals for a specific patient does not necessarily require the newest and dearest medicinal product. It is does not therefore automatically follow that it is correct to use medicinal products with a marginal additional effect when they cost several times as much as the existing therapy. It is nevertheless natural that any patient, often with the support of his or her patients' organization wishes the best possible treatment regardless of cost. The pharmaceuticals companies have a legitimate interest in calling attention to the advantages of their products. The authorities represent the whole community and all patient groups, and must administer the available funds in the best possible way. It is the community that finances most of the costs, not the individual players in the pharmaceutical market. It is therefore the responsibility of the authorities to balance the needs, so that the goal of best possible health can be achieved for the whole population. Medical practitioners meet patients' needs and demands in a treatment situation at the individual level and are able to prescribe medicinal products at the expense of the National Insurance. Medical practitioners therefore have a dual responsibility in that the regard for individual patients and the regard for correct use of the community's resources must be balanced, cf. sections 4 and 6 of the Health Personnel Act.

The health gap and prioritization

The costs associated with treatment of serious diseases with medicinal products are currently mainly reimbursed, but it is not possible in all areas for the community to cover the cost of what the individual patient perceives as optimal treatment. This is an issue which will become increasingly relevant. There is a widening gap between what is medically possible to treat and the capacity of the community to finance all treatment. This is often referred to as the continuously widening "health gap", see figure 3.1. The health gap is an important condition for the shaping of policy in the area of medicinal products, among other reasons, because of constant developments in the direction of increasingly expensive innovations based on new technology. The pressure on public financing of the use of medicine may also increase in line with the anticipated increase in the number of old people in the population, since older people use more medicinal products than other people do.

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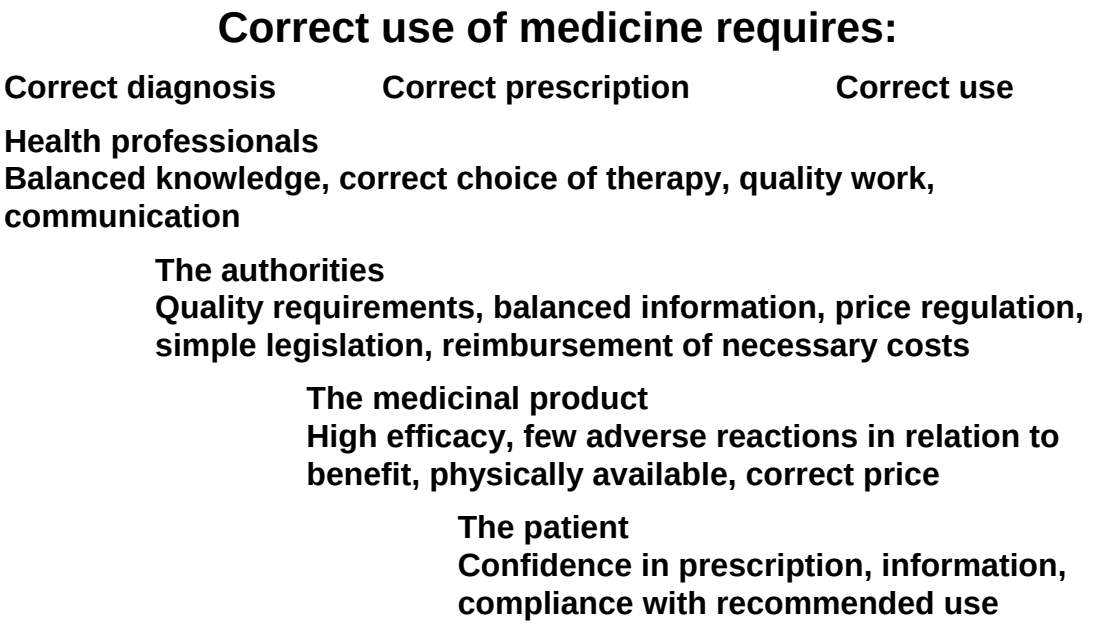

Figure 3.2 Factors conducive to correct use of medicine

The state has responsibility for the financing of much of the cost associated with the use of medicine and must prioritize spending in relation to the available funds. A correct prioritization of medicine costs will result in more health for the community as a whole for each krone spent and a better public health service. The costs associated with treatment with medicinal products must therefore be commensurate with the benefit, so that the community is not made to spend money that might have been used better elsewhere. The challenge for medical practitioners and the authorities is to define what may be deemed sufficient and adequate treatment of patients. Other conditions of major importance for promotion of sound priorities are the further development of a well functioning reimbursement system and maintaining low prices for medicinal products.

Technically and economically sound use of medicine results in positive ripple effects for the whole community. Patients will be able to enjoy improved health and quality of life, the health service frees treatment time, sickness absenteeism is reduced and resources are freed for use in other parts of the health sector. Erroneous use of medicine negatively affects the same factors. This is the background for why technically and economically correct use of medicine is the main goal of the Ministry's medicinal product policy. All measures discussed in this Report to the Storting contribute to the greater achievement of this, see figure 3.2.

8 The new Pharmacies Act

8.1 The purposes of the Pharmacies Act

The new Pharmacies Act entered into force on 1 March 2001. The main purpose of the Pharmacies Act is to ensure responsible supply of medicinal products to end users. This is furthered by continuing the pharmacies' function as a professional supplier of medicinal products and an arena for communication of pharmaceutical competence. The pharmacies have a statutory responsibility to ensure that a medicinal product is supplied as quickly as possible to the consumers and that this is carried out in a responsible manner.

Another major purpose of the Act is to prevent erroneous use of medicinal products by the public. It is therefore the customer's needs that are decisive for the guidance that is to be given. Medicinal products and pharmaceutical services are to be made available to the public throughout the country, partly by means of a satisfactory provision of pharmacies and partly by means of satisfactory availability of the services of the individual pharmacy.

The new Pharmacies Act introduced two basic changes in the area of medicinal products. Firstly, it introduced a freer regulation of establishment and ownership of pharmacies. Whereas it was previously the authorities that decided both the number of and location of pharmacies, the new Act places no restrictions on the number or location of pharmacies. The requirement that owners of pharmacies should hold university degrees in pharmacy has also been abolished. However it is still a requirement that the person responsible for operation of the pharmacy shall hold a university degree in pharmacy. Ownership and operational responsibility are thus two independent functions. Secondly, the pharmacies right to make generic replacement was introduced. This arrangement entails that patients may be supplied with a different medicinal product than that prescribed by the medical practitioner, provided that this is medically equivalent and is included in a special list of medicinal products eligible for generic replacement.

The reason for relaxing the right of establishment was to increase the availability of pharmacies and the service in pharmacies while promoting cost-effectiveness. Improved availability and generic replacement were intended to encourage increased competition between pharmacies and between medicinal products. Such a development was intended to help in reducing the prices of both medicinal products and the pharmacies' services.

8.2 The effect of the Pharmacies Act on market conditions

The traditional supply chain for medicinal products consists of the three players: medicinal product supplier, wholesaler and retailer (pharmacy), see figure 8.1.

Prior to 2001, all pharmacies except the public pharmacies were owned by individual persons and were organized as sole proprietorships. Since the new Pharmacies Act allowed companies to own pharmacies, there has been an extensive horizontal and vertical integration of the pharmacy trade. Horizontal integration has occurred through the formation of pharmacy chains. Each of the three pharmacy chains is vertically integrated through ownership with its wholesaler. The wholesaler and pharmacy chain are thus parts of the same company. The three pharmacy chains dominate the market with a combined market share of approximately 85 per cent, but there are also independent pharmacies and hospital pharmacies. These are largely organized as voluntary chains and purchasing cooperatives, but are not integrated with pharmacy chains. There is no full-range wholesaler that has not been vertically integrated with a pharmacy chain. Independent pharmacies must therefore purchase medicinal products through the pharmacy chains' wholesalers.

The three dominant chains, Apokjeden (Apotek 1), Alliance Unichem and Norsk medisinaldepot (Vitus), are owned by three multinational companies engaged in pharmaceutical and other commercial activities throughout much of Europe. The companies' sales amount internationally to many billions of euros. The chains have expanded in Norway both by buying up existing pharmacies and establishing new ones. Figure 8.2 shows the ownership structure of the three dominant players. In all of the chains, international companies own a Norwegian holding company which in turn owns the pharmacy chain and the wholesaler.

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OLD Supplier Wholesaler Pharmacist

NEW Supplier Pharmacy chain

Figure 8.1 The supply chain for medicinal products – transition to vertically integrated pharmacy chains

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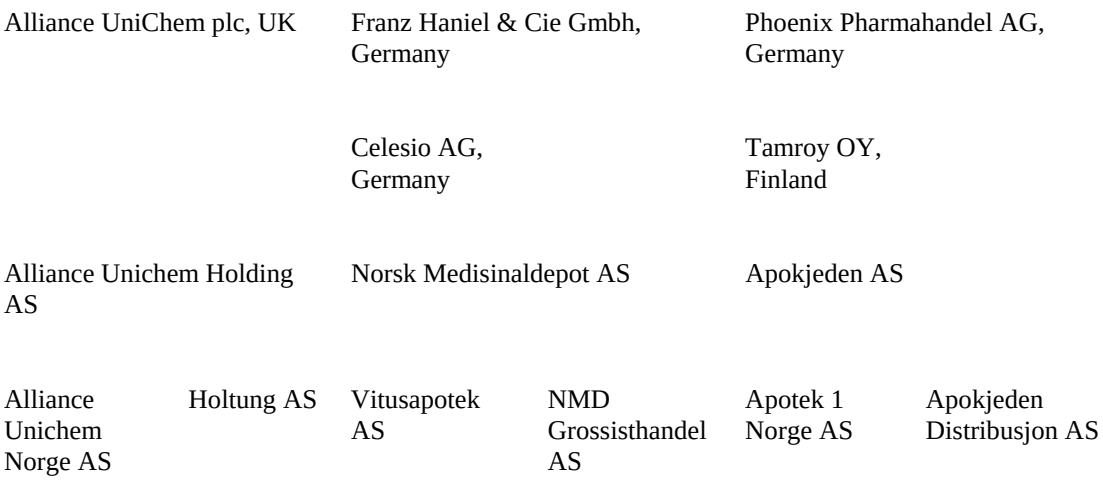

Figure 8.2 The pharmacy chains' ownership structure

The hospital pharmacies and a number of the pharmacies that are not wholly owned by the pharmacy chains are members of the voluntary chain Ditt Apotek associated with NMD Grossisthandel AS. A number of the pharmacies in Ditt Apotek are partly owned by one of the three pharmacy chains. A small number of pharmacies, estimated at 10–15 pharmacies, remain independent of any cooperation with a pharmacy chain. Table 8.1 shows the number of pharmacies by ownership.

From 1987 to the end of 2004, 221 new pharmacies were established in Norway, so the total number is 535, see figure 8.3. This considerable increase has taken place since 2001in connection with the new Pharmacies Act. In 2000 there were 11 300 inhabitants per pharmacy, while at the end of 2004, the number was 8 600.

8.3 External evaluation of the Pharmacies Act

In 2003 and 2004, at the request of the Ministry of Health and Care Services, ECON Analyse AS (ECON) performed an evaluation of whether the aims of the Pharmacies Act had been met. The evaluation concluded that the aims associated with increased availability, increased service and rationalization of the pharmacy trade have been met. However, the Pharmacies Act has not had any clear effect on retail prices.

According to ECON, the increase in the number of pharmacies would not have taken place without the new Act. New pharmacies have primarily been established in the central area of eastern Norway and in other densely populated areas. However, there has been no loss of pharmacies in rural municipalities. The few closures have been in central areas. In addition to the considerable increase in the number of pharmacies, their average opening hours have also increased. Moreover most pharmacies have introduced self-service and direct dispensing of prescriptions. This has resulted in a reduction in pharmacy queues and an improvement in service. The patient survey shows that patients are satisfied with the service.

Table 8.1 The number of pharmacies by ownership

Date	Alliance apotek, wholly owned	Apotek 1, wholly owned	Vitusapotek, wholly owned	Public hospital pharmacies	Others, including partly owned branches of pharmacy chains	Total
01.01.2001	–	–	–	28	369	397
01.01.2002	66	77	91	28	199	461
01.01.2003	89	130	100	30	153	502
01.01.2004	109	155	106	30	120	520
01.01.2005	114	168	113	30	110	535

Source: Norwegian Pharmacy Association

<figurtekster>

Number of pharmacies

Percentage changes

Hospital pharmacies

Private pharmacies

Percentage changes

Figure 8.3 Net increase in the number of pharmacies

The evaluation provides no clear answers as to whether the technical quality of the pharmacies' services has been reduced during the last three years. The workload of pharmacy personnel has increased considerably, and is regarded by many pharmacists as sometimes unreasonable. The scope of professional post-graduate training for pharmacists appears to have been reduced. The pharmacists' potential for providing patients with the necessary professional guidance is perceived by many as reduced, and half of the pharmacists hold the view that the guidance they give to patients is not sufficient. On the other hand, other indicators show no change in the level of quality. The incidence of erroneous dispensing does not appear to have increased, and the pharmacists themselves assess the incidence as unproblematical. Although the pharmacists feel that they are not able to give sufficient professional guidance to patients, they are not afraid, for example, that patients will use medicines incorrectly owing to misunderstandings connected with the supply of a replacement (generic) medicinal product. On the other hand, the medical practitioners are worried that generic replacement may result in an increase in incorrect use of medicines.

ECON points out that the Pharmacies Act has changed the structure of the pharmacy market. Firstly, freer establishment has provided a better basis for competition between pharmacies. Secondly, changed ownership rules have enabled the pharmacy market to be dominated by three separate chains, and has enabled the chains and the wholesalers to be jointly owned. Viewed in isolation, the establishment of pharmacy chains entails a limitation of competition compared with a hypothetical situation with many independent players. The competition between pharmacies is nevertheless greater than it was prior to the lifting of limitations on establishment, and is reflected in improved service and availability. This is described as a socio-economic gain.

The players have derived considerable economies of scale from integration within the pharmacy trade. By means of shared IT systems, coordination of purchasing routines,

new logistics systems, etc. it has been possible to considerably reduce the number of employees at each pharmacy. Integration has also resulted in rationalization gains for wholesale companies.

The Pharmacies Act opens up the prospect of generic replacement, that is to say that pharmacies are able to supply medicinal products that are medically equivalent to the medicinal products prescribed by the medical practitioner. The pharmacies are restricted to replacing medicinal products in accordance with a list of generic replacements prepared by the Norwegian Medicines Agency. Both the medical practitioner and the customer have a right to refuse replacement, and this occurs in approximately 10 to 12 per cent of cases. The customers account for by far the majority of such refusals, although, according to ECON's survey, they are positive and are satisfied with replacements. The medical practitioners rarely object to generic replacement and do so primarily on behalf of patients who have difficulty understanding the arrangement.

The pharmacies' opportunity to propose generic replacements to patients has increased the power of the pharmacy trade to negotiate with manufacturers in the generic pharmaceuticals market. Its negotiation position is further strengthened by the integration of pharmacies and wholesalers through joint ownership. ECON points out that the strengthened market power of the pharmacies and the wholesale pharmaceuticals trade has quite certainly resulted in lower purchase prices for medicinal products. However, the effects on retail prices during the period prior to submission of the evaluation were limited, and ECON considers that the Pharmacies Act has not had a clear effect on retail prices. The prices of medicinal products subject to prescription have fallen since the entry into force of the Pharmacies Act, but these changes are probably due to the annual price revisions of medicinal products carried out by the Norwegian Medicines Agency. This indicates that the pharmacy trade does not compete on retail prices.

ECON points out furthermore that the pharmacy trade has limited incentives to allow reduced purchase prices to benefit patients in the form of reduced retail prices. This is primarily due to the fact that patients attach little importance to price when purchasing medicinal products because a large part of the cost is paid by the National Insurance. It is in cases where patients pay themselves that prices have the greatest significance for the choice of medicinal product. The pharmacy's location and service have greater significance. Nor has sharing of wholesale discounts between the pharmacy and the customers (see box 12.2 on profit sharing), in the same way as for independent pharmacies, provided integrated pharmacies with incentives to reduce retail prices. This is because the group as a whole would then make a loss on the reduction of prices to pharmacies, thus giving part of the discount to the state.

8.4 Experience of supervising pharmacies

Supervision of pharmacy operations has been delegated to the Norwegian Medicines Agency. The Norwegian Board of Health is responsible for supervision of health professionals pursuant to the Health Personnel Act. The two agencies cooperate on the supervision of pharmacies.

The new Pharmacies Act has influenced the need for supervision in a number of ways. A number of the pharmacy chains aim for relatively uniform pharmacies with

the same quality system and quality targets. It is in the interests of the pharmacy owners that pharmacies have a high level of professionalism and that they make active efforts to attain this goal. In the long term, this may reduce the need for random controls.

On the other hand, many new licensees have less experience of Norwegian pharmacies than what was usual under the previous system. This indicates an increased need for supervision.

The internal control requirement has been introduced in order that the pharmacy itself shall be responsible for ensuring compliance with statutory requirements. A well functioning internal control system will increase the efficiency of the supervision.

An increased focus on efficient operations may compromise technical requirements. As a result of a relatively high incidence of erroneous dispensing, a number of pharmacies have been instructed to increase their staff in order to ensure responsible operations.

During 2003 and 2004, inspections were conducted at a total of 82 pharmacies at different places in Norway. Priority areas for supervision are normally staffing, competence, dispensing security and internal control systems. Supervision is also conducted by means of surveys whereby a large number of pharmacies fill in identical questionnaires. Such surveys provide detailed information on a limited area, and may detect individual pharmacies with a need for closer follow-up. Complaints from customers or health professionals are important for selection of pharmacies that need specific follow-up.

8.5 The Ministry's assessment of experience of the new Pharmacies Act

The Ministry is satisfied that the aims of the Pharmacies Act regarding better availability, increased service and rationalization of the pharmacy trade have been followed up. It is positive that the pharmacies compete on achieving these performance targets to a greater extent than previously. This will result in better pharmacy services for the customers. This leads the Ministry to conclude that the principle aims set out on the adoption of the Act have mainly been satisfied.

However, the Pharmacies Act is only one of several instruments for attaining lower prices for medicinal products. The establishment of horizontally and vertically integrated chains with international ownership in combination with generic replacement has laid the foundation for investing the pharmacies and wholesalers with much greater power to negotiate with the pharmaceutical industry in the generic market. Greater negotiating power is a requirement for reducing the prices of medicinal products, but is not in itself sufficient. ECON's analysis shows that the Pharmacies Act has only had a modest effect on the prices of medicinal products to the patient, and that the pharmacy chains have an incentive to sell the medicinal products at the maximum price. This is confirmed by the fact that a number of the chains have publicly maintained that they do not compete on price. These inappropriate incentives are not however due to the Pharmacies Act or to vertical integration as such, but to the orientation of price regulation. The players wish to maximize profits by keeping the prices as high as possible within the current rules.

The medicinal product market must be regulated so that the profits made by the dominant pharmacy chains and wholesalers in relation to the pharmaceutical industry should to a satisfactory extent be shared with consumers and with the National Insurance. There is little reason to believe that the prices of medicinal products would be reduced solely by removing the right to vertical integration between wholesalers and pharmacies. In such case, a new market structure would have to be constructed, with all the practical and economic challenges that would be involved. The Ministry would rather focus first on adapting price regulation to the new market situation, and therefore does not propose removing the right to vertical integration.

The competition authorities may intervene if the vertically integrated players inappropriately exploit their position in the market. In connection with the consideration of Proposition No. 1 to the Storting (2004–2005) (the budget proposition), the Storting adopted the Ministry's proposal for introduction of a stepped pricing model for regulation of the retail price of generic medicinal products. Price regulation is dealt with in chapter 12.

The Ministry aims to ensure as genuine as possible competition between pharmacies. Effective competition motivates the pharmacies and the wholesalers to carry out rationalization measures that result either in improved services or lower prices. However, the competition can only be genuine if access to the market for new players is not impeded by establishment requirements. The rules should therefore be designed so that companies without close ties to the pharmacy chains are able to establish themselves. Efficiency gains in the chain of distribution should also benefit consumers and the National Insurance regardless of the market structure. The Ministry will therefore pay close attention to the competition situation and, if necessary, propose changes to the market regulation that enables increased competition. One such measure is increased access to dispatch from pharmacies, see chapter 11. It may also be appropriate to assess the establishment requirements for new pharmaceutical wholesalers.

The evaluation of the Pharmacies Act provides no clear indications that the quality of the pharmacy services has fallen. The pharmacies' owners are responsible for ensuring that operations are satisfactory and the licensee concerned is responsible for ensuring this in the day-to-day management operations. Health professionals working in pharmacies are obliged to notify the pharmacy management or the authorities when working conditions adversely affect patient safety. When a pharmacy is not capable of operating responsibly, it is necessary to consider whether it must be closed. This may be an indication of overestablishment. The Norwegian Medicines Agency is responsible for supervision of quality and safety in pharmacies.

The Pharmacies Act provides patients with the right to the supply of the medicinal product prescribed. The patient may also choose to purchase the least expensive equivalent alternative. In order that these options shall be genuine, it is required in practice that the pharmacy has the medicinal products in stock. The efficiency of pharmacies' stocking has been improved following the introduction of the Pharmacies Act. The effect may be greatest for generic medicinal products since only a selection of these are stocked. All medicinal products in frequent demand shall however be stocked, cf. section 5-4 of the Pharmacies Act. In the view of the Ministry, this gives customers a good basis for availability of generic medicinal products that are in demand. ECON's report concludes that the great majority of customers interviewed had not noticed any change in supply efficiency. Of those who believed they had

observed a change, a majority considered the supply efficiency to be reduced. Controls have revealed that many pharmacies do not currently comply with the statutory obligation to monitor their own supply efficiency. However, this does not entail that the supply efficiency is actually poor. It is a supervisory responsibility to detect and react to any short supply. The Norwegian Medicines Agency is responsible for supervising this, and focuses on the issue. It therefore seems unnecessary to propose further measures for better supply efficiency at this time.

The Ministry has identified several areas where it is necessary to consider amendments to the Pharmacies Act. The need for such amendments arises out of the medicinal product authorities' work on pharmacy legislation and from input by the pharmacy trade itself. These matters are described in 8.7, below.

12 Price regulation

12.1 The need for price regulation

In a well functioning market, the interaction between supply and demand results in the establishment of a socioeconomically correct price. However, the medicinal product market is characterized by a number of factors affecting both the supply side and the demand side. Therefore, market mechanisms do not ensure socioeconomically correct prices. The most important factors are:

The National Insurance reimburses a considerable proportion of patients' expenditure on medicinal products, and little regard is therefore paid to price when choosing a medicinal product (third-party financing).

The medical practitioner chooses medicinal products on behalf of patients. However, the medical practitioner assumes no economic commitments, and the patient has little opportunity to assess whether the medical practitioner's choice of medicine is correct or whether corresponding efficacy could have been achieved by means of a less expensive medicinal product.

Many medicinal products are protected by patents, that is to say that they have a monopoly, which enables them to demand a high price.

The supply side is dominated by three large pharmacy chains, each integrated with its own wholesaler. The pharmacy chains have an explicit strategy of not competing on price.

These factors explain the need to regulate the medicinal product market in general and the prices of medicinal products in particular. The main purpose of maximum price regulation is to protect the consumers and public budgets from unreasonably high medicinal product prices. Since the market conditions in the medicinal product market are not capable of keeping prices low, the price paid by consumers and the public must be regulated. Without some form of price regulation, the prices paid by customers would probably have been much higher than they are today.

12.2 Current price regulation

Patented medicinal products

Before a medicinal product subject to prescription can be sold in Norway, the Norwegian Medicines Agency sets the pharmacy's maximum purchase price (PPP). Price data from other countries is obtained from the pharmaceutical companies, and the pharmacies' maximum purchase price is set at the average of the three lowest market prices for the medicinal product in nine selected countries in northern Europe. The Norwegian Medicines Agency carries out annual price reassessments. The pharmacy's maximum markup is also regulated so that the maximum pharmacy retail price (PRP) follows from the pharmacy's purchase price. Pharmacies can freely sell the medicinal product at a lower price, but medicinal products protected by patents are in practice sold at the maximum price. In most cases, this is also the price that is reimbursed by the National Insurance. The wholesale purchase price from the pharmaceutical companies (WPP) and the wholesale markup are on the other hand not regulated. The current regulation of the prices of medicinal products is shown in figure 12.1. The Ministry regards the current price level of patented medicinal products as satisfactory in relation to countries that it is natural for Norway to compare itself with.

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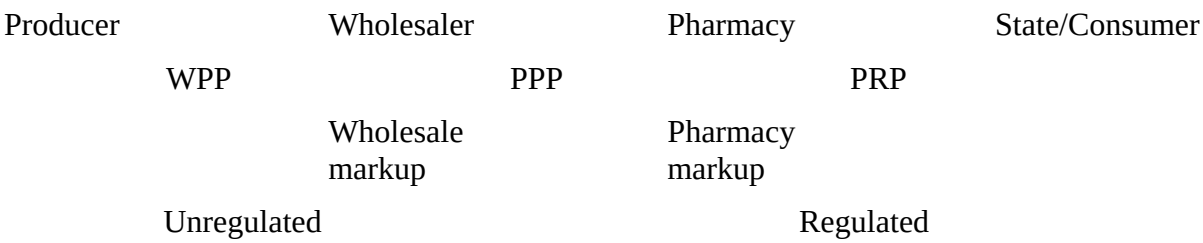

Figure 12.1 Price regulation of medicinal products

WPP = wholesale purchase price PPP = pharmacy purchase price PRP = pharmacy retail price

Generic medicinal products

New drugs are granted patents for 20 years. Owing to the time it takes to develop a medicinal product, this normally results in between 8 and 12 years' protection after the medicinal product is introduced onto the market. During these years, medicinal products containing the protected substance may not be sold by persons other than the patentee. After the expiry of the patent, other manufacturers may produce and sell medicinal products containing the same substance in competition with the original medicinal product. Such medicinal products from other manufacturers are referred to as generic and are normally assigned the same maximum price as the previously patented medicinal product. See box 12.1 for a more detailed description of generic medicinal products.

Competition between two or more identical medicinal products should normally entail greatly reduced prices since several suppliers compete to supply interchangeable products. In the generic market, the pharmacy chains have considerable power to negotiate with the industry on prices, and are therefore able to obtain substantial

discounts. However, the pharmacy chains have insufficient incentives to pass these discounts on to their customers. This is because, as mentioned in 12.1, a number of factors in the medicinal product market reduce the effectiveness of the price competition at the end-user level.

Box 12.1 Generic medicinal products

Generic medicinal products contain the same chemical substance at the same strength and the same form of administration as the original medicinal product. The name, package and appearance may vary, but the treatment efficacy for the patient is the same. The Norwegian Medicines Agency provides monthly updates of a list of interchangeable medicinal products.

The cost of producing a medicinal product is generally low, but the price of the product must also cover the costs of research and development. It is assumed that these costs are covered during the patent period. The price level of medicinal products should therefore be markedly reduced when generic competition occurs. The market for generic medicinal products is estimated at NOK 2 billion a year, and includes nearly 80 different drugs. Several substances with large sales are due to lose their patents in the near future, and the market with generic competition will therefore gain increased economic significance. In 2004 alone, drugs with sales amounting to over NOK 200 million were released for generic competition.

Several instruments have been designed to ensure that patients and the National Insurance receive a share of the discounts from the generic market. The instruments in use today are the profit sharing model and the stepped price model, both of which are described below.

The profit sharing model was introduced in 1995 in order to motivate the pharmacies to sell the least expensive of equivalent medicinal products, see box 12.2. When the pharmacy and the wholesaler both belong to the same company, there are strong incentives to realize the whole discount as profit by the unregulated wholesaler company. Over 70 per cent of Norway’s pharmacies are integrated with a wholesaler. The profit-sharing model combined with PPP regulation is therefore not very effective within the current ownership structure. However, the arrangement is still important for the independent pharmacies.

In order to exploit the competition in the generic market, a price regulation model known as stepped pricing was introduced on 1 January 2005 for a selection of drugs with generic competition, cf. Proposition No. 1 to the Storting 1 (2004–2005). Within each group of interchangeable medicinal products, at least one medicinal product shall be available at stepped prices. For these medicinal products, the stepped price is the maximum price reimbursed by the National Insurance. The stepped price is established as a percentage of the price of the original medicinal product on the date it was exposed to generic competition. The stepped price is established in accordance with the rates summarized in table 12.1.

The stepped price is gradually reduced from the date competition arises between generic medicinal products. In order to ensure that the independent pharmacies are able to transfer discounts they obtain from the suppliers, maximum markups are established for the wholesalers’ supplies to the independent pharmacies of medicinal products subject to the stepped pricing system.

Box 12.2 The profit-sharing model

The profit-sharing model is intended to provide the pharmacies with an incentive to negotiate reductions in purchase prices. If the pharmacies obtain a lower purchase price than the established maximum purchase price (PPP), they are allowed to retain half of the discount. This profit is added to the ordinary maximum markup. The pharmacies thus retain half of each krone of discount obtained, while the remaining half is passed to the customer/the National Insurance in the form of a lower retail price.

Table 12.1 Price reduction in the stepped price model

Time elapsed since establishment of generic competition	Medicinal product with annual sales below NOK 100 million	Medicinal product with annual sales above NOK 100 million
Immediately	Price cut by 30 per cent	Price cut by 30 per cent
6 months	Price cut by 40 per cent	Price cut by 50 per cent
12 months	Price cut by 50 per cent	Price cut by 70 per cent

The profit-sharing model does not apply to medicinal products included in the stepped pricing system.

The stepped price model has been estimated to result in savings for the National Insurance of NOK 450 million in 2005. In addition, the costs to patients will be reduced by an estimated NOK 70 million. If the stepped price model proves not to function according to intentions or other measures would result in lower medicinal product prices, the Ministry will reassess the alternatives to the stepped pricing scheme.

Medicinal products not subject to prescription

The prices of medicinal products not subject to prescription shall not be regulated. Customers pay for these medicinal products themselves, and the market therefore functions more effectively.

12.3 Maximum price regulation at different levels of the value chain

12.3.1 Background

The overall goal of price regulation is low retail prices for consumers and the National Insurance. However, importance must also be attached to how price and markup regulation will affect market structure, market power and competitive conditions in the short and long term. Regard must also be paid to the authorities' potential for control and regulation costs.

The Norwegian Medicines Agency currently establishes a maximum purchasing price for purchase of the medicinal product by the pharmacies (PPP) and a maximum

pharmacy markup for medicinal products subject to prescription. This entails regulation of the maximum pharmacy retail price (PRP).

The specific conditions of competition in the medicinal product market (see 12.1) necessitate a regulation of the PRP for medicinal products subject to prescription. *The Ministry* will therefore continue to regulate retail prices.

The issue is whether the regulation of the PRP should be supplemented by price regulation at other levels of the medicinal product supply chain as well. An alternative to the current regulation might be to establish only the PRP. Another alternative might be to establish the medicinal product's maximum price from the manufacturer to the wholesaler (WPP) in addition to the current regulation of the levels of the PPP and PRP. The various models are described in more detail below.

12.3.2 Regulation of the maximum pharmacy purchase price (PPP)

The Norwegian Pharmacy Association has proposed that only the pharmacy retail price should be regulated, and that regulation of the purchase price should be discontinued. The main reason is that this would strengthen the pharmacy chains in their negotiations with the industry.

In the case of vertically integrated pharmacy chains, the PPP is in practice an internal price, which has little real significance for the total earnings. This is because the pharmacies and the wholesaler are part of the same concern. It is the wholesale purchase price and the pharmacy retail price that decide the total earnings of the chain. It may therefore be maintained that regulation of the PPP has little significance for a major part of the pharmacies' total sales.

The current market for distribution of medicinal products is dominated by three major players, which own both the wholesaler and the pharmacies. However, in the view of the Ministry, the framework conditions must be designed in a manner that enables the operation of pharmacies without affiliation to one of the three chains. Access to information concerning the operations of the independent pharmacies may also provide useful correctives for the authorities' regulation and perception of pharmacy economy. In several places in Norway, individual chains have local monopolies, and independent pharmacies may challenge these.

In the absence of regulation of maximum purchase prices and maximum markups, a vertically integrated chain would to an even greater extent be able to make the pharmacies' economy appear weak by carrying out internal financial transactions between the wholesaler and the pharmacy outlets. In the long term, an appearance of weak pharmacy economy might result in a pressure to improve the pharmacies' framework conditions. This might result in higher costs for the customers and the National Insurance.

A model that solely regulates the PRP would increase the market power of the vertically integrated chains at the expense of the independent pharmacies. This is because wholesalers would be able to offer the independent pharmacies purchase prices that did not provide a basis for economically profitable operations. The Norwegian Pharmacy Association maintains there is effective competition between the various wholesalers and that independent pharmacies would be able to purchase wholesale services where they are cheapest. In the view of the Ministry, it is uncertain to what extent there is actually genuine competition between the wholesalers on

supply to independent pharmacies and how this competition will develop over time. All wholesalers are all attached to a pharmacy chain and, for independent pharmacies, regulation of the PPP provides protection against the chains' potential exploitation of market power. The independent pharmacies maintain themselves that they wish the PPP regulation to be upheld.

If, as a result of the abolition of maximum PPP, independent pharmacies should no longer face competitive framework conditions, it would be extremely difficult to provide for re-establishment of independent pharmacies. This indicates a need for caution. By continuing to regulate the PPP, the authorities would be able to influence the economic framework conditions for medicinal product distribution in Norway. Correspondingly, regulation of the PPP with associated markup regulation would be the authorities' instrument for ensuring the pharmacies framework conditions for carrying out any social obligations imposed.

The Norwegian Medicines Agency establishes the pharmacies' maximum purchase price based on information from other countries. It would be difficult to establish a corresponding model based on the pharmacy retail prices. The reason for this is that markups and local fees differ in comparable countries. Establishment of prices on the basis of comparisons at the PRP level would be affected by these external factors. The PPP is the simplest available level for obtaining international prices. In practice, comparable prices would therefore have to be obtained at the PPP level and then assigned a estimated pharmacy markup. This would in such case entail that the authorities would nevertheless need to consider a pharmacy markup. Moreover, maximum PPP is well-established in the pharmacy trade. The Ministry cannot see that this regulation entails any particular administrative costs for pharmacies.

In view of this, the Ministry will continue to regulate both maximum PPP and the pharmacies' markup.

12.3.3 Regulation of wholesalers' maximum purchase price (WPP)

Several earlier reports – NOU 1997: 6, Dalen and Strøm (2004), Brekke and Straume (2003) – have recommended regulation of the WPP rather than regulation of the PPP. However, somewhat different grounds have been put forward for so doing. NOU 1997: 6 referred to a weakening by the "full range requirement" of the wholesalers' negotiation position in relation to the manufacturers (see 11.3), since the wholesalers do not have effective sanctions in the event of a breakdown of negotiations, and that, out of regard for the wholesalers, one should therefore regulate the maximum WPP. Furthermore, it was stressed that *"by regulating the maximum WPP, the authorities succeed in putting direct pressure on the individual supplier, and that the question of prices between the authorities and the manufacturers is restricted to matters purely concerning production."*.

The two other reports, which took the generics market as their point of departure, maintained that regulation of the PPP in the current market with a high degree of vertical integration was not compatible with the desire for the lowest possible prices. Common to all three reports is the recommendation that a WPP regulation should replace the regulation of the maximum PPP. However, regulation at all three levels (WPP, PPP and PRP) was regarded by all as entailing a risk of erroneous regulation.

The wholesalers' purchase price is not currently regulated, and the wholesalers' markups are therefore established by means of negotiations between the wholesaler and the medicinal product manufacturer. Any regulation of the wholesalers' purchase price would require that the authorities regulated the wholesalers' markup in addition to the pharmacies' markups.

There may be grounds for strengthening pharmacies' and wholesalers' power to negotiate with the pharmaceutical industry in the market for patented medicinal products. This is because there are no alternatives to these medicinal products and because the pharmacies are obliged to supply the medicinal products that are ordered. The wholesalers are normally required to be able to supply what the pharmacy orders within 24 hours. Such a requirement regarding supply of the full range could weaken the wholesalers' negotiating power in relation to the manufacturers of patented medicinal products since the wholesalers are not able to choose between different manufacturers. On the other hand, the suppliers of medicinal products would have a commercial interest in maintaining a provision of the logistical services offered by the wholesalers for sale of their medicinal products. Although it is true that suppliers could be wholesalers for their own product ranges, this would not be particularly practicable under normal market conditions. Through integration with wholesalers, the pharmacy chains have attained greater purchasing power. In the view of the Ministry, there is now less need to ensure the wholesalers reasonable purchasing conditions than there was before the new Pharmacies Act entered into force. The market seems reasonably well balanced, and the pharmacy chains have not expressed any wish for such protection. Another reason for regulating the wholesalers' purchase prices may be in order to ensure by means of profit sharing that patients and the National Insurance receive a share of the discounts obtained by the pharmacy chains, particularly in the generic market.

In box 12.2, an account is given of the current profit-sharing model. Under the new Pharmacies Act, the opportunity for vertical integration has weakened the significance of the profit-sharing model. The wholesalers have currently no incentives to transfer the benefit of any discounts to the customer, since this would entail that they would have to forfeit half of their negotiated discount to the state. The pharmacy purchase price is established by the wholesaler. In a chain that owns both the wholesaler and the pharmacies, this is an internal price within the same concern. Any discount from the medicinal product manufacturer can be retained as increased profit by the wholesale company, and the medicinal product can be sold to the pharmacy at the maximum PPP. The current regulation and current market conditions do not therefore ensure that any discounts benefit the customer. A number of medicinal product manufacturers have stated that discount to the wholesalers does not result in lower prices to the customer.

If one wishes to use the profit-sharing model as an effective price reduction instrument, a maximum WPP must be established. However, regulation of the wholesalers' purchase price combined with profit sharing would require supervision and control of the players in order to ensure that purchase discounts benefited the customers. The many points of reporting and supervision constitute a risk of circumvention of the regulation, and thereby also a risk of distrust of the parties. Supervision and control of the financial regulations in connection with the index price system have proved difficult and resource-consuming. This applies particularly to discounts not reflected in the wholesalers' purchase prices and any purchasing

conditions negotiated by the international parent companies and affiliates of the pharmacy chains.

The potential for transfer of discounts is greatest in connection with the sale of generic medicinal products, where the wholesalers and the integrated pharmacy chains have considerable power to negotiate. In Proposition No. 1 to the Storting (2004–2005), an account was given of various models for generic competition, and it was decided that a model based on stepped pricing should be introduced. Even if one regulates the maximum price to the chain, there is little likelihood that the pharmacies will sell generic medicinal products at a lower price than the stepped price. In the model, it is assumed that any discounts under the stepped price can be retained by the pharmacy. Stepped pricing has thus replaced the use of the profit-sharing model in the market segment for interchangeable generic medicinal products.

In the market for patented medical products, the Ministry assesses that medicinal product manufacturers rarely give discounts except in the case of suppliers of parallel-imported patented medicinal products (medicinal products with the same manufacturer but a different importer). If the market for parallel imports grows considerably above the current level, this reflects that prices are relatively higher in Norway than they are in other EEA countries. This may give grounds for adjusting the way in which the maximum price for patented medicinal products is established.

Establishment of markups for both the wholesalers and the pharmacies may be demanding. Standard markups based on averages might result in a skewed distribution of income in relation to costs. Adaptation to the individual wholesaler, supplier and commodity code would demand continuous maintenance and a relatively large element of discretion. The consequence of erroneous regulation would be too small a margin for the wholesaler or too little payment for the manufacturer. In both cases, a risk of short supply might arise.

The Ministry considers the risk of erroneous regulation on introduction of a maximum WPP and a profit-sharing model to be too great compared with the potential for obtaining further price reductions beyond those that follow from the adopted stepped pricing model. Other, less radical measures seem more likely to reduce medicinal product prices. It will moreover be possible to introduce a regulation of the wholesalers' purchase prices at a later date if other measures prove not to function according to intentions. *The Ministry* will therefore not at this time propose the introduction of a maximum price for the wholesalers' purchase of medicinal products.

14 Background and objectives

The reimbursement system covers costs associated with medicinal products used in the treatment of serious chronic diseases or conditions where prolonged treatment is necessary in order that serious disease shall be avoided in the future. The intention of the reimbursement system is to ensure members of the public equivalent and easy access to medicinal products regardless of their ability to pay for them.

National Insurance costs associated with medicinal products have risen steeply over several years. In 1995, reimbursements for medicinal products amounted to approximately NOK 3.8 billion. In 2003, the figure was approximately NOK 8.2 billion. This is a doubling of costs during this period and, when adjusted for the general increase in prices, costs rose by almost 80 per cent. In 1995, the National

Insurance's share of the total medicine costs was 51 per cent. This share had risen to 57 per cent by 2003. The rise in costs can mainly be explained by a transition to new and more expensive medicinal products. The rise is also due to an increase in the volume of medicinal products sold. This development shows the need for a reimbursement system that provides for correct priorities, targeting of benefits and good compliance.

The reimbursement system for medicinal products is intended to help in attaining the following goals, cf. Proposition No. 29 to the Odelsting (1998–1999):

1. Ensure equivalent and easy access to effective medicinal products for small and large patient groups with a documented need for medicinal treatment.

2. Give the community value for money, that is to say that the authorities shall reimburse costs associated with medicinal products that provide a definite health gain for the patient and have good efficacy in relation to the costs. Good cost management is important for ensuring the best possible utilization of the funds allocated.

3. Encourage responsible and cost-conscious prescription and use of medicinal products by medical practitioners and patients.

4. Make efforts to ensure that individuals with moderate or low risk of future disease, where the treatment efficacy is small or uncertain, take as much responsibility as possible for their own health. The authorities are primarily committed to helping patients with serious disease or high risk of disease in cases where effective medicinal products exist.

5. As far as possible, reflect knowledge of gains and costs associated with the use of medicinal products on the basis of health economy studies and assessments.

6. Be easy to administer and understand.

7. Give the authorities the opportunity to remove medicines when it is documented that the benefit is not in proportion to the costs.

The Ministry regards these requirements as fundamental for the reimbursement system both now and in the future.

Three different schemes have been established for reimbursement of costs associated with medicinal products dispensed outside of hospitals or the municipal health service. Prior-approved reimbursement, whereby the medical practitioner writes out a "blue prescription", is the most usual scheme. It is also possible to apply for reimbursement on a case-by-case basis or for assistance with extraordinary expenses on account of illness.

In connection with its consideration of Proposition No. 1 to the Storting (2004–2005), the Storting decided as follows: "the Storting requests the Government, if the Norwegian Medicines Agency's report concerning the medicinal product Remicade gives grounds for amending the reimbursement conditions, to submit the matter to the Storting with a view to clarification in the Revised National Budget spring 2005". The Ministry has commenced work on investigating the financing arrangements in relation to Remicade and other corresponding medicinal products, and will submit its report to the Storting in connection with the Revised National Budget for 2005. This question has not therefore been given further consideration in this Report to the Storting.

Financing of expensive medicinal treatment by the specialist health service (hospitals), including medicinal products for treatment of cancer, is an issue of current relevance. The Ministry of Health and Care Services has begun work on a review of the financing system for the specialist health service's capacity for keeping informed of developments in such medicinal treatment. The Storting will receive a provisional orientation on this work in connection with the submission of the Revised National Budget for 2005.

15 Prior-approved reimbursement

15.1 The current rules and procedures

15.1.1 Summary

Prior-approved reimbursement, or the "blue prescription" scheme, is the most extensive scheme within the Norwegian reimbursement system. The manufacturer of the medicinal product applies for reimbursement, and the Norwegian Medicines Agency assesses whether the application satisfies the requirements laid down in the Regulations. Medicinal products approved for reimbursement are added to the List of Reimbursable Products. It is then the medical practitioner who must assess whether patients satisfy the conditions laid down by the Norwegian Medicines Agency for reimbursement of the individual medicinal products. If the conditions are satisfied, the medical practitioner may write a "blue prescription", which gives the patient the right to reimbursement. Costs associated with prior approved reimbursement of medicinal products are normally covered pursuant to section 9 of the Blue Prescription Regulations.

The Norwegian Medicines Agency decides 75–100 reimbursement cases each year. This includes applications for reimbursement of generic medicinal products, new forms of administration, new strengths and new drugs. Approximately 10 reimbursement applications are rejected each year.

The following provides a description of the current rules and administrative procedures in connection with reimbursement of new medicinal products. The new procedural rules are briefly described in 15.1.2. In order that a medicinal product may be granted reimbursement, the technical requirements provided in section 14-13 of the Medicinal Product Regulations must be satisfied. These requirements are further described in 15.1.3.

If a new medicinal product satisfies the technical requirements, further processing of the application is dependent on whether the Norwegian Medicines Agency has been delegated decision-making authority. The Norwegian Medicines Agency is empowered to grant reimbursement if it is not necessary to establish a new disease category or medicinal product group in section 9 of the Blue Prescription Regulations (see 15.1.4), and the annual additional costs of reimbursement are less than NOK 5 million (see 15.1.5). In the remaining cases, the reimbursement decision must be submitted to the Storting as part of the total submission of the budget, see 15.1.6.

15.1.2 New procedural rules in 2003

Reimbursement schemes for costs associated with medicinal products are in principle a national concern. However, Council Directive 89/105/EEC of 21 December 1988 (the Transparency Directive) sets out requirements regarding time limits, available remedies and objective criteria for when an application for reimbursement shall be granted. On 6 June 2003, the Ministry issued new regulations concerning consideration of applications for inclusion of medicinal products in "blue prescriptions". A number of requirements were introduced regarding the applications, and criteria for inclusion were laid down in regulations. The Norwegian Medicines Agency was granted the right and obligation to make decisions in all cases. The processing time limit for price and reimbursement cases is a total of 180 days, which terminates when the Norwegian Medicines Agency has made a decision. All decisions may be appealed to the Ministry of Health and Care Services. Another new element is the use of a Blue Prescriptions Board for quality assurance of the basis for decision-making in selected cases. In the view of the Ministry, this has resulted in a more open and predictable process for dealing with reimbursement applications.

15.1.3 Technical requirements regarding the medicinal product

It is a requirement for the granting of reimbursements pursuant to section 9 of the Blue Prescription Regulations that the medicinal product satisfy the overall requirements regarding the severity of the disorder, the duration of the treatment and proportionality between the value of the treatment and the cost. The Norwegian Medicines Agency makes this assessment on the basis of the following technical criteria laid down in section 14-13 of the Medicinal Product Regulations:

a) The medicinal product shall be used for treatment of serious diseases or of risk factors that will most probably lead to or aggravate a serious disease.

b) The disease or risk of disease as referred to in (a) entails a need for or risk of repeated treatment over a prolonged period.

c) The medicinal product has a scientifically well documented and clinically relevant effect in a defined, relevant patient population.

d) The costs of using the medicinal product are in reasonable proportion to the therapeutic benefits and to costs associated with other forms of treatment.

Table 15.1 Example from the disease list in section 9 of the Blue Prescription Regulations

Disease list	Medicinal product groups	Comments
4. […]		
5. Diabetes mellitus	a) Insulin products. b) Other substances for diabetes treatment. c) In connection with frequent hypoglycaemic episodes. d) Thiazolidinediones (glitazones), also as combined products	*To d:* i) Glitazones are only subject to reimbursement as combined treatment, and ii) only for patients who do not achieve sufficient disease control with a combination of metformin and sulfonylurea or who experience unacceptable adverse reactions to metformin and sulfonylurea products or combinations of these, and iii) only for patients for whom alternative treatment would have been insulin, and iv) shall only be prescribed by medical practitioners with extensive experience of treating type 2 diabetes mellitus.
6. […]		

15.1.4 Requirements regarding disease categories and medicinal product groups

Inclusion in the List of Reimbursable Products requires that the medicinal product is approved for treatment of a disease (diagnosis) specified in section 9 of the Blue Prescription Regulations, and prescribed subject to the conditions provided in the associated comments. There are currently over 40 such disease categories in the disease list provided in the Blue Prescription Regulations. The medicinal product must also be included in a medicinal product group referred to under the relevant disease categories. See table 15.1 for an illustration of the structure of the regulations. Together with the List of Reimbursable Products, the disease categories and medicinal product groups define patients' rights in the "blue prescription" scheme.

The great majority of reimbursement applications concern medicinal products in new strengths or generic versions of already reimbursed medicinal products. In these cases, the necessary disease categories and medicinal product groups are already provided in the regulations, and inclusion of the medicinal products in the reimbursement system will not normally increase the costs of the National Insurance. In such cases the Norwegian Medicines Agency continuously updates the List of Reimbursable Products in relation to individual decisions.

New medicinal products based on new treatment principles do not initially fall under the existing disease categories and medicinal product groups in the regulations. Including these products in the List of Reimbursable Products and making them eligible for reimbursement in the "blue prescription" scheme requires an amendment of the regulations. The National Insurance costs associated with medicinal products

through the “blue prescription” scheme follow directly from the rules provided in the Blue Prescription Regulations, and the allocations are therefore governed by rules.

Changes in the diseases or medicinal product groups that give a right to reimbursement may increase total medicine costs. Only the Storting is able to grant funds to extend the reimbursement system. Applications for reimbursement of the cost of medicinal products that do not fall under the categories listed in section 9 of the Blue Prescription Regulations may not therefore be granted by the Norwegian Medicines Agency. This shall apply even though the technical requirements in section 14-13 of the Medicinal Product Regulations are satisfied. Only the diabetes medicines Actos and Avandia have not been granted reimbursement during the last two years owing to the lack of a medicinal product group in the regulations. These medicines were later granted reimbursement on conclusion of a reimbursement contract.

15.1.5 The bagatelle limit

In the majority of cases, reimbursement of medicinal products covered by existing disease categories and medicinal product groups does not result in significant increases in costs for the state. However, some of the disease categories and medicinal product groups are so generally formulated that some new medicinal products based on new treatment principles also satisfy the requirements laid down in the regulations. The background for this is that the medicinal product groups and the disease list provided in section 9 of the Blue Prescription Regulations have been formulated in general terms in connection with inclusion of specific medicinal products. The scope of application may thus be defined so broadly that other medicinal products can also be included although not originally deliberated. The disease categories “*allergic disorders of the upper respiratory tract, eyes and intestine*” may for example have been included owing to the granting of reimbursement for a specific medicinal product for treating a specific form of allergy. However, this disease category has later provided the authority for inclusion of all types of allergy medicine.

If special provisions had not been issued for these cases, the Norwegian Medicines Agency would be obliged to grant reimbursement by means of administrative decisions, which would entail considerable additional expense for the National Insurance. For this reason, it was provided in regulations on 6 June 2003 that the Norwegian Medicines Agency only has the authority to grant reimbursement for a medicinal product without the consent of the Storting, if this results in an estimated additional annual cost to the National Insurance of less than NOK 5 million (bagatelle limit) five years after granting of reimbursement. During the last two years, the Norwegian Medicines Agency considered applications for four medicinal products that would have resulted in greater costs than are allowed by the bagatelle limit (costs over NOK 5 million). The estimated additional costs for these medicines in relation to existing therapy varied between NOK 30 million and NOK 140 million a year. Of these medicines, two have subsequently been granted prior-approved reimbursement and two are still being assessed by the Ministry.

15.1.6 Decisions and further consideration of medicinal products that fail to satisfy the requirements

If all requirements of the regulations are satisfied, the Norwegian Medicines Agency makes a decision concerning inclusion of the medicinal product in "blue prescriptions". If the requirements are not satisfied, the Norwegian Medicines Agency always rejects the application. The applicant may appeal against the decision. Work on the application is discontinued in cases where it is rejected because the technical requirements (prolonged treatment, serious disease and cost effectiveness) are not satisfied.

In cases where an application is rejected because the Norwegian Medicines Agency does not have the authority to grant reimbursement, the agency shall give the Ministry an assessment of whether the technical requirements are satisfied. This is appropriate if the medicinal product is not included in section 9 of the Blue Prescription Regulations or if the bagatelle limit is exceeded. A positive conclusion would be one of several components of the Government's and, if appropriate, the Storting's assessment of whether the reimbursement system should be extended in order to include the medicinal product in question. In April 2004, the Ministry established a Blue Prescriptions Board in order to enlarge and assure the quality of the technical basis for decision-making in such medicinal product cases, among others. The Board is composed of a permanent committee of seven persons with broad competence, including several medical practitioners and a representative for the medicine users. In addition, three clinical specialists with relevant expertise in the medical speciality associated with the medicinal product shall be appointed for each case. The applicant shall have access to the basis for the reimbursement assessment in connection with consideration by the Blue Prescriptions Board, and may provide input to the process. The pharmaceutical companies shall be given the opportunity to provide additional information and correct any misunderstandings that occur during consideration of the case. Furthermore, the Norwegian Medicines Agency may obtain more detailed input from the Board in technically difficult matters.

If the Norwegian Medicines Agency, on the basis of this process, finds the technical requirements to be satisfied, the reimbursement case will be dealt with as part of the Government's ordinary budget process and be prioritized in relation to other measures and costs within the various areas of expenditure of the fiscal budget, see 15.4. The technical assessment of the Norwegian Medicines Agency is restricted to comparison with other treatments for the same disease. This assessment is therefore only input for the main policy assessments concerning whether consent shall be given to extension of the reimbursement system.

The current procedures for inclusion of medicinal products in "blue prescriptions" is summarized in figure 15.1. The new processes and rights provided in the regulations of June 2003 are now fully implemented.

15.2 Comparison of reimbursement and marketing authorization

The conditions for granting reimbursement are not the same as those for granting marketing authorization. The differences are due to the fact that reimbursement access

involves rather more than simple market access. Reimbursement creates rights and obligations for medical practitioners, patients and the authorities.

Permission to sell a medicinal product in Norway is granted to the medicinal product manufacturer by the Norwegian Medicines Agency. Such permission is granted by giving the medicinal product a so-called marketing authorization. The marketing authorization is granted if it is documented that the medicinal product has high quality and efficacy and an acceptable adverse reactions profile. It is generally required that a new medicinal product shall have better efficacy than a placebo (no treatment), and that, viewed as a whole, it shall not have poorer efficacy and safety than other medicinal products for treatment of the disease. The requirements regarding the clinical studies designed to document this are described in the international guidelines. A further requirement for marketing authorization is that new medicinal products shall have better efficacy than medicinal products already authorized for sale. In most cases, marketing authorization is a supranational decision, taken as part of the European pharmaceutical cooperation, which Norway is obliged to comply with pursuant to the provisions of the EEA Agreement. The price of the medicinal product is *not* part of the assessment basis when the Norwegian Medicines Agency grants marketing authorization to a new medicinal product.

<figurtekster>

Company submits application

Norwegian Medicines Agency considers the matter

Norwegian Medicines Agency considers requirements regarding:

- disease category and medicinal product group
- additional expense (currently bagatelle limit)

SATISFIED

NOT SATISFIED

Rejection – outside the scope of the Norwegian Medicine Agency's authority

The company shall have access to documents submitted to the Blue Prescriptions Board, and may submit comments

The Blue Prescriptions Board considers the basis for decision-making and answers questions

The company receives a copy of the Blue Prescriptions Board's opinion

The Norwegian Medicines Agency considers whether the technical conditions for reimbursement are satisfied

The Norwegian Medicines Agency considers whether the technical conditions for reimbursement are satisfied

YES

NO

YES

Decision to include the product in the List of Reimbursable Products

Rejection decision

Ministry considers the medicinal product in relation to other measures in the budget

Appeal to Ministry

The Storting is given the opportunity to consider the prioritization

Figure 15.1 Procedures for inclusion of medicinal products in "blue prescriptions"

New processes and rights are marked yellow.

When a medicinal product has been granted marketing authorization, and not before, the manufacturer applies to the Norwegian Medicines Agency for a maximum price and prior-approved reimbursement ("blue prescription") for the medicinal product. The Agency assesses whether the requirements for granting reimbursement for the medicinal product are satisfied, see 15.1. This is not an reconsideration of the efficacy and safety assessments that follow from the marketing authorization, but an additional requirement since reimbursement eligibility is not assessed when a medicinal product is granted marketing authorization. The additional requirements form the basis for correct priorities and are laid down in section 14-13 of the Medicinal Product Regulations. In table 15.2, the relation between marketing authorization and requirements regarding reimbursement is summarized.

15.3 The requirement regarding inclusion in disease categories and medicinal product groups

If prior-approved reimbursement is to be granted for medicinal products not included in an existing disease category or medicinal product group in section 9 of the Blue Prescription Regulations, the Storting must consent to the necessary amendments to the regulations. This is currently applicable even though reimbursement of medicinal products would result in modest additional expenses for the National Insurance, see 15.1.5.

The requirement that a medicinal product must fall under existing disease categories and medicinal product groups in order to be included in the "blue prescription" scheme delays the granting of reimbursement for medicinal products in the lower part of the cost scale. In the view of the Ministry, since the introduction of the bagatelle limit of NOK 5 million in 2003, this limitation has been unnecessary for ensuring correct prioritization of the community's resources.

Table 15.2 Application requirements

Requirements	In connection with applications for marketing authorization	In connection with applications for reimbursement
The medicinal product has documented efficacy, safety and production quality.	Required	Required
The medicinal product is used to treat a serious disease or risk factors that give rise to serious disease.	Not required	Required
The treatment is prolonged.	Not required	Required
The cost of using the medicinal product must bear a reasonable relation to the efficacy.	Not required	Required. A medicinal product that has a higher price than an already reimbursed treatment, with corresponding efficacy and adverse reactions profile, does not qualify for reimbursement.

On the basis of the above, *the Ministry* will propose that the disease categories and medicinal product groups provided in section 9 of the Blue Prescription Regulations not be used as an inclusion criterion for "blue prescriptions" in the future. This requires an amendment of the Medicinal Product Regulations. The disease categories and medicinal product groups provided in the regulations will however remain decisive for patients' rights and for what medical practitioners may prescribe at the expense of the National Insurance. *The Ministry* will therefore propose that the Ministry be given a general authority to make the amendments to the disease categories and medicinal product groups that are necessary for each inclusion of medicinal products. Such an authority will only apply to medicinal products the cost of which is estimated to lie below the bagatelle limit, see 15.1.5.

15.4 The public administration's authority to grant prior-approved reimbursement

15.4.1 The issue – prioritization

In the view of the Ministry, it is inappropriate that all reimbursement cases are submitted to the Storting regardless of the size of the future costs. The Storting has fixed a cost limit of NOK 5 million for the authority of the medicinal product authorities to admit new medicinal products to the reimbursement system.

Both the Norwegian Association of Pharmaceutical Manufacturers and the patients' organizations have called for more rapid inclusion of new medicinal products in the reimbursement system. In connection with the consideration of Proposition No. 88 to

the Odelsting (2002–2003) relating to reimbursement contracts, the Standing Committee on Health and Social Affairs stated as follows regarding inclusion of new medicinal products in the "blue prescription" scheme set out in the Recommendation to the Odelsting (Innst O) No. 29 (2003–2004):

"The committee establishes that the current rules and procedures entail the submission of specific medicinal products to the Storting in order to secure financing. Members of the Storting therefore consider medical matters concerning whether or not specific medicinal products shall be admitted to the "blue prescription" scheme. The committee agrees with the view of the Ministry and the commenting bodies that it is necessary to establish a reasonable and predictable way of ensuring cost control. In connection with a broader review of the "blue prescription" scheme, the committee will also request the Ministry to assess other models of cost control than reimbursement contracts, where grants based on estimates subject to stringent economic control mechanisms can be made part of the assessment".

The issue is whether medicinal products that satisfy the technical criteria for reimbursement, but which entail increases in costs, shall be granted reimbursement without consideration by the Storting.

15.4.2 Grants based on estimates

There are in principle stringent conditions associated with grants based on estimates. The guide to work on government budgets prepared by the Ministry of Finance states as follows:

"Sickness benefits and National Insurance pensions are typical examples of cases where the term "grants based on estimates" can be used. In such cases, the Storting has generally adopted exhaustive rules concerning the special assistance scheme, and benefits are actuated by objectively decided factors. The costs thus follow automatically from rules provided by the Storting, and cannot be governed by the administration. However, the term "grants based on estimates" does not enable a ministry to exceed the grant by extending the cost basis in relation to the assumptions on which the grant is based, for example, by establishing standard increases or by making the support available to new groups."

None of the items under the Ministry of Health and Care Services' part of the National Insurance budget have been termed "grants based on estimates". Most of the items are however governed by rules in the sense that the National Insurance continues the reimbursement payments although the grants are exceeded. Furthermore, the budget estimates for the items are based not on frameworks but on cost forecasts provided by the National Insurance Estimation Group. Inclusion of new medicinal products in the reimbursement system can be described as a "standard increase" that must be assessed in the collective budget proposal to the Storting. Against this background, introduction of the term "grants based on estimates" will not entail any change in relation to the current practice of inclusion of new medicinal products in the reimbursement system.

15.4.3 The Ministry's assessment

Two priority levels

The state's costs associated with reimbursement of medicinal products have risen steeply for several years. One of the greatest driving forces behind this growth is reimbursement of new and more expensive medicinal products. There are several examples of development of extremely expensive medicinal products for specific diseases. The most recent treatment methods for rheumatoid arthritis include medicinal products that cost approximately NOK 150 000 per patient/year. The example illustrates a development that will result in increasingly greater demands on correct priorities, both between different methods of treatment and different health services, see chapter 3.

The current arrangement for inclusion of medicinal products in the prior-approved reimbursement scheme is based on two separate prioritizations.

The first prioritization is based on medical and health economy considerations. The Norwegian Medicines Agency assesses whether the medicinal product in question satisfies the technical requirements set out in 15.1.3. The question is then whether the medicinal product is as good as or better than other treatment provision for a specific disorder and whether the price is proportionate to the value of the treatment. The medicinal product is not prioritized in relation to medicinal products or health measures used in the treatment of other diseases.

The second prioritization is of a different character. If the medicinal product satisfies the technical requirements of the first prioritization, but reimbursement would result in additional expenses that exceed the bagatelle limit of NOK 5 million, a prioritization must be carried out at a higher level. The question for the Government and the Storting is then whether the new medicinal product should be given a priority higher than that of other measures in the health area.

These prioritizations are based on different conditions, and it is therefore reasonable that they have different results. It therefore does not necessarily follow that reimbursement of a given medicinal product should be given higher priority than other health measures, even if it satisfies technical requirements.

The issue is therefore whether allocations to medicinal products shall be prioritized in relation to other health measures within a total budget proposal or be granted "special priority" based solely on assessments restricted to a specific area of disease.

Such a "special priority" would in practice be implemented by removing or raising the bagatelle limit. If such a solution is chosen, the Norwegian Medicines Agency will be delegated extended responsibility for admitting medicinal products to the list of medicinal products granted prior-approved reimbursement (blue prescription). The bagatelle limit is fixed so as to balance the need for cost control and prioritization in relation to the need for rapid processing of reimbursement cases. The effect of raising the bagatelle limit would be that more medicinal products would be granted reimbursement, although the patients' benefit from other measures may be assessed as greater. However, it must be stressed that most medicinal products can be reimbursed on individual application by patients with special needs. Most medicinal products will therefore be available to patients at a price within the limits of the patient's charge. It

is the aim of the Ministry that patients shall have access to medicinal products within a reasonable time through the application-based individual reimbursement scheme.

The choice between different health measures is difficult, particularly when a new treatment provision targets patients who have a documented need for treatment. In the view of the Ministry, it would be inappropriate to delegate the responsibility for these difficult political prioritizations between different health measures to a government agency. In the majority of cases, a raising of the bagatelle limit would entail delegation of responsibility for difficult priorities within the health service to the Norwegian Medicines Agency. Such decisions may commit the community to considerable costs, and may therefore have major consequences for priorities concerning the total and future health provision available to the public, thereby assigning medicinal products a special priority for which there is no basis. Such a development may have unfortunate consequences for the total provision of health services to the public.

The medicinal product market is dominated by strong players who make considerable efforts to gain access for new and expensive medicinal products to the reimbursement system. Other new treatment provision within the health service may also satisfy basic requirements regarding needs, cost effectiveness and professional competence. Without the support of correspondingly strong interests, such provision must be compared within a total budgetary framework. There is little to indicate that it is more difficult to assess medicinal products in terms of prioritization than it is to assess other health measures. Medicinal products should therefore be subjected to the same political prioritization as other well founded health measures within a total budgetary framework.

During the last two years, the Norwegian Medicines Agency has considered four applications involving costs exceeding the bagatelle limit. The estimated additional costs varied between NOK 30 million and NOK 140 million per year. In view of this, a significant reduction in the number of cases requiring assessment in relation to the budget would require a considerable raising of the bagatelle limit. This indicates that the current bagatelle limit achieves a satisfactory balance of the regard for prioritization and effective procedures.

It is moreover the view of the Ministry that measures other than the bagatelle limit, such as price regulation, information and control measures, would not maintain a good enough cost control and ensure correct prioritization of health funds. Such measures are only effective for medicinal products that have already been admitted to the reimbursement system, and do not enable influencing of the inclusion of new medicinal products. Experience has shown that it is difficult to establish good cost control arrangements within the reimbursement system that attain a sufficient degree of political and professional acceptance.

New quality assurance of administrative procedures

When processing reimbursement cases, it is important that the public administration's preliminary investigations have considerable professional legitimacy, so that the Storting is able to focus on prioritization between different socially beneficial measures. New procedural rules were introduced in 2003 in order to give greater professional legitimacy to the public administration's decisions. These rules have introduced transparency into the process as well as the possibility for the parties to

comment on the basis for decision-making, a clear appeal procedure and the use of a broadly composed Blue Prescriptions Board to assure the quality of the basis for the decision. In the view of the Ministry, this is capable of providing greater confidence that the technical questions are sufficiently elucidated, when the medicinal product authorities, the Government or the Storting considers inclusion of new medicinal products in the "blue prescription" scheme. The Blue Prescriptions Board was set up in April 2004 and has not yet submitted comments concerning reimbursement cases considered by the Storting. The new procedural rules have not therefore been fully implemented until now. This entails that the pharmaceutical companies' arguments concerning the efficacy and social benefits of their own products will in the future be considered by both the Norwegian Medicines Agency and the Blue Prescriptions Board. In the view of the Ministry, this will make it easier for the Storting to focus on the overall prioritization between medicinal products and other health measures.

Conclusion

As long as inclusion of medicinal products is subject to prioritization, there will always be some medicinal products that are not granted reimbursement. Experience shows that a pharmaceutical company whose reimbursement application is rejected will make efforts to have the decision reversed. This applies regardless of the decision level at which the rejection is made.

The Ministry will therefore propose retaining the current bagatelle limit for inclusion of medicinal products in the prior-approved reimbursement scheme. Medicinal products that would result in an additional annual cost of more than NOK 5 million five years after any granting of reimbursement must be prioritized in relation to other measures in the annual budget process.

When an application is made for inclusion to reimbursement for a medicinal product, there is usually limited documentation available concerning the efficacy, adverse reactions and cost effectiveness of the medicinal product. The assessments made by the Norwegian Medicines Agency when a new medicinal product is assessed for reimbursement are therefore often based on uncertain assumptions. When different health measures are assessed against each other within a total budget proposal, the Ministry must take this uncertainty into account. *The Ministry* will therefore propose that, in its assessments in reimbursement cases, the Norwegian Medicines Agency gives greater expression to the uncertainty associated with the conclusions of the investigation concerned.

15.5 Inclusion of new medicinal products through changes in the medicinal product budget

It has been proposed that the price reduction that occurs when the patent for a medicinal product expires may enable more new medicinal products to be admitted to the "blue prescriptions" system. Another alternative is that new medicinal products may be granted reimbursement when older, less cost-effective medicinal products are removed from the scheme.

There are not many examples of new medicinal products that are both less expensive and better than older ones. In such cases, it will normally be possible for reimbursement to be granted within the scope of the authorities granted to the

Norwegian Medicines Agency, see 15.1. However, in most cases, the situation is that a new medicinal product may be somewhat better, but is more expensive than the existing treatment. Although there is a cost associated with inclusion, the medicinal product may nevertheless be deemed cost-effective if the additional cost is considered to be reasonably proportionate to the benefit. Inclusion of such medicinal products in the reimbursement system therefore entails assigning medicinal products a higher priority than other health measures.

Older medicinal products often have poor sales, and there is therefore normally little to be saved by excluding these from reimbursement.

Another question is whether resources freed by the expiry of the patents of older medicinal products shall be directly associated with inclusion of new medicinal products. A decisive objection to this proposal is that it does not satisfactorily provide for overall priorities. It must be possible for the use of resources freed from the National Insurance to be prioritized without being tied to use for medicinal products. This is the case in all other budget areas. In the view of the Ministry, the overall prioritization of inclusion of new medicinal products should therefore be made without regard for cost reductions associated with medicinal products already included in the scheme.

15.6 Provisional reimbursement

The Norwegian Association of Pharmaceutical Manufacturers and the Norwegian Federation of Organisations of Disabled People have proposed that it must be possible to admit medicinal products to “blue prescriptions” provisionally on the condition that detailed documentation is submitted within a specific time limit. If the medicinal product manufacturer fails to satisfy the requirements regarding documentation within the time limit, the medicinal product will no longer hold a right to prior-approved reimbursement. The scheme is therefore referred to as provisional reimbursement, and will in the view of the proposers be an instrument for more rapid access to new medicinal products through the prior-approved reimbursement scheme. The background for the proposal is that the documentation is limited when a medicinal product manufacturer applies for reimbursement for a new medicinal product. According to the associations, the adequate documentation requirement will entail an unnecessary postponement of the right of reimbursement for patients.

If the goal of more rapid access to new medicinal products on “blue prescriptions” is to be achieved, it must also entail a reduction in the requirements regarding the initial inclusion in the “blue prescription” scheme. A decision concerning reimbursement for the medicinal products that satisfy the technical requirements can probably not be made very much more rapidly than today. The potential for more rapid inclusion therefore applies only to the medicinal products that, according to current practice, fail to satisfy the technical requirements. On such conditions, more medicinal products will be granted reimbursement before sufficient documentation is provided. In the view of the Ministry, a decision concerning reimbursement of medicinal products must be based on the knowledge of efficacy, adverse reactions and cost-effectiveness that is available at the time of the processing of the reimbursement application. It would undermine the reimbursement system if reimbursement should be granted on the condition that documentation with a varying degree of certainty can be produced in the future.

Experience also shows that medicinal products that have been granted reimbursement may be difficult to exclude if it later proves that the documentation is not satisfactory. Prior-approved reimbursement is often a precondition for extensive use. In individual cases, doubts may be raised concerning the efficacy of and adverse reactions associated with medicinal products in connection with consideration of reimbursement. If the medicinal product authorities assess the uncertainty to be too great, it should be possible to reject a reimbursement application pending more documentation.

The Ministry will not therefore allow provisional reimbursement in the sense that inclusion criteria are reduced during a trial period.

Section 14-24 of the Regulations relating to Medicinal Products states that the reimbursement decision may be made conditional upon the production of further documentation concerning the medicinal product within a specific period. However, this shall apply only on the condition that the available documentation is deemed satisfactory for inclusion in the reimbursement system. In such cases, there may be a need to elucidate safety issues more thoroughly or obtain confirmation of well founded hypotheses concerning the medicinal product's efficacy. Submission of such documentation may be imposed two or three years after reimbursement is granted. Failure to produce the documentation may result in amendment of the reimbursement conditions or lapse of the inclusion to reimbursement. This is practised to a certain extent in Sweden and has also been used in Norway. *The Ministry* will request the Norwegian Medicines Agency to regularly assess the need to make it a condition for continued reimbursement of a medicinal product that further documentation of uncertain factors is provided during a specified period. This will be supplementary to a continuation of the current professional requirements for inclusion.

15.7 Use of conditions for reimbursement

15.7.1 The need for conditions

Decisions concerning reimbursement of costs associated with medicinal products must be based on the knowledge of the medicinal product's efficacy and adverse reactions documented in clinical studies. Patients with the same disorder may benefit differently from a medicinal product. For example, in the case of cholesterol lowering medicinal products, the benefit is dependent on the patient's risk factors for future disease.

Conditions are established concerning which patients are to be granted prior-approved reimbursement for the following reasons:

1. The reimbursement is targeted at the groups of patients that satisfy requirements regarding documented efficacy, where the efficacy is reasonably proportionate to the costs.

2. Patients receive more rapid and simpler access to medicinal products because the medical practitioner is given the responsibility for controlling that the patient has a right to reimbursement.

The possibility of targeting reimbursement by means of conditions varies between medicinal products. Clear and controllable conditions can be established for some

medicinal products. For others the conditions are more general and the assessment of whether patients satisfy these must largely be made by the medical practitioner on the basis of clinical discretion.

15.7.2 Updating of conditions

The Ministry will implement measures to ensure that the Norwegian Medicines Agency is able to prepare as concrete and controllable reimbursement conditions as possible for most of the medicinal products granted prior-approved reimbursement. The conditions for reimbursement must take into account the medicinal product's efficacy, safety and cost-effectiveness. Examples of conditions are properties of the patient, that another medicinal product shall be tried first, that the treatment with medicinal products shall be started by a specialist or that other medicinal products do not have sufficient efficacy.

After reimbursement has been granted for a medicinal product, studies are often carried out that compare the medicinal product with other relevant treatment and studies that show long-term effects or the efficacy of the medicinal product in everyday clinical use. This may provide new knowledge about the medicinal product and may have significance for the conditions laid down for reimbursement. Knowledge of the medicinal product's consequences for use of health service resources and the patients' quality of life is gradually accumulated. New medicinal products may also appear that alter the place of older medicinal products in the treatment. The prices of competing medicinal products may fall owing to the expiry of patents, and other methods of treatment may replace the use of medicinal products. The conditions laid down for reimbursement must therefore be regularly updated.

The reimbursement status of medicinal products that have been granted prior-approved reimbursement have as yet only been reassessed to a very small extent. An unfounded gap may therefore arise between prescriptions that satisfy current conditions for reimbursement and prescriptions that are correct in relation to updated knowledge. The report "Informasjon og kontroll i blåreseptordningen" *(Information and Control in the "Blue Prescription" Scheme)* issued by Statskonsult in April 2004 states that medical practitioners regard several of the reimbursement conditions as having little relevance and of being technically out of date. An example is the reimbursement conditions for cholesterol lowering medicinal products, which were issued in 1994 and are still in force. It seems clear that the criteria that were adopted on the basis of the information then available regarding the efficacy of these medicinal products is no longer in compliance with what is generally accepted. There is therefore a need for a continuous updating of the reimbursement conditions in order to attain the necessary legitimacy, compliance and follow-up from the authorities with information and control of prescriptions. Continuous assessment of reimbursement status and clearly formulated conditions are also a precondition for the ability to transfer more medicinal products from individual reimbursement to prior-approved reimbursement, see 16.2.

The Ministry will request the Norwegian Medicines Agency to plan a continuous assessment of the status of reimbursement of medicinal products in major areas of therapy. Such an assessment of the first area of therapy is to take place as soon as planning permits. This work must be carried out in cooperation with other agencies and affected parties. The Norwegian Knowledge Centre for the Health Service will be