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Pharmaceutical Pricing and Reimbursement Information

NORWAY

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Pharma Profile

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Executive Summary

Background

The principle of equality in health, both social and geographical, is central when it comes to forming Norwegian health policy. The Norwegian health care system (*Helsetjenesten*) is founded on the principles of universal access, decentralisation and free choice of provider. It is financed through taxation, together with income-related employee and employer contributions and out-of-pocket payments (OPPs) (co-payments). All residents are covered by the National Insurance Scheme (*Folketrygden*, NIS), managed by the Norwegian Labour and Welfare Organisation (Arbeids- og velferdsforvaltningen, NAV). Private medical insurance is limited.

While health care policy is controlled centrally, responsibility for the provision of health care is decentralised. Local authorities at municipal level organise and finance health care services according to local demand. Secondary care, on the other hand, was re-centralised in January 2002 in an attempt to improve the access, quality and efficiency of hospital services and, since then, waiting lists have been reduced. While the central Government has overall managerial and financial responsibility for the hospital sector, counties have a certain amount of financial freedom within set budgets and autonomy regarding the planning, organisation and carrying out of secondary health care services. Norway's five regional health authorities (administrative entities managed by the counties) control the provision of specialised health services by 32 health enterprises (e.g. local hospital trusts).

All Norwegian citizens are invited to choose their general practitioner (GP) from a list in every municipality. More than 90% of Norwegians have chosen to do so. The rest of the citizens can use a private general practitioner (GP) or use the public general practitioner (GP), but these citizens then have to pay more in out-of-pocket payments (OPPs) for the consultation.

Out-patient doctors act as gatekeepers for specialist care.

Pharmaceutical system

The Ministry of Health and Care Services (Helse- og omsorgsdepartementet, HOD) is the legislative authority. The Norwegian Medicines Agency (Statens legemiddelverk, NoMA) (subordinate to the Ministry of Health and Care Services (HOD)) is in charge of market authorisation, classification, vigilance, pricing and reimbursement. The Norwegian Labour and Welfare Organisation (NAV) decides on reimbursement for individual patients for pharmaceuticals without general reimbursement or for indications not covered by general reimbursement. It also monitors the prescriptions completed by out-patient doctors.

All the major international pharmaceutical companies are represented in Norway. The leading national pharmaceutical companies in Norway focus on generics production. Biotechnological companies are emerging in increasing numbers, in particular in areas where Norway enjoys a competitive advantage, such as in the maritime and technical fields of industry.

Most of the Norwegian pharmaceutical industry is represented through the Norwegian Association of Pharmaceutical Manufacturers (Legemiddelindustriforeningen, LMI).

In Norway there are 3 wholesalers providing a full range of products to the market (full-range wholesalers), belonging to the leading European pharmaceutical distribution companies:

- Norsk Medisinaldepot (NMD), owned by Celesio AG (formerly Gehe), with a market share of 45%;
- Apokjeden Distribusjon, owned by Tamro, with a market share of 35%;
- Holtung, owned by Alliance UniChem, with a market share of 20%.

Each of the wholesalers is vertically integrated with their own pharmacy chain.

In general only community and hospital pharmacies (570) are allowed to dispense pharmaceuticals. Of the 570 pharmacies there are 31 public hospital pharmacies. There are approximately 8,800 inhabitants per pharmacy (4.5 Mio. inhabitants).

The total pharmaceutical expenditure (TPE) is estimated to NOK 16 billion in the year 2006. Public expenditure accounts for about 70% of total expenditure in 2006.

Pricing

The Norwegian Medicines Agency (NoMA) is responsible for setting maximum pharmacy purchase prices. All suppliers of prescription pharmaceuticals must apply for a maximum price, whether or not they are seeking reimbursement for the product. Pharmaceuticals can only be sold at or below the maximum price level.

An international price referencing system has been used since July 2002 to set maximum prices for both new and existing pharmaceuticals. Prices are based on the average of the three lowest pharmacy purchasing prices (PPP) in Austria, Belgium, Denmark, Finland, Germany, Ireland, the Netherlands, Sweden and the United Kingdom. If a product is marketed in fewer than three of the reference countries, the mean price is taken of the countries where a market price exists. Because pack sizes in different countries are not always directly comparable, price comparisons are made on the basis of units, e.g. price per tablet/dose. Local currency prices must be converted into NOK, using the mean exchange rate of the last six whole months, as presented by the Bank of Norway.

Wholesalers are free to negotiate mark ups with manufacturers because the Norwegian Medicines Agency (NoMA) sets prices at the ex-wholesaler/pharmacy purchasing price (PPP) level. Mark ups for generics and over-the-counter (OTC) products are significantly higher than for branded pharmaceuticals.

Pharmacy mark ups for prescription products (both reimbursed and non-reimbursed) are fixed at 8% for pharmaceuticals with a pharmacy purchasing price (PPP) below NOK 200, and at 5% for the price over NOK 200. There is also a flat fee of NOK 21.50 per pack, plus value-added tax (VAT) (25%). An additional flat fee of NOK 10 is applied to addictive products, so-called A and B preparations (narcotic and psychotropic substances). Pharmacists are permitted to establish their own margins for non-prescription pharmaceuticals.

Generics prices cannot exceed the maximum market price of the original branded product. A price model called the step-price model (*Trinnprismodellen*) came into effect in January 2005. Under the new scheme, a maximum reimbursement price is set for affected pharmaceuticals (both branded and generics). The maximum price level is automatically reduced in stages (steps) following patent expiry. The size of the cuts depends on annual sales prior to the establishment of generics competition and time since competition was established.

- **Sales over NOK 100 Mio.:** the maximum reimbursement price is cut by 30% when generics competition is established and 75% after one year.
- **Sales below NOK 100 Mio.:** the percentage decreases are 30% and 55%.

Before 1 January 2007 the prices were reduced in three steps during the first year and the final cuts were 50% and 70%.

Within the step-price system there are no regulations of pharmacy mark ups. Pharmacists therefore have a financial incentive to carry out generics substitution and dispense the cheaper product.

Maximum prices also apply to hospital-only products. Most hospital purchasing is carried out by means of tender processes through the Norwegian Drug Procurement Co-operation (*Legemiddelinnkjøpssamarbeidet*, LIS), which is the hospital purchasing agency. Discounts to hospitals are approximately 31% on average.

Since 1995 there is no price control on over-the-counter (OTC) pharmaceuticals by the authorities. The standard value-added tax (VAT) rate of 25% applies to pharmaceuticals.

Reimbursement

Reimbursement decisions are made by the Norwegian Medicines Agency (NoMA). The pharmaceutical companies need to follow the Norwegian guidelines for pharmacoeconomic evaluations when applying for reimbursement.

Generally speaking the Norwegian reimbursement system may be characterised as disease and consumption based. Whether a pharmaceutical is reimbursed and the amount of reimbursement depends on the following criteria:

- the illness must be considered serious and chronic, for which long-term medication (more than three months per year) is necessary;
- the annual consumption (no co-payment above an annual ceiling of NOK 1,615 (€ 205));
- the type of patient (low income pensioner or children under 12).

Pharmaceuticals are grouped into four reimbursement categories.

- **Schedule 9**: General reimbursement. Includes 45 main groups and several subgroups of pharmaceuticals.
- **Schedule 2 and 10a**: Reimbursement on a named patient basis. Reimbursement is granted upon submission of an individual patient application. The Norwegian Labour and

Welfare Organisation (NAV) accepts or rejects claims. One example is multiple sclerosis pharmaceuticals.

- **Schedule 4**: Reimbursement of pharmaceuticals used to treat serious contagious diseases such as tuberculosis, syphilis or HIV/AIDS. 100% reimbursement.

The standard patient co-payment for reimbursed pharmaceuticals is 36% up to an annual maximum spending level of NOK 1,615 (€205) in 2006, with all expenses above this threshold covered by the National Insurance Administration. The annual limit includes co-payments for physician consultations, laboratory tests, radiography, etc.

In-patient pharmaceuticals are covered by the public hospitals.

Rational use of pharmaceuticals

A Pharmacoeconomic evaluation in connection with applications for the reimbursement scheme (*blåresept ordningen*) has been mandatory since 1 January 2002. The pricing and reimbursement process is regulated in detail in Regulation No. 1559 of 22 December 1999 relating to pharmaceutical products (the Pharmaceutical Products Regulations), Sections 12 and 14. In Norway a pharmaceutical can obtain both market authorisation as well as a maximum price without a pharmacoeconomic evaluation. But a pharmacoeconomic evaluation has to be performed for all pharmaceutical for which an application for general reimbursement is submitted, with a few exceptions.

For some therapeutically equivalent pharmaceuticals a system of first choice (a preferred product) has been established. The prescriber has to (by law) prescribe the first-choice product unless there are medical reasons for not doing so. This is an alternative to therapeutic reference pricing and to ensure the use of the most cost-effective medical treatment. Generic substitution in pharmacies has been allowed since 2001.

The “marketing directives” as stated in Directive 2001/83/EC are implemented in Act No. 132 of 4 December 1999 relating to Medicinal Products, Chapter VII, and in the Regulation No. 1559 of 22 December 1999 relating to Medicinal Products, Chapter 13. The Ministry of Health and Care Services (HOD) is responsible for the implementation of these directives. Direct advertising of over-the-counter (OTC) pharmaceuticals to patients is allowed within certain limits. Advertising of pharmaceuticals on the internet is allowed. This is regulated in the same way as advertising generally.

Individual consumption data is monitored through the Norwegian Prescription Database. This is a national health register containing information connected to delivery of all pharmaceuticals from pharmacies in Norway. The Database was founded in 2004 as part of the Norwegian Institute of Public Health (Nasjonalt folkehelseinstitutt, FHI). The Database is used for pharmacoepidemiological research and pharmaceutical statistics.

Current challenges and future developments

Costs are for the time being not growing rapidly, but new and more expensive pharmaceuticals will in the future probably escalate costs.

Table of content

List of tables and figures

List of abbreviations

ATC	Anatomic Therapeutic Chemical classification
BMGF	Austrian Ministry of Health and Women's Issues
DG SANCO	Health and Consumer Protection Directorate General
DRG	Diagnosis-Related Group
FFO	Norwegian Federation of Organisations of Disabled People
FHI	Norwegian Institute of Public Health
GDP	Gross Domestic Product
GGE	General Government Expenditure
GP	General Practitioner
HE	Health Expenditure
HiT	Health Systems in Transition
HOD	Norwegian Ministry of Health and Care Services
HOM	Hospital-Only Medicine
LIS	Norwegian Drug Procurement Co-operation (Hospital Purchasing Agency)
LMI	Norwegian Association of Pharmaceutical Manufacturers
LUA	Pharmaceuticals sold outside of the pharmacies
MAH	Market Authorisation Holder
Mio.	Million
NAF	Norwegian Pharmacy Association
NAV	Norwegian Labour and Welfare Organisation
NCU	National Currency Unit
NFF	Norwegian Association of Pharmacists
NHS	National Health Service
NIGeL	Norwegian Association of Generics-orientated Pharmaceutical Manufacturers
NIS	National Insurance Scheme

NMA	Norwegian Medical Association
NOK	Norwegian currency (kroner)
NoMA	Norwegian Medicines Agency
OECD	Organisation for Economic Co-operation and Development
OPP	Out-of-Pocket Payment
OTC	Over-The-Counter pharmaceuticals
PE	Pharmaceutical Expenditure
POM	Prescription-Only Medicine(s)
PPP	Pharmacy Purchasing Price
PPPa	Purchasing Power Parity
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy Retail Price
QALY	Quality-Adjusted Life Year
SHI	Social Health Insurance
SSB	Statistisk sentralbyrå (Statistics Norway)
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
VAT	Value-Added Tax
VHI	Voluntary Health Insurance
WHO	World Health Organization
WP	Work Package

Introduction

The Pharmaceutical Pricing and Reimbursement Information (PPRI) project is a 31 month-project (2005-2007) commissioned by the Health and Consumer Protection Directorate-General (DG SANCO) of the European Commission and co-funded by the Austrian Federal Ministry of Health, Family and Youth (Bundesministerium für Gesundheit, Familie und Jugend, BMGFJ). The project was coordinated by the main partner Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (GÖG/ÖBIG) and the associated partner World Health Organisation (WHO) Regional Office for Europe. The PPRI project has established a network of 46 participating institutions (competent authorities and other relevant organisations) in the field of pharmaceuticals.

The PPRI project seeks to increase transparency and knowledge and facilitate the exchange of experience in the field of pharmaceuticals by

- establishing and maintaining a network of relevant institutions in the field of pharmaceuticals in the enlarged European Union (EU), in order to facilitate a regular exchange of information and allow a process of learning from each other,
- producing country reports on pharmaceutical pricing and reimbursement systems, the “PPRI Pharma Profiles”,
- developing indicators for the comparison of pharmaceutical pricing and reimbursement information,
- providing a comparative analysis on pharmaceutical pricing and reimbursement in the European Union (EU) and,

disseminating the outcomes of the project.

The PPRI Pharma Profiles are country-specific reports that provide detailed descriptions of the countries pharmaceutical systems and policies. The profiles are written by PPRI participants (country experts from competent authorities, Medicines Agencies, Social Insurance Institutions, research institutes) and edited by experts of the PPRI project coordination.

This Pharma Profile is one of the many PPRI Pharma Profiles, which all are available on the PPRI website at http://ppri.oebig.at. The information and data provided in the PPRI Pharma Profiles refer, in general, to the year 2006.

In order to improve readability and allow for comparisons between countries, the structure of the Pharma profiles follows a template, which was developed by the project coordination team and the PPRI participants. The template is based on a large needs assessment of both national and international stakeholders. In addition to the template a glossary was developed to facilitate the writing process and the readability. The 70-page PPRI Pharma Profile Template and the PPRI Glossary are available at the PPRI website.

1 Background

1.1 Demography

The population of Norway exceeded 4.6 Mio. in 2006. This corresponds to an average of 15.1 people per km^2. The population is unevenly distributed. The major urban areas are located along the coastline of southern Norway, especially in the Oslo, Sandnes/Stavanger, Bergen and Trondheim areas. The inland and the northern parts of Norway are more scarcely populated. As an example, Finmark county accounts for 15% of the total area of the Norwegian mainland, but only 1.6% of the total population (0.67 people per km^2).

The average life expectancy has been increasing steadily and is still increasing. In 2005 the average life expectancy was 77.7 years for men and 82.5 years for women. For the time being the percentage of the population over 64 years is reasonably stable. The percentage is expected to increase significantly as a result of the ageing of the post-war generations.

The total number of deaths in 2004 was 41.257. Diseases of the circulatory system are still the leading cause of deaths, accounting for approximately 38 % of the total. There has, however, been a significant reduction in mortality due to low rates of diseases of the circulatory system since the 1970s. Malign tumours accounted for 25% of deaths and diseases in the respiratory system accounted for 8%.

Table 1.1: Norway - Demographic indicators 1995, 2000-2005

Variable	1995	2000	2001	2002	2003	2004	2005
Total population	4,348,410	4,478,497	4,503,436	4,524,066	4,552,252	4,577,457	4,606,363
Population density per km^2	13.4	13.8	13.9	14.0	14.1	14.1	14.2
Population aged 0–14 (as a % of total)	19.4	20.0	20.0	20.0	20.0	19.9	19.7
Population aged 15–64 (as a % of total)	64.6	64.8	64.9	65.0	65.2	65.4	65.5
Population aged > 64 (as a % of total)	16.0	15.3	15.1	14.9	14.8	14.7	14.7
Life expectancy at birth, total	77.8	78.7	–	–	79.5	–	80.1
Life expectancy at birth, females	80.8	81.4	81.5	81.6	81.9	82.3	82.5
Life expectancy at birth, males	74.8	76.0	76.2	76.5	77.0	77.5	77.7

Source: Statistics Norway (www.ssb.no)

1.2 Economic background

Table 1.2: Norway - Macroeconomic indicators 1995, 2000-2005

Variable (in national currency unit (NCU) or %)	1995	2000	2001	2002	2003	2004	2005
GDP (NOK)	937,445	1,469,075	1,526,233	1,519,131	1,576,745	1,716,933	1,903,841
GDP per capita (NOK)	215,583	328,029	338,904	335,789	346,366	375,084	413,307
GDP per capita in PPPa	–	–	–	–	–	–	–
GGE (NOK)	–	–	–	–	–	–	–
GGE per capita (NOK)	–	–	–	–	–	–	–
Annual growth rate	–	–	–	–	–	–	–
Exchange rate (NCU per €), annual rate	n.a.	8.1109	8.0492	7.5073	8.0039	8.3715	8.0073

GDP = gross domestic product, GGE = general government expenditure, NCU = national currency unit, PPPa = purchasing power parity, NOK = Norwegian kroner (currency)

Source: Statistics Norway (www.ssb.no)

1.3 Political context

Norway has been a constitutional monarchy since 1814, and the country became formally independent in 1905. The King is officially the highest executive authority, although in practice the government cabinet is at the head of the executive power. Norway is governed by a three-tiered parliamentary system, with each tier run by an elected body: the national Parliament, the county councils and the municipalities. There were 19 counties and 431 municipalities in 2006.

1.4 Health care system

1.4.1 Organisation

The health care system in Norway is organised on three levels: the central State, the five regional authorities and the municipalities. While the role of the State is to provide national health policy, to prepare and oversee legislation and to allocate funds, the main responsibility for the provision of health care services lies with the five health regions and the 431 municipalities. At national level, the Parliament serves as the political decision-making body. Overall responsibility for the health care sector rests at national level, with the Ministry of Health and Care Services (HOD).

Norway's 431 municipalities are responsible for the provision and funding of primary health care and social services. All citizens have the right to access to health care services in their community. Norway's five regional health authorities are responsible for the financing, planning and provision of specialised care. This includes somatic care and care of individuals with mental health problems as well as substance abusers, along with other specialised medical services,

such as laboratory-based work, radiology and paramedical services. There are at present 32 health enterprises under the five Regional Health Enterprises (RHEs).

At the national level, the political decision-making body is the Parliament. The executive body is the Government, along with the Ministry of Health and Care Services (HOD). The responsibilities of the national bodies include determining policy, preparing legislation, undertaking national budgeting and planning, licensing institutions and capacity expansion. The municipalities provide primary health care, including nursing care for the disabled and the elderly, while responsibility for specialised health care lies with the regional health authorities that are owned by the central Government. Dental care is still part of the county's responsibilities.

The health care system is mostly publicly owned, although there are some contracts with private agencies, mainly between municipalities and general practitioners (GPs), and between the regional health authorities and specialist physicians. The Ministry of Health and Care Services (HOD) provides instructions to the regional health authorities through a "letter of instruction", which is prepared individually for each of the five authorities and can be seen as a "government supplement". The governance of the municipalities relating to primary health care is, in practice, interplay between a number of different ministries, such as the Ministry of Health and Care Services (HOD), the Ministry of Labour and Social Inclusion, and the Ministry of Local Government and Regional Development.

Decentralisation has long been one of the characteristics of the Norwegian health care system but the Hospital Reform of 2002 changed the system from a decentralised to semi-centralised one. The regional health authorities, represented by the State, are responsible for specialised health care, while the municipalities are responsible for primary health care. In their organisational structure, the regional health authorities and their health enterprises may be seen as state-owned companies. Principal health policy objectives and frameworks are determined by the central Government and form the basis for the management of the health enterprises, while day-to-day management is the responsibility of the general manager and the executive board. The municipalities are run by locally elected politicians together with their administrative staff. Health care is one of many areas for which they are responsible. The municipalities are free to set up their own organisational structure.

1.4.2 Funding

Sources of revenue for health care in Norway include taxation, national social insurance systems and private expenditure. The Norwegian health care system is primarily funded through taxes which are raised at municipality, county and central levels. However, dental care is usually not funded by the national social insurance systems and is therefore mainly funded by private expenditure. Following the Parliament's approval, the central Government sets the municipalities' and counties' maximum tax rates. There is no specific health tax in Norway, and the regional health authorities cannot themselves draw taxes. Since the mid-1980s, the proportion of public expenditure on health has been steady at around 80%.

All residents of Norway or people working in the country are insured under the National Insurance Scheme (NIS), which is run by central Government. The National Insurance Scheme (NIS) is financed by contributions from employer, employees, self-employed people and state funding.

People insured under the National Insurance Scheme (NIS) are entitled to retirement, survivors' and disability pensions, basic benefits and attendance benefit in case of disability, rehabilitation or occupational injury. There are also benefits for single parents, cash benefits in case of sickness, maternity, adoption and unemployment, and medical benefits in case of sickness and maternity, as well as funeral benefits. Health care expenditure by the National Insurance Scheme (NIS) in 2002 was almost NOK 20 000 Mio., or approximately 10% of total National Insurance Scheme (NIS) expenditure. Voluntary health insurance (VHI) does not play any significant role in Norway.

With regard to health care services, in-patient care in general hospitals does not involve out-of-pocket payments (OPPs), but these are payable for consultations with private specialists and general practitioners (GPs), for ambulatory care, X-rays, laboratory tests and pharmaceuticals. Most of these out-of-pocket expenditures are included in the cost-ceiling scheme that was introduced in the early 1980s. The ceiling is set each year: in 2006 it was NOK 1,615 (€ 205). When the cost ceiling has been reached in any calendar year, most of additional out-of-pocket expenses are reimbursed by the National Insurance Scheme (NIS), and any remaining treatment in that calendar year is therefore free of charge. In 2005 around 1 Mio. Norwegians reached this ceiling. According to the Organisation for Economic Co-operation and Development (OECD), the share of out-of-pocket expenditure in the Norwegian health care system has been stable since the mid-1980s at about 15%.

Table 1.3: Norway- Health expenditure, 1995, 2000-2005

Health expenditure (HE)	1995	2000	2001	2002	2003	2004	2005
THE (NOK)	–	124,728	135,266	150,029	159,572	167,259	175,582
THE as a % of GDP	–	8.5%	8.9%	9.9%	10.1%	9.7%	9.2%
THE per capita (NOK)	–	27,850	30,036	33,162	35,053	36,540	38,117
Public HE as a % of THE	–	76.1	76.8	77.6	77.8	–	–
Private HE as a % of THE	–	17.0	15.9	16.0	15.7	–	–

GDP = gross domestic product, HE= health expenditure, THE = total health expenditure, NCU = national currency unit, NOK = Norwegian kroner (currency)

Source: [1]Statistics Norway (www.ssb.no)

1.4.3 Access to health care

1.4.3.1 Out-patient care

For geographical reasons the structure of Norwegian out-patient care varies between out-patient clinics, with mainly general practitioners (GPs) in towns and single- or two-doctor practices in the countryside. The tendency is to develop small clinics, even outside the cities.

[1] Statistics Norway (www.ssb.no)

All Norwegian citizens are invited to choose their general practitioner (GP) from a list in every municipality. More than 90% of Norwegians have chosen to do so. The remaining 10% can use a private general practitioner (GP) or a public general practitioner (GP), but at a higher cost.

In Norway most of the general practitioners (GPs) are public. Specialists are mostly connected by contracts to the hospital, but in the bigger cities there is a market for specialists in private practice.

The general practitioner (GP) acts as a gatekeeper for access to specialists and in-patient care. Normally the patient visits their general practitioner (GP) for a consultation. If required the general practitioner (GP) refers the patient to a specialist. In case of emergency all citizens can obviously be treated directly at the hospital.

All patients can contact a private specialist, but have to carry the total cost themselves.

The listed general practitioners (GPs) are paid a capitation fee from the National Insurance Scheme (NIS). When a patient visits the general practitioner (GP) the National Insurance Scheme (NIS) pays a fee-for-service payment, while the patient pays an out-of-pocket payment (OPP) to the general practitioner (GP). If the patient has reached the ceiling of out-of-pocket expenditures, the National Insurance Scheme (NIS) will also pay this fee to the general practitioner (GP) (cf. 1.4.2).

Specialists who are obliged by contract to provide services are paid a specific amount of money per year from the National Insurance Scheme (NIS). The amount is mainly set on the basis of time spent in the practice (full-time, part-time) but also according to the equipment and assisting personnel in the general practitioners' (GP) office. In addition, these specialists are paid fee-for-service payments from the National Insurance Scheme (NIS) for every visit, and out-of-pocket payments (OPPs) from the patient.

The official, public, National Insurance Scheme (NIS)-supported Norwegian out-patient system is a system where nearly all citizens are patients on a general practitioner's (GP) list. In addition there are specialists on contracts to provide services in out-patient care. The patient will pay out-of-pocket payments (OPPs) for each visit to these specialists, until the ceiling is reached (cf. 1.4.2).

Adjacent to the publicly funded outpatient care, a parallel system with private general practitioners (GPs) and private specialists exists. These private doctors are not supported by the National Insurance Scheme (NIS), and patients are required to pay a fee-for-service payment to the doctor, which is not reimbursed. The number of private specialists is very small, particularly as far as general practitioners (GPs) are concerned.

Table 1.4: Norway – Out-patient care 1995, 2000, 2002, 2004 and 2005

Variable	1995	2000	2002	2004	2005
Total number of doctors	12,871	15,180	16,540	17,529	18,089
Number of doctors per 1,000 inhabitants	2.96	3.39	n. a.	3.85	3.93
Total number of out-patient doctors	n. a.	n. a.	n. a.	n. a.	n. a.
of which GPs	n. a.	n. a.	n. a.	n. a.	n. a.
of which dentists	n. a.	n. a.	n. a.	n. a.	n. a.
Number of out-patient doctors per 1,000 inhabitants	n. a.	n. a.	n. a.	n. a.	n. a.
Number of out-patient clinic departments ("ambulatories")	n. a.	n. a.	n. a.	n. a.	n. a.

GPs = general practitioners

Source: www.legeforeningen.no

1.4.3.2 In-patient care

The Norwegian in-patient care mainly consists of public hospitals. For historical reasons the hospitals are evenly spread throughout the country. The hospitals have traditionally been hierarchically organised, but now the hierarchy has only two levels.

Norway is divided into five health regions, each with a regional health authority. This authority is responsible for the budgeting and planning of all the health enterprises in each region (cf. 1.4.1). The regions typically have a few health enterprises. Each health enterprise consists of a few local hospitals, and in every regional health authority there is a University Hospital. The University hospital is also called a regional hospital. Patients having rare or severe diseases are often transmitted from the local to the regional hospitals.

Norway is working on the issue of giving even the local hospitals special competence on certain diagnostic and treatment areas, but this is a challenging issue. Because Norway is a small country the treatment of really rare diseases is often given to one hospital only. There is no out-of-pocket payment (OPP) for in-patient care. All doctors are employees of the hospital and paid as such.

The central Government funds the Regional Health Authority. This Regional Health Authority funds the local hospital by allocating the funding. All hospitals are remunerated by a mixture of ex-ante fixed budgeting and a diagnosis-related group (DRG) system. The percentage has been changing from one year to the next. In the years 2003, 2004 and 2005 the percentages for diagnosis-related groups (DRGs) were 60%, 40% and 60%, respectively. In 2006 diagnosis-related groups (DRGs) were planned to consume 40% of the budget for clinical patient-related work within in-patient care.

In addition, all University hospitals have special funding from the central Government for educational work.

All citizens can choose in which hospital they want to be treated. They cannot, however, choose a regional hospital if they are admitted to a local hospital. They have to choose between hospitals on the same level. If a patient chooses to be treated in another region s/he has to pay an extra (but small) transportation fee.

The number of private in-patient care beds is low. Few patients choose to pay the bill themselves. It is a small market for insurance-paid private hospitals for in-patient care. Most private hospitals exist because the public hospitals make contracts with them for providing detailed treatments, e.g. fixed numbers of hip-surgery patients, tonsillectomy, glaucoma surgery, etc.

Table 1.5: Norway – In-patient care 1995, 2000, 2002, 2004 and 2005

Variable	1995	2000	2002	2004	2005
Number of in-patient doctors	n. a.	n. a.	n. a.	n. a.	n. a.
Number of in-patient doctors per 1,000 inhabitants	n. a.	n. a.	n. a.	n. a.	n. a.
Number of hospitals	n. a.	n. a.	n. a.	n. a.	n. a.
Number of acute care beds	n. a.	n. a.	n. a.	n. a.	n. a.
of which in private sector	n. a.	n. a.	n. a.	n. a.	n. a.
Acute care beds per 1,000 inhabitants	n. a.	n. a.	n. a.	n. a.	n. a.
Average length of stay in hospital	n. a.	n. a.	n. a.	n. a.	n. a.

Source: n.a.

2 Pharmaceutical system

2.1 Organisation

2.1.1 Regulatory Framework

2.1.1.1 Policy and legislation

The main national laws regulating the pharmaceutical market, including pricing and reimbursement, in Norway are:

- LOV 2000-06-02 nr 39: Lov om apotek (Norwegian Act on Pharmacies), (www.legemiddelverket.no/templates/InterPage____15432.aspx);
- LOV 1992-12-04 nr 132: Lov om legemidler (Norwegian Act on Medicinal Products), (www.legemiddelverket.no/templates/InterPage____15432.aspx).

In conjunction with these laws several regulations give more detail on specific areas (e.g. the Norwegian Regulation relating to Medicinal Products).

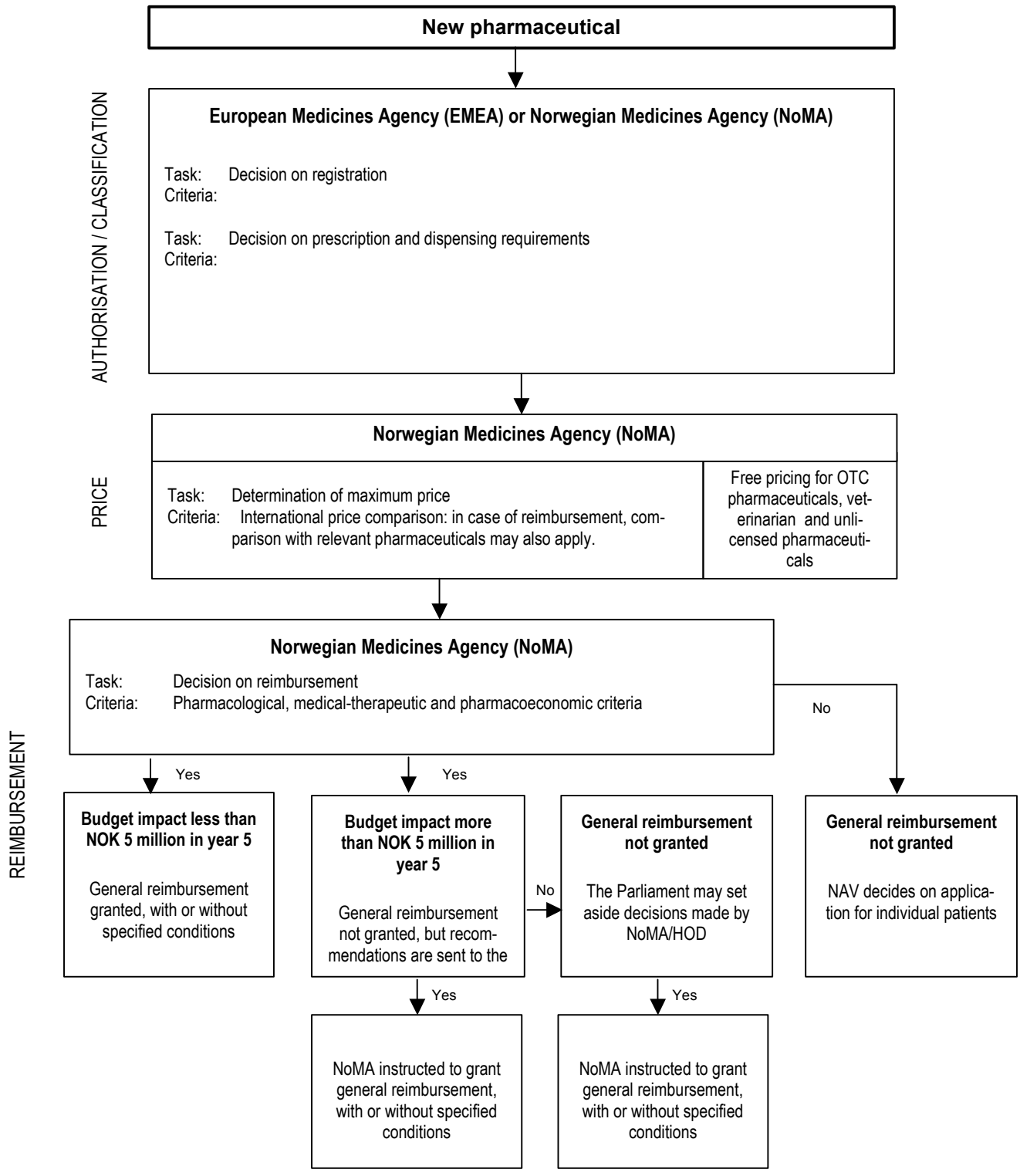
The current overall policy document is: “St.meld. nr. 18 (2004-2005) Rett kurs mot riktigere legemiddelbruk Legemiddelpolitikken” (The right course towards better use of pharmaceuticals)

This document states that the most important goal for national pharmaceuticals policy is to achieve proper use of pharmaceuticals:

- 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.

Figure 2.1: Norway - Flowchart of the pharmaceutical system2006



NoMA = Norwegian Medicines Agency, NAV = Norwegian Labour and Welfare Organisation, HOD = Norwegian Ministry of Health and Care Services, OTC = over-the-counter

Source: NoMA 2006.

2.1.1.2 Authorities

Table 2.1 provides an overview of the relevant authorities and institutions in charge of pharmaceuticals in Norway.

Table 2.1: Norway - Authorities in the regulatory framework in the pharmaceutical system 2006

Name in local language (Abbreviation)	Name in English	Description	Responsibility
Stortinget	The Norwegian Parliament	Parliament	To pass new laws and amend or repeal the existing ones, to adopt the Fiscal Budget and to authorise plans and guidelines for the activities of the State. May allocate resources for reimbursement of specified pharmaceuticals despite negative recommendations or decisions by the NoMA.
Helse- og Omsorgsdepartementet (HOD)	Ministry of Health and Care Services	Regulatory body	Overall planning and legislative authority. Administrative appeal body for decisions made by the NoMA.
Statens legemiddelverk (NoMA)	Norwegian Medicines Agency	Medicines Agency (subordinate to the Ministry of Health)	In charge of market authorisation, classification, vigilance, pricing and reimbursement.
Arbeids- og velferdsetaten (NAV)	Norwegian Labour and Welfare Organisation	Subordinate to the Ministry of Labour and Inclusion	Decides on reimbursement for individual patients for pharmaceuticals without general reimbursement or for indications not covered by the general reimbursement. Monitors the prescriptions completed by out-patient doctors.
Folkehelseinstituttet (FHI)	Norwegian Institute of Public Health	National centre for expert knowledge of epidemiology, infectious disease control, environmental pharmaceuticals, forensic toxicology and research on drug abuse	Monitors the consumption of pharmaceuticals. Wholesaler for human vaccines.

Source: NoMa 2006

2.1.2 Pharmaceutical market

This section gives an overview on the availability of pharmaceuticals as well as market figures.

2.1.2.1 Availability of pharmaceuticals

The number of pharmaceuticals on the Norwegian market is given in detail in Table 2.2: this number has been growing constantly since the mid-1980s.

The rapid increase in authorised pharmaceuticals seen after 1995 is partly due to the lifting of the so called “necessity clause” in the early 1990s. This clause could prevent an individual pharmaceutical from obtaining market authorisation if it was similar to pharmaceuticals already marketed. This led in particular to a limitation in the number of generics.

Table 2.2: Norway - Number of pharmaceuticals 1995, 2000-2006[1]

Pharmaceuticals	1995	2000	2001	2002	2003	2004	2005	2006
Authorised national MA[1]	2,418	2,993	3,153	3,208	3,345	3,636	3,853	–
Authorised centralised MA[2]	–	119	508	1,128	1,592	2,110	2,619	–
On the market national MA[1]	–	2,659	2,618	2,807	2,774	2,837	2,668	–
On the market centralised MA[2]	–	23	89	183	270	363	449	–
Generics	–	–	–	–	–	–	–	–
Parallel traded	–	–	–	–	–	–	–	–
Hospital-only	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

POM = prescription-only medicine(s), MA = market authorisation

[1] As forms and strengths

[2] As MA numbers (package size)

Source: NoMA 2006

2.1.2.2 Market data

Table 2.3: Norway - Market data 1995, 2000-2005

In Mio. NOK / national currency unit (NCU)	1995	2000	2001	2002	2003	2004	2005
Prescriptions							
No. of annual prescriptions (Mio.)	–	–	–	–	–	24.793	25.646
Pharmaceutical sales							
Sales at ex-factory price level	–	–	–	–	–	–	–
Sales at wholesale price level	–	–	–	–	–	–	–
Sales at PRP level	7,448	11,420	12,590	13,970	14,657	15,786	16,230
Sales in hospitals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales of generics	n.a.	2,741	2,971	3,255	3,679	4,389	5,161
Sales of parallel traded pharmaceuticals	15	879	642	880	967	979	1.120
Exports and imports							
Total pharmaceutical exports	–	–	–	–	–	–	–
Total pharmaceutical imports	–	–	–	–	–	–	–

Source: FHI

The overall market has been steadily growing. However, the growth is slowing down. There are several reasons for this. The introduction of a pricing regime linked to prices in other European countries has had a moderating effect on the Norwegian price level. A “step-price” system for generics, introduced in 2005, has ensured that prices for generics have fallen (cf. 3.4.2 for a description of the “step-price system”). As generic prices in Norway are still above those of other Scandinavian countries, this system is currently under revision.

Important steps towards cost-containment have also been taken for reimbursable pharmaceuticals. The use of a “preferred product” system is one tool that has been put to use. With this approach the doctors can only prescribe certain pharmaceuticals (usually generics, low price), unless important medical issues call for the use of others (patent protected, high price). This use of ”preferred pharmaceuticals” has so far been implemented for three groups of reimbursable pharmaceuticals; statins, second-generation antihistamines and proton pump inhibitors.

Areas with significant growth are in biological pharmaceuticals and novel therapies for cancer.

Table 2.4: Norway - Top 10 best-selling pharmaceuticals, by active ingredient 2005

Position	Pharmaceutical, by active ingredient
1	Atorvastatin
2	Etanercept
3	Salmeterol (combined with other anti-asthmatic pharmaceuticals)
4	Esomeprazol
5	Infliximab
6	Olanzapin
7	Metoprolol
8	Formeterol (combined with other anti-asthmatic pharmaceuticals)
9	Losartan (combined with diuretics)
10	Codeine (in combination with other analgesic pharmaceuticals)

Source: FHI

2.1.2.3 Patents and data protection

Patent protection is harmonised under the European Patent Convention and ensures original pharmaceuticals market protection for 20 years. Under European Union (EU) legislation there is the potential for extension for five more years under a supplementary protection certificate.

Under the recently adopted European Union (EU) legislation, authorities are also obliged to provide for data protection for an 8+2+1-year period. This provides for an additional protection period for patented pharmaceuticals. Only after eight years can the Norwegian Medicines Agency (NoMA) process applications for generic pharmaceuticals under the European Union (EU) Bolar amendment. These generics can then be marketed when the 10-year data protection period ends (provided that by that time the patent has also expired). Authorities may provide for an additional year of data protection (and thereby delay generic market entry) for additional innovative indications (e.g. for paediatric indications).

From time to time court cases take place in relation to pharmaceuticals patent protection. However, the pharmaceuticals authorities (Norwegian Medicines Agency (NoMA)) do not take part in these conflicts. There are several examples of “ever greening” of patents (cases where companies seek extensions of market exclusivity by filing new patents on old pharmaceuticals).

2.1.3 Market players

This section describes the key players in the pharmaceutical system, with the exception of the authorities which have been introduced in 2.1.1.2. It gives an overview of the key players in production, distribution, dispensing, prescription and use of pharmaceuticals and their influence on pharmaceutical policy-making.

2.1.3.1 Industry

All the major pharmaceutical companies are represented in Norway, but only a few of them have established their own manufacturing units in the country. The leading pharmaceutical companies in Norway focus on generics production, with considerable success. Biotechnological companies emerge in increasing numbers, in particular in areas where Norway enjoys a comparative advantage, such as in the maritime and technical fields of industry. Most of the Norwegian pharmaceutical industry is represented through the Norwegian Association of Pharmaceutical Manufacturers (LMI) (cf. Table 2.5).

The main industry organisations and the dominating characteristics of their members are:

- Legemiddelindustriforeningen (Norwegian Association of Pharmaceutical Manufacturers, LMI) – research-orientated companies, with or without a generics portfolio;
- Norsk Industriforening for Generiske Legemidler (Norwegian Association of Generics-orientated Pharmaceutical Manufacturers, NIGeL) – generics-orientated companies;
- Paralellimportørforeningen – parallel trading companies.

Direct distribution from the manufacturer to the end-user is not allowed. As a result all distribution, save some minor exceptions, passes through a wholesaler. The main bulk of pharmaceuticals are then further distributed through pharmacies. An important exception is a limited selection of over-the-counter (OTC) pharmaceuticals that can be sold to the end user through other channels as well (cf. 2.1.3.3).

The industry does not take direct part in policy-making, but new policies and changes in the legal framework are normally not put into action before all parties affected have been given an opportunity to formally express their views and present their alternative solutions. The industry organisations may also take part in working groups on specific issues related to policy-making. These views and suggestions may, or may not, influence the final policy or legislation.

A more proactive form of participation in policy-making is lobbying. This usually occurs in the field of pharmaceutical-related politics in general, but as the Parliament has the power to grant reimbursement to individual pharmaceuticals, lobbying for reimbursement is also a relevant issue.

The importance of Norway's domestic pharmaceutical industry to the national economy is rather small. The estimated value of exported pharmaceutical products was approximately € 375 Mio. in 2005 (LMI, 2005).

In 2004, the pharmaceutical industry in Norway invested NOK 831 Mio. in science and development (LMI, 2005), which is 8.7% of the industry's annual turnover. The industry employs 4,500 employees and contributes to the accumulation and diffusion of relevant scientific knowledge in hospitals and private business involved in science.

Authority on prices of pharmaceuticals in Norway is held by the Government. Regulations are delegated to and implemented by the Norwegian Medicines Agency (NoMA). The research-based industry in Norway is rather small. The industry is not represented in pricing or reimbursement committees. There are a few examples of contracts regarding the price and quantity of pharmaceuticals having been made between the Government and individual companies. The industry is not represented in the hospitals' medicines committees or in their pharmaceuticals purchasing cooperation (Norwegian Drug Procurement Co-operation (LIS)).

Table 2.5: Norway - Key data on the pharmaceutical industry 1995, 2000-2005[1]

Pharmaceutical industry	1995	2000	2001	2002	2003	2004	2005
Total no. of companies	168	185	191	181	174	177	178
- research-oriented	n.a	51	51	52	51	47	49
- generic producers	n.a	37	36	39	42	45	49
- biotech	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Number of persons employed[2]	n.a.	n.a.	n.a.	4,572	4,603	4,571	4,564

[1] as of 1 January

[2] counted per head

no. = number, n.a. = not available

Source: LMI / Norwegian Medicines Agency (NoMA)

2.1.3.2 Wholesalers

The Norwegian wholesalers that provide a full range of products belong to the leading European pharmaceutical distribution companies, each with their own pharmacy chain. The companies are listed in Table 2.6.

Table 2.6: Norway - Wholesalers 2006

Company	Market share (%)	Ownership
Apokjeden Distribusjon AS	34..8	Tamro OYJ (Finland) Phoenix Pharmahandel AG& Co KG.
Holtung AS	20.0	Alliance Boots
NMD Grossisthandel AS	45.3	Celesio AG.

Source: LMI. / Norwegian Medicines Agency (NoMA)

In Norway there is vertical integration between the three full-range wholesalers and the biggest pharmacy chains. As a result, only hospital pharmacies and a few independent pharmacies tend to shop in the open market for the best prices among the three wholesalers. In general, pharmacies get supplies from the wholesalers on a daily basis.

Parallel trade wholesalers do not exist per se, but in Norway the imported products are mainly imported by companies specialising in parallel trade. The Norwegian Pharmacy Association (Norges Apotekerforening, NAF) represents the Norwegian pharmacies as well as the big Norwegian wholesalers and has an important role in settling trade terms and developing information systems, ethical standards, etc.

The three leading Norwegian wholesalers have developed a sound economy, delivering yearly good financial results. They have developed a solid capital basis for further expansion. As mentioned, there are only three full-range wholesalers in Norway.

Table 2.7: Norway - Key data on pharmaceutical wholesale 1995, 2000-2005[1]

Wholesalers	1995	2000	2001	2002	2003	2004	2005
Total number of wholesale companies	3	3	3	3	3	3	3
Total number of outlets	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.	n. a.

[1] as of 1 January

Source: The Norwegian Medicines Agency (NoMA)

2.1.3.3 Pharmaceutical outlets / retailers

In general only community and hospital pharmacists (570) are allowed to dispense pharmaceuticals, along with small outlets belonging to the pharmacies (1,200). These small outlets are located where there are no regular pharmacies; they keep in stock a small selection of over-the-counter (OTC) products and can dispense prescription pharmaceuticals sent by the pharmacy. Other dispensaries (drug stores, supermarkets, kiosks and petrol stations), are allowed to distribute a small selection of non-prescription (over-the-counter (OTC)) pharmaceuticals. Medical doctors, along with veterinaries, dentists and nurses, can – in special circumstances – also dispense pharmaceuticals.

Outlets need to be at least 10 km distance from any other pharmacy or outlet. Medical doctors, nurses and dentists can dispense pharmaceuticals when the distance to the nearest pharmacy is long or burdensome.

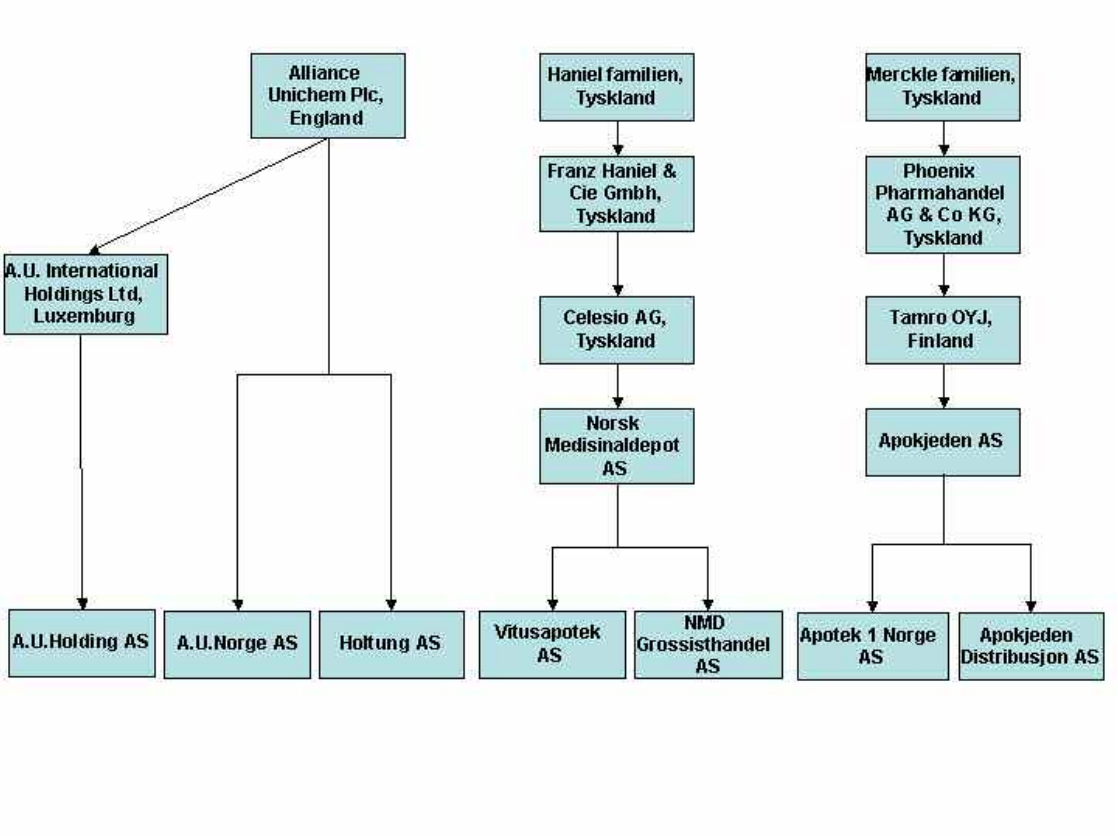
2.1.3.3.1 Pharmacies

The pharmacies' activities are regulated by the Norwegian Pharmacy Act and the associated regulations on pharmacies. The 530 community pharmacies (as of January 2006) are privately owned. Until 2001 you had to be a pharmacist to be able to own a pharmacy. Since 2001 anyone can own a pharmacy, but you still have to be a pharmacist to run a pharmacy. Until 2001 the Norwegian Medicines Agency (NoMA) regulated the number of pharmacies, but since 2001

there have been no limitations on establishing new pharmacies. Since 2001 the pharmacy chain has bought most of the existing pharmacies in Norway and established a lot of new ones.

Pharmacy chains are allowed. As of January 2006 there were three vertical integrated pharmacy chains operating in Norway, owning a total of 442 pharmacies: Alliance Unichem Norge AS (120), Apokjeden AS (202) and Norsk Medisinaldepot AS (120). These are owned by international companies. In addition there is a chain of semi-independent pharmacies (Ditt Apotek) and some totally independent pharmacies.

Figure2.2: Norway – Pharmacy chains 2006



Source: NoMA

Almost all pharmaceuticals are dispensed by pharmacies.

The Norwegian Pharmacy Association (NAF) represents the interests of the owners of the pharmacies, while the Norwegian Association of Pharmacists (Norges Farmceutiske Forening, NFF) represents the professionals' interests and the interests of the profession.

The Norwegian Pharmacy Association (NAF) has some influence on policy-making, as their opinion is routinely heard and sometimes taken into account in public policy-making.

The total remuneration of the pharmacies is not regulated, though the pharmacies' margins for prescription-only medicines (POM) are regulated. The large majority of pharmacists receive an ordinary salary. A few pharmacists still own their own pharmacy.

Subvention according to specific criteria can be applied for to operate pharmacies in rural areas or in urban areas for specific social reasons. In addition, pharmacies may apply to the Government (Norwegian Medicines Agency (NoMA)) for refunding of their freight costs when patients are too sick or have too long or burdensome journeys to the nearest pharmacy.

Out of 570 pharmacies there are 31 hospital pharmacies that are also open for out-patients. Furthermore, there are 32 dispensing doctors in rural areas. There are approximately 8,800 inhabitants per pharmacy (4.5 Mio. inhabitants).

A total of 85% of the pharmacies are totally owned by a wholesale company.

Mail orders are allowed only in the natural geographical district of the pharmacy.

Table 2.8: Norway - Retailers of pharmaceuticals 1995, 2000-2006[1]

Retailers	1995	2000	2001	2002	2003	2004	2005	2006
Number of community pharmacies[2]	328	369	433	472	478	500	506	527
No. of private pharmacies	328	369	433	472	478	500	506	527
No. of public pharmacies	28	28	28	30	30	30	30	31
Number of hospital pharmacies for out-patients (public pharmacies)	28	28	28	30	30	30	30	31
Number of other POM dispensaries: SD-doctors	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	32
Total number of POM dispensaries[1]	n.a.	n.a.	n.a.	446	508	530	536	558
No. of internet pharmacies	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.	n.app.
No. of OTC dispensaries, e.g. drug stores, including small outlets belonging to the pharmacies (1,200)	0	0	0	1,200	1,200	5,200	6,700	7,000

OTC = over-the-counter, POM = prescription-only medicine(s); No. = number, n.a. = not available, n.app = not applicable, SD-doctors = self-dispensing doctors, OTC = over-the-counter

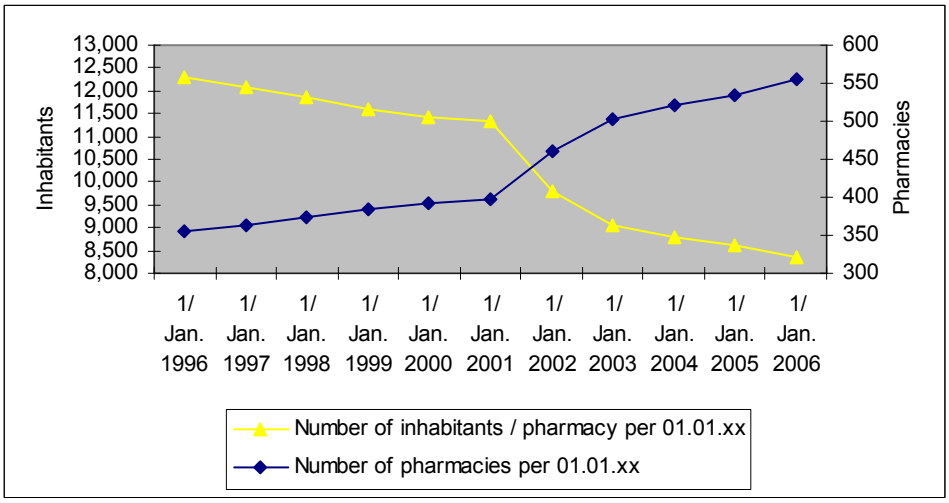
POM dispensaries = including branch pharmacies, self-dispensing doctors, and other university pharmacies (FIN), policlinic pharmacies (NL) and hospital pharmacies acting as community pharmacies

[1] as of 1 January

[2] incl. branch pharmacies

Source: Norwegian Medicines Agency (NoMA)

Figure 2.3: Norway - Number of retail pharmacies, and number of inhabitants per pharmacy 1996-2006



Source: NAF and SSB

2.1.3.3.2 Other pharmacy outlets

Many pharmacies in the districts have established pharmacy outlets from which pharmaceuticals are handed out to patients under the supervision of the pharmacy. There exist some 1,150 to 1,200 such outlets, mainly in the grocery stores in rural areas. These outlets may also sell a restricted number of over-the-counter (OTC) products.

Some 7,000 outlets, e.g. in grocery stores, gasoline stations, health stores, etc. are allowed to distribute a restricted list of over-the-counter (OTC) products; these are known as pharmaceuticals sold outside of the pharmacies (LUA). To get a distribution licence the retailer has to send an application to the Norwegian Medicines Agency (NoMA). There are no pharmacists in these outlets. Promoting of over-the-counter (OTC) pharmaceuticals outside the pharmacies (LUA) is strictly restricted and staff handling the pharmaceuticals are not allowed to give patients any kind of recommendation, nor to engage in marketing of these over-the-counter (OTC) products. Promoting of over-the-counter (OTC) pharmaceuticals within the outlets is also strictly restricted. The outlets are not connected to pharmacies or pharmacists. (i.e. no pharmacists and no recommendations).

2.1.3.3.3 Internet pharmacies

Internet pharmacies are not allowed to operate in Norway, according to current legislation.

The internet has so far not changed the distribution of pharmaceuticals in Norway, but a few European internet pharmacies are introducing new business models that may break up established patterns. Norwegian laws regulate the internet business as long as the pharmacies are established in Norway.

2.1.3.3.4 Dispensing doctors

Out-patient doctors are in general not allowed to dispense pharmaceuticals beyond what is regarded as necessary for the start of treatment before the patient can get access to a pharmacy. Doctors are not allowed to have own any part of a pharmacy.

Doctors in the rural areas operating far from the pharmacy are allowed to dispense pharmaceuticals when normal availability is restricted due to weather or geographical complications. The number of doctors with such a licence is 32. The dispensing doctors are allowed to add a 10% extra mark up on the fixed prices.

Nurses may dispense pharmaceuticals under the same regulations as for dispensing doctors, i.e. when it is highly complicated for the patient to reach a pharmacy or medical doctor.

2.1.3.4 Hospitals

There are 31 hospital pharmacies. These are generally allowed to dispense pharmaceuticals to out-patients. Most hospital pharmacies have a dual function. Their main task is serving the hospital, but they also provide services to out-patients, as does any other pharmacy. For sale to out-patients, the maximum mark up allowed is the same as for normal pharmacies.

Every hospital may be regarded as autonomous regarding which pharmaceuticals to use. It is, however, common to have a “pharmaceutical committee” that decides on the hospital’s general policy and list of pharmaceuticals. Pharmaceuticals not included in the list may be used if regarded necessary and the budget is not constrained as a result.

The patients do not have to pay for the pharmaceuticals used in their treatment as long as the treatment takes place in the hospital, i.e. all pharmaceuticals used are reimbursed. Reimbursement decisions on pharmaceuticals for use in the primary care do not therefore concern pharmaceuticals used in hospitals.

The purchasing process for pharmaceutical for use in hospitals is co-ordinated through the Norwegian Drug Procurement Co-operation (LIS) (hospital purchasing agency). This ensures that prices for patent-protected pharmaceuticals offered by the industry to the hospitals are in general lower than the prices offered by the industry for distribution through wholesalers/pharmacies. This may in some cases encourage a lowering of prices for initial treatment in hospital in order increase the number of patients in primary care being treated with the pharmaceutical in question.

In each of the five Norwegian health regions, a hospital medicines committee works out a limited list of pharmaceuticals. These pharmaceuticals are not part of the national reimbursement list. This limited list of pharmaceuticals is an advisory list to guide the hospitals’ choice of pharmaceuticals. The hospitals’ committees consist of doctors from specialised clinical areas and hospital pharmacists.

In Norway, almost all hospitals are members of a group that organise the mutual procurement of pharmaceuticals (Norwegian Drug Procurement Co-operation (LIS)). Hospitals are budgeted and within that budget they purchase pharmaceuticals according to public procurement regulations. The regional health divisions settle annual framework agreements through the Norwegian

Drug Procurement Co-operation (LIS) and the hospitals' purchases are then considered to be in accordance with this agreement. Pharmaceutical companies have no influence on the hospital list.

Hospital pharmacies are publicly owned, while community pharmacies are privately owned.

2.1.3.5 Doctors

As with the manufacturers, doctors do not play a direct part in policy-making, but new policies and changes in the legal framework are normally not put into action before all parties affected have been given an opportunity to formally express their views and present any alternative solutions.

There is no prescription budget allocated to the individual doctor. This means that there is no limitation on what the doctor may prescribe, as long as the prescription is in line with current regulations and laws. The reimbursement system, however, affects the prescribing, as it puts the doctors in a key position regarding which pharmaceuticals are used, making doctors the primary target for marketing.

More than 90% of Norwegian doctors are members of the Norwegian Medical Association (Norske Legeforening, NMA). The Norwegian Medical Association (NMA) is not connected to the pharmaceutical industry and does not get any support from it. The association is asked to give its opinion on matters concerning pharmaceutical policy-making. When the Government has plans to change the laws and regulations affecting prescription and reimbursement, the association is formally asked for their opinion. Decisions are finally made by the Government. Sometimes the association engages in lobbying members of Parliament.

In Norway all doctors are authorised to prescribe both reimbursable and non-reimbursable pharmaceuticals. A small group of reimbursable pharmaceuticals can only be prescribed by a limited number of doctors. This is usually because the prescription of this specific pharmaceutical only can be carried out by doctors with special qualifications, e.g. authorised specialists in oncology, internal medicine or gynaecology, or doctors working in special clinics with high qualifications on rare diseases.

2.1.3.6 Patients

For prescription-only medicines (POM) the maximum price is set by the Norwegian Medicines Agency (NoMA). The pharmacies are free to charge prices less than the maximum price. The opportunity to charge less than maximum price is mostly used by independent pharmacies. The maximum prizes are available from the Norwegian Medicines Agency (NoMA) web site, but there is no easy way to gain information about the actual price charged in the individual pharmacy. For over-the-counter (OTC) products there are no price regulations. The market has proven to be rather price insensitive. There are no good sources of price information available for this market sector either. The customers can therefore only compare prices by checking on site. This means that location and accessibility are usually of more importance than price when deciding where to buy.

Doctors and patient organisations do not play a direct part in policy-making, but new policies and changes in the legal framework are normally not put into action before all parties affected have been given an opportunity to formally express their views and present any alternative solutions. The patient organisations are permanently represented at the Norwegian Medicines Agency's (NoMA) advisory board for reimbursement decisions.

Doctors prescribe pharmaceuticals during consultations with patients. Normally the patient gets what the doctor recommends. However, regarding generic products the pharmacy may dispense a substitute to the original pharmaceutical unless the doctor insists that this change should not take place. The patients may also refuse generic substitution, but this can result in a higher co-payment for the patient if the prescribed original is more expensive than the generic alternative they are offered by the pharmacy.

The Norwegian Federation of Organisations of Disabled People (FFO) is the cooperative body of disabled people's organisations in Norway. This organisation represents 68 associated organisations, which represent more than 300,000 disabled and chronically ill people throughout the country.

2.2 Funding

This section provides an overview of the funding of pharmaceuticals.

2.2.1 Pharmaceutical expenditure

Pharmaceutical expenditure (PE) in Norway is displayed in Table 2.9.

Table 2.9: Norway - Total pharmaceutical expenditure 1995, 2000-2005

Pharmaceutical expenditure (PE)	1995	2000	2001	2002	2003	2004	2005
TPE in NCU	9,113	12,238	13,237	14,614	14,658	15,700	16,100
TPE as a % of THE	–	10	10	10	9	9	9
TPE per capita[1] in NCU	2100	2730	2940	3230	3220	3430	3500
Public PE as a % of THE	66	69	67	68	70	70	70
Private PE as a % of THE	34	31	33	32	30	30	30

NCU = national currency unit, GDP = gross domestic product, TPE = total pharmaceutical expenditure, PE = pharmaceutical expenditure, THE = total health expenditure

[1] please use population data from Table 1.1 as basis for calculation

Source: Facts and figures LMI

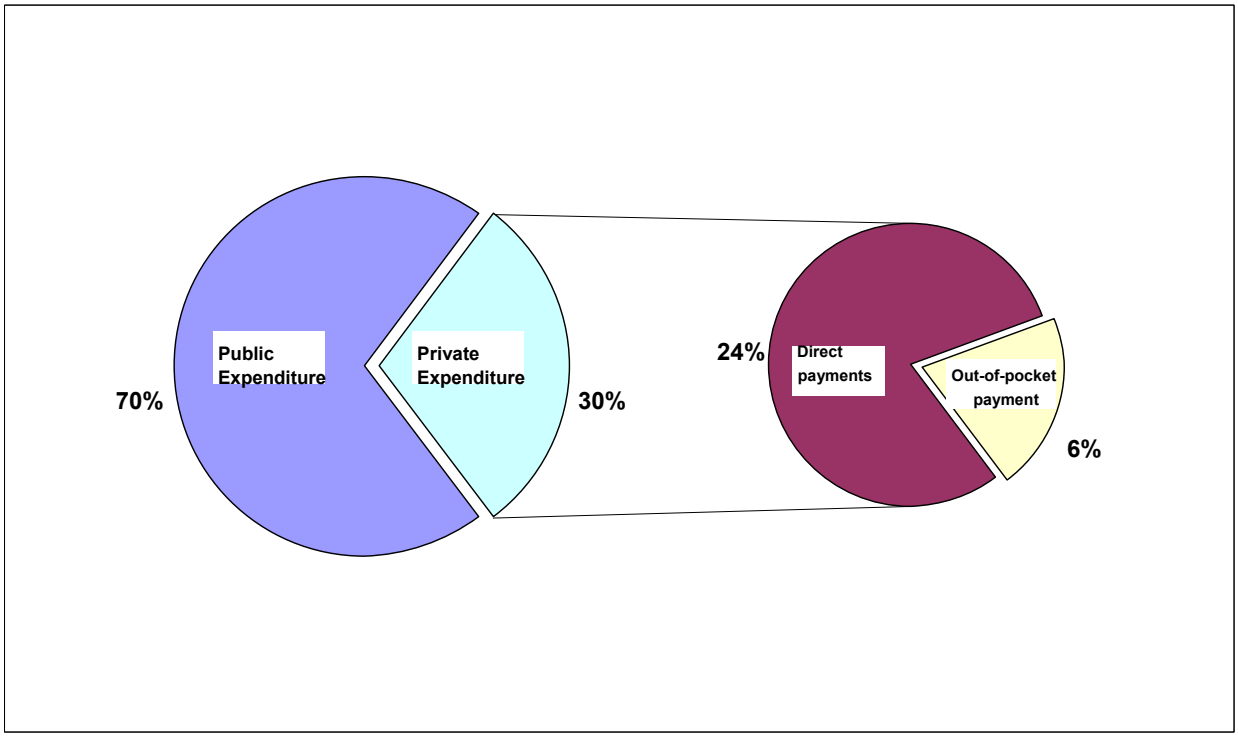
2.2.2 Sources of funds

The majority of both the public and total costs of pharmaceuticals are covered by the Norwegian National Insurance Administration (57% of total costs in 2004) through the reimbursement scheme (National Insurance Scheme (NIS)). Membership of the National Insurance Scheme

(NIS) is mandatory, and costs are covered through taxes from employers and employees. The hospitals cover costs of pharmaceuticals for in-patients, which constitutes almost 12% of total pharmaceutical costs. The hospitals are financed mainly through block grants from central authorities and the National Insurance Administration. Consequently a total of 69% of the costs of pharmaceuticals were covered by public budgets in 2004. The costs covered directly by the patients were derived from non-reimbursable prescription pharmaceuticals (12%), non-prescription pharmaceuticals (11%), and patient co-payments for reimbursable pharmaceuticals (6%). Veterinary products constituted less than 2% of the total market. In 1984 the Norwegian Parliament introduced patient co-payments for reimbursed pharmaceuticals. Currently, the patient co-payment is 36% of the total amount on the prescription.

There is a maximum limit of NOK 500.- (63.5 €) per prescription, and the ceiling for total co-payments in one calendar year was NOK 1,615 (205 €) in 2006. Our-of pocket payments for physician visits, radiology examinations, laboratory tests and pharmaceuticals can also be included in this amount (cf. 4.4.2).

Figure 2.4: Norway - Share of private and public pharmaceutical expenditure 2005



Source: Facts and figures LMI

2.3 Evaluation

Most areas of the pharmaceutical policy are monitored. Some of this is routine monitoring and some is carried out within the framework of specific studies. As far as pricing and reimbursement are concerned, NoMA is responsible for a large amount of the monitoring.

3 Pricing

This chapter gives an overview of the pricing system by describing the process and the regulation of the pricing of pharmaceuticals.

3.1 Organisation

The Ministry of Health and Care Services (HOD) determines the principal pricing criteria for pharmaceuticals, which is regulated in “Forskrift om legemidler” (Chapter 12, in Norwegian)[2].

The Norwegian Medicines Agency (NoMA) is in charge of pricing decisions for individual pharmaceuticals and establishes the more specific guidelines for price determination. The Norwegian Medicines Agency (NoMA) is, among other things, responsible for pricing and reimbursement. The applicant can apply for both price setting and reimbursement at the same time, but more often these procedures are separate. When the Norwegian Medicines Agency (NoMA) determines a price, the third-party payer, the Norwegian Labour and Welfare Organisation (NAV), accepts this price for reimbursement. The process of pricing takes on average 20-25 days, up to a maximum of 90 days.

Table 3.2. gives an overview of the types of pricing policy applied in Norway.

3.2 Pricing policies

3.2.1 Maximum price setting for prescription-only medicine(s) (POM)

The main rule when pricing a medicinal product in Norway is that the price will be set at the mean of the three lowest market prices of that product in a selection of countries. The prices that are set are maximum pharmacy purchasing prices (PPPs). The current pricing system was implemented in 2002.

The countries which are normally included in the price comparison group are: Sweden, Finland, Denmark, Germany, United Kingdom, the Netherlands, Austria, Belgium and Ireland. If there is no price in three or more of the countries which are included in the price comparison group, the price will usually be set at the mean price in the countries where a market price exists. The Norwegian Medicines Agency (NoMA) will set prices according to its own estimates if, on request and within specified deadlines, international price details which are considered necessary for pricing the medicinal product in Norway have not been received from the Market Authorisation Holder (MAH). When setting the price the Norwegian Medicines Agency (NoMA) will, as far as possible, follow the main rules for price setting, which are listed below. Some cases which deviate from the main rules are described. The list presented here is not complete and individ-

[2] http://www.lovdata.no/for/sf/ho/ho-19991222-1559.html

ual assessments therefore have to be made. The Norwegian Medicines Agency (NoMA) aims to ensure, as far as possible, equal treatment of each individual case that is assessed.

Table 3.1: Norway - Ways of pricing of pharmaceuticals

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Free pricing for all products set by the manufacturer/importer (see below).		Free pricing for OTC
Statutory Pricing	No regulations	Maximum prices for all POM. Price is set at the PPP level and is "topped" by a regulated maximum pharmacies margin.	
Price Negotiations	Applied for some HOM cases		Not applied
Discounts / Rebates	Not applied	Not applied	Not applied
Public Procurement	Mainly relevant for products used in hospitals (performed by LIS)		
Institution in charge of pricing	➢ NoMA for maximum prices ➢ NoMA for pharmacy mark-up scheme ➢ NoMA for reimbursement price ➢ LIS – hospital purchasing agency for price negotiations for HOM		
Legal Basis	➢ "Forskrift om legemidler" [3]		

NoMA = Norwegian Medicines Agency, HOM = hospital-only medicines, POM = prescription-only medicine(s), OTC = over-the-counter pharmaceuticals, LIS = Norwegian Drug Procurement Co-operation (hospital purchasing agency), PPP = pharmacy purchasing price

Source: NoMA

3.2.2 Limits at which pack sizes are considered comparable for price setting

Because pack sizes are not always directly comparable, price comparisons with other countries are carried out on the basis of units. This means that price per tablet; price per dose, etc. are compared.

When setting the price, differentiation between price per unit in large and small packs is taken into account. A pack containing 30 or fewer units is normally defined as small. Packs containing more than 30 units are defined as large. For medicinal products which, e.g., are used in the treatment of asthmatic conditions, a package containing 120 or fewer doses is normally defined as small and a package containing more than 120 doses is defined as large. For some medicinal products it is natural to deviate from the main rule. An example of this is products which are used in the treatment of acute migraine attacks. Packages containing this type of pharmaceutical are defined as small if they contain five or fewer tablets, and large if they contain more than five tablets.

[3] http://www.lovdata.no/for/sf/ho/ho-19991222-1559.html

For medicinal products which cannot be included in any of the groups described above the Norwegian Medicines Agency (NoMA) has to determine a natural limit which can be drawn between small and large packages.

3.2.3 Pricing rules

- **The relationship between price per unit in a large and a small package for a medicinal product at a given strength**

  In several of the countries which are included in the price comparison group, only small pack sizes have been registered. This means that if the main pricing rule is followed for a given strength, this may result in a lower price per tablet in a small package than in a large package. In such cases the price per tablet in the large package is set at the same level as the price per tablet in the small package. If the price per tablet is higher in a small package than in a large package the price difference is accepted, provided this difference is not considered to be unreasonable.

- **Price ratios between different strengths of a given medicinal product**

  When setting the price the Norwegian Medicines Agency (NoMA) aims to ensure that the price ratio between different strengths of a given product is reasonable.

- **Comparable pharmaceuticals for price setting**

  When setting the price of a pharmaceutical comparison will mainly be drawn with the same product in the reference countries. If a medicinal product is marketed under different product names in different reference countries they will still be compared for pricing. Different varieties of the same product may also be taken into consideration when comparing prices.

- **Parallel import**

  The prices of medicinal products which are parallel imported to Norway are regulated so that the product is priced as requested, but limited up to the maximum market price of the directly imported medicinal product.

- **Generics**

  The maximum price of generics is regulated so that the medicinal product is priced as requested, but limited up to the maximum market price of the reference product. However, to ensure a price decrease when generics are launched on the market there is a special regulation in place for generics called the “step-price system” (cf. 3.4.2).

- **Time limit for submission of price details**

  Each Market Authorisation Holder (MAH) is obliged, on request, to give the Norwegian Medicines Agency (NoMA) details of prices in other countries. The time limit for submission of price details is 21 days from the submission of the application for price setting. The prices are to be stated at the pharmacy purchasing price (PPP) level.

- **The price set is the pharmacy purchasing price (PPP)**

  The price which is set by the Norwegian Medicines Agency (NoMA) is the permitted maximum market price to the pharmacist. The product can be freely sold at a lower price than the

maximum price. The pharmacies' margin on the pharmacy purchasing price (PPP) is regulated as well, so in fact the maximum pharmacy retail price (PRP) is regulated.

- **Market price is the basis for comparison of prices**

  The basis of price comparisons is the actual market price in each of the individual countries in the price comparison group. Market price is defined as the price the major part of the market pays for the product.

- **Exchange rates**

  Price comparison is based on the price in the local currency, converted to NOK. The mean exchange rate of the last six whole months, as presented by the Central Bank of Norway, is used as the basis for the comparison of prices.

3.2.4 Basis for re-evaluation of price

Prices can change, but the adjustments normally do not occur more frequently than annually. Both the Norwegian Medicines Agency (NoMA) and the pharmaceutical companies can take the initiative concerning price changes. The Norwegian Medicines Agency (NoMA) ultimately decides on the price changes.

The Norwegian Medicines Agency (NoMA) revises the price of the 240 top-selling pharmaceuticals on a yearly basis. This is to make sure that the price level in Norway stays at the "right" level according to the comparison countries. The Norwegian Medicines Agency (NoMA) also revises several of the products that are selling less well every year to make sure that most products are being revised at some point.

The prices in Norway can be adjusted if a price alteration in one or more of the countries included in the price comparison group makes it necessary, or if a significant alteration in the exchange rates has occurred. Exempted from this rule are the prices of new products after their launch onto the market. In a two-year period after launching, the Norwegian Medicines Agency (NoMA) may request information about new prices every six months from the Market Authorisation Holder (MAH) in question.

Withdrawal of a product from one of the reference countries may be cause for an alteration in the price in Norway. Documentation must be produced to show that a product has in fact been withdrawn from the market if this is to give cause for price changes.

3.2.5 Statutory pricing

The Norwegian Medicines Agency (NoMA) sets maximum prices for all prescription-only medicines (POM) at the pharmacy purchasing price (PPP) level. The pharmacy retail price (PRP) is regulated upwards by a maximum pharmacy mark up set by the Norwegian Medicines Agency (NoMA). The maximum price is set due to external reference pricing. The current system was implemented in 2002. It is regulated by law – the Norwegian Act on Medicinal Products.

The Market Authorisation Holder (MAH) has to apply for a maximum price before entering the market. The Norwegian Medicines Agency (NoMA) re-evaluates most of the maximum prices on

a yearly basis. The Norwegian maximum prices are in general based on the average of the three lowest pharmacy purchasing prices (PPP) in Sweden, Finland, Denmark, Germany, the United Kingdom, the Netherlands, Austria, Belgium and Ireland.

3.2.6 Negotiations

The authorities are in general not involved in price negotiations.

As far as reimbursement is concerned the applicant may be recommended, by the Norwegian Medicines Agency (NoMA), to lower their maximum price in order to receive reimbursement for a specific pharmaceutical. Some price negotiations can occur as part of the reimbursement decision process (cf. Chapter 4).

3.2.7 Free pricing

There is free pricing for all non-prescription pharmaceuticals (over-the-counter (OTC)) and pharmaceuticals for animals (veterinary pharmaceuticals).

3.2.8 Public procurement / tendering

Tendering is only used in the hospital sector (cf. 3.4.1).

3.3 Pricing procedures

Table 3.2: Norway - Pricing procedures

Pricing procedure	In use: Yes / No	Level of pricing[1]	Scope[2]
Internal price referencing	Not in general, but elements of internal referencing are used when deciding upon reimbursement	PPP	Reimbursable pharmaceuticals
External price referencing	Yes since 2002	PPP	POM
Cost-plus pricing	No		
Other, e.g. indirect profit control	No		

[1] Level of pricing = at what stage of the pricing process does the pricing take places (e.g. at the retail price level)

[2] Scope = A pricing procedure does not always refer to all pharmaceuticals: e.g. a pricing procedure could only refer to reimbursable pharmaceuticals, whereas for Over-The-Counter pharmaceuticals there is free pricing.

PPP = pharmacy purchasing price, POM = prescription-only medicine(s)

Source: NoMA

3.3.1 External price referencing

The main rule when pricing a medicinal product in Norway is that the maximum price will be set at the mean of the three lowest market prices of that product in a selection of countries. Prices are set at the pharmacy purchasing price (PPP) level. The current pricing system was implemented in 2002. The countries which are normally included in the price comparison group are: Sweden, Finland, Denmark, Germany, the United Kingdom, the Netherlands, Austria, Belgium and Ireland. This is described in detail in 3.2.

3.3.2 Internal price referencing

An element of internal reference pricing might be used when making reimbursement decisions. A pharmaceutical product has to be cost-effective to other pharmaceuticals in order to be reimbursed (cf. Chapter 4).

3.3.3 Cost-plus pricing

Cost-plus pricing is in general not used (cf. Chapter 4).

3.3.4 (Indirect) Profit control

Indirect profit control is not applied in Norway.

3.4 Exceptions

3.4.1 Hospitals-only

All prescription-only medicines (POM), including hospitals-only, are given maximum prices. However, prices for many of the hospitals-only products are negotiated by the Norwegian Drug Procurement Co-operation (LIS) (hospital purchasing agency).[4] Discounts to hospitals are around 31% on average.

3.4.2 Generics

Generics are given the same maximum price as the original pharmaceutical. However, there is a special system for generic pharmaceuticals in Norway, called the “step-price system”. This system was introduced on 1 January 2005. Within the step-price system maximum reimbursement prices are automatically reduced in stages (steps) following patent expiry, with the percentage cut dependent on annual sales, as shown in Table 3.3.

[4] www.Lisnorway.com

Table 3.3: Norway – The step-price system as at 1 January 2005

Time from when generic competition is established	Sales below NOK 100 Mio. (€ 12.5 Mio.)	Sales over NOK 100 Mio. (€ 12.5 Mio.)
Immediate	Prices are cut by 30%	Prices are cut by 30%
After 6 months	Prices are cut by 40%	Prices are cut by 50%
After 12 months	Prices are cut by 50%	Prices are cut by 70%

Source: NoMA 2006

The step-price system applies for generics, parallel traded pharmaceuticals and the originals. The basis for the cut is the maximum reimbursement price of the original pharmaceutical at the time a steady generic competition is established. The reimbursement price is reduced step by step from that time (at which generic competition is established).

The pharmacies are obliged to offer at least one product within each group of products that can be switched to match the step price. The products keep their maximum price that is set according to international reference pricing. If the patient will not switch to the product the pharmacy is offering, then the patient has to pay the difference between the step price and the maximum price. The step-price system applies both for reimbursed and non-reimbursed products.

The step price is set at the pharmacy retail price (PRP), and this implies that the pharmacy mark up is not regulated for pharmaceuticals included in the step-price system.

Based upon an evaluation of the system, the step-price system was ”tightened” from 1 January 2007, changing from containing three steps to two. The final cut is now reached after six months, with the maximum cut being increased from 50% to 55% and from 70% to 75%. For simvastatin the maximum cut was increased from 70% to 85%.

Table 3.4: Norway – The step-price system as at 1 January 2007

Time from when generic competition is established	Sales below NOK 100 Mio. (€ 12.5 Mio.)	Sales over NOK 100 Mio. (€ 12.5 Mio.)
Immediate	Prices are cut by 30%	Prices are cut by 30%
After 6 months	Prices are cut by 55%	Prices are cut by 75%

Source: NoMA 2006

The Norwegian Medicines Agency (NoMA) sets the step prices and the regulations are described in “Forskrift om legemidler“.[5]

[5] http://www.lovdata.no/for/sf/ho/to-19991222-1559-040.html

3.4.3 Over-the-counter pharmaceuticals

There are no statutory or unilateral regulations in place as over-the-counter (OTC) products are freely priced at all price levels.

3.4.4 Parallel traded pharmaceuticals

Parallel traded pharmaceuticals are given the same maximum price as the direct imported pharmaceutical. The step-price system also applies for parallel traded pharmaceuticals (cf. 3.4.2).

3.5 Margins and taxes

This section contains a description of the wholesale and pharmacy margin and mark ups, dispensing fees and sales taxes applied to pharmaceuticals.

Table 3.5: Norway - Regulation of wholesale and pharmacy mark ups 2005

Wholesale mark up			Pharmacy mark up		
Regulation (yes/no)	**Content**	**Scope***	**Regulation (yes / no)**	**Content**	**Scope**
No	n.app.	n.app.	Yes	A fixed amount per package and a percentage of PPP	All POM

PPP = pharmacy purchasing price, POM = prescription-only medicine(s), n.app. = not applicable

Source: NoMA

3.5.1 Wholesale remuneration

Wholesale mark ups are not regulated in Norway. The average wholesale margin is somewhere between 5 % and 7 % for patented pharmaceuticals. For off-patent pharmaceuticals it is much higher.

3.5.2 Pharmacy remuneration

Pharmacy mark ups are regulated (by decree) by the NoMA. The established pharmacy mark ups (cf. Table 3.6) are “maximum” mark ups and are applied for all price-regulated pharmaceuticals, including both reimbursed and non-reimbursed pharmaceuticals.

Table 3.6: Norway - Pharmacy mark-up scheme 2006

Norway		
Pharmacy purchasing price (PPP) from … to… in national currency unit (NCU)/€	**Pharmacy mark up coefficient in % of pharmacy purchasing price (PPP)**	**Additional fixed mark up per package**
NOK 0-200 / € 25	8 %	NOK 21.50 / € 2.7
From NOK 200 / € 25	5 %	NOK 21.50 / € 2.7

Source: NoMA

For addictive drugs / narcotics there is an additional flat rate amount of NOK 10 (€ 1.25) per package allowed.

On average the maximum pharmacy margin is between 17% and 18% for pharmaceuticals regulated by the maximum price.

3.5.3 Remuneration of other dispensaries

Only a very selected range of over-the-counter (OTC) products may be sold outside pharmacies (known as pharmaceuticals sold outside of pharmacies (LUA)). For these free pricing at all price levels is applied.

3.5.4 Value-added tax

Pharmaceuticals follow the standard value-added tax (VAT) rate in Norway which is 25%.

3.5.5 Other taxes

There is a pharmaceutical fee of 1.3% of the pharmacy purchasing price (PPP). The fee applies for all pharmaceuticals including over-the-counter (OTC) products and is paid by the pharmacies and other outlets allowed selling over-the-counter (OTC) pharmaceuticals. The amount is not included in the price build-up. The fee is collected by the wholesalers. Some of this fee is redistributed to the pharmacies as subsidies.

3.6 Pricing-related cost-containment measures

This section contains a description of the price control mechanisms currently used.

3.6.1 Discounts / Rebates

The prices set in Norway are maximum prices, and there is no law against discounts. However, due to the market situation and the existence of a third-party payer, there are seldom discounts on the pharmacy maximum price.

However, prices for many of the hospitals-only products are negotiated by the Norwegian Drug Procurement Co-operation (LIS) (hospital purchasing agency).[6] Discounts granted to hospitals are around 31% on average.

3.6.2 Margin cuts

The pharmacy mark ups have been the same since 2001. During the 1990's there were several cuts in the pharmacy mark ups.

3.6.3 Price freezes / Price cuts

There have been no price freezes in Norway.

3.6.4 Price reviews

Prices are reviewed annually (cf. 3.2.4), and while the method of setting prices is not reviewed on a regular basis, details are constantly being adjusted, where necessary.

[6] www.Lisnorway.com

4 Reimbursement

This chapter gives an overview of the reimbursement system, the reimbursement procedure and the regulation of reimbursement.

4.1 Organisation

The Norwegian health care system has developed in the context of welfare policy in Norway, where equality and justice are highly valued. All individuals should have equal access to a decent standard of living, work, a place to live, and coverage of crucial health and social services, independent of where they reside or their economic situation.

Following from this welfare policy, a key feature of the health care system is the predominance of tax-financed public provision. The hospitals and the primary health care system have been financed largely through block grants from the central authorities and contributions or reimbursement from the state-owned National Insurance Scheme (NIS). Membership of this programme is mandatory and universal, and is financed by compulsory contributions from employees and employers. The National Insurance Scheme (NIS) covers retirement pensions, disablement benefits, sickness benefits, unemployment benefits, and health care, including pharmaceuticals (cf 1.4.2).

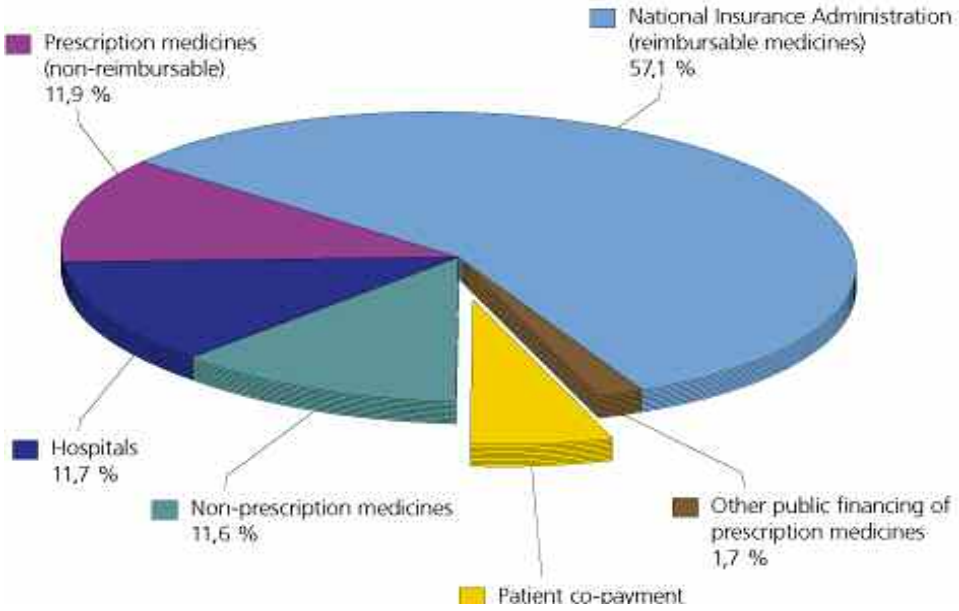
There is a co-payment by patients for ambulatory care and co-payments for reimbursed pharmaceuticals. The ceiling for the total co-payment by a patient is NOK 1,615 / € 205 per year (in 2006).[7] Expenses above this amount (for reimbursed pharmaceuticals and ambulatory care) are covered by the insurance programme (cf 4.4.2).

The Norwegian health care system is organised on three levels, i.e. national, regional and local levels. Overall responsibility for the health care sector rests at the national level, with the Ministry of Health and Care Services (HOD). The regional level is represented by five regional health authorities, which have responsibility for specialist health care and the local level is represented by 434 municipalities that have responsibility for primary health care (cf 1.4.1).

As Figure 4.1 shows, the cost of pharmaceuticals in Norway is covered through public budgets or directly by the patient.

[7] Exchange rate of 31st of July 2006: 7,8745 NOK= € 1

Figure 4.1: Norway - Breakdown of payment for pharmaceutical consumption 2004



Sources: National Insurance Administration, Norwegian Pharmacy Association, Statistics Norway, LMI/Farmastat

The majority of both the public and total costs of pharmaceuticals are covered by the Norwegian National Insurance Administration (57% of total costs in 2004) through the reimbursement scheme (National Insurance Scheme (NIS)). Membership of the National Insurance Scheme (NIS) is mandatory, and costs are covered through taxes from employers and employees. The hospitals cover the costs of pharmaceuticals for in-patients, which constitutes almost 12% of total pharmaceutical costs. The hospitals are financed mainly through block grants from the central authorities and the National Insurance Administration. Consequently a total of 69% of the costs of pharmaceuticals was covered by public budgets in 2004. The costs covered directly by the patients were derived from non-reimbursable prescription pharmaceuticals (12%), non-prescription pharmaceuticals (11%), and patient co-payments for reimbursable pharmaceuticals (6%). Veterinary products constituted less than 2% of the total market. In 1984 the Norwegian Parliament introduced patient co-payments for reimbursed pharmaceuticals. Currently the patient co-payment is 36% of the total amount of the prescription.

There is a maximum limit of NOK 500 (€ 63.5) per prescription, and the ceiling for total co-payments in one calendar year was NOK 1,615 (€ 205) in 2006. Co-payments for physician visits, radiology examinations and laboratory tests can be included in this amount, as well as costs for pharmaceuticals (cf. 4.4.2).

The pricing and reimbursement process is regulated in detail in Regulation No. 1559 of 22 December 1999 relating to pharmaceutical products (the Pharmaceutical Products Regulations), Sections 12 and 14. The reimbursement schemes are regarded as important tools for the Norwegian health authorities to achieve important goals in societal health and welfare policies. Central political principles provide the rationale behind the criteria which serve as a framework for the reimbursement systems in Norway. These main principles are:

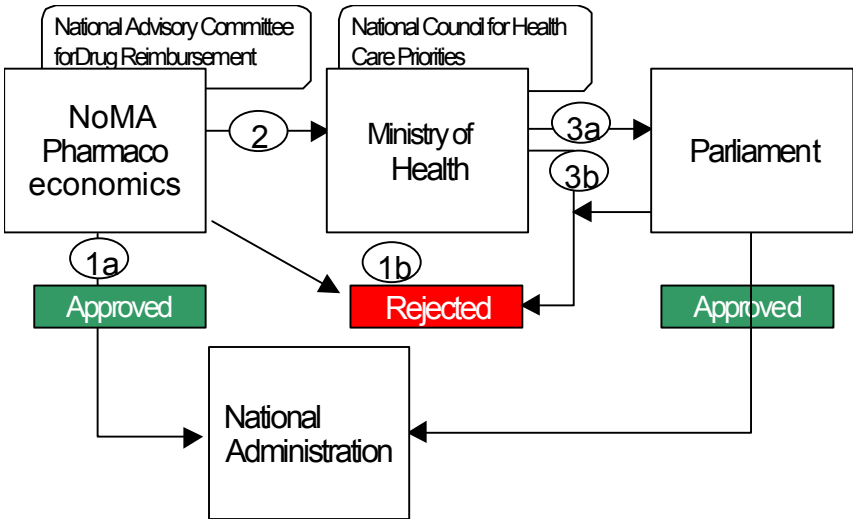
1. Principles concerning medical needs and solidarity in the population:

- Everyone should have the same access to necessary pharmaceuticals regardless of their ability to pay.

2. Principles concerning rationality:

- The reimbursement system should encourage clinically rational and cost-effective use of pharmaceuticals as a tool to ensure investment in health care services.

Figure 4.2: Norway - The decision-making process for reimbursement



NoMA = Norwegian Medicines Agency
1a = approve, 1b = reject, 2 = pass to the Ministry of Health and Care Services (HOD), 3a = bring the case before Parliament in the form a Budget Bill, 3b = reject after further evaluation

Source NoMA 2006

Figure 4.2 displays the decision-making process for reimbursement of pharmaceuticals. A company may send a reimbursement application for a prescription pharmaceutical to the Norwegian Medicines Agency (NoMA). A price application may be submitted concurrently (a fixed initial maximum price is a prerequisite for reimbursement). The Norwegian Medicines Agency's (NoMA) allocated time for dealing with both pricing and reimbursement is 180 days. If the reimbursement application involves a generic product, a new strength, formulation or package size (line extension), and is no more costly than the relevant reimbursed product, the procedure is usually swift and the Norwegian Medicines Agency (NoMA) will approve the application (cf. 1a in Figure 4.2). Reimbursement is then granted by the National Insurance Administration.

If the application concerns a new chemical entity, a new combination or an extension of indication the Norwegian Medicines Agency (NoMA) is obliged to reject the application and pass it on (2) to the Ministry of Health and Care Services (HOD) if either a) the expected annual sales value exceeds 100% of the expenditure on the relevant disease section of the reimbursement list; or b) the annual incremental fiscal impact of approving the application exceeds NOK 5 Mio. by the fifth year after approval.

If these budget conditions do not apply, the Norwegian Medicines Agency (NoMA) may make an independent decision on the basis of its evaluation, and approve (1a) or reject (1b) the application. If the conditions do apply, the Norwegian Medicines Agency (NoMA) will pass its appraisal on to the Ministry of Health and Care Services (HOD) who will assess the matter further. In this process, the Norwegian Medicines Agency (NoMA) may be advised by an external reimbursement committee (National Advisory Committee for Drug Reimbursement) on issues pertaining to the application (i.e. verification of documentation, severity of disease, clinical criteria). The Ministry of Health and care Services (HOD) may in turn consult a body known as the National Council for Health Care Priorities and inquire whether the money "would be well spent" in terms of other health challenges. The Ministry may decide to reject the application following further evaluation (3b), but should it favour approval, it will have to bring the case before Parliament in the form a Budget Bill (3a).

With a complete market authorisation for its product the pharmaceutical industry can either send an application for maximum price and an application for reimbursement simultaneously or apply for maximum price first. Nevertheless the pricing is a decisive factor in cost-effectiveness for any product and therefore also the reimbursement process. There is an increasing tendency toward a distinction between obtaining maximum price and obtaining reimbursement price, the latter being the instance where the Norwegian Medicines Agency (NoMA) finds the pharmaceutical cost-effective, which is not always the case with the maximum price.

A company needs to follow the Norwegian guidelines[8] for pharmacoeconomic evaluation in connection with applications for reimbursement.

The guidelines ask for an explanation of the choice of comparison, the time frame for the analysis, data collection methods, analysis methods and costs. Pharmacoeconomic evaluation is carried out for all pharmaceuticals for which an application for reimbursement is submitted, with the exception of the following cases.

- Pharmaceuticals with the same active ingredient as pharmaceuticals for which reimbursement has already been granted, i.e.: generic pharmaceuticals, parallel imported preparations and preparations in new packaging. This holds under the condition that the pharmaceutical for which the application is being made has the same approved indication as the reimbursement-approved pharmaceutical and that the costs are not higher or the health outcomes different than that of a pharmaceutical with which comparison is natural.
- Pharmaceuticals where a new formulation clearly does not change the costs and health outcomes of treatment.

The reimbursement status of a pharmaceutical does not change automatically as a result of new evidence, price changes, etc. However, this is an ongoing process that depends on the specific pharmaceutical's cost-effectiveness. If a more cost-effective competitor is entering the market, the well-established pharmaceutical may become the second-line treatment. This will only take place after the company with the well-established pharmaceutical has had the opportunity to prove otherwise. A similar situation occurs in the case of new evidence.

[8] http://www.legemiddelverket.no/templates/InterPage____15443.aspx

4.2 Reimbursement schemes

A Pharmacoeconomic evaluation in connection with applications to join the reimbursement scheme has been compulsory since 1 January 2002. The pricing and reimbursement process is regulated in detail in Regulation No. 1559 of 22 December 1999 relating to pharmaceutical products (the Pharmaceutical Products Regulations), Sections 12 and 14. If the Norwegian Medicines Agency (NoMA) has decision-making power to approve reimbursement, it will have a legal time frame of 180 days to discuss the reimbursement application. If the Norwegian Medicines Agency (NoMA) has questions about the application, the company has a maximum of three months to answer. The decision as to whether or not the pharmaceutical will obtain reimbursement will be postponed accordingly. In cases where the Norwegian Medicines Agency does not hold the decision-making power, it sends a recommendation to the Ministry of Health and Care Services (HOD), which has the final word. In the latter case there is no time limit.

Reimbursement is provided only for "long-term" medication for chronic diseases, defined as more than three months' of medication per year. In general the reimbursement programme does not cover short-term therapy (e.g., antibiotics for pneumonia). Over-the-counter (OTC) products are also exempt from reimbursement. The social welfare context in which the programme has developed has led to a number of "escape" clauses to ensure that social welfare goals, particularly equity, are achieved. There are four main ways in which pharmaceuticals can be covered (Table 4.1). Schedules 9 and 4 require that the pharmaceutical has been approved for reimbursement. Pharmaceuticals in these schedules will, when initially approved by the authorities, be reimbursed automatically, while pharmaceuticals in Schedules 10a and 2 require a formal application for each patient.

Table 4.1: Norway - Ways in which pharmaceuticals can be covered

Schedule 9	Doctors prescribe medication specified on an approved list. The medication must be prescribed for the particular conditions listed in the “disease list” under this paragraph. Examples: alendronate (Fosamax) for osteoporosis, statins for hypercholesterolemia.
Schedule 10a	Individual application from specialists. Only relevant specialists can apply for reimbursement based on criteria that an individual patient does not respond to first-choice pharmaceuticals for other reasons. In some cases costly pharmaceuticals can be reimbursed for diagnoses not included in the diagnosis list. Examples: interferon (betaferon) for multiple sclerosis, celekoksib (celebra) for osteoarthritis.
Schedule 4	Full reimbursement for pharmaceuticals for specified communicable diseases. Examples: pharmaceuticals for syphilis, tuberculosis, HIV/AIDS.
Schedule 2	Individual claims for pharmaceuticals not covered by the blue prescription programme.

Source: NoMA 2006

The National Insurance Administration operates with two lists: one for approved conditions, and a corresponding one of approved groups of pharmaceuticals. The groups in the pharmaceuticals list are variably defined; in some cases the chemical compounds are clearly specified (e.g., nitrate compounds), while in others the specifications are very broad (e.g., antidepressants).

Pharmaceuticals approved for general reimbursement (Schedule 9) must be licensed to treat one of the listed conditions and belong to an approved pharmaceutical group. More than 90% of total reimbursement expenditures arise from Schedule 9. If a pharmaceutical is not licensed for the listed diagnosis or is not on the "positive list" of reimbursed pharmaceuticals, it can still be approved for reimbursement based on individual applications (Schedule 10a). Schedule 4 is a remnant from a policy established to eliminate communicable (mainly sexually transmitted) diseases. Schedule 2 fulfils the social intentions of the programme; there is no need to document the severity or duration of the disease or of a pharmaceutical's beneficial treatment effect when applying for coverage in this group.

4.2.1 Eligibility criteria

Market authorisation of a pharmaceutical product is needed before the company can apply for reimbursement for reimbursement. When market authorisation has been granted, the company can apply for a maximum price and reimbursement simultaneously. A company needs to follow the Norwegian guidelines[9] for pharmacoeconomic evaluation in connection with applications for reimbursement and the reimbursement decision is strongly dependent on the result of the pharmacoeconomic evaluation of the product.

The guidelines ask for an explanation of the choice of comparison, the time frame of the analysis, data collection methods, analysis methods and costs. In addition, product-specific criteria are of great importance. The pricing and reimbursement process is regulated in detail in Regulation No. 1559 of 22 December 1999 relating to pharmaceutical products (the Pharmaceutical Products Regulations), Sections 12 and 14. Reimbursement of a pharmaceutical, pursuant to Article 9, is granted only for use with medically approved indications. The pharmaceutical shall only by used in treating severe diseases or diseases with risks factors which are highly likely to cause or exacerbate severe diseases. Reimbursement is provided only for "long-term" medication for chronic diseases, defined as more than three months' worth of medication per year. In general the reimbursement programme does not cover short-term therapy (e.g., antibiotics for pneumonia). The pharmaceutical should have a scientific, well-documented and clinical relevant effect in a defined, actual population.

A pharmacoeconomic evaluation is performed for all pharmaceuticals for which an application for reimbursement is submitted, with a few exceptions (cf. 4.1). For more information cf. 5.4.

The reimbursement category is decided by the Norwegian Medicines Agency (NoMA). However, if the budget impact is huge the final decision is made by the Ministry of Health and Care Services (HOD). If an applicant is rejected the company can complain to the Ministry of Health and Care Services (HOD) within three months. Normally the Norwegian Medicines Agency (NoMA) will discuss the objections and make a recommendation to the Ministry of Health and Care Services (HOD), which has the final word on the matter.

[9] http://www.legemiddelverket.no/templates/InterPage____15443.aspx

4.2.2 Reimbursement categories and reimbursement rates

Generally speaking, the Norwegian reimbursement system may be characterised as disease and consumption based. Whether a pharmaceutical is reimbursed or not and the amount of reimbursement depends on the following criteria.

- Does the patient have a chronic disease requiring more than three months of treatment?
- The type of the disease which the pharmaceutical is for (HIV, tuberculosis, etc.).
- The annual consumption (no co-payment above an annual ceiling of NOK 1,615 (€ 205)).
- The type of patient (low-income pensioner or children under 12).

The main Norwegian legislation with regard to reimbursement, the National Insurance Act, opens up the possibility of obtaining reimbursement for pharmaceuticals through basically four different schedules (cf. Table 4.1), described by four different paragraphs of this law. The long-term treatment is a prerequisite for Schedules 9, 10a and 2. Independently, reimbursement is always 100% for children under the age of 12 and for low-income pensioners.

Table 4.2: Country - Reimbursement of pharmaceuticals

Reimbursement category	Reimbursement rate (%)	Characteristic of the category (when it applies)
Schedule 9	64 / 100[1]	For pharmaceuticals on a positive list, which are reimbursed in case of specified conditions listed in the disease list and only for long-term (>3 months) treatment.
Schedule 4	100	For pharmaceuticals used to treat serious contagious diseases such as tuberculosis, syphilis or HIV/AIDS.
Schedule 2	64 / 100[1]	For pharmaceuticals used to treat rare diseases, which are reimbursed upon submission of an individual application and only for long-term (>3 months) treatment.
Schedule 10a	64 / 100[1]	For pharmaceuticals other than those under Schedules 9, 4 and 2. In this case reimbursement can be granted upon submission of an individual application and only for long-term (>3 months) treatment.

[1] For children under 12 years of age, for low income pensioners and for patients who have reached the co-payment ceiling.

Source: NoMA 2006

General reimbursement – Schedule 9

The system of general reimbursement is the main system for reimbursement of pharmaceuticals, and constitutes more than 90% of reimbursed pharmaceutical sales. It is basically a "positive list" system, based on a list of diseases or conditions for which pharmaceutical treatment can be reimbursed, provided other given criteria are fulfilled. For each disease listed there are defined corresponding product groups of pharmaceuticals that are accepted for general reimbursement (e.g., Disease: Bronchial Asthma, Product group: Long term b-2 agonists). The list of conditions and related product groups are part of Norwegian legislation, and can only be changed by the Ministry of Health and Care Services (HOD). For each defined product group

the Norwegian Medicines Agency (NoMA) handles a list of product brand names that has been accepted for reimbursement for the defined condition (product list). The diseases on the list have in common that they are considered to be serious and chronic. Reimbursement is granted only under the condition that the patient has a chronic disease, for which “long-term” medication (more than three months per year) is necessary. Furthermore, the pharmaceuticals in question must have market authorisation and therefore need to have satisfactory documentation of clinical effect and safety. Furthermore, general reimbursement is granted only for treatment of disease states or conditions that are covered by the product’s medical indication.

Individual reimbursement – Schedule 10a

Under certain conditions reimbursement is granted on the basis of individual patient applications for products not included in the product list for general reimbursement. If a patient suffers from a serious disease or condition which requires long-term treatment, and the accepted products available for general reimbursement do not provide sufficient effect or cause unacceptable adverse reactions, reimbursement for an alternative product can be applied for, on an individual basis. In contrast to the pre-approved pharmaceuticals available for general reimbursement, it is not a prerequisite that the product has obtained a market authorisation to be individually reimbursed; however, in some other countries, this is a requirement. This implies that individual reimbursement can be granted, without a maximum pharmacy purchasing price (PPP) set by the Norwegian Medicines Agency (NoMA). The National Insurance Administration handles approximately 100,000 individual applications every year. Several pharmaceuticals on the Norwegian market achieve significant reimbursed sales before market authorisation. Furthermore, most of the pharmaceuticals which have not been accepted on the list for general reimbursement are available for individual reimbursement. The Norwegian Labour and Welfare Organisation (NAV) decides on reimbursement for individual patients for pharmaceuticals without general reimbursement or for indications not covered by general reimbursement.

Reimbursement may also be granted on an individual basis for pharmaceuticals used in the long-term treatment of conditions which are considered to be serious and rare, but that are not on the list for general reimbursement. This refers to Schedule 2 in Table 4.1.

Pharmaceuticals for dangerous contagious illnesses – Schedule 4

A reimbursement system has also been established to ensure that all patients with serious communicable diseases are given adequate treatment without cost to the patient. There is no patient co-payment for these pharmaceuticals. Pharmaceuticals used to treat, e.g., HIV/AIDS or tuberculosis are reimbursed in this category. Also, vaccines against communicable diseases are reimbursed. When the National Insurance Administration has approved a product for reimbursement in this category, no further applications are necessary to obtain 100% reimbursement. Long-term treatment is not a prerequisite for Schedule 4.

Contribution system

Some prescription pharmaceuticals are not ordinarily reimbursed by any of the above-mentioned systems. However, a contribution system has been established to ensure that all patients have access to necessary medical treatment. The pharmacy receipts are used to docu-

ment patients' expenses for medical treatment. If a ceiling of NOK 1,200 (€ 152) is reached, a patient can claim reimbursement for 90% of all further expenses. There is no need to document the severity or duration of the disease, nor is it necessary to document effect or cost-effectiveness of the products used. The system requires initial out-of-pocket payment (OPP), and the collection of receipts containing information regarding the patient's name, the prescribing physician's name, date, product name, price, and pharmacy identification. Claims can be made at the local social security office.

4.2.3 Reimbursement lists

Norway has a product list regarding general reimbursement, which is updated by the Norwegian Medicines Agency (NoMA) once a month (cf. 4.2.2).

The Norwegian Medicines Agency (NoMA) and the National Insurance Administration are responsible for establishing reimbursement criteria. The list of reimbursed products and associated criteria is published on the Norwegian Medicines Agency (NoMA) web site.[10] Pharmacological therapy recommendations have also been published in print and on the internet. The Norwegian Medicines Agency (NoMA) and the Norwegian Pharmacy Association (NAF) jointly publish a biennial book *The Norwegian drug and therapeutics formulary for health personnel*, in which pharmacological guidelines and recommendations are set out.

There are no procedures in place for adding pharmaceuticals to the list which do not fulfil the inclusion criteria.

4.3 Reference price system

In Norway there is currently no therapeutic reference price system in place. However, the "step-price" system is a kind of a reference price system for off-patent products.

4.4 Private pharmaceutical expenses

The share of total pharmaceutical costs covered directly by the patients is derived from non-reimbursable prescription pharmaceuticals (12%), non-prescription pharmaceuticals (11%), and patient co-payment of reimbursable pharmaceuticals (6%), as shown in Figure 4.1.

In 2006 the patient co-payment amounted to 36% of the total cost of the prescription pharmaceuticals. There is a maximum limit of NOK 500 (€ 63.5) per prescription, and the ceiling for total co-payments is currently NOK 1,615 (€ 205) annually per person. Co-payments for physician visits, radiology examinations, laboratory tests and pharmaceuticals can be included in this amount.

[10] http://www.legemiddelverket.no/pia/vis_preparatlisten.asp

4.4.1 Direct payments

Everything that is not reimbursed is paid directly.

4.4.2 Out-of-pocket payments

For the out-of-pocket payment (OPP) rates cf. Table 4.2.

4.4.2.1 Fixed co-payments

Fixed co-payments are not applied in Norway.

4.4.2.2 Percentage co-payments

Currently the patient co-payment is 36% of the total amount on the prescription. There is a maximum limit of NOK 500 NOK (€ 63.5) per prescription, and the ceiling for total co-payments in one calendar year is currently NOK 1,615 (€ 205).

4.4.2.3 Deductibles

Deductibles are currently not in use in Norway.

4.5 Reimbursement in the hospital sector

The health care system is tax based, ensures universal access and is predominantly public. The 2002 Hospital Reform consisted of two main elements (Ministry of Health and Care Services, 2001). First, and most importantly, the central Government took over responsibility for all somatic and psychiatric hospitals and other parts of specialist care. As a result, about 100,000 employees or 60,000 man labour years and nearly 60% of county councils' budgets were transferred from the counties to the State. Second, specialised health care was organised in five Regional Health Enterprises (RHEs), under the Minister of Health and Care Services (HOD). The total hospital budget is divided among these five Regional Health Enterprises (RHEs). Local hospitals are delegated their fiscal share from each of their Regional Health Enterprises (RHEs) which approve the individual hospitals' budgets.

Independent of the choice of pharmaceuticals there is no co-payment for the in-patients in hospitals. The costs of pharmaceuticals, with a few exceptions, are covered through the hospitals' budgets. Any particularly expensive pharmaceuticals are financed mainly through block grants from central authorities and the National Insurance Administration.

The costs of pharmaceuticals for in-patients constitutes for almost 12% of the total pharmaceutical costs. The majority of hospitals in Norway have joined together in a cooperation for buying pharmaceuticals, inviting the pharmaceutical companies to submit tenders on a yearly basis. This cooperation achieves on average approximately 30% discounts on maximum prices. No such system exists for pharmaceuticals covered by the National Insurance Administration.

Specialists at the hospitals choose the pharmaceuticals they think are the better for the patient, even if these are not discounted pharmaceuticals.

4.6 Reimbursement-related cost-containment measures

4.6.1 Preferred pharmaceutical model

For some therapeutic equivalent pharmaceuticals we have established a first-choice scheme (a preferred product). The prescribing party has to (by law) prescribe the first-choice product unless there are medical reasons for not doing so. This is in place as an alternative to therapeutic reference pricing and to ensure the use of the most cost-effective medical treatment.

As a consequence of the “step-price system”, the annual cost of a treatment using simvastatin was reduced by 70%. In 2006 the cost of one year of treatment using simvastatin (40 mg) was NOK 1,700 (€ 218). Correspondingly, a treatment using atorvastatin (20 mg) cost NOK 4,800 (€ 616). Despite this difference in price, atorvastatin remained the better-selling pharmaceutical of the two. The authorities could have introduced a reference price model, but chose to opt for prescribing control through the so called “preferred pharmaceutical model”. One reason for choosing this model was a reduced administrative burden for both authorities and pharmacies (no need for frequent updates of the reference prices).

Under this model, the health authorities can give medical guidance on which pharmaceuticals are to be used (based on systematic reviews). The system is flexible: in some pharmaceutical classes the physician ought to switch from one pharmaceutical to the recommended pharmaceutical of choice (e.g. for statins and proton pump inhibitors), unless there are serious medical reasons not to. In other pharmaceutical classes, “pharmaceuticals of choice” can be used, as the first-choice option only applies in the case of new patients (e.g., selective serotonin reuptake inhibitors (SSRIs), triptans). This means that the physician doesn’t have to switch. The physician can of course change therapy if the first-choice pharmaceutical is not successful.

Since June 2005 simvastatin has been the first-choice statin, meaning that all statin users not using simvastatin have to switch to simvastatin. Simvastatin has reimbursement for symptomatic atherosclerotic diseases (secondary prevention) and for primary prevention (ie only high risk patients). If the treatment target is not reached, or problems occur such as adverse events or interactions, other statins can be used (atorvastatin, pravastatin, etc.). This should be documented in the patient’s medical records. The National Insurance Administration can perform spot checks of the medical records. Generally speaking, the first-choice system was positively received by patient organisations, The Norwegian Association of Pharmaceutical Manufacturers (LMI) and the Norwegian Medical Association (NMA).

4.6.2 Major changes in reimbursement lists

There have been no major changes in the reimbursement list in recent years.

4.6.3 Introduction / review of reference price system

Not relevant for Norway.

4.6.4 Introduction of new / other out-of-pocket payments

There have been no major changes in the system of out-of-pocket payments (OPPs) since the 1990s.

4.6.5 Claw-backs

Claw-backs are not used in Norway.

4.6.6 Reimbursement reviews

In Norway the reimbursement decisions are neither reviewed nor evaluated on a regular basis, but there are plans to focus more on this issue. Instead, Norway, has implemented a system called the “preferred pharmaceutical” system which includes evaluations of previous reimbursement decisions.

5 Rational use of pharmaceuticals

This chapter gives an overview of the current methods used to promote equitable and efficient use of pharmaceuticals.

5.1 Impact of pharmaceutical budgets

There are no prescribing budgets for doctors, although they are obliged to prescribe the cheapest equivalent product unless there are serious medical reasons for prescribing a more expensive alternative. In a slight departure from this policy, in March 2004 the Government introduced the so-called “first-choice product reimbursement scheme” for the treatment of hypertension (cf. 4.6). The documentation for the first-choice scheme also contains a clause that doctors can prescribe more expensive pharmaceuticals if there are serious medical reasons for doing so.

The scheme was extended in June 2005 to statins, leaving simvastatin as the doctors’ first choice. The incorporation of other pharmaceuticals such as antihistamines, proton pump inhibitors and antidepressants is also expected in a near future. Although the system is aimed at rationalising prescribing in therapeutic areas with high expenditure, doctors still decide whether they will follow the general guidelines for each individual patient.

5.2 Prescription guidelines

Prescription is regulated both directly and indirectly in several ways.

There are several national treatment guidelines, but they are not directly legally binding. Doctors have access to information, e.g. treatment guidelines, which help them in selecting pharmaceuticals. This information is available in printed format and / or in an online database.

The “preferred pharmaceutical” scheme directly influences prescribing (cf. 4.6).

The reimbursement system regulates prescription practices to a certain degree since the prescribing party in general will prescribe a reimbursed pharmaceutical instead of a non-reimbursed therapeutically equivalent pharmaceutical.

5.3 Information to patients / doctors

The “marketing directives” as stated in Directive 2001/83/EC are implemented in Act No. 132 of 4 December 1999 relating to Medicinal Products, Chapter VII, and in Regulation No. 1559 of 22 December 1999 relating to Medicinal Products, Chapter 13.

The Ministry of Health and Care Services (HOD) is responsible for the implementation of these Directives.

- Direct advertising of over-the-counter (OTC) pharmaceuticals to patients is allowed within certain limits.
- Advertising of pharmaceuticals on the internet is allowed. This is regulated in the same way in Norway as advertising generally.
- Advertising to health care professionals cannot be combined with handing out objects, gifts, services, awards or other items of economic value. The aim of this provision is more to reduce the influence of health care professionals than to restrict and control promotional spending of manufacturers.
- Activities of representatives of pharmaceutical companies are to be kept at a reasonable level and are to be subordinate to the main purpose of the meeting.
- Pharmaceutical samples to doctors can only be sent after a written and signed requisition. Delivery is limited to one sample each year per doctor, and the package must be the smallest one marketed. Each sample must be labelled “Free sample – not for sale”. Each sample is to contain a summary of product characteristics. Pharmaceutical companies are obliged to keep lists of pharmaceutical samples sent to doctors.

Beyond these measures, the Norwegian Medicines Agency (NoMA) does not control the quantity of sales promotion activities undertaken by pharmaceutical companies.

5.4 Pharmacoeconomics

A pharmacoeconomic evaluation in connection with applications for the reimbursement scheme has been mandatory since 1 January 2002. The pricing and reimbursement process is regulated in detail in Regulation No. 1559 of 22 December 1999 relating to pharmaceutical products (the Pharmaceutical Products Regulations), Sections 12 and 14.

In Norway a pharmaceutical can obtain both market authorisation and a maximum price without a pharmacoeconomic evaluation. But a pharmacoeconomic evaluation has to be performed for all pharmaceuticals for which an application for reimbursement is submitted, with the exception of the following instances.

- Pharmaceuticals with the same active ingredient as pharmaceuticals for which reimbursement has already been granted, i.e.: generic pharmaceuticals, parallel imported preparations and preparations in new packaging. This holds under the condition that the pharmaceutical for which the application is being made has the same approved indication as the reimbursement-approved pharmaceutical and that the costs are not higher or the health outcomes different than that of a pharmaceutical with which comparison is natural.
- Pharmaceuticals where a new formulation clearly does not change the costs and health outcomes of treatment.

The Market Authorisation Holder (MAH) should follow the Norwegian guidelines for pharmacoeconomic evaluation in connection with applications for reimbursement (http://www.legemiddelverket.no/templates/InterPage____15443.aspx). The guidelines ask for an explanation of the choice of comparison, the time frame of the analysis, data collection

methods, analysis methods and costs. The guidelines have not been updated or revised since 2001.

The choice of comparison

The analysis is to account for the most significant medical treatment possibilities for the disease in question and the established treatment programme for the given indication. Treatment programmes which are chosen as reference alternatives should either be the most prevalent treatment, or the most inexpensive treatment, but other alternatives may also be used. Comparison with "no treatment" is acceptable where this is the relevant treatment alternative (the only offer to the patient). Resources and costs in connection with this alternative are also to be calculated. Where there are other relevant treatments than "no treatment", these are also to always be analysed.

Economic criteria

There are few absolute economic criteria for an application as long as a pharmacoeconomic evaluation is performed. However, the evaluation should show and explain why the pharmaceutical should be reimbursed. Normally, this is carried out using the cost-effectiveness ratio. There is no cut-off ratio determined in Norway. The pharmaceuticals' impact on the budget is required. Pharmacoeconomic analyses performed in the given context are to be evaluated on behalf of society and should therefore be carried out both from a societal perspective (or where relevant a health service perspective), and the perspective of the payer, i.e. the National Insurance Administration. This therefore means that the economic consequences which the illness and any interventions will have for society as a whole and the National Insurance Scheme (NIS) should be clearly explained throughout the process. There is no reference price system in Norway.

Cost-effectiveness analysis is well established in Norway and the use of quality-adjusted life years (QALYs) as an effect parameter is increasing. However, even though there is an ongoing debate on the subject, Norway has not shown maximum willingness to pay per quality-adjusted life year (QALY). A very important aspect of a product's cost-effectiveness is how reliable the results are. A normal way of testing this is by sensitivity analysis. The Norwegian Medicines Agency (NoMA) is in favour of explicit testing and, to a growing extent, the use of probabilistic sensitivity analysis.

Over-the-counter (OTC) pharmaceuticals cannot have reimbursement status and therefore no pharmacoeconomic evaluation is necessary.

5.5 Generics

Pharmacists have been able to substitute branded pharmaceuticals with generics and parallel imports since March 2001. Generic substitution is mainly seen as cost-containment tool. Generic substitution is carried out by the pharmacies, but it is also relevant in the in-patient sector. There is no generic prescription in Norway.

For off-patent pharmaceuticals there is a price system in place called the “step-price system”. Within the step-price system the reference price is determined as a percentage cut of the original product’s maximum price at the time generic competition is established. For information on pricing of generics cf. 3.4.2.

Table 5.1: Norway - Development of the generics market in the out-patient sector, 2000-2005

Generic market share	2000	2001	2002	2003	2004	2005
Volume (number of prescriptions per year)	–	–	–	–	–	–
Value	–	–	–	–	–	–
DDD (%)	24.0	23.6	23.3	25.3	27.8	31.8

DDD = daily defined dose

Source: LMI

5.5.1 Generic substitution

Pharmacists have been able to substitute branded pharmaceuticals with generics and parallel imports since March 2001. Pharmacies are obliged to inform patients if there is a cheaper generic alternative available. Parallel imports are included in the generic substitution system. The pharmacies are not allowed to substitute a generic for a branded pharmaceutical (e.g. the original product) if the branded one is more expensive. If the patient does not want to switch to the cheaper alternative s/he will have to pay out of pocket the price difference between the two alternatives if the product is reimbursed.

Pharmacies have financial incentives for generic substitution. In Norway vertical integration exists between wholesalers and pharmacies. Generic competition increases the wholesalers’ margins dramatically and this leads to an incentive for generic substitution. Pharmacies are not allowed to substitute therapeutically (i.e. dispense a pharmaceutical with equal therapeutic benefits (analogous substitution), but they are allowed to substitute parallel imported pharmaceuticals.

5.5.2 Generic prescription

There is in general not much generic prescription in Norway. The doctors are allowed, but not obliged, to make use of generic prescription.

There is ongoing research into generic prescription in Norway. The aim of this work is to clarify whether generic prescription should be made mandatory.

5.5.3 Generic promotion

Pharmacies promote generic substitution for economic reasons. They do so by offering the generic at a lower price than the original product. Both the pharmacies and the patients benefit

from generic substitution. The use of generic pharmaceuticals is promoted by the authorities for cost-containment reasons.

In Norway, no minimum ratio (percentage) of generic prescription that doctors would have to fulfill has been laid down in any contracts between the doctors' association and the Government.

5.6 Consumption

Individual consumption data is monitored through the Norwegian Prescription Database. This is a national health register containing information connected to all delivery of medicines from pharmacies in Norway. The Database was founded in 2004, as a part of the Norwegian Institute of Public health. The Database will be used for pharmaco-epidemiological research and pharmaceutical statistics. Compliance data are used in decisions regarding individual reimbursement.

~~6~~ Current challenges and future developments

The Norwegian Medicines Agency (NoMA) is currently (2006/2007) performing a structural revision of the pharmaceutical reimbursement scheme (in Norway known as *blåreseptordningen*). The main structure of *blåresepordningen*, Article 9, has prevailed since it was established in the 1950s. Article 9 includes: an illness subsection (*sykdomslisten*), which today comprises a list of 45 illness descriptions and corresponding preparation groups; and a separate pharmaceutical reimbursement list (*preparatlisten*). Especially from the subscriber's point of view, the information on a pharmaceutical's reimbursement status under the old system has suffered from fragmentation and lack of precision, and the relevant information has been rather difficult to access.

Structural changes have been made collecting all relevant information in one pharmaceutical reimbursement list (*refusjonslisten*). The revised list is organised at the pharmaceutical substance level and gives the subscriber precise information on the part of a pharmaceutical's indication that has been approved for reimbursement. The reimbursed indication is described both in text and according to the international classification systems (International Classification of Diseases) ICD-10 and (International Classification of Primary Care) ICPC-2. Information on any specific reimbursement conditions for a pharmaceutical is "targeted", i.e. directly connected to the relevant ICD or ICPC code ("reimbursement code"). The new reimbursement list will be made available both as an internet database and in printed format.

In December 2006 the revision of the pharmaceutical reimbursement scheme underwent a public hearing by order of the Ministry of Health and Care Services (HOD). Depending on the opinions gathered in this process, the new structure can hopefully be implemented early in 2008.

7 Appendixes

7.1 References

See the web links

7.2 Further reading

See the web links

7.3 Web links

http://www.legemiddelverket.no - Norwegian Medicines Agency (NoMA)

http://www.lovdata.no - Norwegian Law database

http://www.lovdata.no/for/sf/ho/ho-19991222-1559.html - Legemiddelforskriften

www.Lisnorway.com – Hospital purchasing agency

http://www.lmi.no – Norwegian Association of pharmaceutical manufacturers

http://www.apotek.no - Norwegian Pharmacy Association

http://www.legeforeningen.no - The Norwegian Medical Association (NMA)

http://www.regjeringen.no/en - The Norwegian Government

www.ssb.no – Statistics Norway