PHIS Pharma Profile

NORWAY

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Norway

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PHIS Representatives
Norwegian Medicines Agency: Helga Festøy, Leung Ming Yu
Drug procurement association: Torfinn Aanes

Authors and Editors
The above mentioned PHIS Representatives
Drug Procurement Association: Anne-Helen Ognøy
Norwegian Medicines Agency: Terje Gregersen
Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG (GÖG/ÖBIG): Bettina Schmickl
International Healthcare and Health Insurance Institute BG (IHHII BG): Gergana Andre

PHIS Project Management
PHIS Project Leader: Gesundheit Österreich GmbH / Geschäftsbereich ÖBIG
WP 5 (Monitoring) Leader: International Healthcare and Health Insurance Institute, Bulgaria

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Executive Summary

Health care system

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 is founded on the principles of universal access, decentralisation and free choice of provider. It is financed by taxation, together with income-related employee and employer contributions and out-of-pocket payments (co-payments). All residents are covered by the National Insurance Scheme (*Folketrygden*, NIS), managed by the Norwegian Health Economics Administration (Helseøkonomiforvaltningen, HELFO). 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 primary health care services according to local demand. The central Government has overall managerial and financial responsibility for the hospital sector. Norway's four regional health authorities control the provision of specialised health services by 27 health enterprises.

All Norwegian citizens are invited to choose their general practitioner (GP) from a list. 99% of Norwegians have chosen to do so. Outpatient doctors act as gatekeepers for specialied 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 HOD) is in charge of marketing authorisation, classification, vigilance, pricing, reimbursement and providing information on medicines to prescribers and the public. HELFO decides on reimbursement for individual patients for pharmaceuticals without general reimbursement or indications not covered by general reimbursement. HELFO also monitors the prescriptions issued by out-patient doctors.

All major international pharmaceutical companies are represented in Norway, but only a few of them have established their own manufacturing units in the country.

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

- Norsk Medisinaldepot (NMD), owned by Celesio AG , with a market share of 47.6%;
- Apokjeden AS, owned by Tamro OYJ, with a market share of 28.9%;
- Boots Norge AS, owned by Alliance Boots Plc with a market share of 23.7%.

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

- In general only community and hospital pharmacies (674) are allowed to dispense medicines. Of the 674 pharmacies there are 33 public hospital pharmacies. There are approximately 7,300 inhabitants per pharmacy (4.9 Mio. inhabitants). In addition medicines

are dispensed by small outlets belonging to the pharmacies (1,100). Grocery stores, gasoline stations e.g. are allowed to distribute a restricted list of OTC (> 7000).

The total pharmaceutical expenditure (TPE) was estimated to NOK 18.15 / € 2.36 billion in the year 2009. Public expenditure accounts for 69% of total expenditure in 2009.

Pricing, reimbursement and volume control in the out-patient sector

Pricing

The Norwegian Medicines Agency (NoMA) is responsible for setting maximum pharmacy purchase prices (PPP). All suppliers of prescription medicines must apply for a maximum price, whether or not they are seeking reimbursement for the product. Medicines 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 medicines. 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 medicine 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 NoMA sets prices at the pharmacy purchasing price level. Mark-ups for generics and over-the-counter (OTC) products are significantly higher than for branded medicines.

Pharmacy mark-ups for prescription products (both reimbursed and non-reimbursed) are fixed at 7% for medicines with a pharmacy purchasing price (PPP) up to NOK 200 / € 25.5, and at 4% of the price above NOK 200.- / € 25.5. There is also a flat rate add-on of NOK 22.00.- / € 2.8 per pack, plus value-added tax (VAT) (25%). An additional flat rate add-on of NOK 10.- / € 1.3 is applied to addictive products (narcotic and psychotropic substances). Mark-ups on OTC are not regulated.

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

Table I.1: Norway - Overview of the step price system

Sales PRP, 12 months before generic competition		< 100 Mio. NOK	> 100 Mio. NOK	
	Time of price-cut			
1st step	generic competition	**30 %**	**30 %**	
2nd step	6 months after generic competition	**55 %**	**75 %**	
Sales PRP, >= 12 months after 2nd step		**> 15 Mio. NOK**	**> 30 Mio. or < 100 Mio. NOK**	**> 100 Mio. NOK**
	Time of price-cut			
3rd step	>= 12 months after 2nd step	**65 %**	**80 %**	**85 %**

NOK = Norwegian Krone, PRP = pharmacy retail price

Source: NoMA

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

Hospital purchasing is carried out by means of tender processes by the Norwegian Drug Procurement Co-operation (*Legemiddelinnkjøpssamarbeidet*, LIS), which is the hospital procurement agency. Discounts to hospitals are approximately 28,5% on average.

Since 1995, there has been no price control on OTC medicines by the authorities. The standard VAT rate of 25% applies to OTC medicines.

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 medicine 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 1,880 / € 240;
- low income pensioners and children under 16 are exempt from copayment.

Medicines are grouped into four reimbursement categories.

- Schedule 2: General reimbursement.
- Schedule 3a and 3b: Reimbursement on a named patient basis. Reimbursement is granted upon submission of an individual patient application.

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

The standard patient co-payment for reimbursed medicines is 38% up to the annual ceiling. All expenses above this threshold are covered by the National Insurance Scheme. The annual limit includes co-payments for physician consultations, laboratory tests, radiography, etc.

In-patient medicines are covered by the public hospitals.

Pricing, reimbursement and volume control in the in-patient sector

Most hospitals in Norway are public hospitals, funded and owned by the state. A small number of hospitals are privately owned. However, most private hospitals are funded by the public. A hospital is an institution for health care providing patient treatment by specialized staff and equipment.

In Norwegian hospitals the major pricing policy is procurement which is done for all public hospitals by the Drug Procurement Cooperation (LIS). LIS negotiates prices for medicines in the hospitals. These prices are considerably lower than maximum prices which the Norwegian Medicines Agency (NoMA) decides for all prescription-only-medicines on the Norwegian market.

In Norway, hospital medicines are covered by the hospital budget. There are pharmaceutical and therapeutic committees established by the hospitals which set up and decide on inclusion of medicines to the hospital pharmaceutical formulary for internal use. No countrywide medicines lists for in-patient care exist.

Hospitals spent NOK 3,700.- / € 472.- million on medicines in 2010 including 25% value added tax.

Interface management and developments

Interface management between the in-patient and out-patient sector in Norway exists with regards to specific medicines as hospitals pay for medicines that patients need after discharge of the hospital. These medicines include tumor necrosis factor (TNF) medicines and medicines for the treatment of Multiple Sclerosis (MS). The funding of these products was transferred from the budget of the National Insurance Scheme (NIS) to hospital budgets in 2006 and 2008 respectively. This was mainly due to the fact that some products in this field were financed by the NIS and some products were financed by the hospital. This created the economic incentive for hospitals to prescribe products funded by NIS. Also it was an aim to achieve more competition and lower prices.

Current challenges and future developments

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

A new system for electronic prescription is currently under deployment. This will enable NoMA to provide information to the prescribers about medicines, e.g. prices and conditions for reimbursement, via the physicians system for electronic patient records. NoMA's focus is to provide information of good quality which is available whenever the prescriber is online.

In 2011-2015 a reform for better interaction between the primary and secondary healthcare systems is implemented. The reform shall give incentives to the municipalities to prevent disease and injury in their population. The municipalities will have to pay a copayment for treatment in hospital for their population. They will also be obliged to provide emergency help and 24 hours-services for patient in need of treatment or observation.

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List of abbreviations

ATC	Anatomic therapeutic chemical classification
DRG	Diagnosis related group
EEA	European Economic Area (EU-countries, Iceland, Lichtenstein and Norway)
GDP	Gross domestic product
GP	General practitioner
Hdir	Helsedirektoratet/Norwegian Directorate of Health
HELFO	Helseøkonomiforvaltningen/Health Economics Administration
HOD	Helse- og Omsorgsdepartementet / Ministry of Health and Care Services
HTA	Health technology assessment
HE	Health expenditure
HOM	Hospital-only medicine
LIS	Legemiddelinnkjøpssamarbeidet / Norwegian Drug Procurement Cooperation
LMI	Legemiddelindustriforeningen / Norwegian Association of Pharmaceutical Manufacturers
LUA	Legemidler utenom apotek/Medicines sold outside of the pharmacy
MA	Marketing Authorisation
Mio.	Million
MS	Multiple Sclerosis
NAF	Apotekforeningen / Norwegian Pharmacy Association
NCU	National currency unit
NIGeL	Norsk Industriforening for Generiske Legemidler / Norwegian Association of Generics-orientated Pharmaceutical Manufacturers
NIPH	Nasjonalt folkehelseinstitutt / Norwegian Institute of Public Health
NIS	National Insurance Scheme
NMA	Den norske legeforening / The Norwegian Medical Association

NMD	Norsk Medisinaldepot
NMEs	New molecular entities
NOK	Norwegian Krone
NoMA	Statens legemiddelverk / Norwegian Medicines Agency
OECD	Organisation for Economic Co-operation and Development
OPP	Out-of-pocket payment
OTC	Over-the-counter
PHIS	Pharmaceutical Health Information System
PE	Pharmaceutical expenditure
POM	Prescription-only medicine
PPP	Pharmacy purchasing price
PRP	Pharmacy retail price
QALY	Quality adjusted life year
RHA	Regional Health Authority
THE	Total health expenditure
TNF	Tumor necrosis factor
TPE	Total pharmaceutical expenditure
VAT	Value added tax
WHO	World Health Organisation
WP	Work package

Introduction

The Pharmaceutical Health Information System (PHIS) project was a research project commissioned by the Executive Agency for Health and Consumers (EAHC) and co-funded by the Austrian Ministry of Health (BMG).

The PHIS project management was a consortium of the project leader Gesundheit Österreich GmbH, Geschäftsbereich Österreichisches Bundesinstitut für Gesundheitswesen / Austrian Health Institute (GÖG/ÖBIG) a research institute situated in Vienna, Austria, and four associated partners: the Italian Medicines Agency (AIFA), Italy, the International Healthcare and Health Insurance Institute - (IHHII), Bulgaria, SOGETI Luxembourg SA., Luxembourg and the State Institute for Drug Control (SUKL), Slovakia. Further key stakeholders of the PHIS project management were the PHIS advisory board covering EU Commission services and agencies and international organisations, and the PHIS network, which comprises national representatives from competent authorities and further relevant institutions from the EU Member States and associated countries.

The PHIS project aimed at increasing the level of knowledge and exchange of information on pharmaceutical policies, in particular on pricing and reimbursement, in the European Union. This was achieved by surveying and monitoring pharmaceutical health system information in the in-patient and out-patient sector from a public health perspective, and by developing key pharmaceutical health indicators which may be included in a European Health Information System.

The PHIS project ran from September 2008 to April 2011 (32 months). Further information and all deliverables are made available at the PHIS project website http://phis.goeg.at.

PHIS Monitoring

The aim of the work package “Monitoring” was to provide up-to-date country-specific information on out-patient and in-patient pharmaceutical systems in the EU Member States and beyond.

The country-specific information was compiled in different sets and for different purposes based on different templates taking into consideration a common terminology (PHIS Glossary) and a set of indicators (PHIS Indicators): e.g.

- Country reports covering information on the pharmaceutical system in the in- and out-patient sectors written by country representatives of the PHIS network (PHIS Pharma Profiles)
- Integrated flowchart of the pharmaceutical system in the in- and out-patient sectors (also part of the PHIS Pharma Profile)
- Country reports with a focus on the pharmaceutical system in the in-patient sector (national PHIS Hospital Pharma Report) and a compilation of the information in a benchmarking report (PHIS Hospital Pharma Report)

All documents together represent the PHIS Library, which has to be understood as an on-line documentation system containing up-to-date information on the pharmaceutical in- and out-patient sectors. The PHIS Library is accessible at the website of the PHIS project (http://phis.goeg.at) and is constantly updated.

PHIS Pharma Profile

The production of the country-specific PHIS Pharma Profiles was based on three steps:

1. Development of a uniform PHIS Pharma Report Template

The PHIS Pharma Profile offers a homogenous, very detailed structure for describing the pharmaceutical pricing and reimbursement system in the in- and out-patient sector of a country. The Template provides detailed guidelines and specific questions, definitions and examples needed to compile the PHIS Pharma Profile. It consists of six chapters, referring to the regulatory situation in 2010 or 2011. Three of the chapters (chapter 1 Health care system, chapter 2 Pharmaceutical system and chapter 5 Interface management and developments) are covering integrated information on the in- and out-patient sectors. Chapters 3 and 4 are dedicated entirely to the pricing, reimbursement and volume control in out-patient sector and respectively to the in-patient sector.

The methodology for developing the PHIS Pharma Profile Template was based on the review of existing surveys – country profiles developed in the PPRI project (Pharmaceutical Pricing and Reimbursement Information) and the PHIS Hospital Pharma report – and by using the common terminology (glossary) developed in Work Package 4 (Terminology) and the pharmaceutical indicators (PHIS indicators) developed in Work Package 6 (Indicators) of the PHIS project. The PHIS Pharma Profile Template was developed by the leader of work package Monitoring Ms. Gergana Andre (IHHII, Bulgaria[1]) in collaboration with the PHIS main partner (GÖG/ÖBIG). The Template was kindly reviewed by the PHIS Advisory Board members. Members of the PHIS network received the draft Template for feed-back, and had the opportunity to discuss and provide personal feed-back during a meeting.

[1] IHHII BG is a 10 years old Bulgarian think tank, independent non-governmental organisation, which provides information and analysis in health policy, healthcare management and organisation in Bulgaria. Through its network of consultants and independent research work it provides reports, early warning statements, organises debates, engages non-governmental stakeholders in health to perform proper government monitoring and enforce civic participation in the development and implementation of health policy. A significant part of the research work of IHHII is dedicated to the pharmaceutical system and market in Bulgaria. Through its reports and analyses the Institute is a reliable partner to many professional organisations in health and the public institutions. IHHII maintains the largest and the oldest health web portal in the country – www.zdrave.net – which is an online arena of information exchange and debates in health reaching at daily average 5, 000 people acting in health and pharmaceutical system.

2. Collecting information and data and drafting the PHIS Pharma Profiles

The country-specific PHIS Pharma Profiles were written by members of the PHIS network. In order to get the needed information and data, experts of the in- and out-patient sectors were contacted and involved in several countries. They provided information and data in written form and during telephone conversation and personal talks. In several countries, the preparatory work for drafting the PHIS Pharma Profiles also included study visits of the authors e.g. to hospital pharmacies. Information on persons and institutions involved can be found in the “Acknowledgements” at the beginning of this PHIS Pharma Profiles. For some countries (out-dated) information on the pharmaceutical system in the in- and out-patient sectors was already available but in form of separated reports (e.g. for the out-patient sector: PPRI report; for the in-patient sector: PHIS Hospital Pharma Report). It was a challenge to integrate the two separated reports into one updated integrated description of the pharmaceutical system. The main partner (GÖG/ÖBIG) of the PHIS project offered PHIS network members to pre-fill the template with already existing information and delivered pre-filled templates for 13 countries.

3. Editorial process

The drafts of PHIS Pharma Profiles were submitted to the project management for review, which was undertaken by IHHII, Bulgaria (Work Package leader of “Monitoring”) in coordination with GÖG/ÖBIG (PHIS project leader). The review focused on checking clarity and consistency in general and with regard to the outline of the Template, terminology (PHIS Glossary) and data provision for filling PHIS Indicators (to be filled in the PHIS database). In the course of the editorial process, the reviewers contacted the authors for providing feedback on language and content, offering suggestions for re-phrasing and change and clarified open and/or misunderstanding points.

1 Health care system

This chapter provides an overview of the country's health care system as of 2011.

1.1 Demography

Table 1.1: Norway – Demographic indicators 2000, 2005–2009

Demography	2000	2005	2006	2007	2008	2009
Total population	4,503,436	4,640,219	4,681,134	4,737,171	4,799,252	4,858,199
Population aged 0-14	902,431	906,811	905,931	907,377	912,216	n.a.
Population aged 15-64	2,922,179	3,050,939	3,089,606	3,136 486	3,182,224	n.a.
Population aged > 64	678,826	682,469	685,597	693,308	704,812	n.a.
Life expectancy at birth	78.7	80.2	80.4	80.5	80.7	80.9
Life expectancy at age 65	18.13	19.18	19.38	19.26	19.43	19.64

n.a. = not available

Source: Statistics Norway, 1st of January following year

The population of Norway reached 4.9 Mio. in 2009. This corresponds to an average of 15 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, Stavanger, Bergen, and Trondheim areas. The inland and the northern parts of Norway are more scarcely populated.

The average life expectancy has been increasing steadily and is still increasing. In 2009 the average life expectancy was 78.6 years for men and 83.1 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 2009 was 41,449. Diseases of the circulatory system are still the leading cause of deaths, accounting for approximately 34% (2008) 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 26% of deaths and diseases in the respiratory system accounted for 10% (2008).

1.2 Organisation

The Norwegian health care system has developed gradually 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, independently 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 by block grants from the central authorities and reimbursement from the state-owned National Insurance Scheme (NIS). Membership of this programme is mandatory and universal, and is financed by compulsory contributions from tax-payers. The NIS covers retirement pensions, disablement benefits, sickness benefits, unemployment benefits and health care, including medicines (cf. section 1.3.2).

The health care system in Norway is organized on three levels: the central State, the four 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 four health regions and the 430 municipalities.

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.

Norway's 430 municipalities are responsible for the provision and funding of primary health care and social services. All citizens have the right to health care services in their community. Norway's four Regional Health Authorities (RHAs) 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. In 2010, there were 27 health enterprises under the four RHAs. They are public and are not working for profit.

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 RHAs and specialist physicians. The HOD provides instructions to the RHAs by a "letter of commission", which is prepared individually for each of the four authorities and can be seen as a "government supplement". The governance of the municipalities relating to primary health care is mainly an interplay between the HOD 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. 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.

Important acts that form the basis for the Norwegian health care system:

- The Municipal Health Care Act - 1982
- The Specialist Health Care Services Act - 1999
- The Social Health Care Act - 1997
- The Dental health Care Act - 1983
- The Mental Health Care Act - 1999
- The Patients Rights Act - 1999

1.3 Funding

This section gives an overview of the health care expenditure and the sources of funding health care.

1.3.1 Health expenditure

Table 1.2: Norway – Health expenditure 2000, 2005–2009

Health expenditure in NCU = NOK, mill.	**2000**	**2005**	**2006**	**2007**	**2008**	**2009**
GDP	1,481,241	1,945,716	2,159,573	2,276,757	2,543,188	2,400,672
THE	124,728	176,984	186,761	201,722	217,085	228,643
- thereof public HE, %	82.5	83.5	83.8	84.1	84.2	84,1
- thereof private HE, %	17.5	16.5	16.2	15.9	15.8	15,9
HE in the out-patient sector	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof public	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
HE in the in-patient sector	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof public	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- thereof private	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Exchange rate (NCU per €)	8.1129	8.0092	8.0472	8.0165	8.2237	8.7278

GDP = gross domestic product, HE = health expenditure, n.a. = not available, NCU = national currency unit, THE = total health expenditure

Source: Statistics – Norway, European Central Bank

1.3.2 Sources of funds

Sources of revenue for health care in Norway include taxation, the National Insurance Scheme (NIS) and private expenditure. The Norwegian health care system is primarily funded by taxes which are raised at municipality, county and central levels. However, dental care is usually not funded by the NIS 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.

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 NIS is financed by contributions from employer, employees, self-employed people and state funding. People insured under the 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. Voluntary health insurance 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, but these are payable for consultations with private specialists and general practitioners, for ambulatory care, X-rays, laboratory tests and medicines. 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 2011 it is NOK 1,880.- (€ 240.-[2]). When the cost ceiling has been reached in any calendar year, most of additional out-of-pocket expenses are reimbursed by the NIS, and any remaining treatment in that calendar year is therefore free of charge. In 2010 approximately 25% of the population reached this ceiling.

The Regional Health Authorities (RHAs), funded by the central Government, fund the health enterprises which in turn fund the local hospitals. All hospitals are remunerated by a mixture of ex-ante fixed budgeting (60%) and a diagnosis-related group (DRG) system (40%) for somatic care/services. Other services are mainly funded by ex-ante fixed budgets.

Treatment for patients from abroad is billed to the patient's insurance scheme. There is no particular billing for medicines only.

Informal payments play no part in funding of health care in Norway.

[2] Exchange rate as of May 2011: 7,8336 NOK per Euro

1.3.3 Out-patient care

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

The listed general practitioners are paid a capitation fee from the National Insurance Scheme (NIS). When a patient visits the general practitioner the NIS pays a fee-for-service, while the patient pays an out-of-pocket payment to the GP. If the patient has reached the ceiling of out-of-pocket expenditures, the NIS will also pay the fee to the general practitioner (cf. section 1.3.2).

The public, NIS-supported Norwegian out-patient system is a system where nearly all citizens are patients on a general practitioner's list. In addition there are specialists on contracts to provide services in out-patient care. The patient will pay out-of-pocket payments for each visit to these specialists, until the ceiling is reached (cf. section 1.3.2).

The specialists who are obliged by contract to provide services are paid a specific amount of money per year from the Regional Health Authorities. 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 specialists' office. In addition, these specialists are paid fee-for-service from the NIS for every visit, and out-of-pocket payments from the patient.

Adjacent to the publicly funded out-patient care, a parallel system with private general practitioners and private specialists exists. These private doctors are not supported by the NIS, and patients are required to pay a fee-for-service payment to the doctor. These payments are not reimbursed and are not included under the ceiling. The number of private doctors is small, particularly as far as GPs are concerned.

1.3.4 In-patient care

The Norwegian in-patient care is mainly provided by public hospitals.

Norway is divided into four health regions, each with a regional health authority (RHA). This authority is responsible for the budgeting and planning of all the health enterprises in each region (cf. section 1.2). The regions typically have a few health enterprises. Each health enterprise consists of a few local hospitals, and in every RHA there is a University Hospital. Patients having rare or severe diseases are often transmitted from the local to the University hospitals. Because Norway is a country with a small population the treatment of really rare diseases is often given to one hospital only. There is no out-of-pocket payment for in-patient care. All doctors are employees of the hospital and paid as such.

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

With regard to health care services, in-patient care in general hospitals does not involve out-of-pocket payments, but these are payable for consultations with private specialists and general practitioners (c.f. section 1.3.2).

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 make contracts with the RHAs, e.g. for performing a fixed number of hip-surgery patients, tonsillectomy, glaucoma surgery.

1.4 Access to health care

1.4.1 Health care professions

Table 1.3: Norway – Doctors and pharmacists development 2000, 2005–2009

Health professionals	2000	2005	2006	2007	2008	2009
Total no. of doctors	14,726	17,436	17,916	18,767	19,380	19,944
- of which GPs	3,694	4,188	4,247	4,333	4,550	4,746
- of which work in hospitals	8,098	9,856	10,222	10,524	10,889	11,178
No. of pharmacists	1,426	1,812	1,883	1,911	1,987	2,064
- of which work in community pharmacies	1,174	1,435	1,486	1,512	1,563	1,622
- of which work in hospital pharmacies	252	377	397	399	424	442

No. of doctors (all categories): registered practising doctors, members of the Norwegian Medical Association,

GP = general practitioner
In hospitals the same doctors work for the in-patient and the out-patient clinic. So there are no specified figures for total number of out-patient doctors.

No. of pharmacists: members of The Norwegian Association of Pharmacists, employed by community or hospital pharmacies.

Data as of 31 December

Source: The Norwegian Medical Association and The Norwegian Association of Pharmacists

1.4.2 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.

All Norwegian citizens are invited to choose their GP from a list in every municipality. More than 99% of Norwegians have chosen to do so (Hdir, 2009).

The GP acts as a gatekeeper for access to specialists and in-patient care. Normally the patient visits their general practitioner for a consultation. If required the GP refers the patient to a specialist. In case of emergency all citizens can obviously be treated at hospital without referral. The patient is allowed to change GP twice per year.

1.4.3 In-patient care

Table 1.4: Norway – In-patient care 2000, 2005–2009

In-patient care	2000	2005	2006	2007	2008	2009
No. of hospitals	n.a.	87	87	87	87	87
Classified according to ownership						
thereof public hospitals	*n.a.*	*78*	*78*	*78*	*78*	*78*
thereof not-for-profit privately owned hospitals		*9*	*9*	*9*	*9*	*9*
thereof for-profit private hospitals	*n.app.*	*n.app.*	*n.app.*	*n.app.*	*n.app.*	*n.app.*
Classified according to subtypes[1]						
thereof general hospitals	*n.a.*	*87*	*87*	*87*	*87*	*87*
No. of acute somatic care beds	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
thereof in the public sector and not-for-profit privately owned hospitals	n.a.	12,948	12,835	12,518	11,883	*n.a.*
thereof in not-for-profit privately owned hospitals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
thereof in for-profit private hospitals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Average length of stay (acute somatic care) in days	n.a.	3.4	3.2	3.1	3.1	n.a.
No. of hospital pharmacies	n.a.	28	29	31	32	33

n.a. = not available, n.app = not applicable, No. = number

Number of hospitals: the number of hospitals the LIS serves in drug procurement co-operation.

Source: Samdata, LIS

"No. of acute somatic care beds" in the table includes beds available for acute and planned (scheduled) treatment.

In Norway a hospital is an institution that provides medical, surgical or psychiatric care and treatment for the sick and the injured. They are mainly publicly owned. A few hospitals are privately owned by non-profit organisations; however, they are also funded by the public. This report refers to the publicly financed hospitals.

All hospitals provide in-patient care. Most of them also provide out-patient care in out-patient departments.

2 Pharmaceutical system

This chapter gives an introduction to the pharmaceutical system, including organisation, key statistic data, market players, and funding.

2.1 Organisation

Figure 2.1: Norway – Flowchart of the pharmaceutical system, 2011

Source: NoMA

2.2 Regulatory framework

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 Pharmacies Act), http://www.lovdata.no/cgi-wift/wiftldles?doc=/app/gratis/www/docroot/all/nl-20000602-039.html&emne=apoteklov*&&

LOV 1992-12-04 nr 132: Lov om legemidler (Norwegian Act on Medicinal Products), (http://www.lovdata.no/all/hl-19921204-132.html)

In conjunction with these laws several regulations give more details 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 medicines) http://www.regjeringen.no/en/dep/hod/Subjects/Pharmaceutical-products/On-course-towards-more-correct-use-of-me.html?id=226373. This document states that the most important goal for national pharmaceuticals policy is to achieve proper use of medicines:

- 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;
- medicines shall have the lowest possible price.

Table 2.1: Norway – Legal basis and actors (authorities and market players) of the pharmaceutical system, 2011

Fields	Legal basis	Scope (in-patient, out-patient sector)	Authorities in English (local name, local abbreviation)	Activity / responsibility in the pharmaceutical system	Actors and interest associations
Market authorisation	- The Norwegian Act on Medicinal Products Norwegian Regulation relating to Medicinal Products	In- and out-patient sector. All registered/licensed medicines (POM, OTC).	The Norwegian Medicines Agency (Statens legemiddelverk, SLV)	In charge of market authorisation, classification and pharmacovigilance.	Norwegian Association of Pharmaceutical Manufacturers (LMI) Norwegian Association of Generics-oriented Pharmaceutical Manufacturers (NIGeL)
Pricing / Purchasing	The Norwegian Act on Medicinal Products. Norwegian Regulation relating to Medicinal Products	In- and out-patient sector. Registered POM.	The Norwegian Medicines Agency (Statens legemiddelverk, SLV)	In charge of pricing.	LMI NIGeL Norwegian Pharmacy Association
Reimbursement	The Norwegian Act on Medicinal Products. Norwegian Regulation relating to Medicinal Products	Out-patient sector. Registered POM (and some OTC) medicines.	The Norwegian Medicines Agency (Statens legemiddelverk, SLV)	In charge of deciding reimbursement-status.	LMI NIGeL
Promotion	The Norwegian Act on Medicinal Products. Norwegian Regulation relating to Medicinal Products	All interaction between manufacturers/MA-holders and health personnel/patients/distribution chain.	The Norwegian Medicines Agency (Statens legemiddelverk, SLV)	In charge of monitoring information/promotion activities.	LMI NIGel
Distribution	The Norwegian Act on Medicinal Products. Regulation on wholesalers	All market players in the distribution chain	The Norwegian Medicines Agency (Statens legemiddelverk, SLV)	In charge of supervising importers, wholesalers and pharmacies.	Wholesalers, Pharmaceutical Wholesalers Association (Legemiddelgrossist-foreningen)
Vigilance	The Norwegian Act on Medicinal Products. Norwegian Regulation relating to Medicinal Products	MA-holder	The Norwegian Medicines Agency (Statens legemiddelverk, SLV)	In charge of pharmacovigilance.	LMI NIGeL

Source: Norwegian Medicines Agency

2.3 Statistics

This section gives an overview on the number of medicines as well as on market figures and consumption.

2.3.1 Availability of medicines

2.3.1.1 Market authorisation

Table 2.2: Norway – Number of active substances 2011

Active substances	2000	2005	2006	2007	2008	2009	2010
Authorised	1144	1387	1414	1449	1449	1476	1485

Active substances with market authorization in Norway.

The numbers includes human and veterinary medicines.

Herbal medicines, radiopharmaceutical and parallellimported medicines are excluded.

Source: Norwegian Medicines Agency

The number of medicines on the Norwegian market has been growing constantly since the mid-1980s. The rapid increase in authorised medicines 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 medicine from obtaining market authorisation if it was similar to medicines already marketed. This led in particular to a limitation in the number of generics.

NoMA decides whether a medicin falls under prescription group A, B (addictive medicines), C (prescription-only) or F (OTC). A prescription-only-medicin can on the basis of new information, change from prescription group C to F or vice versa. This is regulated by the Norwegian Regulation Relating to Medicinal Products. The last few years more medicines have been changed from C to F than vice versa.

2.3.1.2 Access to medicines

The time it takes from a new medicine is granted a market authorisation (MA), to it actually being available on the market, can vary a lot. Some products that are granted a MA never actually hit the market. After obtaining a MA, the MA-holder must apply for a maximum pharmacy purchasing price (PPP) before the product can be marketed. The maximum processing time for a price application is 90 days, but the average processing time in 2010 was 32 days. Maximum processing time for general reimbursement applications is set to 180 days. In 2010, the average processing time was 65 days, but depending on the application, the processing time can vary a lot.

Table 2.3: Norway – Number of new molecular entities, 1999-2009

New molecular entities	1999 – 2009	2004 – 2009
Number of new molecular entities	429	242

Source: NoMA

2.3.2 Prescriptions

Table 2.4: Norway – Annual prescriptions 2000, 2005–2009

Prescriptions	2000	2005	2006	2007	2008	2009
No. of prescriptions (in volume)	n.a	25,646	26,751	27,903	29,020	30,088
Prescriptions in value (in NCU = NOK)	n.a	12,268	12,400	12,620	12,764	12,966

n.a. = not available, Prescription in volume = number of prescriptions settled in pharmacies, human and veterinary.

Source: Norwegian Pharmacies Association

Prescription in value = public expenditure of prescribed medicines.

Source: Norwegian Prescription Database, The Norwegian Institute for Public Health

There is no limit to the number of products/packages per prescription. In average there was 1.5 medicine per reimbursed prescription and 1.2 medicine per non-reimbursed prescription in 2010 (Norwegian Pharmacies Association). These figures have been stable since 2005.

2.3.3 Sales

*Table 2.5: Norway – Pharmaceutical sales 2000, 2005 –2009**

Sales (in billions NOK)	2000**	2005	2006	2007	2008	2009
Sales at pharmacy purchasing price	7.4	10.6	10.8	11.1	11.3	12.0
– Sales in out-patient sector	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
– Sales at hospitals	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sales of parallel traded medicines	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a. = not available

* Including sales of products with approved market authorization in Norway, excluding sales of veterinary medicines.

** Exluding sales of some vaccines and blood products, which in that year amounted to appr. 200 mio. NOK.

Source: *Norwegian Drug Wholesales Statistics, Norwegian Institute of Public Health*

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. The “step-price” system for generics, introduced in 2005, has ensured that prices for generics have fallen (cf. section 3.1.2.1 for a description of the “step-price system”).

Important steps towards cost-containment have also been taken for reimbursable medicines. The use of a “preferred product” system is one tool that has been put to use, cf. section 3.3.1.

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

2.3.4 Consumption

*Table 2.6: Norway – Annual pharmaceutical consumption 2000, 2005–2009**

Consumption	2000**	2005	2006	2007	2008	2009
Total pharmaceutical consumption (in Mio?)						
In packs	68.7	81.1	83.9	87.8	84.2	86.3
In DDD***	1,754	2,230	2,310	2,410	2,500	2,558
Pharmaceutical consumption in the in-patient sector						
In packs	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
In DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Pharmaceutical consumption in the out-patient sector						
In packs	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
In DDD	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

DDD = defined daily doses, n.a. = not available

* Including sales of products with approved market authorization in Norway, excluding sales of veterinary medicines.

** Exluding sales of some vaccines and blood products.

*** Including only the ATC groups where DDDs are assigned.

Source: *Norwegian Drug Wholesales Statistics, Norwegian Institute of Public Health*

2.3.5 Generics

Table 2.7: Norway – Development of the generic shares 2000, 2005–2007

Generic share	Volume		Value	
	2005	2007	2005	2007
Shares in % of total market (in-patient/ out-patient) 1)	31.8	38.4	n.a.	n.a.
Shares in % of total out-patient market	n.a.	n.a.	n.a.	n.a.
Shares in % of out-patient reimbursement market 2)	19.6	23.9	8.8	10.1
Shares in % of out-patient off-patent market	n.a.	n.a.	n.a.	n.a.
Shares in % of the in-patient market	n.a.	n.a.	n.a.	n.a.

n.a. = not available

1)Volume measured by DDD, Norwegian Association of Pharmaceutical Manufacturers

2)Volume measured by packs, NoMA, “Årsaker til ulik generikaandel i nordiske land” - 2009

Source: NoMA

Pharmacists have been able to substitute branded medicines 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 mandatory generic prescribing in Norway.

For off-patent medicines there is a price system in place called the “step-price system”, cf. section 3.1.2.1.

2.3.6 Top 10 medicines

Table 2.8: Norway – Top 10 active ingredients in value and volume in the out-patient sector, prescription only medicines, 2010

Position	Top active ingredients used in the out-patient sector, ranked with regard to consumption		Position	Top active ingredients used in the out-patient sector, ranked with regard to expenditure	
1	B01AC06	Acetylsalisylic acid	1	R03AK06	Salmeterol & flutikason
2	C10AA01	Simvastatin	2	N02BE01	Paracetamol
3	C10AA05	Atorvastatin	3	R03AK07	Formoterol & budesonid
4	C08CA01	Amlodipin	4	C10AA01	Simvastatin
5	N05CF01	Zopiklon	5	A02BC05	Esomeprazol
6	R06AE07	Cetirizin	6	M01AE01	Ibuprofen
7	C09AA05	Ramipril	7	N07BA01	Nikotin
8	C07AB02	Metoprolol	8	C10AA05	Atorvastatin
9	H03AA01	Levotyroksinnatrium	9	C09CA06	Candesartan
10	C09CA06	Candesartan	10	N02AA59	Codein & combinations

Source: Consumption: Norwegian Institute of Public Health, Expenditure: Norwegian Pharmacies Association

Consumption measured by DDD.

Table 2.9: Norway – Top 10 active ingredients in value and volume in the in-patient sector, 2010

Position	Top active ingredients used in the in-patient sector, ranked with regard to consumption	Position	Top active ingredients used in the in-patient sector, ranked with regard to expenditure	
1	n.a.	1	L04AB01	Etanerecept
2		2	L04AB04	Adalimumab
3		3	L04AB02	Infliksimab
4		4	L01XC02	Rituksimab
5		5	L01XC03	Trastuzumab
6		6	L04AA23	Natalizumab
7		7	L03AX13	Glatirameracetat
8		8	L03AB07	Interferon beta
9		9	L01XC07	Bevacizumab
10		10	L04AB06	Golimumab

n.a. = not available

Source: LIS

2.4 Market players

2.4.1 Industry

Table 2.10: Norway - Key data on the pharmaceutical industry, 2000–20091

Pharmaceutical industry	2000	2005	2006	2007	2009
Total no. of companies	185	178	179	180	150
- research-oriented	51	49	44	44	50[3]
- generic producers	37	49	46	47	46[4]
- biotech	n.a.	n.a.	n.a.	n.a.	n.a
Number of persons employed[2]	n.a.	4,564	4,691	4,670	4,440

[2] counted per head

n.a. = not available

Source: Norwegian Association of Pharmaceutical Manufacturers

All the major pharmaceutical companies are represented in Norway, but only a few of them have established their own manufacturing units in the country. 10 companies have production facilities in Norway. The biggest ones are General Electric, Nycomed Pharma and Fresenius Kabi.

[3] Companies represented with a turnover of more than 100 000 NoK

[4] Companies represented with a turnover of more than 100 000 NoK

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.

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. Most of the Norwegian pharmaceutical industry is represented by LMI.
- Norsk Industriforening for Generiske Legemidler (Norwegian Association of Generics-orientated Pharmaceutical Manufacturers, NIGeL) – generics-orientated companies;

Direct distribution from the manufacturer to the end-user is in general not allowed. As a result all distribution, save some minor exceptions, is done by a wholesaler. The main bulk of medicines are then further distributed by pharmacies. An important exception is a limited selection of over-the-counter medicines that can be sold to the end user by other channels as well (cf. section 2.4.3.5).

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.

The importance of Norway's domestic pharmaceutical industry to the national economy is rather small. The estimated value of exported pharmaceutical products was approximately NOK 4.- bill (€ 500.- mill). in 2008. (LMI 2010).

In 2008, the pharmaceutical industry in Norway invested NOK 1.- billion. (€ 125 mill) in science and development (LMI 2010).The industry employs 4,400 employees and contributes to the accumulation and diffusion of relevant scientific knowledge in hospitals and private business involved in science. The research-based industry in Norway is rather small.

2.4.2 Wholesalers

Table 2.21: Norway – Key data on pharmaceutical wholesale 2000, 2005–2010

Wholesalers	2000	2005	2006	2007	2008	2009	2010
Total number of wholesale companies	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	59
Total number of importers	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	147
Total number of outlets (pharmacies and other POM dispensaries)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	1774

n.a. = not available

Data as of 1 July 2010.

Source: NoMA

The three 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 the table below.

Table 2.12. Norway - Wholesalers, 2010

Company	Market share (%)	Ownership
Apokjeden Distribusjon AS	28.9	Tamro OYJ (Finland)/ Phoenix Group
Alliance Healthcare Norge AS AS	23.5	Alliance Boots Plc
NMD AS	47.6	Celesio AG.

Source: Norwegian Association of Pharmaceutical Manufacturers/Farmastat

In Norway there is vertical integration between the three full-range wholesalers and the biggest pharmacy chains. In general, pharmacies get supplies from the wholesalers on a daily basis.

Parallel trade wholesalers do not exist per se.Parallel import to Norway is done by special-ised companies. Parallel export is conducted by the wholesalers. The Norwegian Pharmacy Association (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.

2.4.3 Retailers

In general only community and hospital pharmacists (674) are allowed to dispense medicines, along with small outlets belonging to the pharmacies (1,100). Other dispensaries (> 7,000), drug stores, supermarkets, kiosks and petrol stations), are allowed to distribute a small selection of OTC.

2.4.3.1 Community pharmacies

Table 2.33: Norway – Retailers of medicines 2000, 2005–2010

Retailers	2000	2005	2006	2007	2008	2009	2010
No. of community pharmacies	360	503	518	542	580	636	641
– *Thereof: No. of private pharmacies*[1]	360	503	518	542	580	636	641
– *Thereof: No. of public pharmacies*	–	–	–	–	–	–	–
No. of hospital pharmacies for out-patients	28	30	31	31	33	34	33
No. of dispensing doctors	n.a.	n.a.	32	10	10	10	10
No. of other POM disp.	n.appl.	n.appl.	_	_	_	_	_
Total no. of POM dispensaries	n.a.	n.a.	581	583	623	**680**	684
No. of internet pharmacies	?	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of OTC disp., like drugstores	n.a.	6,700	7,000	7,000	7,000	7,000	7,000

Disp. = dispensaries, n.a. = not available, n.appl. = not applicable No. = number, OTC = over-the-counter medicines, POM = prescription-only medicines

POM dispensaries are facilities that are allowed to sell POM to out-patients (PHIS Glossary).

1 Private pharmacies are pharmacies owned by private persons or entities; public pharmacies are in public ownership.

Data as of 1 January

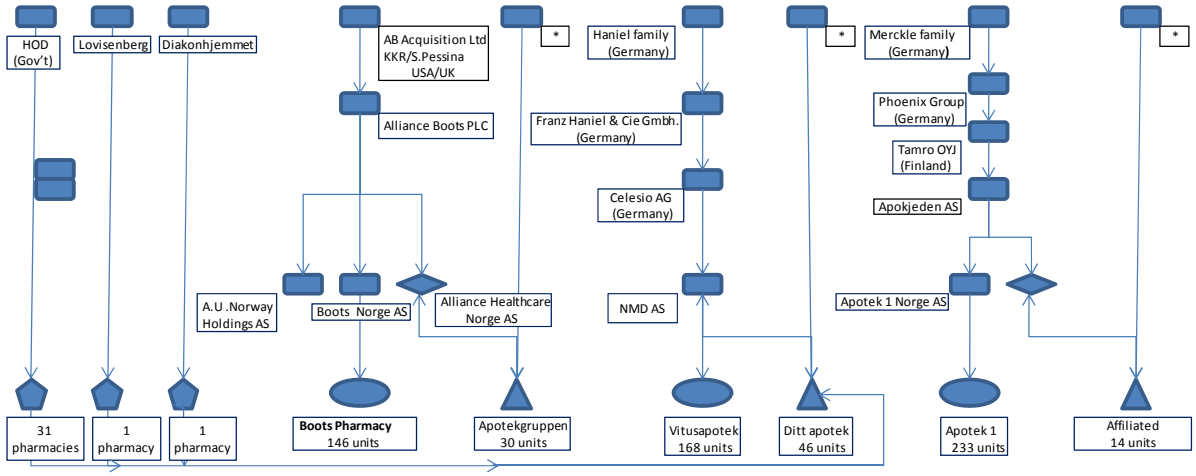
Source: NoMA

The pharmacies' activities are regulated by the Norwegian Pharmacy Act and the associated regulations on pharmacies. The 641 community pharmacies (as of January 2010) are privately owned. Until 2001 you had to be a pharmacist to own a pharmacy. Since 2001 anyone can own a pharmacy, but you still have to be a pharmacist to run it. Until 2001 the NoMA regulated the number of pharmacies, but since 2001 there have been no limitations on establishing new pharmacies. Since 2001 the pharmacy chains have bought most of the existing pharmacies in Norway and established a lot of new ones.

Pharmacy chains are allowed. As of July 2009 there were three vertical integrated pharmacy chains operating in Norway, owning a total of 540 pharmacies: Boots Norge AS (146), Apokjeden AS (2226) and NMD AS (168). These are owned by international companies. In

addition there is a chain of semi-independent pharmacies (Ditt Apotek) and some totally independent pharmacies.

Figure 2.2 : Norway - Pharmacy chains, 2011



Source: NoMA

The Norwegian Pharmacy Association represents the interests of the owners of the pharmacies, cf. section 2.4.2. The Norwegian Association of Pharmacists represents the professionals' interests and the interests of the profession. Membership is voluntary in both associations.

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 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 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 674 pharmacies there are 33 hospital pharmacies that are also open for out-patients. Furthermore, there are approximately 10 dispensing doctors in rural areas. There are approximately 7,300 inhabitants per pharmacy (4.9 Mio. inhabitants).

A total of 84% of the private pharmacies are totally owned by a wholesale company.

2.4.3.2 Dispensing doctors

Outpatient doctors are in general not allowed to dispense medicines 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 own any part of a pharmacy.

Doctors in the rural areas operating far from the pharmacy are allowed to dispense medicines when normal availability is restricted due to weather or geographical complications. The Act on Medicinal Products § 17 gives the legal basis for this. The number of doctors with such a licence is estimated to be around 10. The dispensing doctors are allowed to add a 10% extra mark-up on the fixed prices.

Nurses may dispense medicines 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. Public health nurses may prescribe contraceptive pills.

2.4.3.3 Hospital pharmacies

33 out of 78 public hospitals operate a hospital pharmacy. These hospital pharmacies are owned by the Regional Health Authorities. The 33 hospital pharmacies are responsible for procurement of medicines, production of ready to use injection/infusion and pharmaceutical services including clinical pharmacies (some clinical pharmacy). The hospital pharmacies differ in size from 5 to 90 employees. The hospital pharmacies are nonprofit units.

The principal task of hospital pharmacies is to provide medicines for the hospital. However, all hospital pharmacies have a department open to the public, mainly to serve patients, hospital employees and visitors. The pharmacies dispense prescriptions and sell health related products.

Pharmacies, wholesalers and suppliers are allowed to deliver medicines to hospitals. Pharmacies are allowed to deliver any medicine to hospitals and wholesalers are entitled to deliver medicines on a specified list. Suppliers may act as wholesalers and deliver their own products. In practice most medicines are delivered to hospitals by a pharmacy, mostly by a hospital pharmacy. There is an agreement/contract between each hospital pharmacy and the hospital. LIS organize it`s distribution of medicines by a contract agreement with one wholesaler, for the time beeing NMD AS. .

2.4.3.4 Other POM dispensaries

Many pharmacies in rural areas have established pharmacy outlets from which medicines are handed out to patients under the supervision of the pharmacy. There exist some 1,100 such outlets, mainly in the grocery stores. These outlets are located where there are no regular pharmacies (at least 10 km distance from any other pharmacy or outlet). They keep in stock a small selection of over-the-counter (OTC) products and can dispense prescription medicines sent by the pharmacy. The legal basis for these outlets is Act on Medicinal Products § 16.

2.4.3.5 Other retailers

Some 7,000 outlets, e.g. in grocery stores, gasoline stations, health stores, etc. are allowed to distribute a restricted list of OTC; these are known as medicines sold outside of the pharmacies (LUA). These outlets are not connected to a pharmacy and don't employ pharmacists. Promoting of OTC outside pharmacies is restricted and staff handling the medicines is not allowed to give patients any kind of recommendation, nor to engage in marketing of the products. Promoting of OTC within the outlets is also restricted. The legal basis for these outlets is Act on Medicinal Products § 16.

There are a few internet pharmacies in Norway which are allowed only to sell OTC. The internet has so far not changed the distribution of medicines 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.

Mail orders on prescription only medicines are allowed only in the geographical district of the pharmacy, whereas over-the-counter-medicines may be sold by mail or internet outside of the geographical district.

2.4.4 Promotion

The "marketing directives" as stated in Directive 2001/83/EC are implemented in Act No. 132 of 4 December 1992 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.

The Norwegian Medicines Agency is responsible for monitoring of all information activities by the industry. The main intention of the monitoring of advertising is to secure safe use of medicinal products and that all information activities are in accordance with the reimbursement decisions.

The NoMA sometimes detect infringement of the law by supervising written advertising. The NoMA also conducts unannounced inspections to control verbal information given at promotion- meetings.

- Direct advertising to patients is allowed for over-the-counter (OTC) medicines only.
- Advertising of medicines on the internet is allowed. This kind of advertising is regulated in the same way in Norway as advertising generally.
- No measures are implemented in order to restrict or control promotional spending of manufactures.
- Advertising to health care professionals cannot be combined with handing out objects, gifts, services, awards or other items of economic value. The intention of this provision is

to reduce the obligation between the health care professionals and the pharmaceutical industry.

- Any supply of free medicines samples to doctors shall be in response to a written request, signed and dated from the prescribing doctor. The number of samples for each medicinal product each year is limited to one sample of each formulation and strength. Each sample shall be no larger than the smallest presentation on the market.
- There is no control over the quantity of sales promotion activities undertaken by pharmaceutical companies.
- Actions taken to inform patients on the rational use of medicines are taken both by the state, the pharmaceutical industry and doctors.
    - Some of the information is available in a printed version like a brochure, booklet, or folder, and some of the information is available in an online search like homepages of the pharmaceutical industry, patient associations, NOMA and on Facebook, Twitter etc.
    - Printed information is provided by pharmacists for OTC medicines only.
- There are no specific regulations for information to patients in the in-patient sector.
- There has not been any public discussion as yet on patient information in Norway.

2.5 Funding

This section provides an overview of the funding of medicines.

2.5.1 Pharmaceutical expenditure

Table 2.3: Norway – Total pharmaceutical expenditure 2000, 2005–2009

Expenditure (in million NOK)	2000	2005	2006	2007	2008	2009
Total pharmaceutical expenditure (TPE)	13,211	16,971	16,652	16,900	17,100	18,150
- thereof TPE public	9,060	11,905	11,775	11,686	11,970	12,524
- thereof TPE private	4,151	5,066	4,877	5,214	5,130	5,627
Pharmaceutical expenditure in hospitals (HOSPE)	1,462	2,065	2,757	3,055	3,360	3,630
- thereof HOSPE public	1,462	2,065	2,757	3,055	3,360	3,630
- thereof HOSPE private[1]	n.app.	n.app.	n.app.	n.app.	n.app.	n. app

HOSHE = total health expenditure in hospitals, HOSPE = pharmaceutical expenditure in hospitals, n.a. = not available, n.app. = not applicable, THE = total health expenditure, TPE = total pharmaceutical expenditure

Expenditure calculated on PRP-level, on the basis of sales on PPP-level. 2009 includes sales of vaccines from the Norwegian Institute of Public Health. This was not included in previous years.

[1] private pharmaceutical expenditure in hospitals is negligible in Norway. Private hospitals are mainly publicly funded.

Source: Norwegian Association of Pharmaceutical Manufacturers

There has been a rise in total pharmaceutical expenditure from 2000 to 2009 of 37%. This is in average 4.2% per year, and a real growth of 2% per year.[5] Generic competition and the "stepped price model" have contributed to keeping medicine prices and expenditures low, On the other hand, new innovative and expensive medicines for arthritis and cancer treatment has pushed the expenditures up.

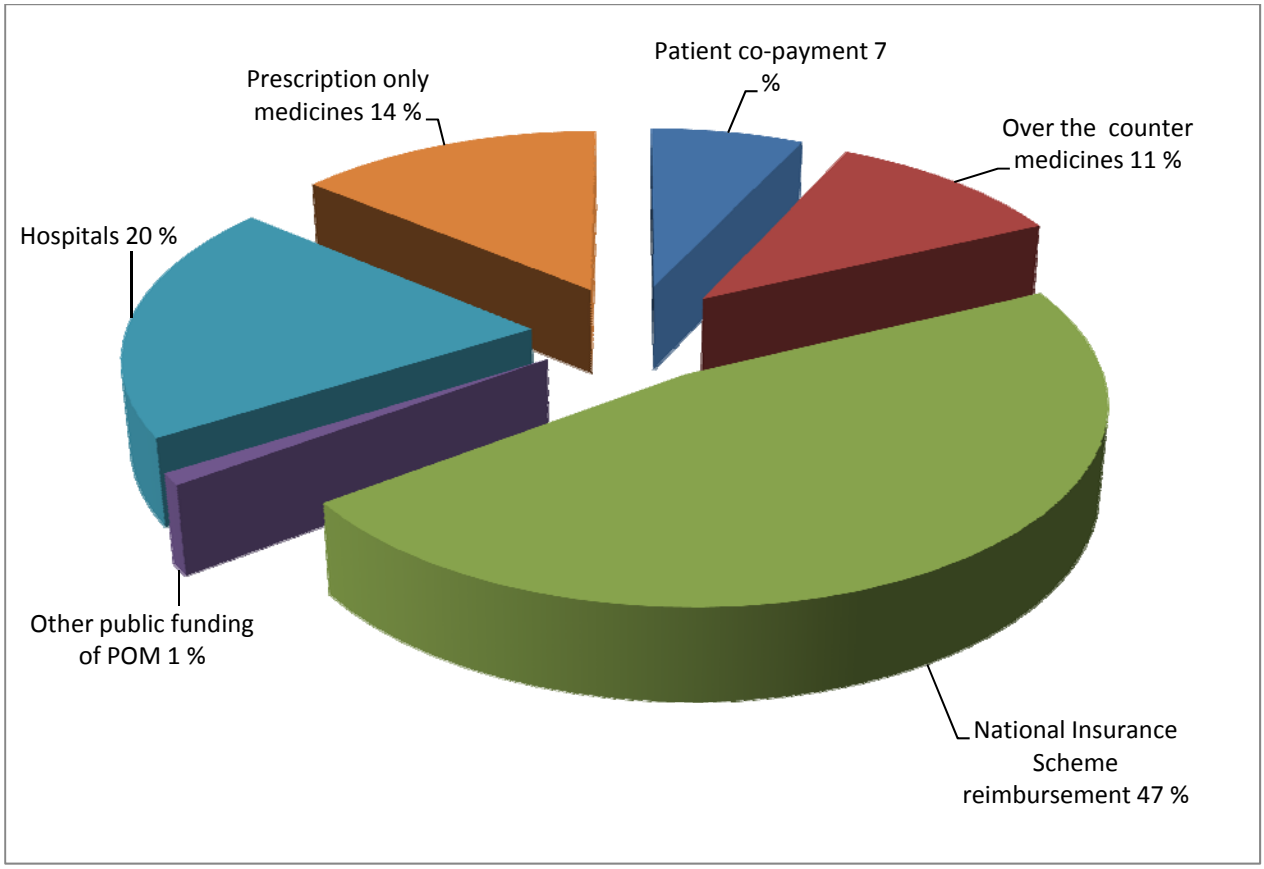
2.5.2 Sources of funds

In all the public sector covers (69% of total costs for medicines in 2009. The majority of the costs of medicines in the out-patient sector is covered by the Norwegian National Insurance Scheme (NIS), This constitutes 48% of the total costs. Membership of the NIS is mandatory, and costs are covered by taxes. The hospitals cover costs of medicines for in-patients, which constitutes of around 20% of total pharmaceutical costs. The costs covered directly by the patients were derived from non-reimbursable prescription medicines (12%), non-prescription medicines (12%), and patient co-payments for reimbursable medicines (7%).

In 1984 the Parliament introduced patient co-payments for reimbursed medicines. Cf. section 3.2.4.2.2 for information on co-payments.

[5] Inflation of 19,1 % from 2000- 2009 (KPI), Statistics Norway.

Figure 2.3: Norway – Split of funding of medicines, 2009



Sources: HELFO, Pharmaceutical Industry Association/Farmastat

3 Pricing, reimbursement and volume control in the out-patient sector

This chapter gives an overview of the pricing and reimbursement system as well as volume control mechanisms in the out-patient sector.

3.1 Pricing in the out-patient sector

3.1.1 Organisation of pricing

The Ministry of Health and Care Services (HOD) determines the principal pricing criteria for pharmaceuticals by the Regulation on Medicinal Products (Chapter 12, in Norwegian)[6]

The Norwegian Medicines Agency (NoMA) is in charge of pricing decisions for individual medicines and establishes the more specific guidelines for price determination. NoMA sets maximum prices for all prescription only medicines (POM) at the pharmacy purchasing price (PPP) level. The pharmacy retail price (PRP) is set by adding the maximum pharmacy mark-up (also set by NoMA). Price changes are normally made once per year and may result in higher or lower prices. Maximum prices for all POM are made publicly available on NoMA's website: www.legemiddelverket.no.

The applicant can apply to the NoMA for both price setting and reimbursement at the same time, but more often these applications are separate. When NoMA determines a price, the third-party payer, the National Insurance Scheme reimburses this price. The process of pricing takes on average 30-60 days, up to a maximum of 90 days.

[6] http://www.lovdata.no/for/sf/ho/ho-20091218-1839.html

3.1.2 Pricing policies

Table 3.1: Norway - Ways of pricing of medicines, 2011

	Manufacturer Level	Wholesale Level	Pharmacy Level
Free Pricing	Free pricing for all products set by the manufacturer/ importer (see below).		Free pricing for Over-the-counter medicines (OTC)
Statutory Pricing	Not applied	Maximum prices for all POM. Price is set at the PPP level & is "topped" by a statutory maximum pharmacies margin.	
Price Negotiations	Not applied	Not applied	Not applied
Discounts/Rebates	Not applied	Not applied	Not applied
Tendering	Applied for in-patient sector		
Others – specify	Not applied	Not applied	Not applied
Institution in charge of pricing	➢ NoMA for maximum prices ➢ NoMA for pharmacy mark-up scheme ➢ NoMA for reimbursement price ➢ LIS - hospital procurement agency for tendering		
Legal Basis	➢ Regulation on Medicinal Products		

NoMA = Norwegian Medicines Agency, POM = Prescription-only medicine(s), PPP = Pharmacy purchasing price

Source: NoMA

3.1.2.1 Statutory pricing

All prescription-only medicines (POM) are given maximum prices by the NoMA. NoMA sets maximum prices for all POM at the PPP-level. The pharmacy retail price (PRP) is regulated upwards by a maximum pharmacy mark-up set by 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. 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 PPP in Sweden, Finland, Denmark, Germany, United Kingdom, the Netherlands, Austria, Belgium and Ireland.

For generics there is a special price model, the stepped price model (*Trinnprismodellen*). It was introduced on January 2005 to reduce the costs of the National Insurance Scheme and the patients related to the use of generic medicines. In the stepped price model the price of a pharmaceutical product is reduced step by step by predefined rates. This occurs after the pharmaceutical product has lost patent protection and has been exposed to generic competition. The model has been modified twice after its introduction to reduce prices. The latest change was implemented January 2008.

Table 3.2: Norway - Overview of the stepped price system (Trinnprismodellen), 2011

Sales PRP, 12 months before generic competition		**< 100 Mio. NOK**	**> 100 Mio. NOK**	
	Time of price-cut			
1st step	Start of generic competition	30%	30%	
2nd step	6 months after generic competition	55%	75%	
Sales PRP, >= 12 months after 2nd step		**> 15 Mio. NOK**	**> 30 Mio. or < 100 Mio. NOK**	**> 100 Mio. NOK**
	Time of price-cut			
3rd step	>= 12 months after 2nd step	65%	80%	85%

NOK = Norwegian Krone, PRP = Pharmaceutical Retail Price

Source: NoMA

The stepped price is the maximum price reimbursed by the National Insurance Scheme or the price the patients pay for a pharmaceutical product that is incorporated in the system. The NoMA publishes a list of the generic substances included in the system[7] and a list of the current prices[8].

The maximum reimbursement price for a generic substance is set as a percentage of the maximum retail price (PRP) of the original medicine at the time it was exposed to generic competition. The reimbursement price is cut by two or three steps, whereby the reduction rate depends on the annual sale of the product. The first price-cut takes place when generic competition arises. The second cut is implemented six months after generic competition has occurred. The third step is applicable 12 months or more after the time of the second step.

The pharmacies are obliged to secure the capacity to deliver at least one pharmaceutical product at a retail price equal to the stepped price. If a medicine is delivered in both small and large packages, the pharmacy is obliged to deliver both small and large packages to a retail price equal to the stepped price. The wholesalers are obliged to offer the pharmacies medicines that enable them to fulfil these obligations.

Parallel traded medicines are given the same maximum price as the direct imported medicines. The stepped price system also applies for parallel traded medicines.

Price notification is not a part of the statutory pricing system in Norway.

[7] http://www.legemiddelverket.no/upload/Kopi%20av%20Oversikt%20over%20virkestoff%20i%20trinnprismodellen-på%20nett-2008-03-01.xls

[8] http://www.legemiddelverket.no/upload/Trinnprispakninger%202008-04-01.xls

3.1.2.2 Negotiations

The NoMA is in general not involved in price negotiations regarding statutory pricing. As far as reimbursement is concerned, the applicant may be recommended by NoMA to lower their maximum price, in order to receive reimbursement for a specific medicine. Price negotiations may also occur as part of the reimbursement decision process.

3.1.2.3 Free pricing

There is free pricing for all non-prescription medicines (OTC) and veterinary medicines.

There is no obligation to notify prices to the authorities.

3.1.2.4 Tendering

Tendering is only used in the in-patient sector.

3.1.2.5 Others

There are no other pricing policies.

3.1.3 Pricing procedures

Table 3.3: Norway – Pricing procedures, 2011

Pricing procedure	In use: yes / no	Price type[1]	Scope[2]
External price referencing	Yes	PPP	POM
Internal price referencing	Yes	PRP	Generic segment
Cost-plus pricing	No	-	-
Indirect profit control	No	-	-

[1] Price type = the level (manufacturer, pharmacy purchasing, pharmacy retail) at which the price is set.

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

Source: NoMA

The pricing procedures have been rather stable during the last years.

3.1.3.1 External price referencing

According to Regulation on Medicinal Products, § 12-2 the price decision should take into account the price of the medicine in other countries in the EEA (European Economic Area). This has been operationalised by setting the price at the mean of the three lowest market prices of that product in a selection of countries. The price that is set is the maximum pharmacy purchasing price (PPP). This system was implemented in 2002. The countries which

are included in the price comparison group are: Sweden, Finland, Denmark, Germany, United Kingdom, the Netherlands, Austria, Belgium and Ireland.

When setting the price of a medicine comparison will mainly be drawn with the same product in the reference countries. If a medicine is marketed under different product names in different reference countries they will still be compared for pricing. 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 for comparison of prices.

Different varieties of the same product may also be taken into consideration when comparing prices. In several of the countries which are included in the price comparison group, only small pack sizes have been registered. If there is a lower price per tablet in a small package than in a large package, the price per tablet in the large package is set at the same level as the price per tablet in the small package. On other casus the price difference is accepted, provided this difference is not considered to be unreasonable.

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

The price which is set by NoMA is the permitted maximum price to the pharmacy (PPP). The product can freely be sold at a lower price than the maximum price. The pharmacies' mark-up on the PPP is regulated as well, so in fact the maximum pharmacy retail price (PRP) is regulated.

NoMA revises the price of the 240 top-selling active ingredients 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. NoMA also revises several of the products that sell less to make sure that most prices will be revised at some point.

In general, prices will not be adjusted more often than once a year. Exempt from this rule are prices of new products after their launch onto the Norwegian market. In a two-year period after launching, 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.

3.1.3.2 Internal price referencing

Internal price referencing is applied to the generic segment (cf. section 3.1.2.1).

3.1.3.3 Cost-plus pricing

Cost-plus pricing is in general not used.

3.1.3.4 (Indirect) profit control

Indirect profit control is not applied in Norway.

3.1.3.5 Others

There are no other pricing policies.

3.1.4 Discounts / rebates

The statutory prices are maximum prices, and discounts are allowed. However all discounts should be given simultaneously with the sale, and all prices reported to the authorities should be reported as net-prices (Law on Medicinal Products §§ 6 and 14).

However, due to the market situation and the existence of a third-party payer, the discounts on the pharmacy purchasing price and the pharmacy retail price are negligeable.

3.1.5 Mark-ups and taxes

This section contains a description of the wholesale and pharmacy margins and mark-ups, dispensing fees and sales taxes applied to medicines, as of 2010.

Table 3.4: Norway – Regulation of wholesale and pharmacy mark-ups, 2011

	Wholesale mark-up			**Pharmacy mark-up**		
	Regulation	**Content**	**Scope***	**Regulation**	**Content**	**Scope**
Norway	No	N.app.	N.app.	Yes	Regressive mark-ups and fixed mark-up	POM

Source: NoMA

3.1.5.1 Wholesale remuneration

Wholesale mark-ups are not regulated in Norway. The average wholesale margin was in 2008 7% for POM.[9]

[9] Average wholesale margin for all POM calculated by using data from diagram 3 and 4 in report “Evaluering av apotekavansen 29. juni 2010

3.1.5.2 Pharmacy remuneration

Table 3.5: Norway – Pharmacy mark-up scheme, 2011

Pharmacy purchasing price in €	Maximum mark-up in % of pharmacy purchasing price
NOK 0-200 / € 0 – 25.5	7%
From NOK 200 / € 25.5	4%
	Fixed mark-up per package
All POM packages	NOK 22.- / € 2.8
Additional for addictive medicines/narcotics	NOK 10.- / € 1.3

Source: NoMA

Pharmacy mark-ups are regulated (by decree) by the NoMA, according to Regulation on Medicinal Products § 12-3. The established pharmacy mark-up is a maximum mark-up and is applied for all price-regulated medicines, including both reimbursed and non-reimbursed medicines. The scheme is regressive.

Every fourth year the NoMA performs an evaluation of the pharmacy mark-up. The most recent is the report "Evaluering av apotekavansen 29. juni 2010" (in norwegian)[10].

The pharmacy margin for POM that are not included in the stepped price model was in 2008 17%. The same year the average pharmacy margin for all POM was 19%.[11]

3.1.5.3 Remuneration of other dispensaries

The same mark-up regulation applies to both hospital and community pharmacies, cf. Table 3.5 .

Self-dispensing doctors, which are very few in Norway, may charge a mark-up of 10%.

Only a very selected range of OTC products may be sold outside pharmacies (known as medicines sold outside of pharmacies, or short: LUA). For these free pricing at all price levels is applied.

3.1.5.4 Taxes

3.1.5.4.1 Value-added tax

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

[10] http://www.legemiddelverket.no/templates/InterPage____81132.aspx?filterBy=CopyToPharma

[11] Average pharmacy margin for all POM calculated by using data from diagram 3 and 4 in report "Evaluering av apotekavansen 29. juni 2010

3.1.5.4.2 Other taxes

There is a pharmaceutical tax of 0.55% of the pharmacy purchasing price. It applies to all medicines, including OTC products, and is paid by the pharmacies and other outlets allowed selling OTC medicines. The amount is not included in the price build-up but the tax is collected by the wholesalers.

Some of the tax is redistributed to the pharmacies as subsidies. There is also a pharmaceutical tax of 0.6% of the wholesalers purchasing price. The tax is collected by NoMA from the producers.

There is a tax of 2% on sales in retailers such as grocery stores, gasoline stations etc, cf. section 2.4.3.5. The tax is paid by the wholesalers.

3.2 Reimbursement in the out-patient sector

This section describes the scope of the reimbursement system, the regulatory framework and the main authorities in the out-patient sector as of 2011.

3.2.1 Organisation

The pricing and reimbursement process is regulated in detail in Regulation No. 1839 of 18 December 2009 relating to pharmaceutical products (the Pharmaceutical Products Regulations), Sections 12 and 14.

The reimbursement schemes are important tools for the Norwegian health authorities to achieve 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 medicines regardless of their ability to pay.

2. Principles concerning rationality:

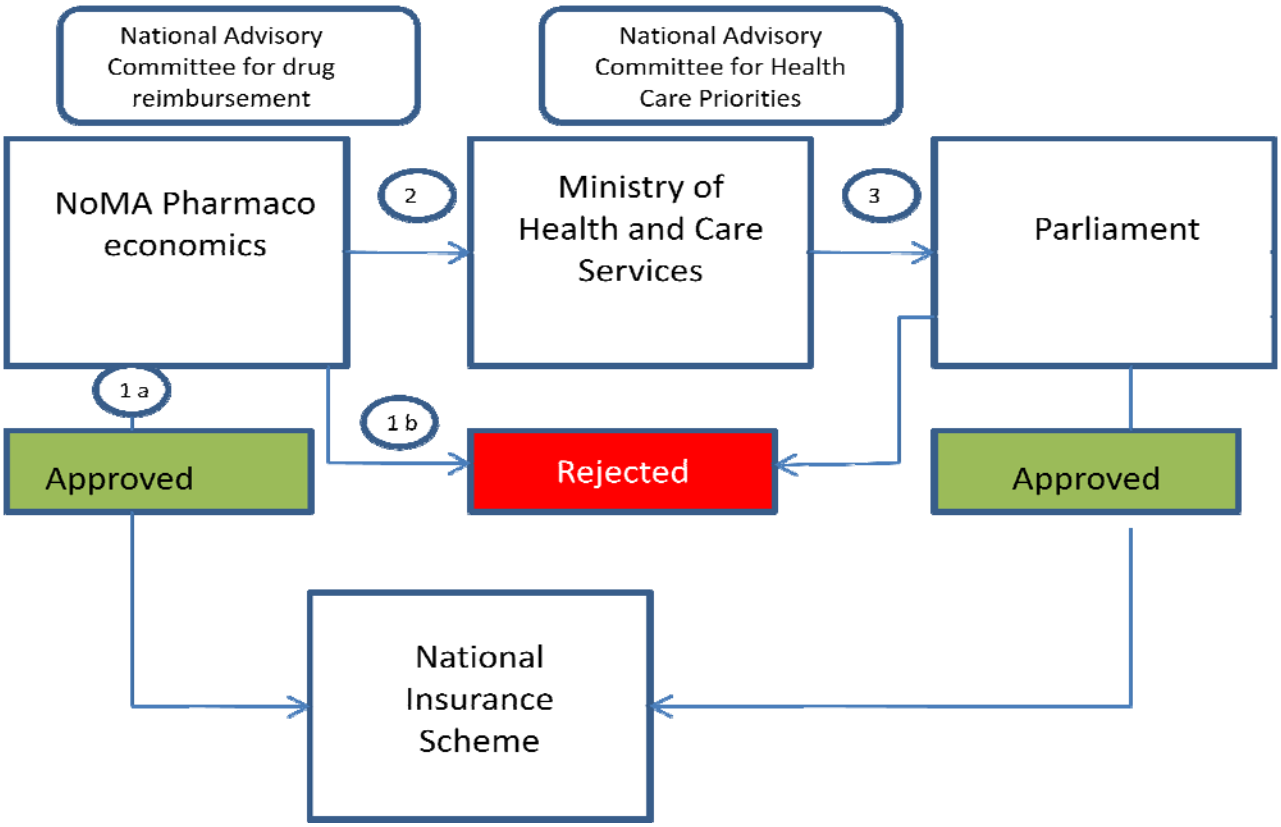
   The reimbursement system should encourage clinically rational and cost-effective use of medicines as a tool to ensure investment in health care services.

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 in general exempt from reimbursement.

The main system is general reimbursement on the basis of positive lists. There is also a system for individual application, cf. to section 3.2.2.

Decision making process

Figure 3.1: 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), 3 = bring the case before Parliament in the form a Budget Bill

Source: NoMA 2011

Figure 3.1 displays the decision-making process for reimbursement of medicines. A company may send a reimbursement application for a prescription medicine to the Norwegian Medicines Agency (NoMA). A price application may be submitted in parallel (a fixed initial maximum price is a prerequisite for reimbursement). The time allocated to NoMA for dealing with both pricing and reimbursement is 180 days. If the NoMA has questions about the application, the company has a maximum of three months to answer. Cf. section 2.3.1.2 for information on processing time.

If the reimbursement application involves a generic product, a new strength, formulation or package size (line extension) which is no more costly than the relevant reimbursed product, the procedure is usually swift and the NoMA will approve the application (cf. 1a in figure 3.1). Reimbursement is then granted in the National Insurance Scheme. If the application concerns a new chemical entity, a new combination, a new indication or an extension of indication which will have an annual incremental fiscal impact above 5 Mio. NOK/0,64 Mio. Euro by the fifth year after approval, the NoMA is not authorized to grant reimbursement. In this case, provided that the application fullfills the other conditions, the NoMA will pass its appraisal on

to the Ministry of Health and Care Services who will assess the matter further (cf. 2 in figure). In this process, the 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 may in turn consult a body known as the National Council for Health Care Priorities (cf. section 4.3.2.1) and inquire whether the money "would be well spent" compared to other health challenges. So far, the Ministry has not consulted the Council in these matters. Should the Ministry favour the approval, it will have to bring the case before Parliament in the form of a Budget Bill (c.f. 3 in figure). The Budget Bill is voted on in the Parliament, and so far the Parliament has voted in favour of reimbursement in every case.

In 2010 the NoMA decided on 138 applications for reimbursement. 134 were approved of, out of these 5 cases exceeded the limit of 5 Mio. NOK and were submitted to the HOD. In 4 cases reimbursement was rejected.

With a complete market authorisation for its product the marketing authorization holder (MAH) can either send an application for maximum price and an application for reimbursement simultaneously or apply for maximum price first. In general the maximum price is set according to the general rule, cf. section 3.1.2.1. Nevertheless the price is a decisive factor in cost-effectiveness for any product and therefore also the reimbursement process. Sometimes the MAH will therefore agree to put a lower price on the product in order to make the medicine cost-effective.

Pharmaco-economic evaluation

A pharmaco-economic evaluation in connection with applications to join the reimbursement scheme has been compulsory since 1 January 2002. A company needs to follow the Norwegian guidelines[12] for pharmaco-economic evaluation.

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

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

Over-the-counter (OTC) medicines are in general not reimbursed and therefore no pharmaco-economic evaluation is necessary.

[12] http://www.legemiddelverket.no/templates/InterPage____28315.aspx?filterBy=CopyToGeneral

There are few absolute economic criteria for an application as long as a pharmaco-economic evaluation is performed. However, the evaluation should show and explain why the medicine should be reimbursed. Normally, this is carried out using the cost-effectiveness ratio. There is no cut-off ratio determined in Norway. Pharmaco-economic analyses performed in the given context are to be evaluated on behalf of the 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 Scheme (NIS). This therefore means that the economic consequences the illness and any interventions will have for society as a whole and the NIS should be clearly explained throughout the process.

The applicant may appeal against decisions made by the NoMA within three weeks of the date of the decision. If the NoMA decides not to consent to the appeal, the NoMA must submit the appeal to the Ministry, according to the Public Administration Act.

3.2.2 Reimbursement schemes

The legal framework for the reimbursement scheme is the Social Services Act and Regulation on Medicinal Products.

There are four main ways in which medicines can be covered (Table 3.6). Schedule 2 requires that the medicine has been approved for reimbursement. Medicines in these schedules will, when initially approved by the authorities, be reimbursed automatically, while medicines in Schedules 3a and 3b require a formal application for each patient. The purpose of schedule 4 is to eliminate severe communicable diseases.

Approximately 80% of total reimbursement expenditures arose from Schedule 2 in 2010. Schedule 3a and 3b accounted for respectively 11 and 5% of total reimbursement. Reimbursement by schedule 4 was 4% of total reimbursement.

3.2.2.1 Eligibility schemes

Cf. Section 3.2.2.3.

3.2.2.2 Reimbursement lists

Norway has a reimbursement list (positive list) regarding general reimbursement (schedule 2), which is updated by the Norwegian Medicines Agency (NoMA) once a month (cf. section 3.2.2.3). The list of reimbursable medicines and associated criteria is published on the NoMA website.[13] as a searchable database on the web. The list is organized at the medicine substance level and gives the subscriber precise information on the part of a medicines indication approved for reimbursement. The reimbursement indication is described both in text and according to two different diagnostic codes (ICD-10 and ICPC-2).
In the database, the search criteria can be the medicine‘s product name, the generic name, the ATC-code, the diagnostic code or the name of the disease it has been granted reimbursement for.

[13] http://www.legemiddelverket.no/custom/templates/Refusjonsliste____71552.aspx

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

3.2.2.3 Reimbursement categories and reimbursement rates

Table 3.6: Norway – Reimbursement categories of medicines, 2011

Reimbursement category	Reimbursement rate (%)	Description
Schedule 2	62 / 100[1]	For medicines on the reimbursement list, which are reimbursed in case of specified diagnoses in the list and only for long-term (> 3 months) treatment.
Schedule 3a	62 / 100[1]	For medicines other than those under Schedules 2, 4 and 3b. In this case reimbursement can be granted upon submission of an individual application and only for long-term (> 3 months) treatment.
Schedule 3b	62 / 100[1]	For medicines used to treat rare diseases, which are reimbursed upon submission of an individual application and only for long-term (>3 months) treatment.
Schedule 4	100	For medicines used to treat serious contagious diseases such as tuberculosis, syphilis or HIV/AIDS.

[1] Cf. section 3.2.4.2.2

Source: NoMA 2011

General reimbursement – Schedule 2

Schedule 2 is basically a "positive list" system, based on a list with medicines that can be reimbursed for specified diagnoses, provided other given criteria are fulfilled. The Norwegian Medicines Agency (NoMA) handles the reimbursement list of product brand names that has been accepted for reimbursement for the defined diagnoses. Reimbursement is granted only under the condition that the patient has a serious and chronic disease, for which "long-term" medication (more than three months per year) is necessary. Furthermore, the medicines in question must have market authorisation and therefore need to have satisfactory documentation of clinical effect and safety. General reimbursement is granted only for treatment of disease states or conditions that are covered by the product's medical indication.

Individual reimbursement – Schedule 3a and 3b

Under certain conditions reimbursement is granted on the basis of individual patient applications for products not included in the 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. This refers to Schedule 3a in Table 3.6.

Reimbursement may also be granted on an individual basis for medicines used in the long-term treatment of conditions which are considered to be serious and rare, but for which no medicines are included in the list for general reimbursement. This refers to Schedule 3b in Table 3.6.

The Health Economic Administration (HELFO) decides on reimbursement for individual patients for medicines without general reimbursement or for indications not covered by general reimbursement (approximately 100,000 individual applications every year). In contrast to the preapproved medicines available for general reimbursement, it is not a prerequisite that the product has obtained a market authorisation to be individually reimbursed. The medicines may achieve significant reimbursed sales before market authorisation in Norway, with no statutory maximum pharmacy purchasing price.

Medicines 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 costs to the patient. There is no patient co-payment for these medicines. Medicines used to treat, e.g. HIV/AIDS or tuberculosis are reimbursed in this category. Also, vaccines against communicable diseases are reimbursed. All medicines with ATC-code J (i.e. antiinfectives for systemic use) or L03A (immunostimulants) are automatically included in this schedule. No further application is necessary to obtain 100% reimbursement. Long-term treatment is not a prerequisite for Schedule 4.

Contribution system

Some prescription medicines 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. If a ceiling of NOK 1,600.- (€ 204.-) 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 contribution system is however only valid for prescription only medicines. There is a negative list attached to this system, and medicines on this negative list are not reimbursed. Generally, expenses for medicines used to treat erectile dysfunction, smoking cessation, hair-loss and addictive medicines are not reimbursed by this system. Additionally, some of the medicines that are reimbursed by the above mentioned reimbursement schemes (schedule 2, 3a, 3b and 4) will not be granted reimbursement by the contribution system. The system requires initial out-of-pocket payment (OPP). Receipts containing information regarding the patient's name, the prescribing physician's name, date, product name, price, and pharmacy identification will serve to document the claim.

3.2.3 Reference price system

In Norway there is no therapeutic reference price system in place.

3.2.4 Private pharmaceutical expenses

The share of total pharmaceutical costs covered directly by the patients is derived from non-reimbursed prescription-only medicines (14%), non-prescription medicines (11%) and patient co-payment of reimbursable medicines (7%). Cf. diagram in section 2.5.2.

3.2.4.1 Direct payments

Medicines that are not reimbursed must be paid directly by patients, i.e. the same amounts specified under section 3.2.4.

3.2.4.2 Out-of-pocket payments

For the out-of-pocket payment (OPP) rates cf. table 3.6 (38% or 0%). In addition to these payments there is OPP when patients refuse generic substitution, cf. section 3.3.2.1.

3.2.4.2.1 Fixed co-payments

There are no fixed co-payments in place.

3.2.4.2.2 Percentage co-payments

In 2011 the patient co-payment is 38% of the total cost of the reimbursed medicine. There is a maximum limit of NOK 520.- / € 66.4 per prescription, and the ceiling for total co-payments is currently NOK 1,880.-/ € 240.- annually per person. Co-payments for physician visits, radiology examinations, laboratory tests and medicines are included in this amount. This applies also to out-patient treatment given by hospitals. Expenses above this amount (for reimbursed medicines and ambulatory care) are covered by the insurance scheme.

There is no minimum co-payment threshold.

3.2.4.2.3 Deductibles

There are no deductibles in place.

3.2.4.3 Mechanism for vulnerable groups

Cf. section 3.2.2.3.

3.3 Volume control in the out-patient sector

3.3.1 Pharmaceutical budgets

Pharmaceutical budgets are not implemented in the out-patient sector. However there is a number of measures in place to contain costs.

The reimbursement system regulates prescription practices to a certain degree since the prescribing party in general will prescribe a reimbursed medicine instead of a non-reimbursed therapeutically equivalent pharmaceutical. In addition a substantial amount of the reimbursement decisions made by the Norwegian Medicines Agency are based on conditions that have to be fulfilled for the medicine to be reimbursed. Examples of such conditions can be that the patient has to be in a severe stage of the disease, that reimbursement is only granted to patients within a certain age-segment, or that another named medicine must be tried first.

In general doctors are obliged to prescribe the cheapest equivalent product unless there are serious medical reasons for prescribing a more expensive alternative.

In March 2004 the Government introduced the so-called “first-choice product reimbursement scheme” for the treatment of hypertension. The documentation for the first-choice scheme also contains a clause that doctors can prescribe more expensive medicines if there are serious medical reasons for doing so. The scheme was extended in June 2005 to statins. Other medicines, such as antihistamines, proton pump inhibitors and triptans have been incorporated during the last few years. 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.

The “preferred medicine” scheme directly influences prescribing. For some therapeutic equivalent medicines a first-choice scheme (~ a preferred product) is established. The prescribing party 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 was introduced to ensure the use of the most cost-effective medical treatment.

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

The first preferred products introduced were tiazides. From March 2004 tiazides were to be the first choice in the treatment of hypertension. The reason for introducing such preferred products are large differences in price within a group of similar medicines that cannot be justified by a large difference in effect.

3.3.2 Generic policies

3.3.2.1 Generic substitution

Generic substitution has been allowed in Norway since 2001. According to a web-survey, commissioned by The Norwegian Pharmacy Association, 64% of the consumers have experienced a suggestion to generic substitution from a pharmacist in 2009. The share of consumers that report a positive experience from generic substitution has fallen from 50% in 2005 to 39% in 2009. The share of consumers having had a negative experience rose from 19% to 25%.

Pharmacies are obliged to inform patients if there is a cheaper generic alternative available. 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. The doctor may also put a reservation on the prescription when substitution should be avoided for medical reasons. In such cases the National Insurance Scheme will reimburse the cost with no extra payment for the patient.

Pharmacies have financial incentives for generic substitution. In Norway there is vertical integration 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 medicine with equal therapeutic benefits), but they are allowed to substitute parallel imported medicines.

The NoMA evaluates new medicines on the norwegian market regarding their substitutability. If the medicine is regarded as substitutable with an existing product, the substitutable packages are put on a list. The updated "substitution-list" is published monthly and is distributed to all pharmacies and doctors. [14]

The market share of generics on the reimbursed out-patient sector has been rising during the last years and was 17,7% in 2008 (on PRP-level). (NoMA-report "Årsaker til ulik generikaandel i nordiske land", November 2009.[15]

3.3.2.2 INN prescribing

There is in general not much INN prescription in Norway. The doctors are allowed, but not obliged, to prescribe by INN. The NoMA is working to increase INN prescription. The new system for electronic prescribing will facilitate this. This system is currently under deployment.

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14 http://www.legemiddelverket.no/templates/InterPage____80122.aspx?filterBy=CopyToPharma.

15 http://www.legemiddelverket.no/templates/InterPage____81078.aspx?filterBy=CopyToPharma.

There is no system for systematic evaluation of the doctor's prescribing habits in Norway.

3.3.2.3 Other generic promotion policies

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 medicines is promoted by the authorities for cost-containment reasons.

Due to generic substitution and the stepped price model NoMA assumes that the NIS and the patients save in all approximately 2.- billion NOK every year. These savings are substantial in view of the fact that the NIS reimbursed medicines for 7,8 billion NOK in 2010.

Generics are permitted to have the same maximum prices as the original product. This makes the processing of the price application rather simple. Regarding reimbursement, if the generic has the same indications as the original and the MA-holder also applies for reimbursement for the same indications, the processing of the application will also be simple and swift.

The authorities "first-choice product reimbursement scheme", cf. 3.3.1, promotes the sale of generics because active ingredients off-patent often are selected as the preferred product,

The NoMA made a campaign in 2009 to make prescribers and patients better understand the purpose of generic substitution. The NoMA informs about generic substitution in various ways: by NoMAs website, by distributing brochures to pharmacies, by presenting in seminars/conferences and by interviews and articles in the media.

There is no minimum ratio (percentage) of generic prescription that doctors would have to fulfil.

3.3.3 Claw-backs / Pay back

Claw-backs are not used in Norway.

3.3.4 Monitoring

This section provides an overview of the programmes and methods used to evaluate the pharmaceutical policy and system, and its impact on health, access to medicines, and cost-containment. It mainly focuses on monitoring of prescriptions, price, expenditure and consumption.

In Norway there are two main registers that serve the monitoring of prescriptions, price, expenditure and consumption. Both are managed by the Norwegian Institute of Public Health:

The Norwegian Prescription Database is a national health register containing information connected to all delivery of medicines from pharmacies in Norway. The Database was

founded in 2004. The database has individual consumption data. The Database is used for pharmaco-epidemiological research and pharmaceutical statistics. http://www.norpd.no/

Medicines Statistics from Wholesalers cover all sales of medicines from wholesalers to pharmacies, hospitals/nursing homes and non-pharmacy outlets with permission to sell medicines. Both POM and OTC are included in the statistics. It has been in place since the 1970-ties.

The information can be used by researchers to study the pharmaceutical issues and by the health authorities in planning and controlling. The statistics are justified in the Regulations concerning Medicine Wholesale Activities and Business.[16]

3.3.4.1 Prescription monitoring

The HELFO performs random checks to see if the doctors prescribe according to the criteria. Prescriptions are selected for control, and the prescribing doctors are asked to provide relevant information from the patients journal.

The frequency of monitoring different measures regarding prescribing may vary, depending on the importance of the measure and the expected value of new information. The NoMA has been monitoring the market shares of the preferred products on a monthly basis, cf. section 3.3.1.[17]

The preferred product-scheme for tiazides and statins were evaluated by external parties. [18]

3.3.4.2 Price monitoring

Prices of POM are collected regularly on WPP and PPP-level in the Medicines Statistics from Wholesalers and on PRP-level in the Norwegian Prescription Database, cf. section 3.4. The data is used in various types of analyses.

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[16] http://www.fhi.no/eway/default.aspx?pid=238&trg=Area_5954&MainLeft_5812=5954:0:&Area_5954=5825:67872::0:5955:1:::0:0

[17] http://www.legemiddelverket.no/templates/InterPage____80590.aspx

[18] Statins: Sakshaug S, Furu K, Karlstad Ø, Rønning, M, Skurtveit, S. Switching statins in Norway after new reimbursement policy—a nationwide prescription study. Br J Clin Pharmacol 2007, doi:10.1111/j.1365-2125.2007.02907.x
http://www3.interscience.wiley.com/journal/117977741/abstract?CRETRY=1&SRETRY=0
Tiazides: Evaluering av nytt refusjonsvilkår for blodtrykksbehandling (tiazidregelen) Fretheim A, Håvelsrud K, MacLennan G, Kristoffersen DT, Oxman A
Notat 2006. ISBN 82-8121-079-6
http://www.kunnskapssenteret.no/Publikasjoner/Evaluering+av+nytt+refusjonsvilk%C3%A5r+for+blodtrykksbehandling+%28tiazidregelen%29.2210.cms

The SNF, Institute for Research in Economics and Business Administration, has compared prices of POM in Norway to prices in the nine countries in the external reference system, cf. 3.1.2.1.[19]

Although there is free pricing on OTC, the NoMA has conducted price surveys on the segment that is allowed sold also outside of pharmacies (LUA). The latest survey was done in 2010. [20]

Pharmaceutical expenditure monitoring
The overall pharmaceutical expenditure on the out-patient sector is monitored by the Directorate of Health as an input to the state budget. The NoMA monitors pharmaceutical expenditure as an input to reimbursement decisions. The Norwegian Institute of Public Health (NIPH) monitors the expenditure and consumption in the yearly publication "Drug Consumption in Norway" – [21]
The focus (per region, per patient, per diagnosis) for the monoitoring depends on the case.

In addition private parties as the Pharmacies Association and the Association of Pharmaceutical Manufacturers (LMI) produce yearly reports on pharmaceutical consumption and expenditure:

"Facts and Figures" http://www.apotek.no/Default.aspx?ID=68&ShowIpaper=10

"Facts and Figures" http://www.lmi.no/91/Legemiddelstatistikk/146.html

The LMI also owns Farmastat AS, a company which provides statistics on pharmaceutical sales which have been collected from the wholesalers. http://www.farmastat.no/.

3.3.4.3 Consumption monitoring

The pharmaceutical consumption is monitored by the Norwegian Institute of Public Health Institute on a yearly basis, cf. link to publication in section 3.3.4.3. This report has been made public since 1977. NIPH also produces an annual report based on the Norwegian Prescription Database: http://www.norpd.no/Publications.aspx

The NoMA monitors consumption as an input to reimbursement decisions.

Research institutions and universities also monitor consumption when it is relevant to their research field/assignments.

Consumption is also monitored by private parties, cf. to links in section 3.3.4.3.

[19] R08/10 Are Pharmaceuticals Still Inexpensive in Norway? A Comparison of Prescription Drug Prices in Ten European Countries - Kurt Richard Brekke, Tor Helge Holmås and Odd Rune Straume - http://www.snf.no/Publications/SNF-publications-3.aspx?mode=detail&RowId=11&ViewPID=134&PubID=4386

[20] http://www.legemiddelverket.no/templates/InterPage____82791.aspx?filterBy=CopyToGeneral

[21] http://www.fhi.no/eway/default.aspx?pid=238&trg=Area_5954&MainLeft_5812=5954:0:&Area_5954=5825:85007::0:5955:1:::0:0

3.3.5 Assessment and evaluation

3.3.5.1 Decision-making tools

As stated in 3.2 a pharmaco-economic 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. The applicant is obliged to perform pharmaco-economic analyses. The NoMA assesses the quality of the analysis as part of the processing of the application and sometimes performs such analysis as part of the processing. The NoMA har published guidelines for pharmaco-economic evaluations since 2002. Revised guidelines are currently on a hearing.[22]

In Norway a medicine can obtain both market authorisation and a maximum price without a pharmaco-economic evaluation. But a pharmaco-economic evaluation has to be performed for all medicines for which an application for reimbursement is submitted, with the exception of some instances, cf. section 3.2.1.

Cost-effectiveness analysis is well established in Norway and the use of quality-adjusted life years (QALYs) as an effect parameter is increasing. Norway has not defined a maximum willingness to pay per quality-adjusted life year (QALY). The Directorate of Health is currently arranging a hearing of new guidelines for assessment of societal effects in the health sector.[23]

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.

3.3.5.2 Evaluation of measures

As stated in 3.3.5.1 a pharmaco-economic evaluation has to be performed for all medicines for which an application for reimbursement is submitted, with a few exceptions.

When a pharmaco-economic evaluation has to be performed, the Market Authorisation Holder (MAH) should follow the Norwegian guidelines for pharmaco-economic evaluation in connection with applications for reimbursement[24]. 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 are currently under revision.

[22] http://www.legemiddelverket.no/templates/InterPage____83076.aspx

[23] http://www.helsedirektoratet.no/fagnytt/horinger/saker/samfunns_konomiske_analyser_i_helsesektoren__ute_p__h_ring__809424

[24] http://www.legemiddelverket.no/templates/InterPage____25644.aspx

3.3.5.3 Reports and results

The Norwegian Knowledge Centre for the Health Services performs health technology assessments. It publishes all HTAs on the website: http://www.kunnskapssenteret.no/Home.

Other institutes may also perform HTAs on commission from various principals, e.g. the regional health authorities.

3.4 Overview on policy measures in the out-patient sector

Table 3.8: Norway – Policy measures in the out-patient sector, 2005–2011

Measures	Description	Year
Changes in the pricing policies (e.g. new policies or methodology and changes, external price referencing; price freezes / cuts, (obligatory) discounts	Stepped price model for generics	2005
Changes in the regulation of the mark-ups	Minor change in maximum pharmacy mark-up	2009
Changes regarding the reimbursement lists and schemes (e.g. de-listings, new reimbursement scheme)	Preferred product – statins, antihistamines, PPIs, triptans Delisting of cox2-inhibitors, atorvastatin (10 and 20 mg), Lyrica. Revision of reimbursement scheme	2005 – 2011 2008
Changes concerning OPP in the out-patient sector (e.g. introduction of a prescription fee, increase of percentage co-payments)	Introduction of electronic issuing of “free pass” when low cost ceiling is reached.	2010
Changes in the generics policies (e.g. introduction of INN prescribing, generics substitution)	Piloting and deployment of system for electronic pre-scription which facilitates INN prescribing. Campaign to improve knowledge of generic substitution by prescribers and patients.	2008-2011

OPP = out-of pocket payment

Source: NoMA

For the time being, pharmaceutical expenditure rates are growing moderately which is partly attributable to the stepped price model, but new and more expensive medicines will in the future probably drive expenditure up.

In 2008 the Norwegian Medicines Agency established a new unit to improve information towards physicians and other prescribers. This unit informs about safe and economically rational prescribing to balance the marketing provided by the industry. The aim is to increase the physicians trust in the authorities’ guidelines and regulations.

In 2011 a new system for electronic prescription is under deployment. This will enable NoMA to provide information about medicines, e.g. prices and conditions for reimbursement, via the physicians system for electronic patient records. NoMAs focus is to provide information of good quality which is available whenever the prescriber is online. To be able to do this NoMA implemented a new database for information on pharmaceutical products for the out-patient and in-patient sector.

The electronic prescription system will also facilitate INN-prescribing.

4 Pricing, reimbursement and volume control in the in-patient sector

4.1 Pricing and procurement in the in-patient sector

4.1.1 Pricing

4.1.1.1 Framework

4.1.1.2 Hospital prices

LIS negotiates the pharmacy purchasing price (PPP). Delivery costs are included in the PPP. The Regional Health Authorities (RHAs) or sometimes hospitals decide on or negotiate the pharmacy mark-up. The pharmacy retail price includes 25% value added tax. Other discounts than the ones given in the tendering process are prohibited.

The wholesale mark-up is subject to a separate tender. One wholesaler is selected for providing distribution services to the hospitals, usually for a period of three years. The tender is performed by the Hospital Pharmacies Health Enterprise, on behalf of the four RHAs.

The tenders include all publicly funded hospitals, the information on purchasing is therefore available to these hospitals. The exchange of information is organised by the hospital procurement agency Norwegian Drug Procurement Cooperation (LIS). There is no legal obligation for hospitals or hospital owners to publish the pharmaceutical prices or to notify the price to a competent authority.

The tendering may in some cases encourage a lowering of prices for initial treatment in hospital in order to increase the number of patients in primary care being treated with the medicine in question.

Hospitals spent NOK 3,700.- / € 472.- million on medicines in 2010 including 25% value added tax.

4.1.2 Purchasing policies

4.1.2.1 Tendering

The sole pricing policy in Norwegian hospitals is tendering.

Procurement for all publicly funded hospitals is done by the Norwegian Drug Procurement Cooperation (LIS). This includes all medicines financed by the hospitals and is done on a yearly basis. The only exceptions are solutions and x-ray contrasts where the procurement process takes place every second year. All suppliers, manufacturers and wholesalers are addressed and the Public Procurement Law applies. This law is in line with the European Union procurement law.

This ensures that prices for patent-protected medicines 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 to increase the number of patients in primary care being treated with the medicine in question.

LIS tenders have given 28.5% price reduction for the Norwegian hospitals for 2010, compared to the statutory maximum prices (for information on statutory prices c.f section 3.1.2.1). In the out-patient sector the products are usually sold at maximum prices. The cooperation also contributes to more efficient and better use of the medicines in hospitals. The savings of more efficient use amount to approximately 15% of the total pharmaceutical expenditure.

For the group of tumor necrosis factors (TNF) the discounts range from 2-46%. For the remaining medicines covered by LIS agreements the discounts are 46% compared to the statutory maximum prices in Norway.

4.1.2.2 Negotiations

In hospitals there are no other pricing policies besides tendering.

4.1.2.3 Other purchasing policies

In hospitals there are no other pricing policies besides tendering.

4.1.3 Organisation of procurement

The LIS, hospital pharmacies, hospital pharmacists, hospitals with pharmaceutical and therapeutic committees (PTC) and hospital departments are involved in the procurement process for medicines for use in hospitals.

In Norway, almost all publicly funded hospitals are members of LIS. Hospitals purchase medicines according to public procurement regulations within their budget. The regional health authorities (RHAs) settle annual framework agreements through LIS and the hospitals' purchases are then considered to be in accordance with this agreement.

LIS has all prices hospitals pay for medicines. All prices are the same for all hospitals. The tenders are published in the Doffin[25] and TED[26] database, due to legal provision.

The process is co-ordinated by LIS.

The assignment criteria are the following:

- price,
- functional characteristics, such as durability and ability to blend,

[25] http://www.doffin.no

[26] http://ted.europa.eu

- packages such as unit-dose,
- labelling (readability, strength specification),
- generic name (according to European Pharmacopoeia),
- package varieties (unity),
- product variety such as administration form,
- formulation,
- strength varieties,
- service such as training (product knowledge) and
- help with medical enquiries and delivery.

There is no bundling of products in the tendering process.

The hospitals buy the medicines from pharmacies and the selected wholesaler. The largest quantities of medicines are bought from the hospital pharmacies. There is an agreement or contract between each hospital pharmacy and the hospital. Some hospital pharmacies serve more than one hospital.

But smaller quantities are also bought by smaller hospitals from community pharmacies. More than 500 pharmacies delivered goods and medicines to hospitals in 2009.

Some hospital pharmacies supply the hospitals with single dose units. Other pharmacies supply the hospitals with a patient labelled dose unit.

4.2 Reimbursement in the in-patient sector

4.2.1 National framework

Pharmaceutical expenditure in publicly funded hospitals is covered by the hospital budgets. The patients do not have to pay for the medicines used in their treatment as long as the treatment takes place in the hospital, i.e. the medicines are purchased and paid by the hospital. Reimbursement decisions on medicines for use in the primary care do not therefore concern medicines used in hospitals. In each of the four RHAs, a hospital medicines committee works out a limited list of medicines. This limited list of medicines is an advisory list to guide the hospitals' choice of medicines. The hospitals' committees consist of doctors from specialised clinical areas and hospital pharmacists. For information on the funding of the hospitals, cf. section 1.3.2.

The major reason for the growth in pharmaceutical expenditure of hospitals the last years was the transferral of the funding of products from the budget of the National Insurance Scheme (NIS) to the hospital budgets in 2006 and 2008 respectively. These products include tumor necrosis factor (TNF) medicines and medicines for the treatment of Multiple Sclerosis (MS) (cf. section 5.1).

The share of private funding of private hospitals is very low. In 2006 it was less than 1 percent of total health expenditure in hospitals[27].

In Norway there are no country-wide positive/negative lists that apply for hospital in-patient care.

There are no out-of pocket payments (OPP) for in-patient treatment. OPP are however required for consultations at the hospitals out-patient departments, cf. section 3.2.4.2.2.

4.2.2 Hospital pharmaceutical formularies

There are no hospital pharmaceutical formularies in Norway.

4.2.3 Pharmaceutical and Therapeutic Committees

There are 22 pharmaceutical and therapeutic committees (PTC) established by the hospitals. In almost every health enterprise there is a PTC. The PTCs consist of doctors from specialised clinical areas, hospital pharmacists and sometimes specialists in procurement. The PTCs work out a list of preferred products/suppliers. The lists usually include the 300 most commonly used substances with corresponding products/suppliers. The criteria for selecting products/suppliers for the list are the same as referred in section 4.1.3. This list is indicative to guide the doctor's choice of products. The doctors may choose other medicines for treatment for medical reasons. The lists are updated on a yearly basis. They are available for internal use in the hospital and are not published externally.

The medicines on the list are covered by the hospital budgets, in the same way as any other medicine provided for in-patient care at the hospital.

4.3 Volume control in the in-patient sector

4.3.1 Monitoring

4.3.1.1 Price monitoring

The pharmacies and wholesaler give statistics on prices, expenditure per article and active substance. The hospital is the owner of the statistics. A computer system (Farmapro) is used by the pharmacies to track supply to the hospitals. The pharmacy can track the consumption of medicines for the hospital and each department in the hospital per volume and price at any time.

The LIS also has the prices the hospitals pay for the medicines. The prices are the same for all hospitals.

[27] Statistics Norway

4.3.1.2 Pharmaceutical expenditure

The total national consumption of medicines in hospitals is provided from the LIS annually by expenditure per active ingredient and expenditure per package per article. The statistics can be given by LIS on request.

4.3.1.3 Consumption monitoring

The total national consumption of medicines in hospitals is provided from the LIS annually by expenditure per active ingredient and expenditure per package per article. The statistics can be given by LIS on request.

Refer also to section 3.3.4. for information on other statistics that cover the in-patient sector.

4.3.2 Assessment and evaluation

4.3.2.1 Decision-making tools

The Norwegian Knowledge Centre for the Health Services[28] (Kunnskapssenteret) prepares reports concerning cost-effectiveness in use of medicines. Specifically the Centre has prepared reports concerning cost-effectiveness in the use of medicines for osteoporosis, hypertension and cancer.

The Norwegian Ministry of Health and Care Services established the Norwegian Council for Quality Improvement and Priority Setting in Health Care. First and foremost, the Council shall secure a comprehensive national approach to the work on quality and prioritisation. The council does not do health technology assessments.

Stakeholders can discuss and deal with key issues associated with quality and prioritisation by their collective participation in the Council. With the Government's National Health Plan for Norway as starting point, they will initiate professional analyses when necessary and assess the various aspects of complex issues. Assessments of patient benefit, cost-effectiveness and total costs will provide an important foundation for the Council's evaluations.

Reports are published which can be downloaded from the website of the Council[29].

4.3.2.2 Evaluation of measures

Cost-effectiveness analysis is well established in Norway and the use of quality-adjusted life years (QALYs) as an effect parameter is increasing. Refer to section 3.3.5.1 for more information on QUALYs. However, even though there is an ongoing debate on the subject, Norway has not defined a maximum willingness to pay per QALY. A very important aspect of a product's cost-effectiveness is how reliable the results are. A normal way of testing this is

[28] www.kunnskapssenteret.no

[29] http://www.kvalitetogprioritering.no

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.

4.3.2.3 Reports and results

Refer to www.kunnskapssenteret.no.

5 Interface management and developments

This concluding chapter covers information about the interface management and the most important pharmaceutical developments for the health care system.

5.1 Interface management

Interface management between the in-patient and out-patient sector in Norway exists with regard to specific medicines as hospitals pay for medicines that patients need after discharge of the hospital. These medicines include tumor necrosis factor (TNF) medicines and medicines for the treatment of Multiple Sclerosis (MS). The funding of these products was transferred from the budget of the National Insurance Scheme (NIS) to hospital budgets in 2006 and 2008 respectively. This was mainly due to the fact that some products in this field were funded by the NIS and some products were funded by the hospital. This created the economic incentive for hospitals to prescribe products funded by NIS. Also it was an aim to achieve more competition in the area and lower prices.

A development with further transferral from the NIS to the hospitals has been predicted, but has not yet taken place.

5.2 Developments in the out-patient and the in-patient sectors

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

The Government is implementing a reform for better interaction between the primary and secondary healthcare systems.[30] The reform shall give incentives to the municipalities to prevent disease and injury in their population. In 2012 a co-payment from the municipalities will be required for some treatments in secondary healthcare. Municipalities will have to pay 20 per cent of the cost of consultations and treatment at hospitals for all patients resident in their municipality with somatic diseases/injuries. Municipalities will also have to pay for patients who have finished their treatment at hospital and are waiting to be moved to their municipality. The municipality will have to pay NOK 4,000.- per extra day the patient stays in the hospital after treatment there is finished. 5,000.- million NOK will be moved from the hospitals budgets to the municipalities in order to fund their co-payment. The age? of the population will decide how the amount is distributed between the municipalities.

The municipalities will be obliged to provide acute help and 24 hours-services for patients in need of treatment or observation. This will be implemented in 2012 – 2015 and the Government will provide funding to the municipalities.

[30] http://www.regjeringen.no/nb/dep/hod/pressesenter/pressemeldinger/2011/vil-sikre-data-fra-kreftregisteret.html?id=643114

A new system for electronic prescription is currently under deployment. This will enable NoMA to provide information to the prescribers about medicines, e.g. prices and conditions for reimbursement, via the physicians system for electronic patient records. NoMA's focus is to provide information of good quality which is available whenever the prescriber is online.