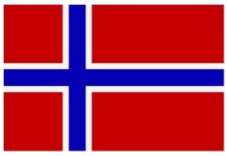
WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI Pharma Profile

Norway 2015



Gesundheit Österreich GmbH

PPRI Pharmaceutical Pricing and Reimbursement Information

PPRI Pharma Profile Norway

Update: June 2015

PPRI Representatives
Norwegian Medicines Agency: Helga Festøy
Drug Procurement Cooperation: Torfinn Aanes

Authors
Norwegian Medicines Agency: Helga Festøy
Drug Procurement Cooperation: Anne Helen Ognøy

Editors
PPRI Secretariat, Gesundheit Österreich GmbH (Austrian Public Health Institute)

Reviewed by
Nina Zimmermann, PPRI Secretariat

ÖBIG
Österreichisches Bundesinstitut für Gesundheitswesen

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

BUNDESMINISTERIUM FÜR GESUNDHEIT

Acknowledgements

The Norwegian Medicines Agency is grateful for contributions from:

Solveig Sakshaug, National Institute of Public Health

Karianne Johansen, Norwegian Association of Pharmaceutical Manufacturers

Stian Lekang, Farmastat

Introduction

PPRI Pharma Profiles: national reporting systems on pharmaceutical pricing and reimbursement

The need for accurate and up-to-date country information has been broadly acknowledged. Information about specific issues of a country is of key importance for decision makers and researchers, even if their needs with regard to the level of detail may vary.

Within the framework of the PPRI (Pharmaceutical Pricing and Reimbursement Information) research project (2005 – beginning of 2008), the project consortium, consisting of the Austrian Public Health Institute (Gesundheit Österreich GmbH / Österreichisches Bundesinstitut für Gesundheitswesen) and the World Health Organization (WHO) developed the so-called "PPRI Pharma Profiles" as a tool for understanding, collecting and analysing pharmaceutical pricing and reimbursement information. A key principle of the PPRI Pharma Profiles was that the Profiles were written by national country experts, usually staff of competent authorities for pharmaceutical pricing and reimbursement (Ministries of Health, Medicines Agencies, Social Health Insurance institutions) represented in the PPRI network and that they were critically reviewed by project consortium members.

PPRI Pharma Profiles, which primarily focused on the out-patient pharmaceutical sector, for 23 countries were published within the years 2007 to 2009. Even if the PPRI project officially ended at the beginning of the year 2008, the PPRI network members continued contributing by updating the PPRI Pharma Profiles.

As a further development, information on the in-patient sector was integrated: The PHIS (Pharmaceutical Health Information System) project surveyed, for the first time, information about the in-patient pharmaceutical sector. The PHIS project consortium, including the Austrian Public Health Institute, the International Healthcare and Health Insurance Institute (IHHII) in Bulgaria and the Slovak Medicines Agency (SUKL), developed the PHIS Hospital Pharma report about medicines management in the hospital sector and the PHIS Pharma Profile as a comprehensive report about the pharmaceutical out-patient and in-patient sectors. The principle of involving national experts as authors remained the same. 19 PHIS Hospital Pharma reports and 5 PHIS Pharma Profiles were published. All published country reports and profiles are publicly accessible at the website of WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies at http://whocc.goeg.at/Publications/CountryReports.

Additionally, in order to allow information at a glance, posters about pharmaceutical systems and policies were produced. They are also available at the WHO Collaborating Centre's website at http://whocc.goeg.at/Publications/CountryPosters.

In order to support the production of the PPRI and PHIS Pharma Profiles, templates were matched and were made available to the authors. In the course of the years, the templates for the comprehensive profiles (in 2015 the "PPRI/PHIS Pharma Profiles were renamed again to "PPRI Pharma Profiles") were revised, further developed and updated.

The PPRI Pharma Profile 2015 is designed to comprise up-to-date information as of 2015 (or latest available year) about pharmaceutical pricing and reimbursement in both the out-patient and in-patient sectors and data for the latest available years.

Templates and glossaries

All PPRI Pharma Profiles are based on a template which provides a homogenous outline for reporting. The templates were developed in the PPRI and PHIS projects, were circulated for review and feed-back to the PPRI/PHIS network members, were tested by the authors of the profiles and afterwards revised by consortium members, taking into account the experiences made.

Editorial guidelines provide advice to authors and reviewers and aim to increase the readability of the profiles. Readers can expect a universal approach with regard to citations, data presentations, spelling etc. across the PPRI Pharma Profiles.

To achieve clarity for authors, reviewers and readers and thus to create a common understanding of the concepts and terms used, a glossary was developed in the early times of the PPRI project. It has been regularly updated since. The most updated version of the Glossary of WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies can be found at the WHO Collaborating Centre's website at http://whocc.goeg.at/Glossary/About. Authors of the PPRI Pharma Profiles are requested to adhere to the Glossary.

PPRI, PHIS, and WHO Collaborating Centre

Pharmaceutical Pricing and Reimbursement Information (PPRI) was originally a research project, co-funded by the European Commission, Directorate-General Public Health and Consumers. It was performed from 2005 till early 2008. In the course of the project the PPRI network was established, and a set of pharmaceutical indicators, filled with real data from 27 PPRI countries, as well as more than 20 country reports (PPRI Pharma Profiles) and brief overviews on the pharmaceutical systems (country information) were produced.

Today, Pharmaceutical Pricing and Reimbursement Information (PPRI) is a networking and information-sharing initiative on burning issues of pharmaceutical policies from a public health perspective. The PPRI network involves representatives from around 80 institutions: These are public authorities and third party payers from 45 countries (mainly European countries, including all 28 EU Member States) as well as European and international institutions such as European Commission services and agencies, OECD, WHO (HQ and Regional Office for Europe) and World Bank.

In the on-going PPRI initiative, the networking of the public authorities continues via regular networking meetings and continuous sharing of relevant information for decision-making, including updates of country-specific information. The PPRI secretariat is hosted at the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies (see below).

The PPRI project was selected by the Executive Agency for Health and Consumers, in collaboration with the Health Programme's National Focal Points (NFP) and the Directorate

General for Health and Consumers (DG SANCO), as a good practice example of EU Public Health projects with an important impact for EU Member States (http://whocc.goeg.at/Literaturliste/Dokumente/FurtherReading/EAHC_NFP_EUHealthProgramme_ImpactProjects.pdf).

Pharmaceutical Health Information System (PHIS) was a European Commission co-funded project which ran from September 2008 to April 2011. The project aimed to increase knowledge and exchange of information on pharmaceutical policies, in particular on pricing and reimbursement, in the EU Member States, covering both the out-patient and the in-patient sectors. A special focus of the project was on Hospital Pharma, with a European survey of medicines management in hospitals in the EU Member States and an investigation and analysis of official and actual prices of medicines in hospitals in selected case study countries. Methodology tools, in particular with regard to terminology, indicators and reporting tools, were further developed based on work started in PPRI.

The Health Economics Department of the Austrian Public Health Institute was nominated as WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies in summer 2010 and re-designated in 2014. The Centre continues methodology work started under the framework of the PPRI and PHIS projects: One of the Centre's explicit tasks is to develop the tool for for describing and analysing national pharmaceutical pricing and reimbursement systems ("Pharma Profiles"). WHO Collaborating Centre staff are also involved as experts in the development of the WHO Pharmaceutical Country Profiles by supporting to expand the current tool of the "PPRI Pharma Profiles" for the European countries, and adapting it so that it can describe the pharmaceutical sector in other health system arrangements.

Within the PPRI and PHIS projects, websites were established. Policy makers, researchers and the interested public are thus offered open access to our findings and methodological tools developed. The PPRI and PHIS project websites are no longer maintained, all relevant PPRI and PHIS information was integrated in the website of the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies: http://whocc.goeg.at. The website of the Centre is designed to serve as an information platform about pharmaceutical policies, and it includes published profiles, indicators of the PHIS database, glossaries and templates for reporting of pharmaceutical pricing and reimbursement information.

Table of content

List of tables

List of abbreviations

ATC	Anatomic therapeutic chemical classification
DRG	Diagnosis related group
INN	International Non-proprietary Name
GDP	Gross domestic product
GP	General practitioner
HE	Health expenditure
HELFO	Norwegian Health Economics Administration
HOD	Ministry of Health and Care Services
HTA	Health technology assessment
LIS	The Norwegian Drug Procurement Cooperation
LMI	Norwegian Association of Pharmaceutical Manufacturers
NCU	National currency unit
NIS	National Insurance Scheme
NorPD	The Norwegian Prescription Database
NPA	The Norwegian Pharmacy Association
Mio.	Million
OECD	Organisation for Economic Co-operation and Development
OPP	Out-of-pocket payment
OTC	Over-the-counter medicine
PE	Pharmaceutical expenditure
POM	Prescription-only medicine
PPP	Pharmacy Purchasing Price
PPRI	Pharmaceutical Pricing and Reimbursement Information project
PRP	Pharmacy retail price

QALY	Quality adjusted life year
RHA	Regional Health Authority
THE	Total health expenditure
TPE	Total pharmaceutical expenditure
VAT	Value added tax
WHO	World Health Organisation

1 Health care system

This section gives a brief introduction to the demographic and economic situation of the country as well as on the access to the health care system.

1.1 Population and age structure

Table 1.1: Norway – Demographic indicators 2000, 2005, 2010–2013

Demography	2000	2005	2010	2011	2012	2013
Total population*	4,503,436	4,640,219	4,920,305	4,985,870	5,051,275	5,109,056
Population aged 0-14*	902,431	906,811	921,709	923,575	927,384	930,845
Population aged 15-64*	2,922,179	3,050,939	3,256,353	3,294,281	3,333,277	3,365,653
Population aged > 64*	678,826	682,469	742,243	768,014	790,614	812,558
Life expectancy at birth	78.7	80.2	81.0	81.3	81.5	81.7
Life expectancy at age 65	83.0	84.0	84.5	84.7	84.7	84.9

*1st of January following year

Source: Statistics Norway

The population of Norway reached 5.1 Mio. in 2013. This corresponds to an average of 15.8 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 2013 the average life expectancy was 79.7 years for men and 83.6 years for women. The percentage of the population over 64 years is rising slowly. It is expected to increase significantly as a result of the ageing of the post-war generations.

The total number of deaths in 2012 was 41,992. Diseases of the circulatory system are still the leading cause of deaths, accounting for approximately 31% (2012) of the total. There has, however, been a significant reduction in mortality due to lower 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% (2012).

1.2 Organisation of the health care system

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 pharmaceuticals.

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 428 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.

The 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. There are 25 health enterprises under the four RHAs.

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. 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.

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 of the RHA. The municipalities are governed by locally elected politicians. Health care is one of many areas for which they are responsible.

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

- The Health and Care Services Act - 2011
- The Specialist Health Care Services Act - 1999

- The Dental health Care Act - 1983
- The Mental Health Care Act - 1999
- The Patients Rights Act - 1999

1.3 Health expenditure

Table 1.2: Norway – Health expenditure 2000, 2005, 2010–2013

Health expenditure in NCU = NOK, mill.	**2000**	**2005**	**2010**	**2011**	**2012**	**2013**
GDP	1,481,242	1,958,907	2,544,266	2,750,780	2,908,924	3,011,410
THE	124,728	176,984	239,730	255,366	270,052	288,283
- thereof public HE, %	82.5	83.5	84.7	84.8	85.0	85.5
- thereof private HE, %	17.5	16.5	15.3	15.2	15.0	14.5
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 €)	8.11	8.01	8.01	7.79	7.47	7.81

GDP = gross domestic product, HE = health expenditure, NCU = national currency unit, THE = total health expenditure

Source: Statistics – Norway, European Central Bank

1.4 Sources of funding

Sources of revenue for health care in Norway include budgets from government and municipal level, the National Insurance Scheme (NIS) and private expenditure. The Norwegian health care system is primarily funded by taxes. However, dental care is mainly funded by private expenditure. 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. 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. Private health insurance does not play a significant role in Norway, but is increasing. In 2013 approximately 340,000 persons

were covered by additional private health insurance. Employers paid the insurance for nine out of ten. (Source: www.vg.no/Finance Norway).

The Regional Health Authorities, funded by the central Government, fund the health enterprises which in turn fund the local hospitals. The hospitals are remunerated by a mixture of ex-ante fixed budgeting (50%) and a diagnosis-related group (DRG) system (50%) 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.

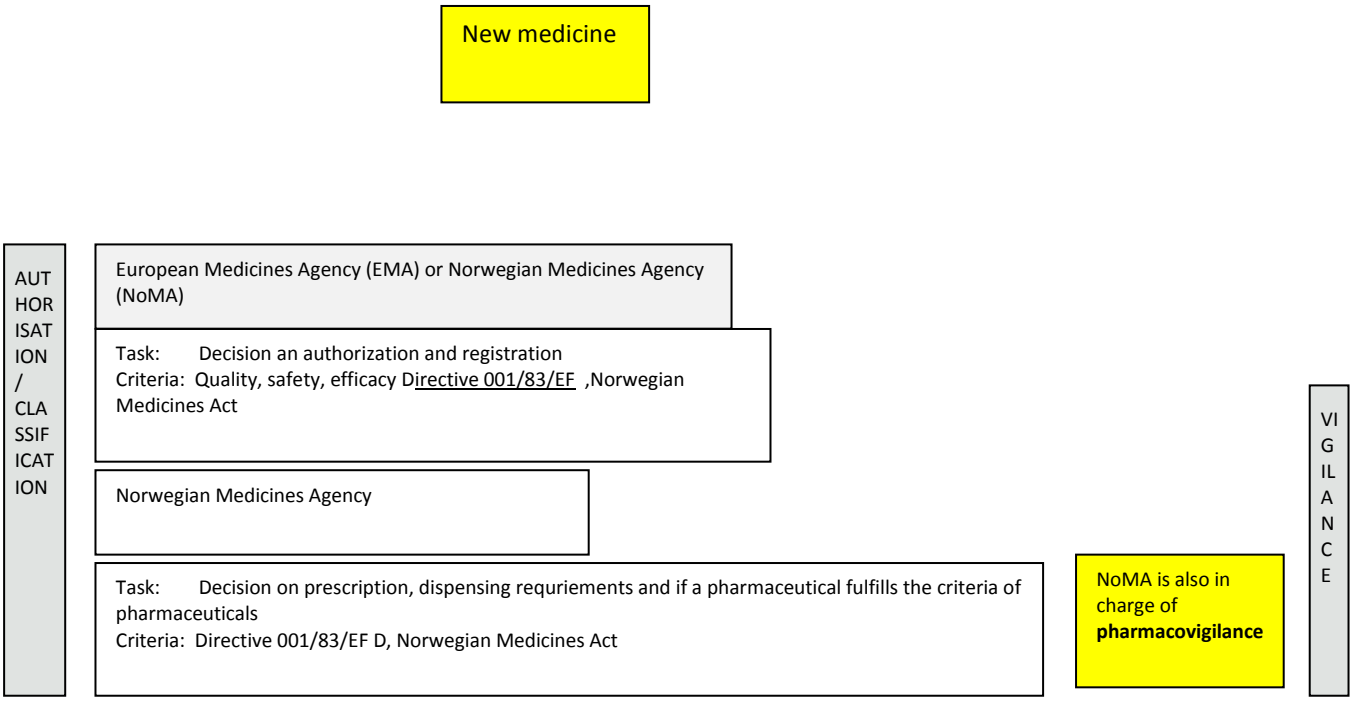
2 Pharmaceutical system

This section provides a description of the pharmaceutical system; its organisation, regulatory framework and authorities, the market players and the funding of the system for the out-patient and the in-patient sectors as of 2015.

2.1 Organisation of the pharmaceutical system

Norway, as part of the European Economic Area, adheres to EU-regulations regarding marketing authorisations (MA). The Norwegian Medicines Agency (NoMA) contributes to the work of the European Medicines Agency (EMA), alongside agencies from the EU-member states.

Figure 2.1: Norway – authorisation, 2015

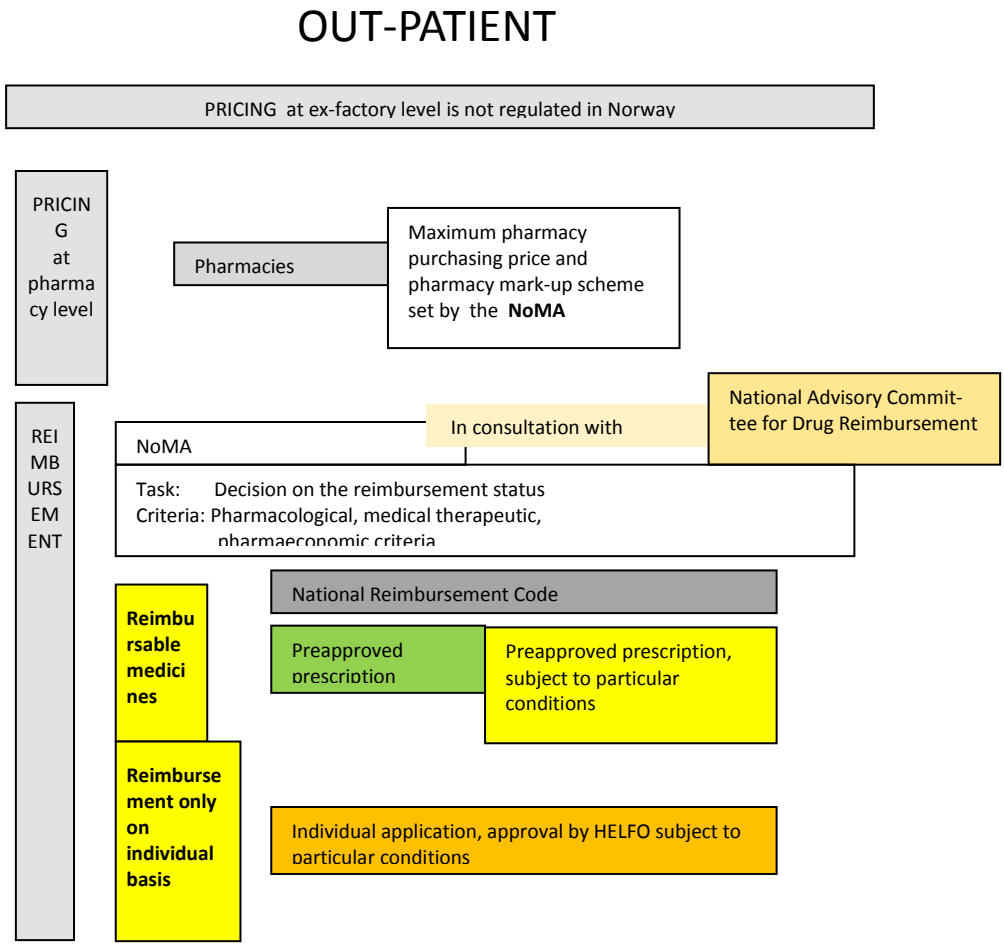


Source: NoMA

The EU-regulations regarding MA do not differ between out- and in-patient medicines, and the NoMA is responsible for MA for both sectors, cf. figure 2.1.

The Norwegian system for pricing and reimbursement is different from other countries, as these systems are largely decided on national level. Also the systems for pricing and reimbursement in Norway differ between the two sectors, cf. figures 2.2 and 2.3.

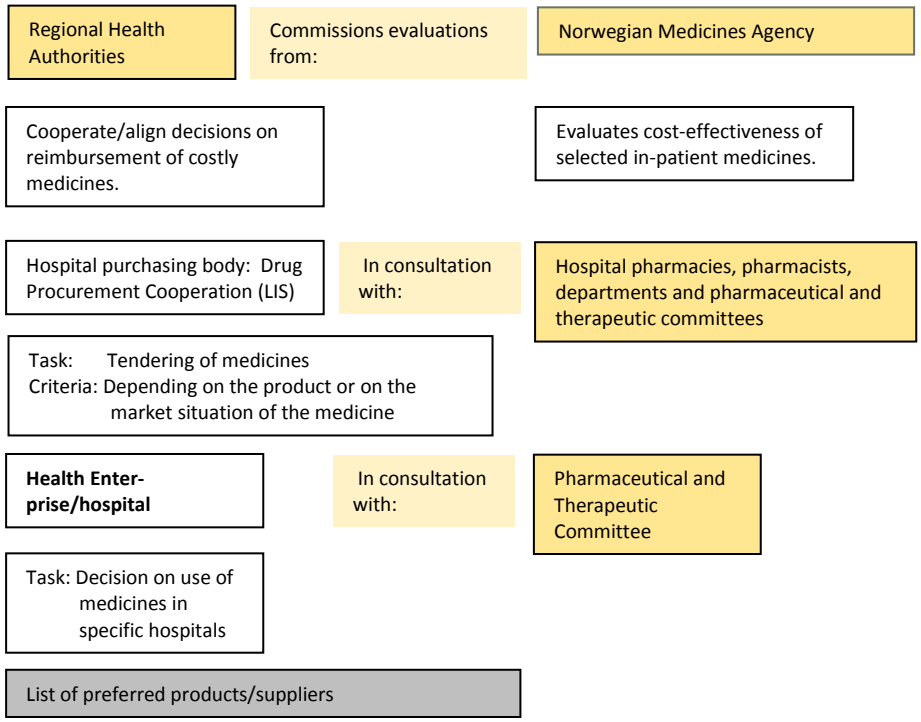
Figure 2.2: Norway – Flowchart of pricing and reimbursement in out-patient sector, 2015



Source: NoMA

HELFO, the Norwegian Health Economics Administration, is responsible for the actual reimbursement of all services, medical devices and pharmaceuticals that are covered by the NIS.

Figure 2.3: Norway – Flowchart of pricing and reimbursement in in-patient sector, 2015



Source: NoMA

Table 2.1: Norway – Legal basis and actors of the pharmaceutical system, 2015

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 in English (local name, local abbreviation)
Market authorisation	The Norwegian Act on Medicinal Products Norwegian Regulation relating to Medicinal Products	In- and out-patient sector. All registered/licensed pharmaceuticals (POM, OTC).	The Norwegian Medicines Agency (Statens legemiddelverk, SLV)	In charge of market authorisation, classification and pharmaco-vigilance.	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	All registered POM. In-patient	The Norwegian Medicines Agency (Statens legemiddelverk, SLV) LIS	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) pharmaceuticals. In-patient	The Norwegian Medicines Agency (Statens legemiddelverk, SLV), Norwegian Health Economics Administration (HELFO) Regional Health Authorities/Health Enterprises	In charge of deciding reimbursement-status In charge of reimbursing. Subordinate of The Directorate of Health (Helsedirektoratet),	LMI NIGeL Patient organisations
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)

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 in English (local name, local abbreviation)
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: NoMA

The legal basis and the actors in the pharmaceutical system have been stable since 2002

.

2.2 Availability of and access to medicines

Table 2.2: Norway – Annual prescriptions in the out-patient sector 2000, 2005, 2010–2014

Prescriptions	2005	2010	2011	2012	2013	2014
No. of prescriptions (in volume)*	25,646	30,658	32,640	43,729*	48,833*	49,878*
Prescriptions in value ** (NOK)	12,268	13,199	13,118	13,524	13,901	15,332

*Prescription in volume = number of prescriptions settled in pharmacies, human and veterinary. Source: NPA
**Prescription in value = public expenditure of prescribed medicines. Source: NorPD, NIPH

*In the electronic prescription system each package is defined as a prescription, whereas there can be several packages prescribed on a paper prescription. Implementation of electronic prescriptions started in 2011. In 2012 15% of the prescriptions were electronic, in 2014 75%. The number of prescriptions 2011 – 2014 is therefore not comparable. The growth in prescriptions from 2013 to 2014, by the definition of electronic prescriptions, was 1.8%. (Norwegian Pharmacies Association, NPA)

The figures also include “H-prescriptions”. These are prescriptions that are reimbursed by the hospitals, cf. section 4.1. In 2014 0.3% of the prescriptions were “H-prescriptions”. The medicines on “H-prescriptions” are rather costly, and their value (PRP) in 2014 was NOK 2.0 billion, approximately 11% of the total prescriptions. (NPA)

Table 2.3: Norway – Number of new molecular entities with Marketing Authorisation, 2003-2013

New molecular entities	2003 – 2013	2008 – 2013
Number of new molecular entities	450	212

Source: NoMA, LMI Tall og fakta 2014

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 before the product can be marketed. The average processing time of a price-application was 26 days in the first quarter in 2015. Applications for general reimbursement were in average processed in 78 days in 2014. The maximum processing times are 90 and 180 days respectively.

2.3 Development of the pharmaceutical sales

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 3.2.1).

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 pharmaceuticals and novel therapies for cancer.

Parallell import was in 2014 1.5% of the total volume (POM, packages) and 2.5% of value (Farmastat).

2.4 Pharmaceutical consumption

*Table 2.4: Norway – Annual pharmaceutical consumption 2000, 2005, 2010–2013**

Consumption (mio.)	**2000****	**2005**	**2010**	**2011**	**2012**	**2013**
Total pharmaceutical consumption						
In packs	68.7	81.1	84.7	87.0	88.6	88.7
In DDD***	1,754	2,230	2,582	2,625	2,689	2,734
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 authorisation 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

2.5 Generics

Table 2.4: Norway– Development of the generic shares in volume and value, 2008, 2013

Generic share	Volume - DDD		Value	
	2008	2013	2008	2013
Shares in % of total market (in-patient/ out-patient)	39.8	44.6	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	n.a.	n.a.	n.a.	n.a.
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.

Source: LMI

The volume of generics in the total market has been growing the last ten years. There are several causes for this. Generic substitution in pharmacies was implemented in 2001 and patents of several major medicines have expired during the period.

There are no specific legal regulations regarding marketing authorisations for generics in Norway. EU-regulations apply (cf. section 2.1).

2.6 Top 10 medicines

Table 2.5: Norway – Top 10 active ingredients in value in the out-patient sector, 2014

Position	Top active ingredients used in the out-patient sector, ranked with regard to consumption* 2013		Position	Top active ingredients used in the out-patient sector, ranked with regard to expenditure** 2014	
1	J01CE02	Phenoxymethylpenicillin	1	R03AK06	Salmeterol
2	M01AB05	Diclofenac	2	N02BE01	Paracetamol
3	N02BE01	Paracetamol	3	R03AK07	Formoterol
4	N02AA59	Codeine, comb. Excl. phycholeptics	4	B02BD02	Coagulation factor VIII
5	B01AC06	Acetylic Acid	5	J05AX15	Sofosbuvir
6	N05CF01	Zopiclone	6	N07BA01	Nicotine
7	C10AA01	Simvastatine	7	M01AE01	Ibuprophen
8	R06AE07	Cetirizine	8	A02BC05	Esomeprazole
9	C07AB02	Metoprolol	9	R03BB04	Tiotropiumbromid
10	R05DA01	Ethylmorphine	10	N06BA04	Metylphenidate

* Ranked by number of users of POM, Source: NIPH/NorPD

** Ranked by sales from community pharmacies (excl. of hospital pharmacies and “H-prescriptions”).

Source: NPA

Table 2.6: Norway – Top 10 active ingredients in value in the in-patient sector, 2014

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.	n.a.	1	L04AB04	Adalimumab
2	n.a.	n.a.	2	L04AB01	Etanercept
3	n.a.	n.a.	3	L04AB02	Infliximab
4	n.a.	n.a.	4	L01XG02	Rituximab
5	n.a.	n.a.	5	L04AA27	Fingolimod
6	n.a.	n.a.	6	L04AB06	Golimumab
7	n.a.	n.a.	7	L02BX03	Aberatiron
8	n.a.	n.a.	8	L01XC03	Trastuzumab
9	n.a.	n.a.	9	L04AA23	Natalizumab
10	n.a.	n.a.	10	L04AB05	Certolizumab pegol

"H-prescriptions" included

Source: LIS

2.7 Market players

2.7.1 Industry

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

Biotechnological companies emerge in increasing numbers, such as in the cancer medicines area, neurological disorders, maritime and technical fields of industry.

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

- Legemiddelindustrien (Norwegian Association of Pharmaceutical Manufacturers, LMI) – research-orientated companies, with or without a generics portfolio and small-medium sized Norwegian biotech companies. In addition all pharmaceutical companies specialising in aquacultures are members. 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, with some minor exceptions, is done by a wholesaler. The main bulk of pharmaceuticals 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 2.7.3).

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

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 4.6 billion /€ 550 Mio.) in 2013 (LMI 2014).

In 2012, the pharmaceutical industry in Norway invested approximately NOK 1 billion / € 120 Mio. in science and development (LMI 2014).The industry has approximately 3,800 (LMI members) employees and contributes to the accumulation and diffusion of relevant scientific knowledge in hospitals and private business involved in science.

2.7.2 Wholesalers

There are three major wholesalers of medicines in Norway, each with their own pharmacy chain. They belong to the leading European pharmaceutical distribution companies. The companies are listed in the table below.

Table 2.7: Norway - Wholesalers, 2014

Company	Market share (%)	Ownership
Apokjeden Distribusjon AS	33.0	Tamro OY/Phoenix
Alliance Healthcare Norge AS	14.7	Alliance Boots Ltd
NMD AS	52.3	Celesio AG

Source: LMI and NPA

In general, pharmacies get supplies from the wholesalers on a daily basis. As of January 2015 the obligation on wholesalers that distribute to pharmacies, to sell the full range of medicines with market authorisation was omitted.

As of January 2015 Alliance Healthcare took over as wholesaler for hospitals and hospital pharmacies after NMD. The market share of the latter will therefore be lower from 2015 and higher for Alliance.

Parallel trade wholesalers do not exist per se, but the major wholesalers engage in parallel export. There are also 2-3 companies that specialise in parallel import.

2.7.3 Retailers

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

2.7.3.1 Community pharmacies

The pharmacies' activities are regulated by the Norwegian Pharmacy Act and the associated regulations on pharmacies. The 768 community pharmacies (as of January 2015) are privately owned. Until 2001 one had to be a pharmacist to own a pharmacy. Since 2001 anyone can own a pharmacy, but one has to be a pharmacist to run it. 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. A total of 84% of the private pharmacies are totally owned by a wholesale company.

Pharmacy chains are allowed. There are three vertical integrated pharmacy chains operating in Norway, owning a total of 643 pharmacies. In addition there is a chain of semi-independent pharmacies and a few independent pharmacies.

There are approximately 6,400 inhabitants per pharmacy (incl. hospital pharmacies, NPA).

The Norwegian Pharmacy Association represents the interests of the owners of the pharmacies. The Norwegian Association of Pharmacists represents the interests of the profession.

The pharmacies' margin for prescription-only medicines (POM) is regulated, but the total margin is not.

Subvention, according to specific criteria, can be applied for to operate pharmacies in rural areas to ensure accessibility to pharmacy. In addition, pharmacies may apply for 50% refund of freight costs when patients are too sick or have too long or burdensome journeys to the nearest pharmacy.

Mail orders or sale by Internet of POM from the pharmacy to the end-user, is allowed only in the geographical district of the pharmacy, whereas over-the-counter-medicines may be sold outside of the geographical district. The Government plans to alter the regulation in order to allow sale also outside of the geographical district. This will probably make sale by Internet more profitable for the pharmacies.

2.7.3.2 Dispensing doctors

Out-patient 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 a 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.

2.7.3.3 Hospital pharmacies

The hospital pharmacies are owned by the Regional Health Authorities. The 32 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 principal task of hospital pharmacies is to provide pharmaceuticals 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. The distribution to the hospitals (cf. section 4.2) is organized by a contract with one wholesaler.

2.7.3.4 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 about 900 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.

2.7.3.5 Other retailers

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. Staff handling the medicines is not allowed to give patients any kind of recommendation, nor to engage in marketing of the products. The legal basis for these outlets is Act on Medicinal Products § 16.

Table 2.7: Norway – Retailers of medicines 2000, 2005, 2010–2013

Retailers	2000	2005	2010	2011	2012	2013
No. of community pharmacies[1]	369	506	650	682	714	739
– *Thereof: No. of private pharmacies*[2]	369	506	650	682	714	739
– *Thereof: No. of public pharmacies*	0	0	0	0	0	0
No. of hospital pharmacies for out-patients	28	30	33	32	32	32
No. of dispensing doctors	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
No. of other POM disp.	n.appl.	n.a.	n.a.	n.a.	n.a.	≈900
Total no. of POM dispensaries						
No. of internet pharmacies	n.appl.	n.appl.	n.appl.	n.appl.	n.appl.	n.appl.
No. of OTC disp., like drugstores	0	7,000	7,000	7,000	7,000	7,000

Disp. = dispensaries, No. = number, OTC = over-the-counter medicines, POM = prescription-only medicines

POM dispensaries are facilities that are allowed to sell POM to out-patients

1hospital pharmacies dispensing to out-patients are not included in this figure

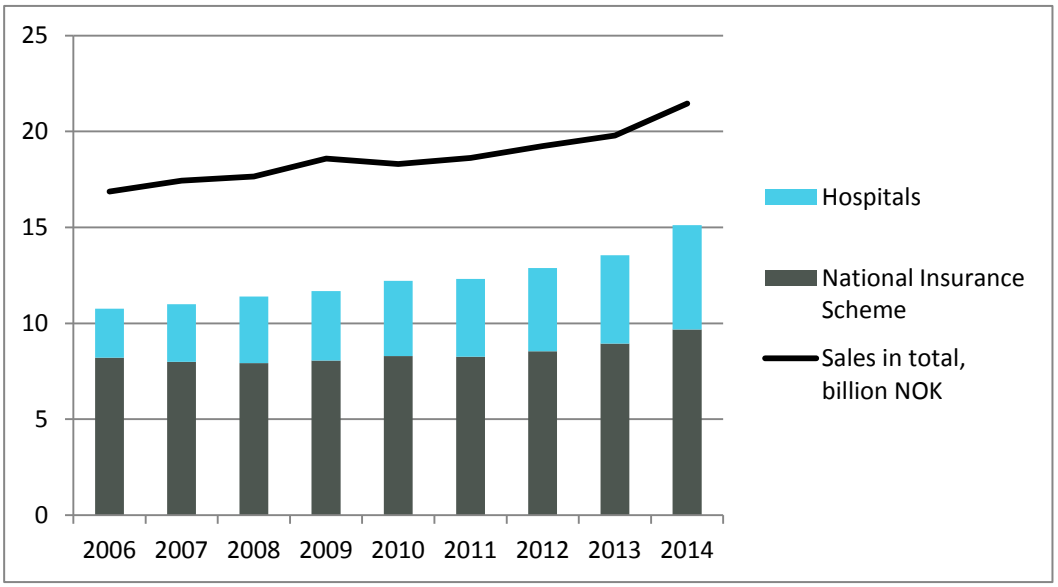
2Private pharmacies are pharmacies owned by private persons or entities; public pharmacies are in public ownership.

Data as of 1 January

Source: NPA

2.8 Pharmaceutical expenditure

Figure 2.4: Norway – pharmaceutical expenditure, 2006-2014



Sources: NPHI, Directorate of Health, Hospital Pharmacy Statistics

The increase from 2013 to 2014 is mainly due to changes of the exchange rate which has led to higher maximum prices. New medicines for treatment of hepatitis C, some types of cancer and anticoagulants also contribute to the growth.

The hospitals share of the funding has been increasing the latest years. This is due to transferral of funding from the NIS to the RHAs (cf. section 5.1) and the development of costly medicines for in-patient use.

Table 2.8: Norway – Total pharmaceutical expenditure 2006, 2008, 2010–2014

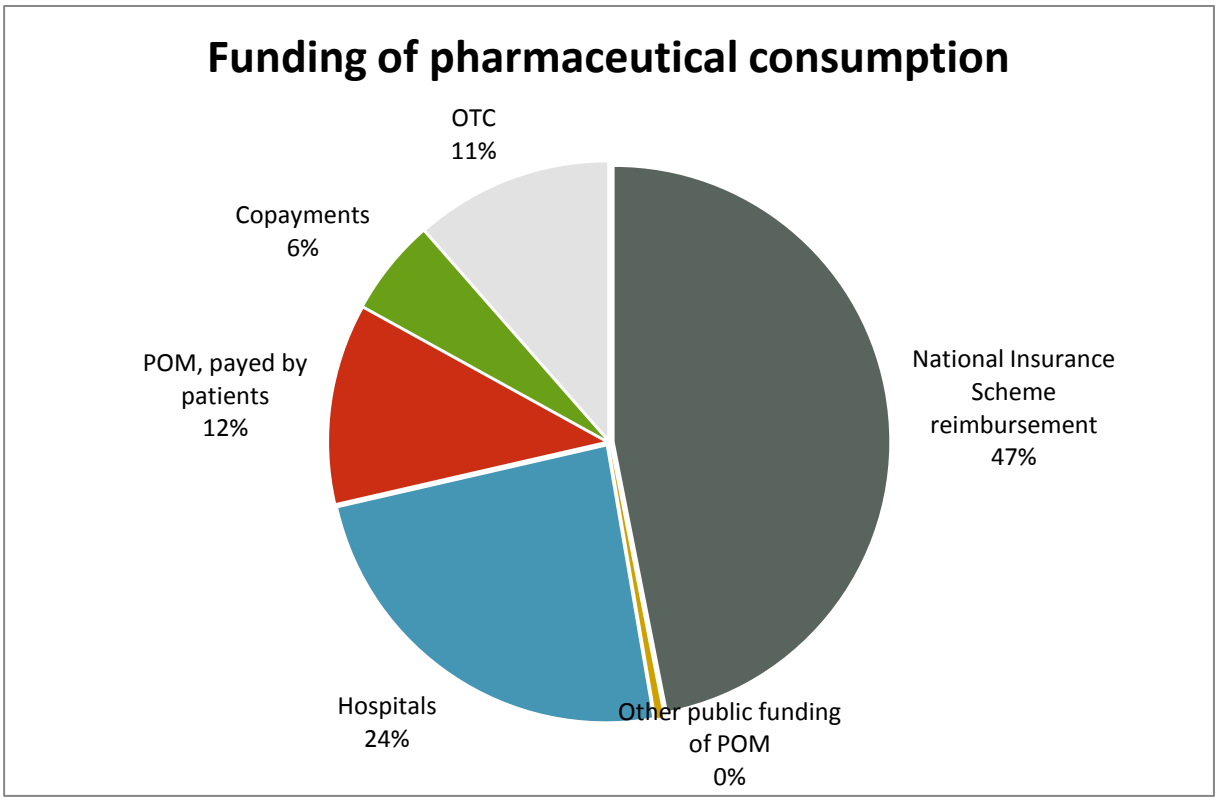
Pharmaceutical expenditure	2006	2008	2010	2011	2012	2013	2014
TPE in bill. NOK	16.9	17.7	18.3	18.6	19.2	19.8	21.5
- thereof National Insurance Scheme	8.2	7.9	8.3	8.3	8.5	9.0	9.7
- thereof Hospitals	2.6	3.5	3.9	4.1	4.3	4.6	5.4

TPE = total pharmaceutical expenditure, POM and OTC

Source: NPHI, Directorate of Health, Hospital Pharmacy Statistics

2.9 Sources of funding

Figure 2.5 Norway – Split of funding of medicines, 2013



Source: LMI/Farmastat

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

This section covers a description of the organisation of the pricing system and policies. It describes also the organisation of the reimbursement system, the reimbursement schemes, reference price system, private pharmaceutical expenses and the volume control mechanisms in the out-patient sector as of 2015.

3.1 Organisation of the out-patient sector

Refer to figure 2.2 and table 2.1 for an overview of the organization of the pricing and reimbursement systems in the out-patient sector.

3.2 Pricing of medicines

3.2.1 Pricing policies

All prescription-only medicines are given maximum prices by the Norwegian Medicines Agency (NoMA). NoMA sets maximum prices for all POM at the pharmacy purchasing price-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 in January 2005 to reduce costs incurred by the National Insurance Scheme and patients in relation to the use of generic medicines. In the model the price of a pharmaceutical product is reduced stepwise through predefined rates. This occurs after the pharmaceutical product has lost patent protection and hence is exposed to generic competition. The model has been modified three times after its introduction with the aim of reducing medicine prices. The latest change was implemented in January 2015.

Table 3.1: Norway - Overview of the stepped price system (Trinnprismodellen), 2015

Sales PRP, 12 months before generic competition		**< 100 Mio. NOK**	**> 100 Mio. NOK**	
	Time of price-cut			
1st step	Start of generic competition	35%	35%	
2nd step	6 months after generic competition	59%	81%	
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	69%	88%	90%

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 that patients pay for a pharmaceutical product that is incorporated in the system. NoMA publishes a list of substances that are included in the system and a list of their current prices[1].

The maximum reimbursement price for a generic substance is set as a percentage of the maximum pharmacy purchasing price (PPP) of the original medicine at the time it was exposed to generic competition. The price is cut by two or three steps. 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 maximum pharmacy mark-up (cf. section 3.2.4) is added to the reduced PPP. The reduction rates depend on the annual sale of the product prior to generic competition. There are specific cut rates for simvastatine and atorvastatine, 96 and 94% respectively. The NOMA may, on a discretionary basis, decide lower cuts than the standard cut rates. This is sometimes done when the turn-over of the substance is very low.

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 at 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 directly imported medicines. The stepped price system also applies to parallel traded medicines.

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

There is no regulation of prices at manufacturer level in Norway.

[1] www.noma.no

3.2.2 Pricing Procedures

There is external price referencing on all POM marketed in Norway. According to Regulation on Medicinal Products, § 12-2 the price decision should take into account the price of the pharmaceutical 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 2000. 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 the conversion.

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.

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 250 top-selling active ingredients on a yearly basis. This is to make sure that the price level in Norway stays at the right level compared to the reference countries. NoMA also revises several of the products that sell less to make sure that most prices will be revised at some point.

Normally prices will not be adjusted more often than once a year.

Table 3.2: Norway – Pricing procedures, 2015

Pricing procedure	In use: yes / no	Price type1	Scope2
External price referencing	Yes	Pharmacy purchasing price	All prescription only medicines for humans
Internal price referencing	Yes	Pharmacy retail price	Prescription only medicines with generic competition
Cost-plus pricing	No		
Indirect profit control	No		
Risk/cost sharing	No		
Price/volume agreements	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

3.2.3 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 negligible.

3.2.4 Remuneration of wholesalers and pharmacists

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. The scheme was revised as of the 1st of January 2014 and was made more regressive as the percentage for medicines with a PPP > NOK 200 was reduced from 4 to 3%. The fixed mark-up was increased from NOK 22 to 25.

Table 3.3: Norway – Pharmacy mark-up scheme, 2015

Pharmacy purchasing price in €	Maximum mark-up in % of pharmacy purchasing price
NOK 0 - 200 / € 0 – 24	7%
From NOK 200 / € 24	3%
	Fixed mark-up per package
All POM packages	NOK 25 / € 3
Additional for addictive drugs/narcotics	NOK 10 / € 1

Source: NoMA

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%.[2]

The wholesale mark-up is not regulated.

3.2.5 Taxes

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

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 retailers. The amount is not included in the price build-up. The tax is collected by the wholesalers who in turn pay the tax to the authorities. 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 Market Authorisation Holder.

There is a tax of 1.6% on sales in other retailers than pharmacies, such as grocery stores, gasoline stations etc, cf. section 2.7.5. The tax is paid by the wholesalers.

3.3 Reimbursement of medicines

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

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

3.3.1 Reimbursement policies

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.

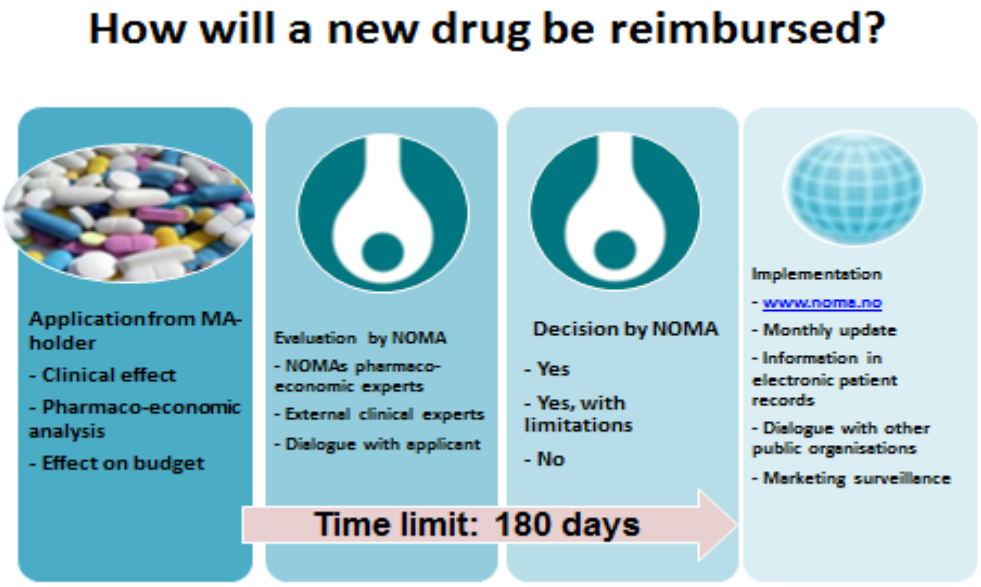
2. Principles concerning rationality:

   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.

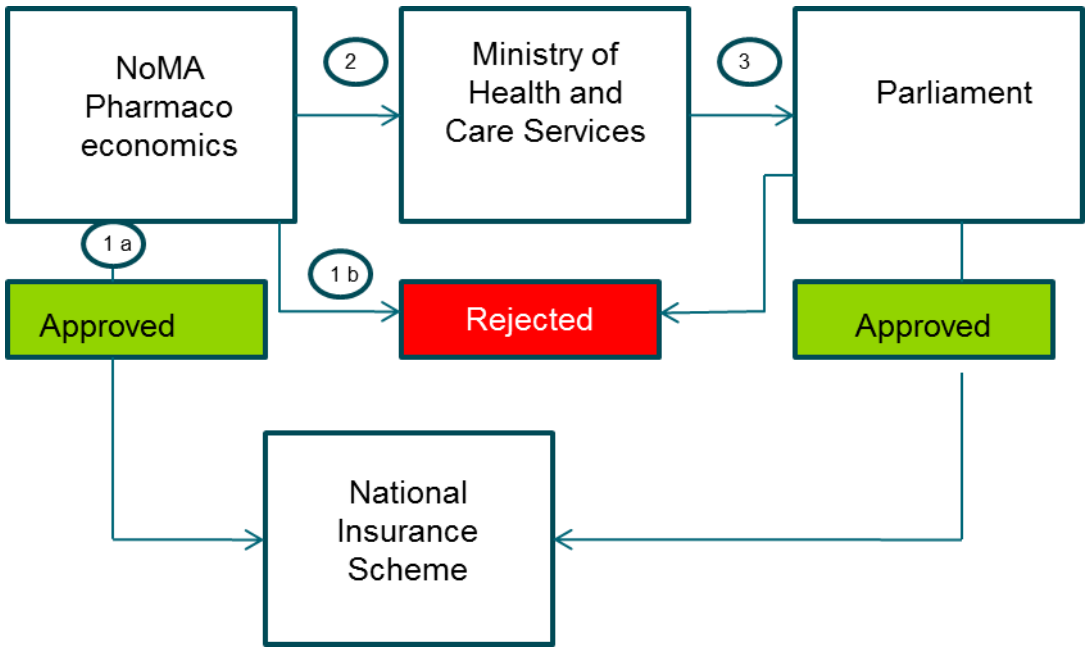
The main system is general reimbursement on the basis of positive lists. There is also a system for individual application.

3.3.2 Reimbursement procedure



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

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 2.2 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 NOK 25 Mio. / € 3.2 Mio. 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 (HOD) who will assess the matter further (cf. 2 in figure 3.1). 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). 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 3.1). The Budget Bill is voted on in the Parliament, and so far the Parliament has voted in favour of reimbursement in every case.

In 2014 the NoMA approved on 102 applications for reimbursement. In addition 5 cases exceeded the limit of NOK 5 Mio. / € 0.6 Mio. and were submitted to the HOD. The limit was however raised to NOK 25 Mio. / € 3 Mio. in 2015 and the 5 cases that had been submitted to the HOD were granted reimbursement. 1 application was rejected.

With a complete market authorisation for its product the marketing authorisation 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[3] 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.

- Pharmaceuticals with the same active ingredient as medicines for which reimbursement has already been granted, i.e.: generic pharmaceuticals, parallel imported preparations and preparations in new packaging. This holds under the condition that the 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.
- Pharmaceuticals 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.

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

[3] www.noma.no

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.

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 3.4). Schedule 2 requires that the medicine has been approved for reimbursement. Pharmaceuticals 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 73% of the total reimbursement expenditure of NOK 9.7 billion / €? arose from Schedule 2 in 2014. Schedule 3a and 3b accounted for respectively 14 and 6% of total reimbursement. Reimbursement by schedule 4 was 7% of total reimbursement. (Directorate of health)

Eligibility schemes

All members of the National Insurance Scheme are eligible for reimbursement, cf. section 1.4.

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. The list of reimbursable medicines and associated criteria is published on the NoMA website[4] as a searchable database on the web. The list is organized at the drug substance level and gives the subscriber precise information on the part of a drugs indication approved for reimbursement. The reimbursement indication is described both in text and according to two different diagnostic codes (ICD-10 and ICPC-2).

[4] www.noma.no

In the database, the search criteria can be the pharmaceutical's product name, the generic name, the ATC-code, the diagnostic code or the name of the disease it has been granted reimbursement for.

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 pharmaceutical'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.

Reimbursement categories and reimbursement rates

Table 3.4: Norway – Reimbursement categories of medicines, 2015

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, hepatitis C or HIV/AIDS.

1 Cf. section 3.3.3

Source: NoMA

Copayments are included in the cost-ceiling scheme that was introduced in the early 1980s. All copayments for consultations with specialists and general practitioners, for ambulatory care, X-rays, laboratory tests and medicines go under the ceiling. In 2015 the ceiling is NOK 2,185 / € 260[5]. 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 2012 approximately 29% of the population (age over 16) reached this ceiling (www.helfo.no).

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

[5] Exchange rate as of 5th of August 2014: 8,39 NOK per Euro

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. NOK 9.0 billion / €? were reimbursed on schedule 2 in 2014, for 2.3 million individual persons.

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 3.4.

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 3.4.

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. This implies that several medicines will achieve significant reimbursed sales before market authorisation in Norway, with no statutory maximum pharmacy purchasing price.

In 2014 NOK 1.3 and 0.6 billion / € 15.5 and 72 Mio. were reimbursed on schedule 3a and 3b respectively. 101,000 individuals received medicines reimbursed on schedule 3a. The corresponding figure for 3b was 16,000.

Pharmaceuticals for dangerous contagious illnesses – Schedule 4

A reimbursement system has also been established to ensure that all patients with serious communicable diseases are given adequate treatment without cost to the patient. There is no patient co-payment for these medicines and the patient does not have to be a member of the National Insurance Scheme. Medicines used to treat, e.g. HIV/AIDS, Hepatitis C or tuberculosis are reimbursed in this category. Also, vaccines against communicable diseases are reimbursed. All medicines with ATC-code L03A (immunostimulants) and most medicines within ATC-code J (i.e. antiinfectives for systemic use) 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.

Reimbursement of some new and expensive medicines against Hepatitis C was restricted as of November 2014. The patient must be a member of the National Insurance Scheme. The medicines must be prescribed by a specialist or a hospital department, and are only reim-

bursed on the basis of individual application. Criteria regarding severity, benefit and cost effectiveness were also introduced. Ribavirin and peginterferon are however still preapproved for reimbursement under schedule 4, also for non-members.

In 2014 NOK 0.7 billion / € 83 Mio. were reimbursed on schedule 4, regarding 35,000 individual persons.

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. The contribution system is valid for prescription only medicines. If a ceiling of NOK 1,732 / € 206 is reached, a patient can claim reimbursement for 90% of all further expenses. The system requires initial out-of-pocket payment (OPP). Receipts from the pharmacy serve to document the claim. In 2014 71 Mio. / € 8.5 Mio. were reimbursed by the contribution system (Directorate of Health).

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. 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.

For contraceptives for women of age 16-20 the contribution system covers a cost of NOK 108 / € 13 per three months. Infertility treatment is also subsidised as the NIS covers costs that supersede NOK 15,887 / € 1,900.

Reference price system

In Norway external price reference pricing is used for setting of maximum pricing. There is also reference pricing of medicines on generic substitution (the stepped price system). Cf. section 3.2.1. There is no therapeutic reference price system in place.

3.3.3 Private pharmaceutical expenses

In 2013 29% of the total pharmaceutical costs are covered directly by the patients. This number is derived from non-reimbursed prescription-only medicines (12%), OTC medicines (11 %) and patient co-payment of reimbursable medicines (6%). Cf. diagram in section 2.9.

Table 3.5: Norway – Out-of-pocket payments for medicines, 2015

Out-of-pocket payments	Amount	Vulnerable groups
Fixed co-payments	n.a.	-
Percentage payments	38%, max. NOK 520 / € 62 per prescription	Low-income pensioners and children under 16 are exempt
Deductibles	NOK 2,185 /€ 260	-
Reference price system	Price difference between stepped price and maximum price when patient refuses generic substitution.	-

Source: www.helfo.no

3.4 Volume control

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

Pharmaceutical budgets are not implemented in the out-patient sector.

3.4.1 Generic substitution

Generic substitution has been allowed in Norway since 2001. According to The Norwegian Pharmacy Association's survey "Apotekbarometeret" 72% of the consumers experienced a suggestion to generic substitution from a pharmacist in 2013. 8 out of 10 were positive or indifferent to this experience, whereas 2 out of 10 had a negative experience.

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 put a reservation on the prescription when substitution should be avoided for medical reasons. Doctors reserve against substitution for 7 – 8 % of the prescribed medicines (Hdir). 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 whole-

salers' 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).

The NoMA evaluates new pharmaceuticals on the norwegian market regarding their substitutability. If the pharmaceutical 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.[6]

3.4.2 INN prescribing

Doctors are allowed, but not obliged, to prescribe by INN. The system for electronic prescribing, which was implemented in 2011, facilitates INN prescription.

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

3.4.3 Other generic promotion

Pharmacies promote generic substitution for economic reasons. They do so by offering the generic at a lower price than the original product. The use of generic medicines is promoted by the authorities for cost-containment reasons. The NoMA informs about generic substitution in various ways to make prescribers and patients better understand the purpose of generic substitution. Information is distributed by NoMAs website, brochures to pharmacies, presentations in seminars/conferences and by interviews and articles in the media.

Due to generic substitution and the stepped price model NoMA assumes that the NIS and the patients save in all approximately NOK 2 billion / €? 238 mio. every year. These savings are substantial in view of the fact that the NIS reimbursed medicines for NOK 9.0 billion /€ 1,100 Mio. in 2013 (Directorate of Health).

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.

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

[6] www.noma.no

3.4.4 Claw-backs

Claw-backs are not used in Norway.

3.4.5 Managed-entry agreements

Managed-entry agreements are currently not used on the out-patient sector in Norway.

3.5 Evaluation

As stated in section 3.3.2, 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.

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 Norwegian Knowledge Centre for the Health Services performs health technology assessments. When relevant, they are considered for reimbursement decisions. The Centre publishes all HTAs on the website: http://www.kunnskapssenteret.no.

3.5.1 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 patient's journal.

The frequency and scope of NoMA's monitoring of prescribing may vary, depending on the importance of the measure and the expected value of new information. The preferred product-scheme for tiazides and statins were evaluated by external parties.[7]

Refer also to section 3.5.2 as the monitoring of prescriptions and consumption often overlaps.

[7] 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 www.kunnskapssenteret.no

3.5.2 Pharmaceutical consumption monitoring

The pharmaceutical consumption is monitored by the Norwegian Institute of Public Health Institute on a yearly basis, cf. to the report "Drug consumption in Norway"[8]. NIPH also produces an annual report based on the Norwegian Prescription Database[9].

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:

- LMI's "Facts and figures"[10]
- Norwegian Association of Pharmacies' "Facts and figures"[11]

3.5.3 Decision making tools

As stated in section 3.3.2 a pharmaco-economic evaluation in connection with applications for the reimbursement scheme has been mandatory since 1 January 2002. 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 has published guidelines for pharmaco-economic evaluations since 2002, latest revision in 2012.[12]

A medicine can obtain 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.

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 has published guidelines for assessment of societal effects in the health sector.[13]

[8] http://www.fhi.no/eway/default.aspx?pid=240&trg=Content_6899&Main_6664=6898:0:25,7586:1:0:0:::0:0&Content_6899=6689:112847::1:6891:2:::0:0

[9] http://www.norpd.no/BadUrlError.aspx

[10] http://www.lmi.no/tall-og-fakta

[11] http://www.apotek.no/Files/Filer_2014/B%c3%b8ker%20og%20brosjyrer/key%20figures%202015.pdf

[12] www.noma.no

[13] https://helsedirektoratet.no/statistikk-og-analyse/samfunnsokonomiske-analyser/veiledere-helseeffekter-i-samfunnsokonomiske-analyser

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

This section describes the organisation of the pricing system and policies in the hospital sector. It covers the reimbursement and the volume control and the reimbursement related cost-containing measures in the in-patient sector.

4.1 Organisation of the in-patient sector

Refer to chapter 1.2 for information about the organization of the in-patient sector. Refer also to figure 2.3 and table 2.1 for an overview of actors and legal basis for pricing and reimbursement.

Regarding organization of pricing and reimbursement in the specialized health care system, there are some features that differ from the general rule because the hospitals reimburse some medicines for treatment outside of the hospital. This concerns medicines prescribed on "H-prescriptions" and medicines for rehabilitation of drug-abusers.

Since 2006 doctors in specialized care have issued "H-prescriptions".[14] "H" stands for health enterprise. The medicine will be reimbursed by the health enterprise. The patient will collect the pharmaceutical in a community or hospital pharmacy. Until 2013 "H-prescriptions" have been used for TNF-inhibitors and MS-medicines and for about NOK 1.5 billion / € 180 mio. were reimbursed per year. From 2014 they are also in use for some cancer medicines. Cf. section 5.1 for more information.

In 2004 the main responsibility for treatment of substance abusers was transferred from the municipalities to the health enterprises. The abusers are however partly treated by general practitioners and partly by the health enterprises. The general practitioners may prescribe methadone and buprenorphine (incl. combinations) to users that have enlisted in a program for rehabilitation. In these cases the user may collect the medicine in any pharmacy, but the expenditure is reimbursed by the health enterprise. In 2013 medicines for NOK 208 Mio. /€ 25 Mio. were handed out to users by the pharmacies (www.reseptregisteret.no).

4.2 Pricing and purchasing policies

The main pricing policy in Norwegian hospitals is tendering.

The Norwegian Drug Procurement Cooperation (LIS) negotiates the pharmacy purchasing price on behalf of the hospitals. The Regional Health Authorities (RHAs) or sometimes

[14] Doctors in specialized care are either employed by the hospital or private specialists contracted by the health enterprises.

hospitals decide on or negotiate the pharmacy mark-up. Other discounts than the ones given in the tendering process are not common. As of June 2015 LIS has been merged with HINAS – a joint Procurement Organization of the RHAs. HINAS has since 2003 been responsible for procurement for the health enterprises of other goods than pharmaceuticals.

The wholesale services are subject to a separate tender. One wholesaler is selected for providing distribution services to the hospitals 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 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 5.4 / € 0.64 billion on medicines in 2014, including 25% value added tax (Meld. St. 28 (2014-2015).

LIS performs tenders on all pharmaceuticals financed by the hospitals. This 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 to the out-patient sector. 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 gave in 2014 a price reduction of 28% in average for the Norwegian hospitals, compared to the statutory maximum prices (for information on statutory prices c.f section 3.2). 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.

4.3 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[15] and TED[16] 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,
- 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. Smaller quantities are also bought by smaller hospitals from community pharmacies.

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

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

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

4.4 Reimbursement

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. 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. sections 1.2 and 1.4.

A major reason for growth in pharmaceutical expenditure of hospitals the last years is the transferral of the funding of products from the budget of the National Insurance Scheme (NIS) to the hospital budgets cf. section 5.1.

The share of private funding in specialized care is low. In 2013 it was 1.7 percent of total expenditure in specialized care[17].

There are no out-of pocket payments (OPP) for in-patient treatment. When patients are treated in the hospitals out-patient departments however, OPPs are required for consultations and medicines that are reimbursed by the NIS.

4.4.1 Hospital pharmaceutical formularies

There are no hospital pharmaceutical formularies in Norway.

4.4.2 Pharmaceutical and Therapeutic Committees

In almost every health enterprise there is a pharmaceutical and therapeutic committees (PTC). The PTCs consist of doctors from specialized 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 4.3. The lists are indicative to the doctor's choice of products and the doctor 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 pharmaceutical provided for in-patient care at the hospital.

[17] Statistics Norway

4.5 Volume Control in the in-patient sector

4.5.1 Monitoring

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

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 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. Prices of a few medicines on new and expensive cancer-drugs are however confidential, cf section 5.2.

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 3.5.2 for information on other statistics that also cover the in-patient sector.

4.5.2 Decision-making tools

Refer to chapter 5.2 for information about new system for introduction of new health technologies.

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 and can be downloaded from the website of the Council[18].

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

4.5.3 Evaluation of measures

Refer to section 5.2.

4.5.4 Reports and results

Refer to section 5.2 for information about new system for introduction of new health technologies. The reports are published at https://nyemetoder.no/metoder.

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

Reform for better interaction between primary and secondary healthcare systems

The Government is implementing a reform for better interaction between the primary and secondary healthcare systems.[19] The reform gives incentives to the municipalities to prevent disease and injury in their population. From 2012 a co-payment from the municipalities is required for some treatments in specialized healthcare. Municipalities 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 must also pay for patients who have finished their treatment at hospital and are waiting to be moved to their municipality. The municipality pays NOK 4000 / € 480 per extra day the patient stays in the hospital after treatment there is finished. NOK 5,000 Mio. / € 4 Mio. has been transferred from the hospitals budgets to the municipalities in order to fund their co-payment. The age of the population decides 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 within 2015.

The Government also aims at a gradual implementation of economic incentives for treatment of substance abuse and mental health care.

"H-prescriptions"

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 and lower prices.

[19] https://www.regjeringen.no/nb/tema/helse-og-omsorg/helse--og-omsorgstjenester-i-kommunene/samhandlingsreformen/status-samhandling/id708254/

In 2014 further medicines have been transferred from the NIS to the hospitals:

- Vemurafenib (Zelboraf), dabrafenib (Tafinlar) and trametinib (Mekinist) for treatment of malign melanom
- Abirateronacetat (Zytiga) (prostatakreft) and enzalutamide (Xtandi) for treatment of prostate cancer
- Rituksimab (MabThera) for treatment of Non-Hodgkins lymphome, trastuzumab (Herceptin) for metastatic breast cancer, tocilizumab (RoActemra) for rheumatoid arthritis and denosumab (Xgeva) for bone metastases.

The Government has also delegated to the Directorate of Health to decide on further transfers.

The aforementioned medicines are prescribed on “H-prescription”, cf. sections 2.2 and 4.1.

5.2 Developments

National system for introduction of new health technologies

A national system for the introduction of new health technologies within the specialist health service has been implemented in 2013-2014.[20] The purpose of this system is to promote better and safer patient care. This will be made possible through the systematic assessment of new health technologies with regard to effect, safety and consequences for patients, the health service and society in general.

The key elements of the new system are:

- Horizon scanning
- Health technology assessment
- Prioritisation and decision making
- Implementation

The systematic introduction of new pharmaceuticals within the specialist health service will be carried out as health technology assessments (HTAs) or single technology assessments (STA). The HTAs will be conducted by the Norwegian Knowledge Centre for Health Services.

An STA is an appraisal of a single pharmaceutical in relation to a particular area of use/indication, at an early stage. The NoMA will conduct the STAs on a national level.

The Regional Health Authorities (RHA) commissions the STAs from NoMA. The RHAs have established a Forum for the commissioning. Stakeholders will be encouraged to submit proposals on potential topics for consideration. The RHA Forum will then prioritise and decide which assessments should be carried out. Since the start in 2013 the NoMA has

[20] https://nyemetoder.no/english

completed 16 assessments (by April 2015), mostly concerning medicines for cancer or multiple sclerosis.

The assessments have in average been completed in 156 days (the time-limit is 180 days).

After the assessments are finished, they are taken into consideration by the RHAs to decide on whether or not, and under which circumstances, the medicine will be used at the hospitals. The assessments also serve as an input to price negotiations.

Electronic prescription and decision support

In 2010 deployment of a system for electronic prescription started. It enables NoMA to provide information to the prescribers and other health care providers. The prescribers get information about the medicines, conditions that have to be fulfilled for the pharmaceutical to be reimbursed and prices via the electronic patient record system. Nearly all general practitioners and all pharmacies use the system. Other parts of the municipal health and care services will soon become users: dentists, public health nurses and midwives. Some hospitals have adopted the system, whereas all other hospitals are planning to implement it within 2016.

6 Bibliography

6.1 Literature

All references to articles, publications e.g. are included in the text in chapter 1 - 5.

6.2 Legislation

Refer to section 1.2.

6.3 Web links

Relevant web links are included in the text in chapter 1 – 5.