

PPRI Pharma Profile

Norway 2018



PPRI Pharma Profile Norway

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Disclaimer

The data provided in this document by the members of the PPRI network and other authors represent the current situation. The data have no legally binding value and are meant especially for the information of PPRI network members who are committed to sharing information on pharmaceutical pricing and reimbursement.

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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 (IHII) 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 2018 is designed to comprise up-to-date information as of 2018 (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 46 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.¹

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 (since 2016: Pharmacoeconomics Department) of the Austrian Public Health Institute (GÖG) was nominated as WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies in summer 2010 and redesignated in 2014 and 2018. 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 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.

Since Sept. 2016 the Centre is located at the Pharmacoeconomics Department of the Austrian Public Health Institute (GÖG).

¹ Cf. http://whocc.goeg.at/Literaturliste/Dokumente/FurtherReading/EAHC_NFP_EUHealthProgramme_ImpactProjects.pdf.

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List of abbreviations

AI	Active Ingredient
ATC	Anatomic therapeutic chemical classification
EMA	European Medicines Agency
EU	European Union
INN	International Non-proprietary Name
GDP	Gross domestic product
GP	General practitioner
HELFO	Norwegian Health Economics Administration
HOD	Ministry of Health and Care Services
HTA	Health technology assessment
HE	Health expenditure
LIS	The Norwegian Drug Procurement Cooperation
LMI	Norwegian Association of Pharmaceutical Manufacturers
LUA	Medicines sold outside of the pharmacies
NCU	National currency unit
NIS	National Insurance Scheme
NIPH	Norwegian Institute of Public Health
NoMA	Norwegian Medicines Agency
NorPD	The Norwegian Prescription Database
NPA	The Norwegian Pharmacy Association
MA	Marketing Authorisation
Mio.	Million
OECD	Organisation for Economic Co-operation and Development
OPP	Out-of-pocket payment

OTC	Over-the-counter medicine
PHIS	Pharmaceutical Health Information System
POM	Prescription-only medicine
PPP	Pharmacy Purchase 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, 2015–2017

Demography	2000	2005	2010	2015	2016	2017
Total population*	4,503,436	4,640,219	4,920,305	5,213,985	5,258,317	5,295,619
Population aged 0-14*	902,431	906,811	921,709	933,955	937,710	938,934
Population aged 15-64*	2,922,179	3,050,939	3,256,353	3,424,930	3,445,785	3,460,260
Population aged > 64*	678,826	682,469	742,243	855,100	874,822	896,425
Life expectancy at birth	78.7	80.2	81.0	82.2	82.4	82.6
Life expectancy at age 65	83.0	84.0	84.5	85.2	85.4	85.5

*1st of January following year

Source: Statistics Norway

The population of Norway reached 5.3 Mio. in 2017. This corresponds to an average of ca. 16 people per km². 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 2017, the average life expectancy was 80.9 years for men and 84.3 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 2017 was 40,774. Malign tumours are now the leading cause of deaths, accounting for approximately 27% (2016) of the total. There has been a significant reduction in mortality due to lower rates of diseases of the circulatory system since the 1970s, with a death rate slightly below the one due to malign tumours (almost 27%). Diseases in the respiratory system accounted for 11% (2016).

1.2 Organisation of the health care system

The Norwegian health care system has developed gradually in the context of welfare policy, where equality and fairness have been highly valued. The health care system has also benefited from a strong national economy.

Following from this welfare policy, membership of the state-owned National Insurance Scheme (NIS) is mandatory and universal. The NIS covers retirement pensions, disablement benefits,

sickness benefits, unemployment benefits and health care, including pharmaceuticals. 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

The health care system is predominantly financed by taxes, and mostly publicly owned. However, it also includes contracts with private agencies and financing by private health care insurances. In 2016, about 10% of the Regional Health Authorities (RHAs) cost was used for purchase private health care services, e.g. private hospitals.²

There are three levels in the Norwegian health care system: 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 RHAs and the 422 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 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.

Norway’s four RHAs are responsible for the financing, planning and provision of specialist care. This includes somatic care and mental health care services as well as care services for substance abusers, along with other specialist medical services, such as laboratory-based work, radiology and paramedical services. Some of those services include prescriptions of medicines dispensed by community pharmacies (“H-prescriptions”). Financing responsibility of specialist care therefore includes in-patient, but also some outpatient expenditures. (Cf. section 4.1 and 5.1) There are 26 health enterprises under the four RHAs.³ The RHAs fund the health enterprises, which in turn fund the local hospitals. The hospitals are remunerated by a mixture of

² <https://www.ssb.no/helse/artikler-og-publikasjoner/en-av-ti-driftskroner-gar-til-kjop-av-tjenester-fra-private>, July 2018.

³ <https://web.archive.org/web/20100328222704/http://www.regjeringen.no/nb/dep/hod/tema/sykehus/sykehus-i-norge-3.html>, July 2018.

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.⁴

The 422 municipalities are responsible for the provision and funding of primary health care and social services (usually referred to as “out-patient”). All citizens are entitled to health care services, and to be listed on a “patient-list” of GPs, contracted by the community. Citizens may then consult their GP for primary health care. The municipalities are in charge of contracting GPs in their community. Remuneration of the contracted general practitioners, administered by the Norwegian Health Economics Administration HELFO on behalf of the municipalities, depends on the number of patients listed, the activities undertaken for primary health care, as well as a certain out-of-pocket payment.⁵ In 2017, there were 4,759 contracted GPs. Each contracted general practitioner had 1,106 patients listed on average (1,120 in 2016).⁶

The Directorate of Health has received the mandate to administer interface management and financing decisions for coordination of specialist care and primary care, cf. section 5.1.

Dental care is part of the counties’ responsibilities.⁷

⁴ <https://helsedirektoratet.no/Lists/Publikasjoner/Attachments/1265/Innsatsstyrt%20finansiering%202017%20IS-2568.pdf>, July 2018.

⁵ <https://lovdata.no/dokument/SF/forskrift/2012-08-29-842>; August 2018.
<https://www.regjeringen.no/no/tema/helse-og-omsorg/helse--og-omsorgstjenester-i-kommunene/innsikt/fastlegeordningen/id115301/>, August 2018.
<https://helfo.no/helseaktor/kommuner-og-fylkeskommuner/kommunen-og-legetjenesten/kommunen-sitt-ansvar-for-legetenesta>; August 2018.
<https://helfo.no/>; August 2018.

⁶ <https://helsedirektoratet.no/statistikk-og-analyse/fastlegestatistikk>, August 2018.

⁷ <https://www.kartverket.no/Kunnskap/Fakta-om-Norge/Fylker-og-kommuner/Tabell/>, July 2018.

1.3 Health expenditure

Table 1.2: Norway – Health expenditure 2000, 2005, 2010, 2015-2017

Health expenditure in NCU = NOK, mill.	2000	2005	2010	2015	2016	2017
GDP	1,507,886	1,988,942	2,593,739	3,018,166	3,177,032	3,299,005
THE	124,728	176,984	239,730	315,207	327,309	342,059
- thereof public HE, %	82.5	83.5	84.7	85.5	84.8	85.0
- thereof private HE, %	17.5	16.5	15.3	14.5	15.2	15.0
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 specialist care 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	8.95	9.29	9.32

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

Source: Statistics – Norway, European Central Bank

According to OECD, Norway's spending on healthcare was 10.4% of GDP in 2017, of which the public share amounted to 8.8 % and the private share to 1.6%.⁸

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), the Regional Health Authorities (RHA) and private expenditure. The Norwegian health care system is primarily funded by taxes, with some out-of-pocket payments.⁹ Further, dental care is mainly funded by private expenditure. There is no specific health tax in Norway, and the RHAs cannot draw taxes themselves.

All residents of Norway or people working in the country are insured under the NIS, which is run by the 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.

⁸ <https://data.oecd.org/healthres/health-spending.htm>, July 2018.

"Private share" includes e.g. households' out-of-pocket payments, NGOs and private corporations.

⁹ Compare also chapter 2.9.

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

Private funding and health insurances have been gaining in importance over the past years. According to an annual survey, 44% of Norwegians would consider paying more for having access to faster and easier access to health care.¹⁰ OECD numbers imply that 17% of total spending on healthcare is private (cf. chapter 1.3). For instance, in 2016, about 9% of the population have a private health insurance, often paid by the employer.¹¹

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

¹⁰ KantarTNS Helsepolitisk barometer 2018.

¹¹ <https://www.nrk.no/norge/nesten-en-halv-million-nordmenn-har-privat-helseforsikring-1.12967399>Norway, July 2018.
www.vg.no/Finance Norway, July 2018.

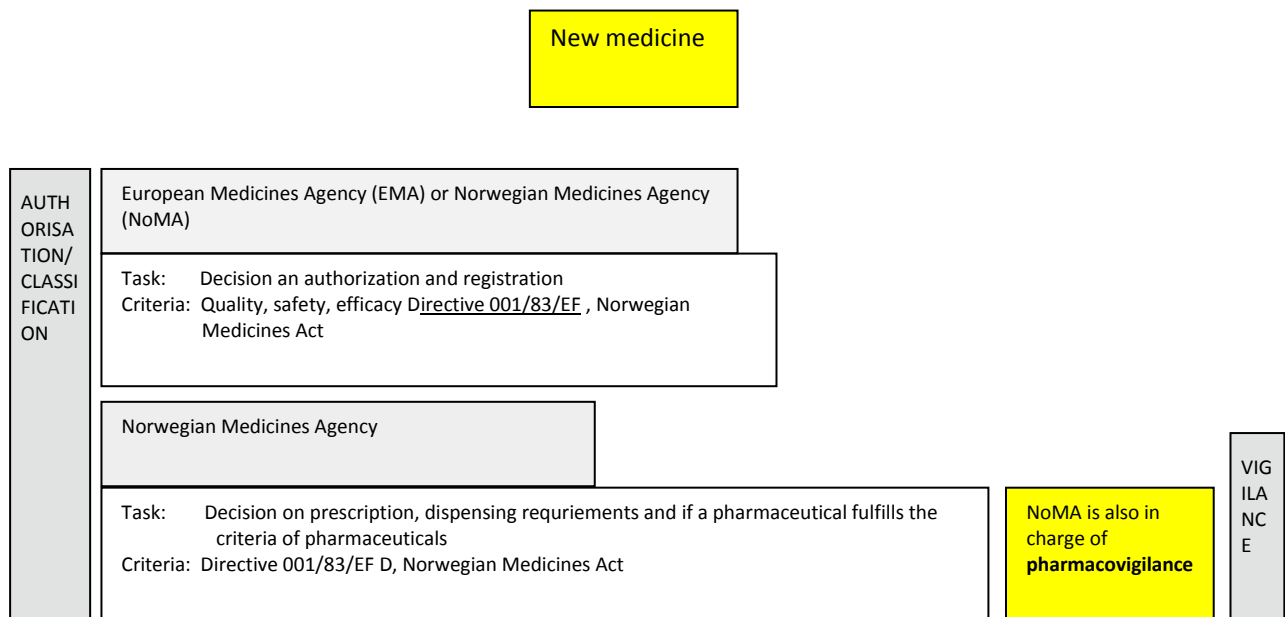
2 Pharmaceutical system

This section provides a description of the pharmaceutical system; its organisation, regulatory framework and authorities, availability and access to medicines, pharmaceutical expenditure, the market players and the funding of the system for the primary care (major part of “out-patient” care) and specialist care (“in-patient”, including some out-patient care) sectors, cf. section 4.1 and 5.1.

2.1 Organisation of the pharmaceutical system

Norway, as part of the European Economic Area, adheres to European Union’s (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, 2018



Source: NoMA

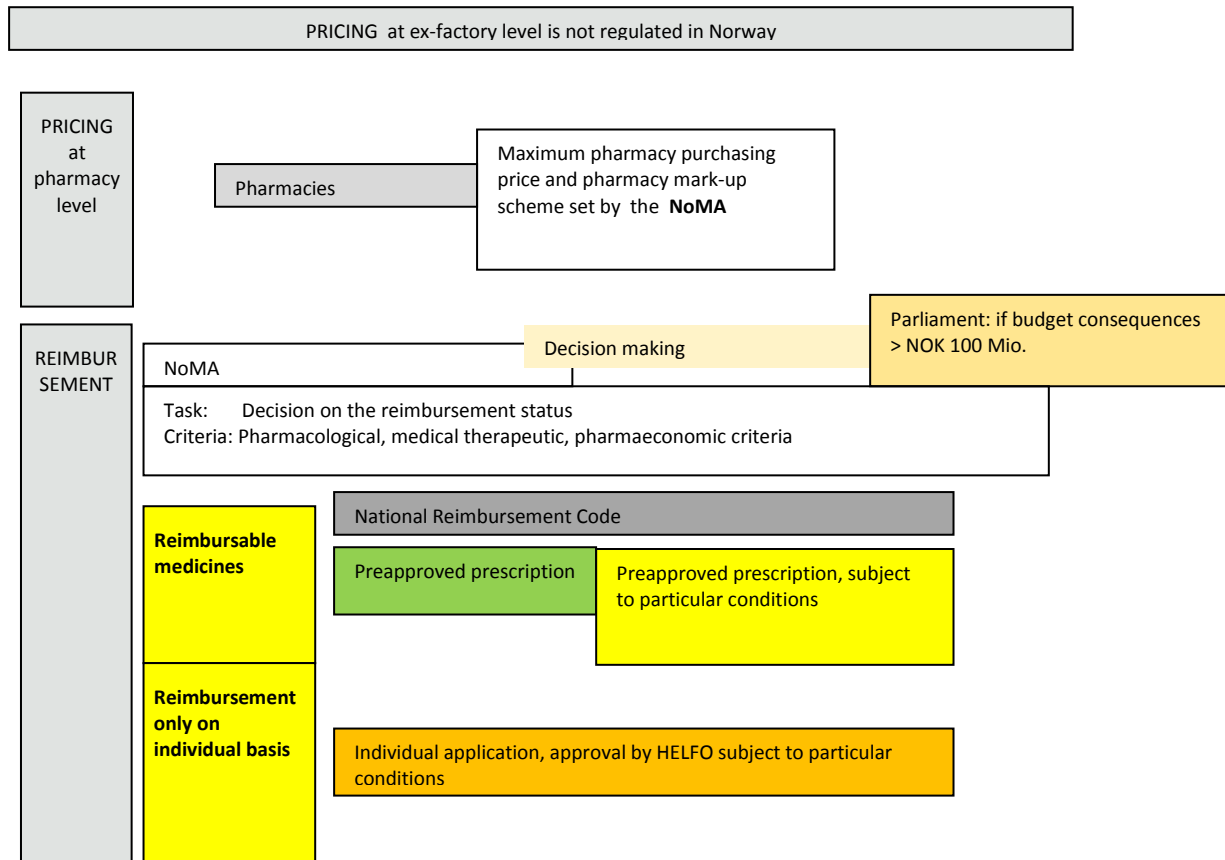
The EU-regulations regarding MA do not differ between medicines for primary and specialist care, and the NoMA is responsible for MA for both sectors, cf. figure 2.1.

The Norwegian system for pricing and reimbursement of medicines 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.

The definitions “out-patient” and “in-patient” are not relevant for describing the health system in Norway. Instead, the two sectors are defined as primary care, and specialist care. Some

medical “out-patient” medicines, so-called, H-prescriptions, are reimbursed by the specialist care sector (the RHAs), but are dispensed in community pharmacies (cf. section 4.1 and 5.1).

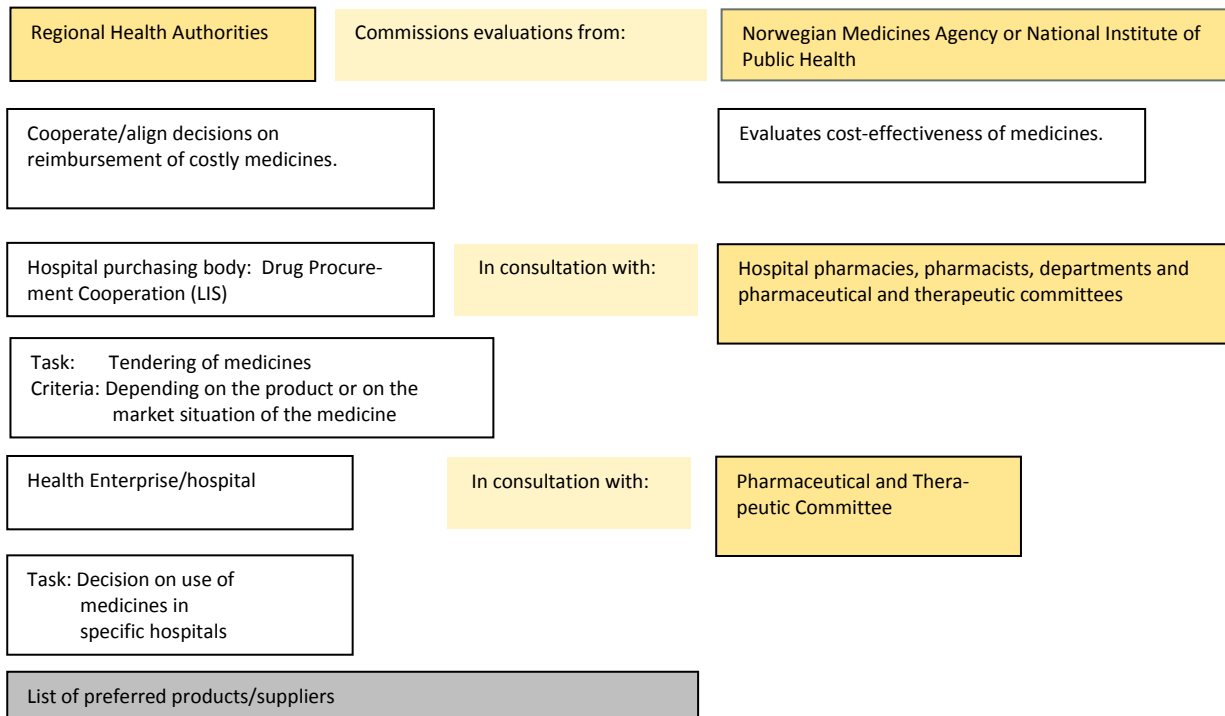
Figure 2.2: Norway – Flowchart of pricing and reimbursement in primary care sector, 2018



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. HELFO also undertakes reimbursement payments to pharmacies and patients for medical services covered by the Regional Health Enterprises, if applicable.

Figure 2.3: Norway – Flowchart of pricing and reimbursement in the specialist care sector, 2018



Source: NoMA

Table 2.1: Norway – Legal basis and actors of the pharmaceutical system, 2018

Fields	Legal basis	Scope (specialist care, primary care sector)	Authorities in English (local name, , local abbreviation)	Activity / responsibility in the pharmaceutical system	Actors and interest associations in English (local name, local abbreviation)
Marketing authorisation	The Norwegian Act on Medicinal Products Norwegian Regulation relating to Medicinal Products	Specialist & primary care sector. All registered/licensed pharmaceuticals (POM, OTC).	The Norwegian Medicines Agency (Statens legemiddelverk, SLV)	In charge of marketing authorisation, classification and pharmaco-vigilance.	Norwegian Association of Pharmaceutical Manufacturers (LMI)
Pricing / Purchasing	The Norwegian Act on Medicinal Products. Norwegian Regulation relating to Medicinal Products	All registered POM. Specialist care	The Norwegian Medicines Agency (Statens legemiddelverk, SLV) LIS (Sykehusinnkjøp)	In charge of pricing.	LMI Norwegian Pharmacy Association
Reimbursement	The Norwegian Act on Medicinal Products. Norwegian Regulation relating to Medicinal Products The Specialist Health Care Services Act - 1999 The Patients Rights Act – 1999	Primary and secondary care Primary care sector: Registered POM (and some OTC) pharmaceuticals. Specialist care	Directorate of Health Norwegian Health Economics Administration (HELFO) The Norwegian Medicines Agency Regional Health Authorities/Health Enterprises	Deciding financing-responsibility: primary or specialist care In charge of reimbursing. Subordinate of The Directorate of Health (Helsedirektoratet) In charge of deciding reimbursement-status in the primary care sector In charge of deciding reimbursement-status in the specialist care sector	LMI Patient organisations

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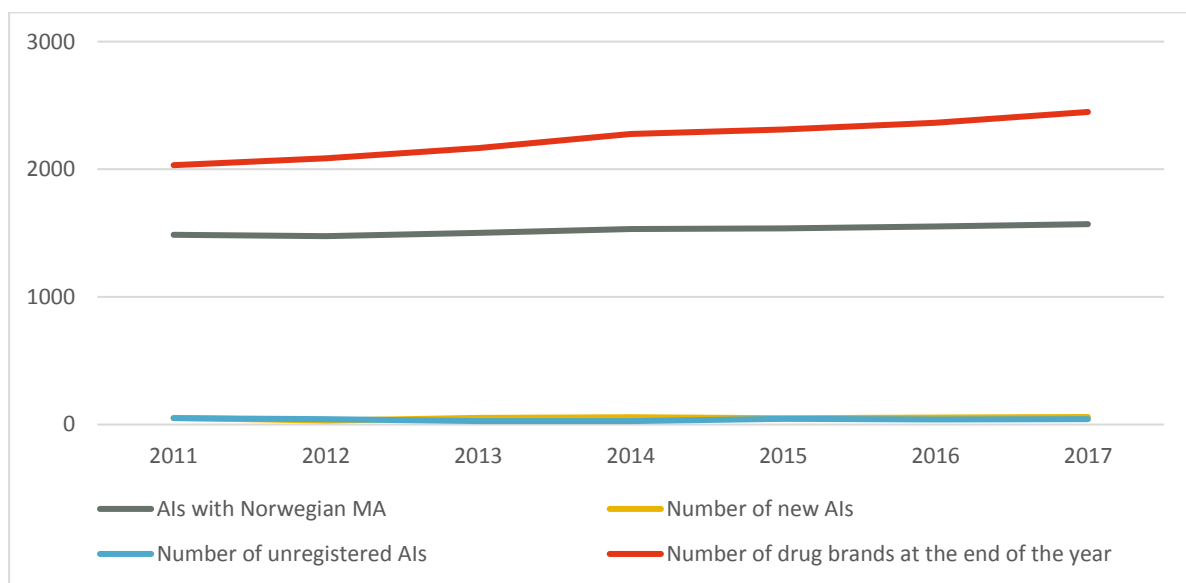
Fields	Legal basis	Scope (specialist care, primary care sector)	Authorities in English (local name, , local abbreviation)	Activity / responsibility in the pharmaceutical sys- tem	Actors and interest associa- tions in English (local name, local abbrevia- tion)
Promotion	The Norwegian Act on Medicinal 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
Distribution	The Norwegian Act on Medicinal Products. Regulation on wholesalers	All market players in the distribution chain	The Norwegian Medicines Agency (Statens legemiddelverk, SLV)	In charge of supervising importers, wholesalers and pharmacies.	Wholesalers, Pharmaceutical Wholesalers Association (Legemiddelgrossist-foreningen)
Vigilance	The Norwegian Act on Medicinal Products. Norwegian Regulation relating to Medicinal Products	MA-holder	The Norwegian Medicines Agency (Statens legemiddelverk, SLV)	In charge of pharmaco-vigilance.	LMI

Source: NoMA

2.2 Availability of and access to medicines

The number of approved medicines in Norway is increasing. As of 2018, there were 1,570 active ingredients (AI) registered in Norway. In 2017, 59 new AIs have been registered, while 41 have been unregistered. The AIs are distributed across 2,449 different (brand) names, including all strengths, package sizes and dosage forms.

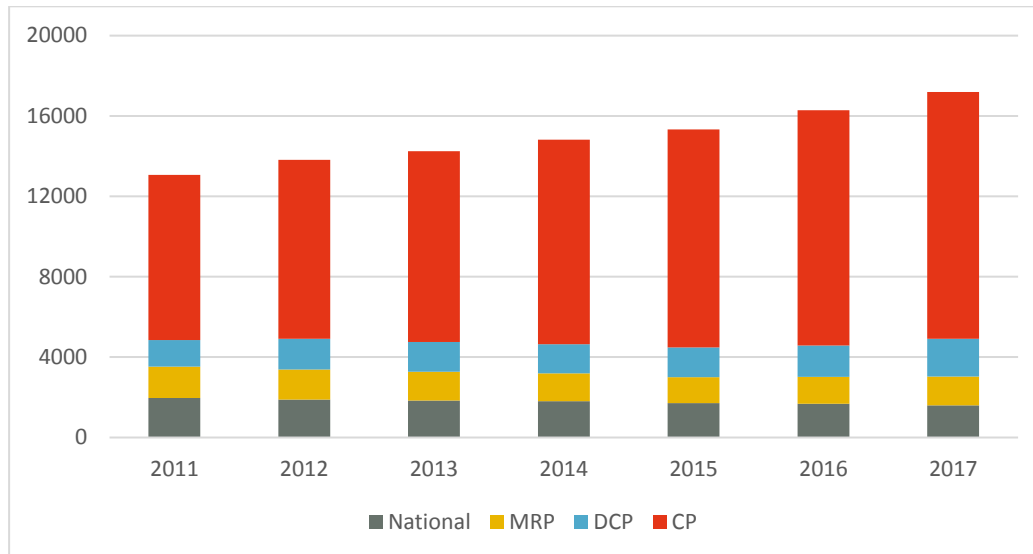
Figure 2.4: Norway - Number of approved active ingredients and drug brands



Source: NoMA

«Unregistered AIs» are active ingredients without approved Marketing Authorisations (MA). The registered and unregistered AIs and drug names are distributed on 16,294 approved MAs in 2017. Of these, 11,710 have been approved via Central Procedure, 1,571 via Decentral Procedure, 1,340 via Mutual Recognition Procedure and 1,673 via National Procedure.

Figure 2.5: Norway - Number of Marketing Authorisations at the end of the year - per procedure



Source: NoMA

The time it takes from a new medicine is granted a MA, to it actually being available on the market, varies a lot. Some products that are granted a MA are never launched on the Norwegian 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 for applications for a maximum price was 39 days in 2017 (maximum processing time: 90 days). In the same year, the average time for applications for general reimbursement was 68 days (including generics). 93% of those applications were processed within 180 days.¹²

2.3 Development of the pharmaceutical sales

The number of prescriptions in Norway has been steadily increasing in the past years. Between 2015 and 2017, prescription volume increased with ca. 8%, while prescription value has increased by more than 16%.

Along with prescriptions, spending on pharmaceuticals has been steadily growing in the past years. Between 2013 and 2017, spending on pharmaceuticals has increased by 40% (PPP).¹³ Particularly novel drugs for treatment of HIV, cancer and rare diseases have contributed to higher cost. In addition, the ageing population contributes to an increased use of pharmaceuticals.

¹² SLV Årsrapport 2017.

¹³ <https://fhi.no/nyheter/2018/legemiddelkostnadene-har-okt-med-40-prosent-pa-fire-ar/> September 2018.

Table 2.2: Norway – Annual prescriptions in community pharmacies 2005, 2010, 2015–2017

Prescriptions	2005	2010	2015	2016	2017
No. of prescriptions (in volume)*	30,658	32,640	51,824*	54,158*	56,139*
Prescriptions in value (PRP) ** (Mil. NOK)	13,199	13,118	16,874	18,348	19,624

PRP = pharmacy retail price incl. VAT

*Prescription in volume = number of prescriptions settled in pharmacies, human and veterinary. Source: NPA

**Prescription in value = public expenditure of prescribed medicines (including H-prescriptions). Source: NorPD

*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 2015 79%, and in 2016 83%. The number of prescriptions 2011 – 2017 is therefore not comparable.¹⁴

The figures also include “H-prescriptions”. These are prescriptions that are reimbursed by the Regional Health Authorities (RHA), cf. section 4.1. In 2017, 0.4% of the prescriptions were “H-prescriptions”. The medicines on “H-prescriptions” are rather costly, and their value (PRP) in 2017 was NOK 4.2 billion, approximately 17.1% of the value of total prescriptions.¹⁵

Norway introduced a pricing regime linking national prices to other European countries in 2002. Also, generic prices have decreased over the time due to the “step-price” system for generics, introduced in 2005 (cf. section 3.2). Further, the use of a “preferred product” system is one tool that has been put into use, cf. section 3.3.1.

Important steps towards cost-containment for reimbursable medicines have been taken. One important step has been the establishment of the Norwegian Drug Procurement Cooperation (LIS), centralizing procurement for the RHAs, as well as further interface management: Financing of several medicines that often are dispensed in public pharmacies, but prescribed in hospitals (H-prescriptions), have been allocated from primary care (NIS) to specialist care (RHAs). Financing of some medicines are still to be moved (C.f. section 4.1).

Parallel import in 2017 was 3.0% of the total volume (POM, packages) and 2.7% of value, and almost constant since 2007.¹⁶

¹⁴ NPA 2018.

¹⁵ See above.

¹⁶ Farmastat/LMI tall og fakta 2018.

2.4 Pharmaceutical consumption

The sales volume measured in number of DDDs increased by 2.2% in 2017. Sale in DDDs has been relatively constant the latest 10 year period.

Table 2.3: Norway – Annual pharmaceutical consumption 2005, 2010, 2015–2017*

Consumption (mio.)	2005	2010	2015	2016	2017
In packs	81.1	84.7	92.3	94.7	96.5
In DDD**	2230.1	2582.4	2868.2	2955.9	3019.6
In packs	n.a.	n.a.	n.a.	n.a.	n.a.
In DDD	n.a.	n.a.	n.a.	n.a.	n.a.
In packs	n.a.	n.a.	n.a.	n.a.	n.a.
In DDD	n.a.	n.a.	n.a.	n.a.	n.a.

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

*Including sales of products with approved marketing authorisation in Norway, excluding sales of veterinary medicines.

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

Source: Norwegian Drug Wholesales Statistics, NIPH

2.5 Generics

Generic substitution in pharmacies was implemented in 2001. Since then, the volume share of generics has been increasing until reaching about 70% of the substitutable market today.

Table 2.4: Norway – Development of the generic shares in volume and value, 2013, 2017

Generic share	Volume - DDD		Value (PPP)	
	2013	2017	2013	2017
Shares in % of substitutable market	70	71	47%	56%
Shares in % of total primary care market	n.a.	n.a.	n.a.	n.a.
Shares in % of primary care reimbursement market	n.a.	n.a.	n.a.	n.a.
Shares in % of primary care off-patent market	n.a.	n.a.	n.a.	n.a.
Shares in % of the specialist care market	n.a.	n.a.	n.a.	n.a.

Source: LMI

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

Novel oral anticoagulants have increased in sales in the past years, with two of them leading list of the top-10 AI in value in 2017 in the primary care sector. Off-patent medicines are those leading the list in terms of volume, with two statins among the top-three.

*Table 2.5: Norway – Top 10 active ingredients in volume and value in the primary care sector, 2017**

Position	Top active ingredients used in the primary care sector, ranked with regard to consumption** 2017		Position	Top active ingredients used in the primary care sector, ranked with regard to expenditure 2017	
1	C10AA05	Atorvastatin	1	B01AF02	Apixaban
2	B01AC06	Acetylic Acid	2	B01AF01	Rivaroxaban
3	C10AA01	Simvastatin	3	R03AK07	Formoterol
4	R06AE07	Cetirizine	4	N06BA04	Ritalin
5	A01AA01	Natrium fluoride	5	R03AK06	Salmeterolxinafoat, Flutika-sonpropionat
6	N02BE01	Paracetamol	6	C07AB02	Metoprolol
7	C08CA01	Amlodipin	8	R03BB04	Tiotropium bromide
8	C09Ca06	Kandesartan	8	C10AA05	Atorvastatin
9	C09AA05	Ramipril	9	G04BE08	Tadalafil
10	N05CF01	Zopiklon	10	N02AJ06	Paracetamol

** Ranked by DDD

Source: NPA, NIPH

Table 2.6: Norway – Top 10 active ingredients in volume and value in the specialist care sector, 2017

Position	Top active ingredients used in the specialist care sector, ranked with regard to consumption		Position	Top active ingredients used in the specialist care sector, ranked with regard to expenditure	
1	n.a.	n.a.	1	L04AB04	Adalimumab
2	n.a.	n.a.	2	L04AX04	Lenalidomid
3	n.a.	n.a.	3	L04AA27	Fingolimodhydroklorid
4	n.a.	n.a.	4	L01XC18	Pembrolizumab
5	n.a.	n.a.	5	L04AB05	Certolizumab pegol
6	n.a.	n.a.	6	L04AB02	Infliximab
7	n.a.	n.a.	7	L04AB01	Etanercept
8	n.a.	n.a.	8	J05AP55	Sofosbuvir, Velpatasvir
9	n.a.	n.a.	9	L01XC02	Rituksimab
10	n.a.	n.a.	10	J06BA02	Immunglobulin, normalt (humant)

“H-prescriptions” included (c.f. chapter 4.1)

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 representative organisation is Legemiddelindustrien (Norwegian Association of Pharmaceutical Manufacturers, LMI). It represents research-orientated companies, often also with a generics portfolio, and small-medium sized Norwegian biotech companies. In addition, all pharmaceutical companies specialising in aquacultures are members. The Norwegian Association of Generics orientated Pharmaceutical Manufacturers (Norsk Industriforening for Generiske Legemidler) was dissolved by its members in March 2018.

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 part in policy-making directly, 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 6.4 billion (€ 686 Mio.) in 2017.¹⁷

In 2018, the pharmaceutical industry in Norway invested approximately NOK 1 billion / € 120 Mio. in science and development.¹⁸ The industry has approximately 4,000 (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 international pharmaceutical distribution companies. The companies are listed in the table below.

Table 2.7: Norway – Wholesalers, 2017

Company	Market share (%)	Ownership
Apokjeden Distribusjon AS	32	Phoenix International Beteiligung GmbH
Alliance Healthcare Norge AS	45	Wallgreens Boots Alliance Inc.
NMD AS	23	MC Kesson Corporation

Source: LMI, NPA, SLV

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

Alliance Healthcare Norge AS took over as wholesaler for hospitals and hospital pharmacies after NMD AS. NMD AS, on the other hand, became the contracted wholesaler for H-prescription products in 2017 (c.f. section 4.3).

¹⁷ www.lmi.no, August 2018, excluding parallel export.

¹⁸ See above.

Parallel trade wholesalers do not exist per se, but the major wholesalers engage in parallel export. There are also two to three companies specialising 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 899 community pharmacies (as of January 2018) 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. Pharmacy chains are allowed, and there have been no limitations on establishing new pharmacies. There are three vertically integrated pharmacy chains operating in Norway. Since 2001, the pharmacy chains have bought most of the existing pharmacies in Norway and established many new ones. 85% of the private pharmacies are owned by a wholesale company. In addition, there is a chain of semi-independent pharmacies and a few independent pharmacies.

There are approximately 5,850 inhabitants per pharmacy (incl. hospital pharmacies).¹⁹

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

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 100% refund of freight costs for supplying medical aid to patients with certain diseases.

Mail orders or sale by Internet of POM from the pharmacy to the end-user is allowed.

2.7.3.2 Dispensing doctors and health personnel

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.

¹⁹ NPA 2018.

Doctors in rural areas, operating far from a pharmacy, are allowed to dispense medicines, if 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.²⁰

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.²¹ Public health nurses may prescribe contraceptive pills.²²

2.7.3.3 Hospital pharmacies

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 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 in general, wholesalers and suppliers can deliver medicines to hospitals. Pharmacies are allowed to deliver any medicine to hospitals, while wholesalers only are entitled to deliver medicines on a specified list.²³ Suppliers may act as wholesalers and deliver their own products. In practice, medicines are usually delivered 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 970 such outlets, mainly in grocery stores. There is no obligation for a pharmacist to be present in these outlets. The 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.

²⁰ Forskrifter om legers og veterinærers levering av legemidler m.v. mot betaling, § 5.

²¹ Legemiddeloven, § 17.

²² Forskrift om rekvirering og utlevering av legemidler fra apotek, § 2-5.

²³ Forskrift om grossistvirksomhet med legemidler, § 13.

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). As of 2018, there are more than 8,500 of those retailers. These outlets are not connected to a pharmacy and do not 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 2.8: Norway – Retailers of medicines 2005, 2010, 2015–2017

Retailers	2005	2010	2015	2016	2017
No. of community pharmacies ¹	506	650	802	863	867
– <i>Thereof:</i> <i>No. of private pharmacies²</i>	506	650	802	863	867
– <i>Thereof:</i> <i>No. of public pharmacies</i>	0	0	0	0	0
No. of hospital pharmacies for out-patients	30	33	32	32	32
No. of dispensing doctors	n.a.	n.a.	n.a.	n.a.	n.a.
No. of other POM disp.	n.a.	n.a.	n.a.	≈970	≈970
Total no. of POM dispensaries					
No. of internet pharmacies ³	n.appl.	n.appl.	n.appl.	n.a.	≈ 16
No. of OTC disp., like drugstores	7,000	7,000	7,000	n.a.	≈ 8,500

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

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

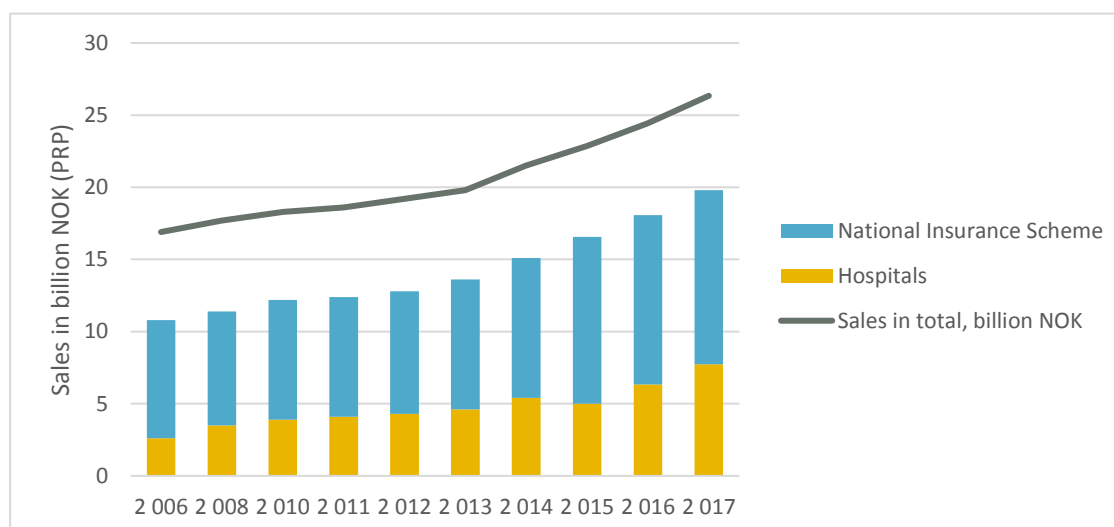
2 Private pharmacies are owned by private persons or entities; public pharmacies are in public ownership.

3 Approved internet pharmacies (websites). A website may have several supplying pharmacies.

Source: NPA, SLV

2.8 Pharmaceutical expenditure

Figure 2.6: Norway – pharmaceutical expenditure for human use, Rx and OTC, 2006-2017



Sources: NIPH, Directorate of Health, NPA

The increase from 2015 to 2017 is due to new medicines for treatment of hepatitis C, some types of cancer, anticoagulants as well as orphan diseases. Also, changes of the exchange rate has led to higher maximum prices.

The Regional Health Authorities' share (including hospitals) 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 mainly prescribed by doctors in the specialist care sector.

Table 2.9: Norway – Total pharmaceutical expenditure 2006, 2008, 2010, 2014, 2014-2017

Pharmaceutical expenditure	2006	2008	2010	2012	2014	2015	2016	2017
TPE in bill. NOK	16.9	17.7	18.3	19.2	21.5	22.9	24.4	26.3
- thereof National Insurance Scheme	8.2	7.9	8.3	8.5	9.7	11.6	11.7	12.1
- thereof hospitals	2.6	3.5	3.9	4.3	5.4	5.0	6.3	7.7

TPE = total pharmaceutical expenditure, POM and OTC, without veterinary drugs

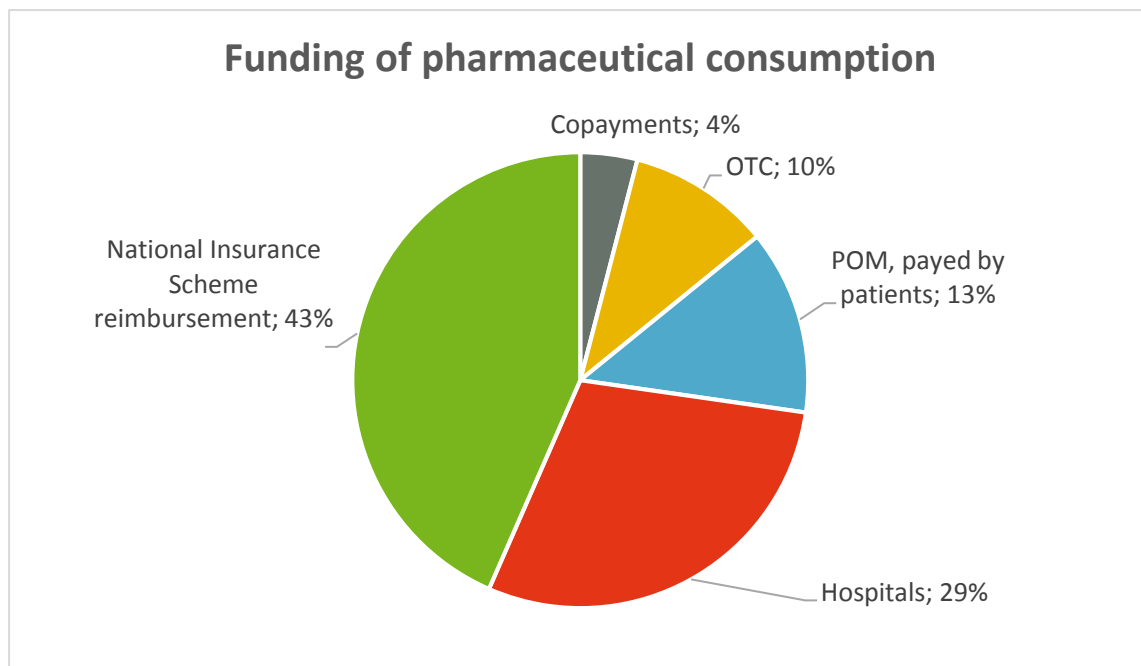
Source: NPHI, Directorate of Health, NPA

2.9 Sources of funding

The Norwegian Directorate of Health (Helsedirektoratet) decides which pharmaceuticals should be funded and reimbursed by the National Insurance Scheme (NIS), or the Regional Health Authorities, (cf. section 2.1).

Public funding of medicines accounted for almost 75% of overall pharmaceutical spending in 2016. As compared to 2015, the share of funding by the NIS decreased from 49% to 43%. Share of funding of the specialist care (hospitals) increased from 26% to 29%. POMs payed by patients increased from 10% to 13%. The share of patient co-payments decreased slightly, while the share of OTC medicines remained the same.

Figure 2.5 Norway – Split of funding of medicines, 2016



Source: LMI

3 Pricing, reimbursement and volume control in the primary care sector

As mentioned, the definitions “out-patient” and “in-patient” are not relevant for describing the health system in Norway. Instead, the two sectors are defined as primary care, and specialist care. This section covers a description of the organisation of the pricing system and policies in the primary care sector. 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 primary care sector.

3.1 Organisation of the primary care sector

Refer to figure 2.2 and table 2.1 for an overview of the organization of the pricing and reimbursement systems in the primary care sector.

3.2 Pricing of medicines

3.2.1 Pricing policies

Norway has a statutory pricing policy for prescription-only medicines (POM) with MA for human use. The policy is currently put into practice by the maximum price regulation and the stepped-price (*Trinnpris*) regulation.

The maximum price regulation at pharmacy purchase price (PPP) level, regulated in the Norwegian Act on Medicinal Products, has been implemented in 2002. Before entering the Norwegian market, the Marketing Authorisation Holder (MAH) has to apply for a maximum price with the Norwegian Medicines Agency (NoMA).

The stepped price model (*Trinnprismodellen*) is a special price model for medicines with generic competition. It was introduced in January 2005 to reduce costs incurred by the National Insurance Scheme (NIS) 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.

Table 3.1: Norway – Ways of pricing of medicines at pharmacy level, 2018

Pricing policies	(Non) prescription market		(Non) reimbursement market	
	POM	OTC	Reimbursable	Non-reimbursable
Free pricing		Yes	Yes, if individually approved OTC.	OTC
Statutory pricing	Yes	Yes, if reimbursable & on positive list*	Yes	POM

POM = prescription-only medicine, OTC = over-the-counter medicines

*If the medicine has been included in the positive list. (cf. section 3.3.1).

OTC drugs are usually not price regulated.

There is no price notification in the statutory pricing system in Norway.

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

3.2.2 Pricing Procedures

There are two pricing procedures practiced in Norway. External price referencing is the key mechanism for setting maximum prices, while internal price referencing is used for setting the stepped prices, once generic competition arises for a substitutable medicine.

Table 3.2: Norway – Pricing procedures, 2018

Pricing procedure	In use: yes / no	Price type ¹	Scope ²
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

3.2.2.1 Maximum price

The Norwegian Medicines Agency (NoMA) sets maximum prices for all prescription-only medicines (POM) at pharmacy purchasing price (PPP)-level. In practice, the maximum pharmacy retail price (PRP) is regulated as well, since the NoMA regulates the pharmacies' mark-up on the PPP.

The maximum price is set based on external reference pricing. 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 European Economic Area (EEA). 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 set by the NoMA is the permitted maximum PPP. However, the product can freely be sold at a lower price than the maximum price. 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.

For medicines that require obligatory emergency stock for wholesalers, the NoMA adds an additional 1% to the PPP. An example are ready-to-use adrenaline injections.

Each Marketing Authorisation Holder (MAH) is obliged, on request, to provide the 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 PPP level, if available.

The NoMA revises the price of the 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. Products that sell at a lower level will also be revised, but not as frequently. Every autumn, the NoMA publishes a plan for next year's price revision: <https://legemiddelverket.no/offentlig-finansiering/maksimalpris#revurdering-av-maksimalpriser>

The MA-holder may also apply for a price revision (if the medicine is not already on the revision plan). Normally prices will not be adjusted more often than once a year.

3.2.2.2 Stepped Price

The stepped price is put into practice when generic competition for a substitutable medicine arises. The NIS reimburses the stepped price, or the patient has to pay it in case of non-reimbursable drugs. See also section 3.4.1 regarding patient payment. The NoMA publishes a list of substances that are included in the system and a list of their current prices.²⁴

The stepped price for a substance with generic competition is set as a percentage of the maximum PPP of the original medicine at the time it first 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 simvastatin and atorvastatin, 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 turnover of the substance is very low. Also, minimum stepped-price (PRP) is 50 NOK.

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 at prices 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.

²⁴ www.noma.no, September 2018.

Table 3.3: Norway – Overview of the stepped price system (Trinnprismodellen), 2018

Sales PRP, 12 months before generic competition		< 100 Mio. NOK	> 100 Mio. NOK	
1 st step	Time of price-cut Start of generic competition	35%	35%	
2 nd step	6 months after generic competition	59%	81%	
Sales PRP, >= 12 months after 2 nd step		> 15 Mio. NOK	> 30 Mio. & < 100 Mio. NOK	> 100 Mio. NOK
3 rd step	Time of price-cut >= 12 months after 2 nd step	69%	88%	90%

NOK = Norwegian Krone, PRP = Pharmaceutical Retail Price

Source: NoMA

3.2.3 Discounts / rebates

The statutory prices are maximum prices, and discounts are allowed. Discounts should be given simultaneously with the sale, except for medicines funded by the public (Law on Medicinal Products § 6). All prices reported to the authorities should be reported as net-prices (Law on Medicinal Products § 14). Due to the market situation and the existence of a third-party payer, there is no evidence of major discounts to patients.

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 prescription-only medicines (POM), including both reimbursed and non-reimbursed medicines. The scheme was simplified as of 1st of January 2018. All POM medicines have a flat mark-up of 2.25%. The fixed mark-up was increased from NOK 25 to 29. Additionally, pharmacies may increase their mark-up by 0.5% of the PPP for products requiring cooling or refrigeration.

Further, since 2016, pharmacies receive compensation for training patients in use of inhalators for Asthma/CLD. Pharmacies are refunded NOK 80 / € 8.3 for each training to patients. A similar compensation has been introduced in 2018 for medicines treating high blood pressure, cholesterol and anti-coagulants. Pharmacies have to offer two information meetings per patient starting to use those medicines. Pharmacies receive NOK 225 / EUR 23.4 for each information meeting. Both schemes are publicly funded and free of charge for patients. The aim of the meetings is to improve compliance.²⁵

²⁵ Cf. <https://helfo.no/viktige-meldinger/starter-med-veiledning-i-apotek>; <https://legemiddelverket.no/nyheter/astma-og-kolspasienter-far-inhalasjonsveiledning-i-apotek>, July 2018.

Table 3.4: Norway – Pharmacy mark-up scheme, 2018

Pharmacy purchasing price	Maximum mark-up in % of pharmacy purchasing price
All POM packages	2.25%
	Fixed mark-up per package
All POM packages	NOK 29 / € 3
Additional for drugs requiring refrigeration	0.5%
Additional for addictive drugs/narcotics	NOK 15 / € 1.6

Source: NoMA

The average pharmacy margin for POM included in the stepped price model was 71% in 2015. The same year, the average pharmacy margin for patented POM was 12.6%.²⁶

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 0.3% (2018) of the pharmacy purchasing price (detaljstavgift). It applies to all medicines, including OTC products. Charging the retailers, the tax is collected by the wholesalers who in turn pay the tax to the authorities. The amount collected is not included in the price build-up and compensation for pharmacies.

There is also a supplier tax (leverandøravgift) of 1.0% (2018) of the wholesalers purchasing price (ex-factory price). The tax is to be reported-in and payed to the NoMA by the Marketing Authorisation Holder.

There is a tax of 1.2% (2018) on sales in other retailers than pharmacies (LUA-avgift), such as grocery stores, gasoline stations etc. (cf. section 2.7.5). The tax comes in addition to the pharmaceutical tax, and is also collected and 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 primary care sector.

²⁶ Evaluering av apotekavanse og trinnpris, SLV 2016.

3.3.1 Reimbursement policies

In June 2016, the government described principles for priority-setting in a White Paper 34 (2015-2016) (1), hereafter referred to as the Priority-setting White Paper (“Prioriteringsmeldingen”). The Pharmaceutical Products Regulations, Sections 12 and 14, which regulates the pricing and reimbursement of medicines by the National insurance scheme, has been adapted according to these principles.

In the Priority-setting white paper, the government proposes a set of principles for priority setting in the health care sector that will contribute to fair access to health services and legitimacy to difficult decisions in the health care sector.

Health service interventions are to be evaluated against three prioritisation criteria – 1) the benefit, 2) resource and 3) severity criteria. The priority-setting criteria are to be evaluated together and weighted against each other. Reimbursement can only be pre-approved if the relation between resources and benefit to patients is reasonable. The cost-effectiveness ratio will be weighted against the severity of the relevant condition/disease. For more severe conditions, a higher cost-effectiveness ratio will be accepted.

- The benefit should be measured by how many life-years in good quality the measure provides for patients in the current patient group, compared with relevant treatment practices.
- Resource usage includes average pharmaceutical costs and other resource utilization in health and care services, compared to relevant treatment practices.
- Severity should be measured by how many life-years in good quality for patients in the particular group are lost on average as a result of not making the treatment under assessment available, i.e. absolute shortfall.

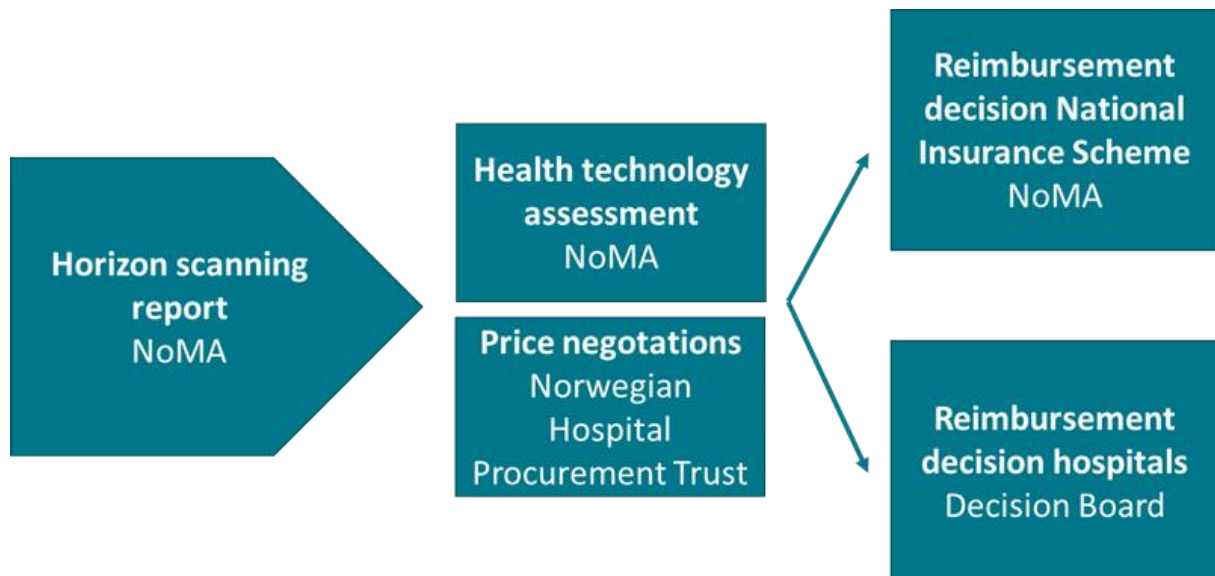
The National Insurance Scheme (NIS) provides reimbursement only for severe diseases and a need for a "long-term" treatment, defined as more than three months' of medication per year. In general the reimbursement programme does not cover short-term therapy (e.g. antibiotics for pneumonia). Most over-the-counter (OTC) products are not reimbursed.

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

3.3.2.1.1 Decision making process

Figure 3.1: Norway - The decision-making process for reimbursement



NoMA = Norwegian Medicines Agency

Source: NoMA

Figure 3.1 displays the decision-making process for reimbursement of medicines (cf. also figure 2.2). The Norwegian Medicines Agency (NoMA) is responsible for identifying and assessing new pharmaceuticals in a horizon scanning document. The horizon scanning document supports the marketing authorization holder (MAH) to prepare all the necessary analyses and documentation for the Health Technology Assessments (HTA). This means that all new medicines (including new indications) that are to be publicly financed must be assessed. HTA will be used as a tool for supporting appropriate prioritization and decisions making. This is done to ensure that new technologies introduced are proven as safe and effective.

The price is a decisive factor for cost effectiveness and therefore the reimbursement decision. Sometimes the MAH will therefore agree to lower the price on the product to a level lower than the statutory maximum price, in order to ensure a medicine becomes cost-effective. The HTA is utilized in potential price negotiations with the MAH. The Norwegian Drug Procurement Cooperation (LIS) is responsible for price negotiations for medicines reimbursed by both hospitals and the National Insurance scheme (NIS).

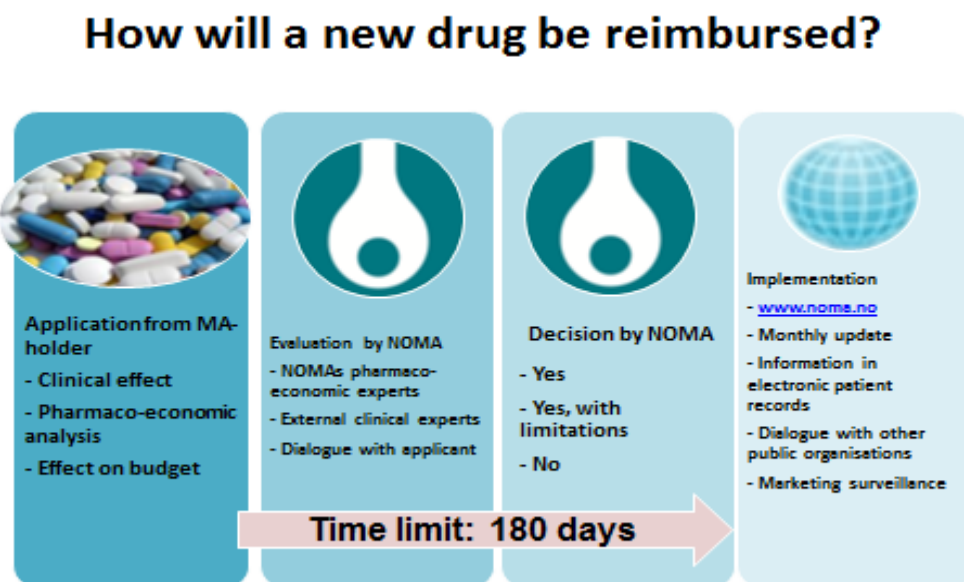
The NoMA is responsible for reimbursement decisions on behalf of the NIS. If the reimbursement decision is estimated to have an annual incremental fiscal impact above NOK 100 Mio. /

€ 10.5 Mio. by the fifth year after approval, NoMA is not authorized to grant reimbursement. In this case, provided that the application fulfils all prioritisation criteria, the NoMA will pass its appraisal on to the Ministry of Health and Care Services (HOD) who will assess the matter further. Should the Ministry favour the approval, the case will be brought before Parliament in the form of a Budget Bill.

For decisions regarding drugs paid by the Regional Health Authorities see section 4.

The time allocated to the NoMA for processing the reimbursement application is 180 days. Effective processing time may arise due to clock-stops, e.g. in case the NoMA needs further information to process an application. Cf. section 2.2 for information on processing time.

Figure 3.2: Norway – Reimbursement process in the primary care sector



Source: NoMA

In 2017, the NoMA approved 82 medicines for inclusion in the reimbursement list. In addition, three cases exceeded the limit of NOK 100 Mio. / € 10.5 Mio. and were submitted to the HOD. For those cases, with major estimated budget impact, all were granted reimbursement.

With a complete marketing authorisation for its product, the MAH can send an application for maximum price before, or simultaneously with an application for reimbursement.

3.3.2.2 Pharmacoeconomic evaluation

A pharmacoeconomic evaluation is a vital part of the HTA. In connection with applications to join the reimbursement scheme, it has been compulsory since 1 January 2002. Companies need to follow the Norwegian guidelines²⁷ for pharmacoeconomic evaluation.

The guidelines require an explanation of the choice of comparison, the time frame for the analysis, data collection methods, analysis methods and costs. Pharmacoeconomic evaluation is carried out for all publicly financed medicines, with the exception of the following cases:

- a) 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. Also the cost must not be higher, or the health outcomes different than those of a medicine with which comparison is natural.
- b) Pharmaceuticals where a new formulation clearly does not change the costs and health outcomes of treatment.

The assessment results in a cost effectiveness ratio (cost per QALY ratio). The cost effectiveness ratio is compared to a threshold representing the opportunity cost in the health care sector. This threshold is fixed at NOK 275 000 per QALY gained. The opportunity cost threshold is adapted from a study of opportunity costs in Great Britain.²⁸ For severe conditions, a higher cost effectiveness ratio may be accepted. Severity is measured as absolute QALY shortfall.

With some exceptions, over-the-counter (OTC) medicines are not reimbursed. Therefore, a pharmacoeconomic evaluation is usually not necessary.

3.3.2.3 Reimbursement schemes

There are three reimbursement schemes in Norway (schedule 2-4). The legal framework for the reimbursement scheme is the Social Services Act and Regulation on Medicinal Products. All new medicines are subject to a Health Technology Assessment (HTA) before any reimbursement (except schedule 4).

There are three main ways in which medicines can be covered (Table 3.5). Schedule 2 requires that the medicine has been approved for reimbursement. Pharmaceuticals in schedule 2 will be reimbursed automatically, while medicines in Schedules 3 require a formal application by

²⁷ www.noma.no, September 2018.

²⁸ Claxton et al (2015) Methods for the estimation of the National Institute for Health and Care Excellence cost-effectiveness threshold.

the physician for each patient. For individual reimbursement to be granted, the patient must be considered different from the patient group assessed for general reimbursement (schedule 2). The purpose of schedule 4 is to eliminate severe communicable diseases.

In 2017, approximately 76% of the total NIS reimbursement expenditure of NOK 11.0 billion / € 1.1 billion arose from Schedule 2. Schedule 3a and 3b accounted for respectively 14% and 5% of total reimbursement. Reimbursement by schedule 4 was 5% of total reimbursement.²⁹

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). This positive list is updated by the Norwegian Medicines Agency (NoMA) once a month. The list of reimbursable medicines and associated criteria is published on the NoMA website³⁰ as a searchable database on the web. The list is organised at the pharmaceutical substance level and gives the subscriber precise information on the indication approved for reimbursement. The reimbursement indication is described both in text and according to two different diagnostic codes (ICD-10 and ICPC-2).

In the database, the search criteria can be the pharmaceutical's product name, the generic name, the ATC-code, the diagnostic code or the name of the disease the medicine 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, depending 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

Co-payments are included in the cost-ceiling scheme that was introduced in the early 1980s. All co-payments for consultations with specialists and general practitioners, for ambulatory care, X-rays, laboratory tests and medicines go under the ceiling for co-payments. In 2018, the ceiling is NOK 2,258 / € 235.³¹ When the cost ceiling has been reached within the calendar year, most of additional out-of-pocket expenses are reimbursed by the National Insurance

²⁹ Directorate of health, 2018.

³⁰ www.noma.no, September 2018.

³¹ Exchange rate: 9,6 NOK per Euro (Aug/Sept. 2018).

Scheme (NIS), and any remaining treatment in that calendar year is therefore free of charge. In 2017 approximately 28% of the population (age over 16) reached this ceiling.³²

Table 3.5: Norway – Reimbursement categories of medicines, 2017

Reimbursement category	Reimbursement rate (%)	Description
Schedule 2	61 / 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. A HTA-assessment will assess whether the three prioritization criteria are fulfilled for the patient group.
Schedule 3	61 / 100 ¹	For medicines other than those under schedules 2 and 4. In this case reimbursement can be granted upon submission of an individual application and only for long-term (> 3 months) treatment. The patient must be considered different from the patient group assessed for general reimbursement (schedule 2).
Schedule 4	100	For medicines used to treat serious contagious diseases.

Source: Directorate of Health

There are several conditions that may exempt from paying co-payments. This is e.g. applicable for children below 16, treatment of contagious diseases or transfer between institutions.

General reimbursement – Schedule 2

Schedule 2 is a positive list system, which consists of pre-approved medicines for reimbursement. The NoMA handles the reimbursement list of product brand names that have been accepted for reimbursement for the defined diagnoses. Reimbursement is granted only under the condition that the patient has a severe disease and need for long-term treatment. Furthermore, the medicines in question must have marketing 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. In 2017, NIS reimbursed NOK 8.3 billion / € 0.86 billion on schedule 2, for 2.4 million individuals.

Individual reimbursement – Schedule 3

Under certain conditions, reimbursement is granted on the basis of individual patient applications for products not included in the list for general reimbursement. If the accepted products available for general reimbursement do not provide sufficient effect or cause unacceptable adverse reactions, and the patient differs from the patient group assessed for general reimbursement (schedule 2), reimbursement for an alternative product can be applied for, on an individual basis. This refers to Schedule 3 in Table 3.4.

³² Helfo, Helfo i 2017; helsenger.no, 2018.

In contrast to the pre-approved medicines available for general reimbursement, it is not a prerequisite that the product has obtained a marketing authorisation in order to be individually reimbursed. This implies that some medicines may achieve significant reimbursed sales before marketing authorisation in Norway, with no statutory maximum pharmacy purchasing price.

In 2017, NIS reimbursed NOK 2.1 billion / € 0.2 billion on schedule 3, for 156,000 individuals.

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 NIS. Also, vaccines against communicable diseases are reimbursed. All medicines with ATC-code L03A (immunostimulants) and most medicines within ATC-code J (i.e. anti-infectives 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 4.³³

In 2017, NIS reimbursed NOK 0.5 billion / € 52 Mio. on schedule 4, for 34,000 individuals.

Financing responsibility for several medicines for dangerous contagious illnesses have been moved from the NIS to the Regional Health Authorities (“H-prescriptions”, c.f. section 4.1). Examples are medicines for treatment of HIV and hepatitis C.

3.3.3 Private pharmaceutical expenses

In 2016, 27% of the total pharmaceutical costs were directly covered by the patients. This number is derived from non-reimbursed prescription-only medicines (13%), OTC medicines (10 %) and patient co-payment of reimbursable medicines (4%). Cf. diagram in section 2.9.

There is no co-payment for H-prescriptions (hospital financed) or schedule 4 drugs.

Table 3.6: Norway – Out-of-pocket payments for medicines, 2018

Out-of-pocket payments	Amount	Vulnerable groups
Fixed co-payments	-	-
Percentage payments	39%, max. NOK 520 / € 54 per prescription	Low-income pensioners and children under 16 are exempt
Deductibles	NOK 2,258 /€ 2,350	-
Reference price system	Price difference between stepped price and maximum price if patient refuses generic substitution.	-

Source: www.helfo.no ; www.nav.no

³³ <https://lovdata.no/dokument/SF/forskrift/2007-06-28-814?q=blåresept>, August 2018.

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 alternative. 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 should prescribe the cheapest equivalent product, unless there are serious medical reasons for prescribing a more expensive alternative.

Pharmaceutical budgets are not implemented in the primary care sector.

3.4.1 Generic substitution

Generic substitution has been allowed in Norway since 2001. According to The Norwegian Pharmacy Association's survey "Apotekbarometeret", over 80% were positive or indifferent to this experience, whereas 17% had a negative experience.³⁴

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. 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.³⁵ In such cases the National Insurance Scheme will reimburse the cost with no extra payment for the patient.

Pharmacies have financial incentives for generic substitution. In Norway, there is vertical integration between wholesalers and pharmacies. Generic competition increases the wholesalers' margins and this leads to an incentive for generic substitution. Pharmacies are not allowed to substitute therapeutically (i.e. dispense a medicine with a different INN and 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.³⁶

³⁴ Cf. <https://www.apotek.no/nyhetsarkiv/helsepolitikk/7-av-10-tenker-positivt-om-apoteket>, August 2018.

³⁵ Helsedirektoratet.

³⁶ www.noma.no, September 2018.

3.4.2 INN prescribing

Doctors are allowed, but not obliged, to prescribe by International Non-proprietary Names (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, the NoMA assumes that the National Insurance Scheme (NIS) and patients save in all approximately NOK 2 billion / € 208 mio. every year. These savings are substantial in view of the fact that the NIS reimbursed medicines for NOK 11.0 billion /€ 1.1 billion in 2017.³⁷

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.

3.4.4 Claw-backs

Claw-backs are usually not used in Norway. Exceptions are managed-entry agreements with confidential prices (c.f. 3.4.5).

3.4.5 Managed-entry agreements

The Directorate of Health is authorized to enter into managed-entry agreements (MEA) with MA-holders for medicines reimbursed by the National Insurance Scheme.

³⁷ Directorate of Health, 2018.

The first MEAs were entered in 2017, consisting of reimbursement agreements with two MA-holders to access the PCSK9 inhibitors Repatha and Praluent. The criteria for entering into this agreement were that the treatment was addressing a highly unmet need, the definition of a patient group, where treatment proved to be cost-effective with the confidential discount given, and the total budget impact did not exceed NOK 100 million a year. The MEAs include an agreed and confidential discount per sold package, which is paid back by MA-holder every month. In order for a patient to access these medicines, the doctor must apply for individual reimbursement (schedule 3) and must fulfil a defined set of terms.

3.5 Evaluation

As stated in section 3.3.2, a pharmaco-economic evaluation must be carried out for all publicly financed medicines, 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 (HTA). When relevant, they are considered for reimbursement decisions. The Centre publishes all HTAs on the website: <https://www.fhi.no>.

3.5.1 Prescription monitoring

The HELFO performs random checks to see if 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 HELFOs monitoring of prescribing may vary, depending on the importance of the measure and the expected value of new information.

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

3.5.2 Pharmaceutical consumption monitoring

The pharmaceutical consumption is monitored by the Norwegian Institute of Public Health Institute (NIPH) on a yearly basis, cf. to the report “Drug consumption in Norway”³⁸. NIPH also produces an annual report based on the Norwegian Prescription Database.³⁹

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”⁴⁰
- Norwegian Association of Pharmacies’ “Facts and figures”⁴¹

3.5.3 Decision making tools

As stated in section 3.3.2 a pharmaco-economic evaluation in the reimbursement scheme has been mandatory since 1 January 2002. The Market Authorization Holder (MAH) 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 2018.⁴²

A pharmaco-economic evaluation has to be performed for all publicly financed medicines, with some exceptions (c.f. section 3.3).

³⁸ <https://fhi.no/en/publ/2018/legemiddelforbruket-i-norge--20132017>, July 2018.

³⁹ www.reseptregisteret.no, September 2018.

⁴⁰ <http://www.lmi.no>, July 2018.

⁴¹ <http://www.apotek.no>, July 2018.

⁴² www.noma.no, July 2018.

4 Pricing, reimbursement and volume control in the specialist care sector

This section describes the organisation of the pricing system and policies in the hospital sector, as well as medicines prescribed in hospitals, but dispensed in community pharmacies (cf. section 4.1 and 5.1). In Norway, this sector is called “specialist care sector”. The section covers the reimbursement and the volume control and the reimbursement related cost-containing measures in the specialist care sector.

4.1 Organisation of the specialist care sector

Refer to chapter 1.2 for information about the organization of the specialist care sector, comprising, but not limited to, 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.

A national system for the introduction of new health technologies within the specialist health service was implemented in 2013-2014.⁴³ The purpose of this system is to promote better and safer patient care. This is 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 follow the similar pathway as for medicines reimbursed by the National Insurance Scheme, reference to section 3.3. The Norwegian Medicines Agency (NoMA) issue a horizon scanning document of all new pharmaceuticals. This initiates the HTA process with the Marketing Authorisation Holder (MAH).

Formally, the Regional Health Authorities (RHA) commission the Health Technology Assessments (HTA) from the 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 have discretion to prioritise and decide which assessments should be carried out,

⁴³ <https://nyemetoder.no/english>, September 2018.

however, effectively, the NoMA carries out a HTA for all new pharmaceuticals and indications. The assessments have in average been completed in 156 days (the time-limit is 180 days).

The RHAs have established a Decision Board, consisting of the CEOs of the 4 RHAs and a patient representative (no voting power). The Decision Board utilizes the HTA to decide on whether or not, and under which circumstances, a medicine will be used in the specialist care sector. The assessments also serve as an input to price negotiations. The Norwegian Drug Procurement Cooperation is responsible for price negotiations.

Hospitals also 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 specialist care have issued “H-prescriptions”.⁴⁴ “H” stands for health enterprise. The medicine will be reimbursed by the health enterprise, e.g. a hospital. 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. About NOK 3.7 billion / € 390 Mio. were reimbursed per year. 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. However, the abusers are partly treated by general practitioners and partly by the health enterprises. For example, 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 still reimbursed by the health enterprise. In 2015 medicines for NOK 274 Mio. / € 28.5 Mio. were handed out to users by the pharmacies.⁴⁵

4.2 Pricing and purchasing policies

The main pricing policy in Norwegian hospitals is tendering.

The Norwegian Drug Procurement Cooperation (LIS) negotiates prices mainly on behalf of the hospitals, and in some circumstances for the NIS. The Regional Health Authorities (RHAs) or sometimes hospitals decide on or negotiate the pharmacy mark-up. Other discounts than the ones given in the tendering process are not common.

The wholesale services are subject to two separate tenders. One selected for providing distribution services to the hospitals for a period of three years. One wholesaler is selected for

⁴⁴ Doctors in specialist care are either employed by the hospital or private specialists contracted by the health enterprises.

⁴⁵ Helsedirektoratet.no, 2018.

distributing medicines on H-prescriptions to pharmacies. The tenders are 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 the hospitals. The exchange of information is organised by the 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 9.5 / € 0.1 billion on medicines between September 2017 and August 2018, including 25% value added tax.⁴⁶

The 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.

The LIS tenders gave in 2018 a price reduction of 40% in average for the Norwegian hospitals, compared to the statutory maximum prices (for information on statutory prices c.f. section 3.2).⁴⁷ In the primary care sector, 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 Norwegian Drug Procurement Cooperation (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.

⁴⁶ www.sykehusinnkjop.no, September 2018.

⁴⁷ See above.

LIS has all prices that hospitals pay for medicines. Prices are the same for all hospitals and are often confidential. The tenders are published in the Doffin⁴⁸ and TED⁴⁹ database, due to legal provision.

The process is co-ordinated by the LIS.

The assignment criteria are the following:

- Price
- Security of continuous supply
- 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 two selected wholesalers (use in hospitals & H-prescriptions). 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.

⁴⁸ <http://www.doffin.no>, September 2018.

⁴⁹ <http://ted.europa.eu>, September 2018.

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 specialist care sector, i.e. the medicines are purchased and paid by the RHAs. 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. However, also other medicines can be prescribed. The hospitals' committees consist of doctors from specialist 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.

There are no out-of-pocket payments (OPP) for specialist care treatment. When patients are treated in the hospitals' outpatient 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 on the advisory list. 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 specialist care at the hospital, or a community pharmacy.

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

Refer also to section 3.5.2 for information on other statistics that also cover the specialist care sector.

4.5.2 Decision-making tools

Refer to section 4.4. and 5.2 for decision making tools.

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 has been implementing a reform for better interaction between the primary and specialized healthcare systems between 2012 and 2015.⁵⁰ The reform gives incentives to the municipalities to prevent disease and injury in their population. For example, the municipalities will be obliged to provide acute help and 24 hours-services for patients in need of treatment or observation. Financing has also been worked on. Since 2012, a co-payment from the municipalities is required for some treatments in specialist 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. This is why NOK 5,600 Mio. / € 540 Mio. have 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.⁵¹

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 outpatient sector in Norway exists with regard to specific medicines, as hospitals pay for medicines that patients need after discharge of the hospital. The funding of such products was transferred from the budget of the National Insurance Scheme (NIS) to the Regional Health Authorities' (RHA) budgets, starting from 2006. This was mainly due to the economic incentive for hospitals to prescribe products funded by NIS, as well as to achieve more competition and lower prices. “H-prescription” medicines now funded by the hospitals include, among others, medicines for treatment of tumour necrosis factor (TNF) Multiple Sclerosis (MS), HIV as well as Hepatitt C and B.⁵²

⁵⁰ <https://www.regjeringen.no/nb/tema/helse-og-omsorg/helse--og-omsorgstjenester-i-kommunene/samhandlingsreformen/status-samhandling/id708254/>, September 2018.

⁵¹ <https://www.regjeringen.no/no/aktuelt/komm-pressemelding-1-2/id657073/?id=657073>, September 2018.
<https://www.regjeringen.no/no/tema/helse-og-omsorg/helse--og-omsorgstjenester-i-kommunene/samhandlingsreformen/om-samhandlingsreformen/utskrivningsklare-pasienter/id650123/>, September 2018.

⁵² <https://sykehusinnkjop.no/legemidler#h-preparater>, September 2018.

In 2017, the RHAs reimbursed H-prescriptions for NOK 4.2 billion (PPP).

The Government has delegated to the Directorate of Health to decide on further transfers. The Directorate of Health transfers financing responsibilities to the RHAs if

- Initiation, evaluation and termination of a treatment is steered by a doctor in the specialist care sector
- Intake or administration of a medicine requires physic monitoring or readiness in case of emergency at the specialist care provider
- Intake or administration of medicines requires equipment usually owned in the specialist care sector.

Medicines proposed to be transferred in 2019 can be found here:

<https://helsedirektoratet.no/legemidler/helseforetaksfinansierte-legemidler-brukt-utenfor-sykehus-h-reseptlegemidler#plassering-av-finansieringsansvar-for-legemidler>

Financing of medicines fulfilling these criteria, which currently are financed by the NIS will gradually be transferred to the RHAs. This means that the RHAs are responsible for funding and reimbursement of these medicines.

5.2 Developments

FINOSE – Nordic collaboration on HTA

Already in 2004, the European Commission and Council of Ministers declared joint health technology assessment (HTA) to be a priority area for the European Union.⁵³

FINOSE is a Nordic collaboration of Finland, Norway and Sweden in HTA (Health Technology Assessment). The collaborating agencies are Sweden's Dental and Pharmaceutical Benefits Agency (TLV), the Norwegian Medicines Agency (NoMA) and the Finnish Medicines Agency (Fimea). It is a collaboration in parallel to the EUnetHTA initiative.

The collaboration was launched in March 2018. The overall intention of the collaboration is to ensure earlier access to drugs through cooperation on assessment of relative efficacy and relevant parts of the health economic framework. A joint team across the three countries will be assigned to share work for accepted applications and reduce the regulatory burden on both the agencies and the applying pharmaceutical companies (i.e., simultaneous submission to the three agencies). The access and reimbursement decision is still subject to the individual agencies' national regulations country-by-country.

⁵³ www.tlv.se, September 2018.

The FINOSE collaboration aims to:

- Support timely and equal access to medical technologies
- Gain additional knowledge about the products
- Increase efficiency in production of assessment reports
- Less divergence in HTA methodologies and evidence requirements
- Reduced complexity in industry submissions

FINOSE is now accepting applications for joint assessment.

Inhalers for Asthma/COD are substitutable in pharmacies

Asthma/Chronical Lung disease inhalers have been included in the list of products that are generically substitutable in pharmacies (cf. section 3.4.1) Salmeterol/fluticasone (Seretide) and formoterol/budesonide (Symbicort) were included in generic substitution and the stepped-price system in 2018. (cf. section 3.2). Pharmacies may offer a training on new users for appropriate uses of inhalers (cf. section 3.2.4).

Agreement of collaboration in negotiations with Denmark

The ministers of Health in Denmark and Norway signed in 2018 an agreement for collaboration in negotiations of expensive drugs. More information can be found here: www.sykehusinnkjop.no.

6 Bibliography

6.1 Literature

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

6.2 Legislation

Refer to section 1.2.

6.3 Web links

Relevant web links are included in the text.