

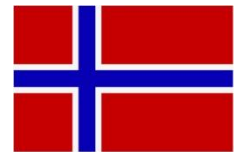


PPRI

Pharmaceutical Pricing and
Reimbursement Information

PPRI Pharma Profile

Norway 2022



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 reporting systems on pharmaceutical pricing and reimbursement

Accurate and up-to-date country information is of key importance for decision makers and researchers. As the level of detail they are interested in may vary, different reporting formats are useful.

To respond to this need, the PPRI Secretariat developed the PPRI Pharma Profiles as well as further reporting systems as tools for understanding, collecting and analysing pricing and reimbursement information on medicines (and medical devices).

PPRI Pharma Profiles and other reports are written by members of the PPRI network, including national country experts, such as staff of competent authorities for pharmaceutical pricing and reimbursement (Ministries of Health, Medicines Agencies, Social Health Insurance institutions).

Between 2005 and 2022, 35 PPRI Pharma Profiles, 19 PHIS Hospital Reports, 9 PPRI / PHIS Pharma Profiles, 5 PPRI Pharma Briefs and 1 PPRI Medical Devices Brief (France) were produced. The different deliverables (of different lengths and with specific focus) highlight the variety of reporting tools.

All published country reports and profiles are publicly accessible at https://ppri.goeg.at/ppri_country_information.

This PPRI Pharma Profile on Norway offers up-to-date information as of 2022 (or latest available year) on pharmaceutical pricing and reimbursement in both the outpatient and inpatient sectors.

Quality assurance

All PPRI Pharma Profiles and similar reports are based on a template which provides a standardised outline for each of the reporting tools (accessible at: https://ppri.goeg.at/methodology_documents).

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 and reports.

To achieve clarity for authors, reviewers and readers and thus to create a common understanding of the concepts and terms used, a glossary of pharmaceutical terms has been developed. The most updated version of the Glossary of WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies can be found at <https://ppri.goeg.at/ppri-glossary>.

All PPRI Pharma Profiles and further reports are subject to review processes by the PPRI Secretariat and/or PPRI network members.

About PPRI

Pharmaceutical Pricing and Reimbursement Information (PPRI) dates back to a research project (2005–2007), co-funded by the European Commission, Directorate-General Public Health and Consumers and the Austrian Federal Ministry of Health, Family and Youth. It was managed by the Austrian National Public Health Institute (Gesundheit Österreich GmbH / GÖG) supported by the WHO Regional Office for Europe. 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.

The PPRI project has proved long-term sustainability.

Nearly two decades later, 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 90 institutions: These are public authorities and third party payers from 50 countries (mainly European countries, including all 27 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 Pharmacoeconomics Department of (GÖG). The Department has also been nominated as a WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies.

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List of abbreviations

AI	Active Ingredient
ATC	Anatomic therapeutic chemical classification
DRG	Diagnosis-related group
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
LMI	Norwegian Association of Pharmaceutical Manufacturers
LUA	Medicines sold outside of the pharmacies
NIS	National Insurance Scheme
NIPH	Norwegian Institute of Public Health
NME	New molecular entities
NOK	Norwegian currency unit
NoMA	Norwegian Medicines Agency
NorPD	The Norwegian Prescription Database
NPA	The Norwegian Pharmacy Association
NPM	Non-prescription medicine(s)

MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
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 2010, 2015, 2019, 2021.

Demography	2010	2015	2019	2021
Total population*	4,920,305	5,213,985	5,367,580	5,425,270
Population aged 0–14*	921,709	933,955	930,127	915,987
Population aged 15–64*	3,256,353	3,424,930	3,495,637	3,519,809
Population aged > 64*	742,243	855,100	941,816	989,474
Life expectancy at birth	81.0	82.2	82.9	83.1
Life expectancy at age 65	84.5	85.2	85.7	85.8

*1st of January following year.

Source: Statistics Norway.

The population of Norway was 5.4 Mio. in 2021. This corresponds to an average of 16.7 people per km² (mainland and islands). The population is unevenly distributed. The major urban areas are located along the coastline of southern Norway, especially in the Oslo, Bergen, Stavanger, and Trondheim areas. The inland and the northern parts of Norway are more scarcely populated.

The average life expectancy continues to increase. In 2021, the average life expectancy was 81.5 years for men and 84.7 years for women. The percentage of the population above 64 years is rising, and it will increase significantly as a result of the ageing of the relatively large post-war generations.

The total number of deaths in 2021 was 41676.¹ Malign tumours are now the leading cause of deaths, accounting for approximately 26% 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 of 24%. Diseases in the respiratory system accounted for 8.7%.²

¹ All figures in this paragraph are collected from the Norwegian Cause of Death Registry, NIPH, as of October 2022.

² Infection control measures contributed to a significant decline in deaths caused by diseases in the respiratory system. Deaths related to Covid-19 are not included.

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 are 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 2021, 10.4% of the Regional Health Authorities (RHAs) cost was used for purchase of private health care services, e.g. private hospitals.³

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 356 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.

The four RHAs are responsible for the financing, planning and provision of specialist care services. This includes somatic care and mental health care services as well as care service for persons with substance use disorder, 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

³ Statistics Norway. Specialist health services. Expenses incl. RHE, HE, private institutions, by type of expenditure, activity and health enterprise 2005 – 2021.

pharmacies – H-prescriptions⁴. Financing responsibility of specialist care therefore includes in-patient, but also some outpatient expenditures, cf. chapter 4. There are 27 health enterprises under the four RHAs.⁵ The RHAs fund the health enterprises, which in turn fund the local hospitals. The hospitals are remunerated by a mixture of ex-ante fixed budgeting (50%) and a diagnosis-related group (DRG) system (50%) for somatic care/services. Other services are mainly funded by ex-ante fixed budgets.⁶

The 356 municipalities are responsible for the provision and funding of primary health care and social services (often 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 oversee contracting GPs in their community. Remuneration of the contracted GPs, 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. In 2020, there were 4,951 contracted GPs. Each contracted general practitioner had an average of 1,068 patients listed. The trend has been decreasing since 2005, where each GP had around 1200 patients listed.⁷

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.

Children receive free public dental treatment in Norway. Some types of dental treatment are covered by the rules for the exemption card for health services. The counties are responsible for the public dental health care and for providing dental services for the inhabitants in the county.

⁴ “H” stands for health enterprise.

⁵ <https://www.regjeringen.no/no/tema/helse-og-omsorg/sykehus/innsikt/oversikt-over-landets-helseforetak/id485362/>. October 2022.

⁶ <https://www.helsedirektoratet.no/tema/finansiering/innsatsstyrt-finansiering-og-drg-systemet/innsatsstyrt-finansiering-isf/ISF-regelverk%202022.pdf>.

⁷ <https://www.helsedirektoratet.no/statistikk/fastlegestatistikk>. September 2022.

1.3 Health expenditure

Table 1.2:

Norway – Health expenditure 2010, 2015, 2019, 2021.

Health expenditure in NCU = NOK, mill ¹	2010	2015	2019	2021
GDP	2,591,479	3,111,168	3,563,484	4,141,882
THE	239,730	315,207	331,638	349,497
– <i>thereof public HE</i>	84.7%	85.5%	85.7%	85.6%
– <i>thereof private HE</i>	15.3%	14.5%	14.3%	14.4%
HE in the outpatient sector	n.a.	n.a.	n.a.	n.a.
– <i>thereof public</i>	n.a.	n.a.	n.a.	n.a.
– <i>thereof private</i>	n.a.	n.a.	n.a.	n.a.
HE in the in-patient sector	n.a.	n.a.	n.a.	n.a.
– <i>thereof public</i>	n.a.	n.a.	n.a.	n.a.
– <i>thereof private</i>	n.a.	n.a.	n.a.	n.a.
<i>Exchange rate (NOK per €)</i>	8.01	8.95	9.85	10.17

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 10.1% of GDP in 2021, of which the public share amounted to 8.6% and the private share to 1.5%. "Private shares" includes e.g. households' out-of-pocket payments, NGOs and private corporations.⁸

1.4 Sources of funding

Sources of funding 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. However, 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

⁸ OECD (2022), Health spending (indicator). doi: 10.1787/8643de7e-en. October 2022.

⁹ Cf. section 2.9.

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.

Treatment for patients from abroad is billed to the patient's insurance scheme. There are 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, 36% of Norwegians would consider paying more for having access to faster and easier access to health care.¹⁰ Table 1.2 (cf. section 1.3) shows that 14.4% of total spending on healthcare is private. For instance, in 2020, about 12% of the population have a private health insurance, often paid by the employer.¹¹

¹⁰ Kantar TNS Helsepolitisk barometer 2021.

¹¹ <https://kommunikasjon.ntb.no/pressemedling/antall-helseforsikringer-okte-med-53-prosent-i-2020?publisherId=17846751&releaseld=17905265>, April 2021.

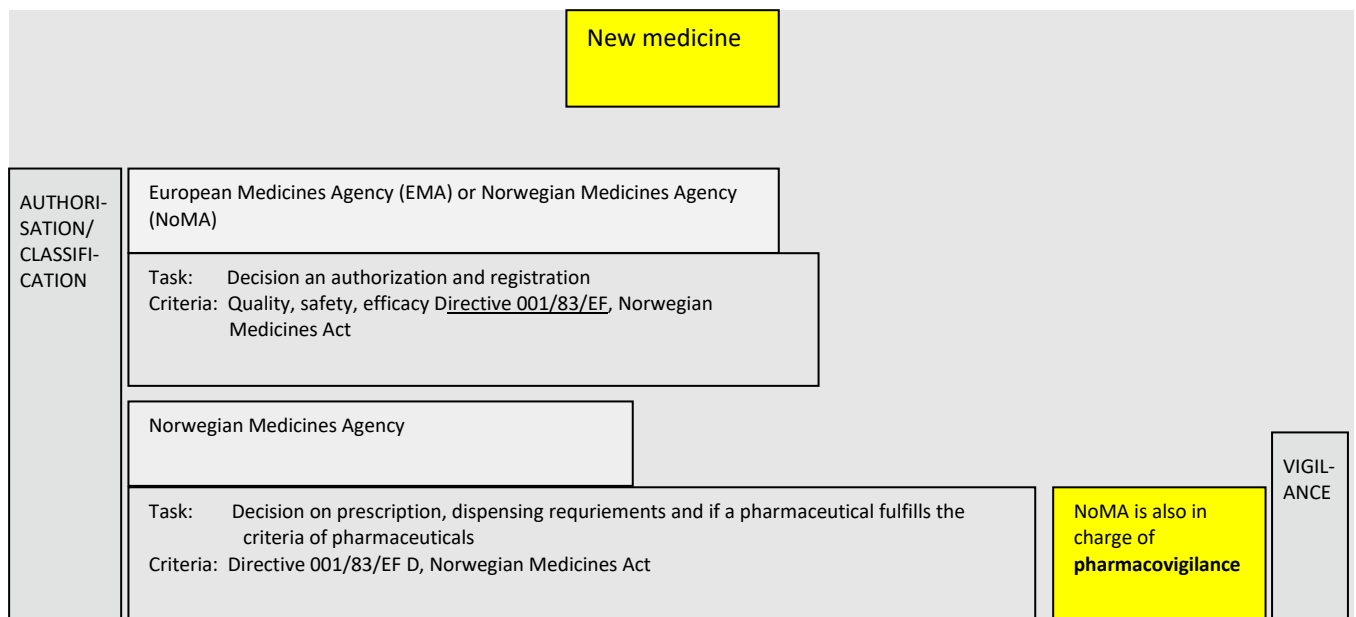
2 Pharmaceutical system

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. chapter 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, 2022.

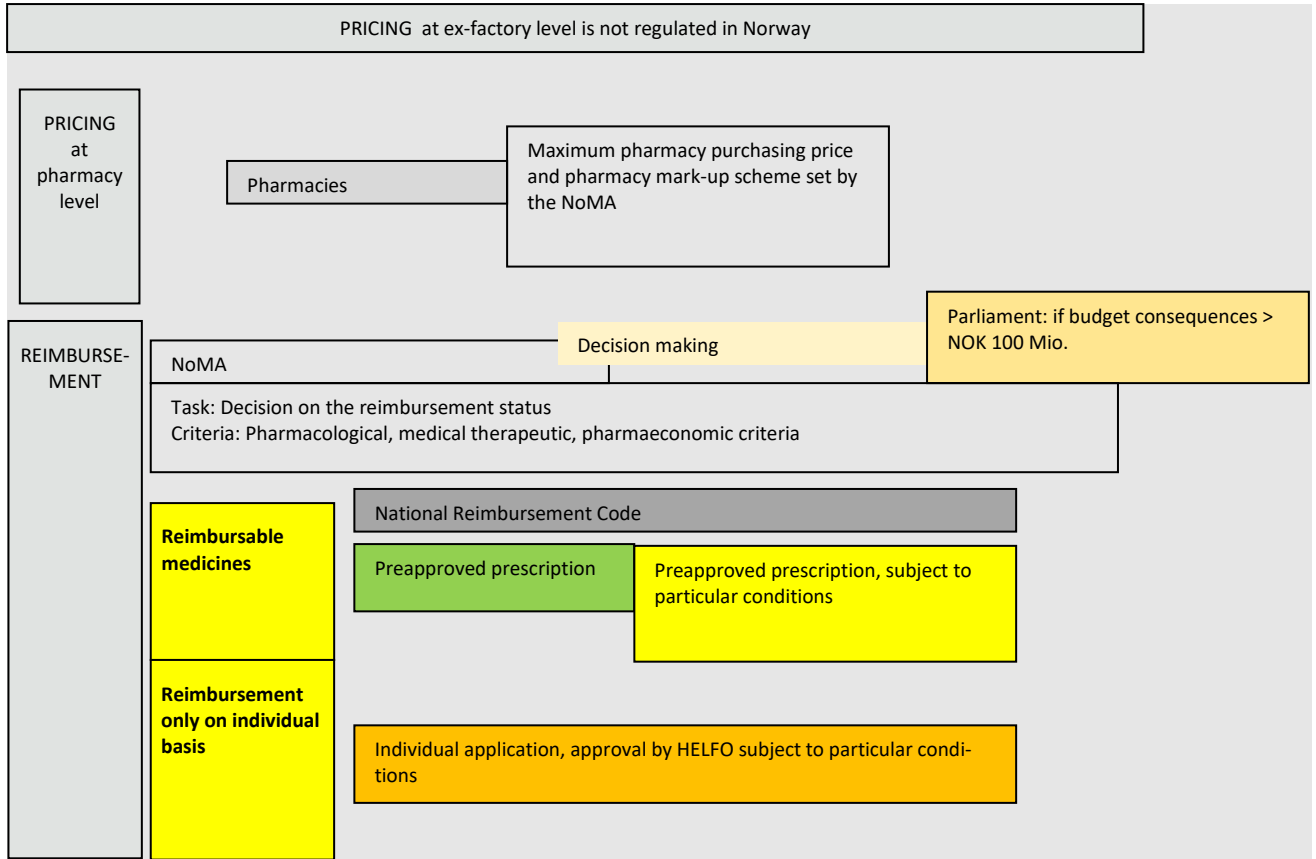


Source: NoMA.

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. However, the systems for pricing and reimbursement in Norway differ between the two sectors, cf. figures 2.2 and 2.3.

The frequently used terms “out-patient” and “in-patient” are not adequate for describing the health system in Norway. Instead, the two sectors are defined as primary care services, and specialist care services. 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, 2022.



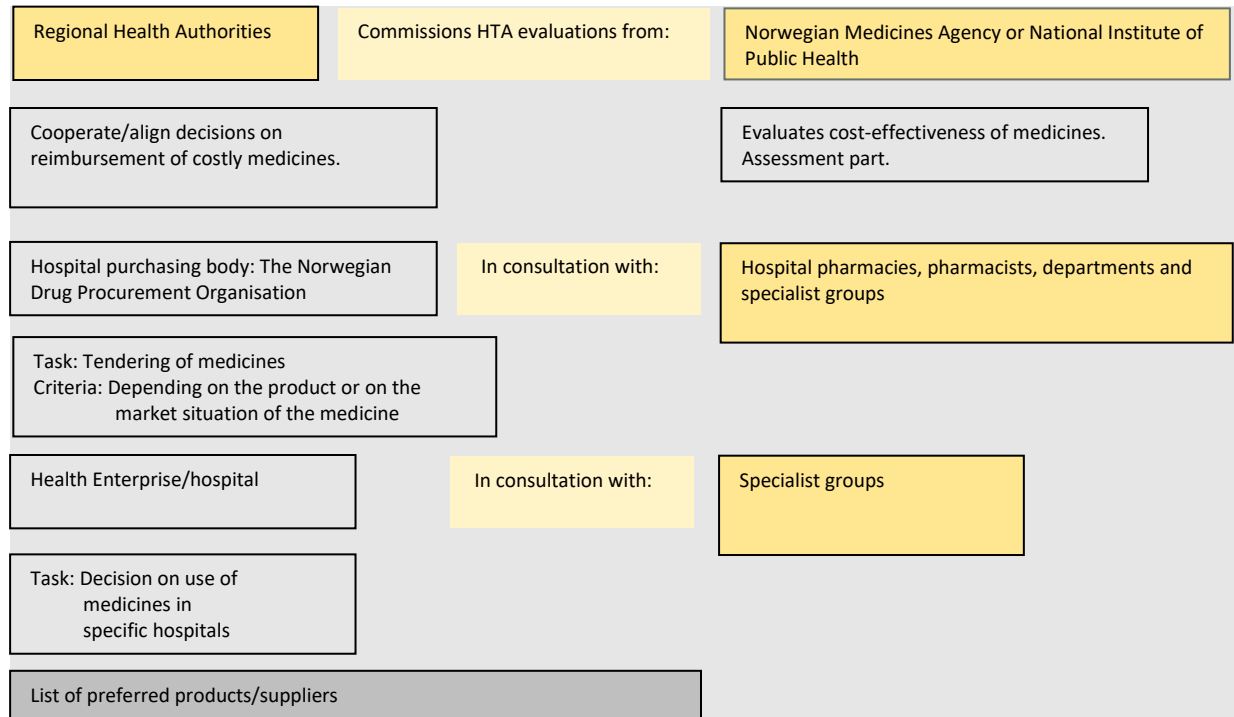
Source: NoMA.

The Norwegian Health Economics Administration – Helfo, 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.

Norway

Figure 2.3:

Norway – Flowchart of pricing and reimbursement in the specialist care sector, 2022.



Source: NoMA.

Norway

Table 2.1:

Norway – Legal basis and actors of the pharmaceutical system, 2022.

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 associa- tions in English (local name, local abbrevia- tion)
Marketing au- thorisation	The Norwegian Act on Medicinal Products. Norwegian Regulation relating to Medicinal Products.	Specialist & primary care sector. All registered/licensed pharmaceuticals (POM, OTC).	The Norwegian Medi- cines Agency (Statens legemiddelverk, SLV).	In charge of marketing authorisation, classifica- tion and pharmaco-vigi- lance.	Norwegian Association of Pharmaceutical Manufactur- ers (Legemiddelindustrien, LMI).
Pricing / Pur- chasing	The Norwegian Act on Medicinal Products. Norwegian Regulation relating to Medicinal Products.	All registered POM. Specialist care.	The Norwegian Medi- cines Agency (Statens legemiddelverk, SLV). The Norwegian Drug Procurement Organisa- tion (Sykehusinnkjøp HF).	In charge of pricing.	Norwegian Association of Pharmaceutical Manufactur- ers (Legemiddelindustrien, LMI). Norwegian Pharmacy Associ- ation (Apotekforeningen).

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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 system	Actors and interest associations in English (local name, local abbreviation)
Reimbursement	<p>The Norwegian Act on Medicinal Products.</p> <p>Norwegian Regulation relating to Medicinal Products.</p> <p>The Specialist Health Care Services Act - 1999.</p> <p>The Patients' Rights Act - 1999.</p>	<p>Primary and secondary care.</p> <p>Primary care sector: Registered POM (and some OTC) pharmaceuticals.</p> <p>Specialist care.</p>	<p>Directorate of Health (Helsedirektoratet).</p> <p>Norwegian Health Economics Administration (HELFO).</p> <p>The Norwegian Medicines Agency (Statens legemiddelverk, SLV).</p> <p>Regional Health Authorities/Health Enterprises Regionale helseforetakene (RHF)/ Helseforetakene (HF).</p>	<p>Deciding financing-responsibility: primary or specialist care.</p> <p>In charge of reimbursing. Subordinate of The Directorate of Health (Helsedirektoratet).</p> <p>In charge of deciding reimbursement-status in the primary care sector.</p> <p>In charge of deciding reimbursement-status in the specialist care sector.</p>	<p>Norwegian Association of Pharmaceutical Manufacturers (Legemiddelindustrien, LMI).</p> <p>Patient organisations.</p>
Promotion	<p>The Norwegian Act on Medicinal Products.</p> <p>Norwegian Regulation relating to Medicinal Products.</p>	<p>All interaction between manufacturers/MA-holders and health personnel/ patients/distribution chain.</p>	<p>The Norwegian Medicines Agency (Statens legemiddelverk, SLV).</p>	<p>In charge of monitoring information/promotion activities.</p>	<p>Norwegian Association of Pharmaceutical Manufacturers (Legemiddelindustrien, LMI).</p>

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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 system	Actors and interest associations in English (local name, local abbreviation)
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 (Legemiddel-grossist-foreningen, LGF).
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.	Norwegian Association of Pharmaceutical Manufacturers (Legemiddelindustrien, LMI).

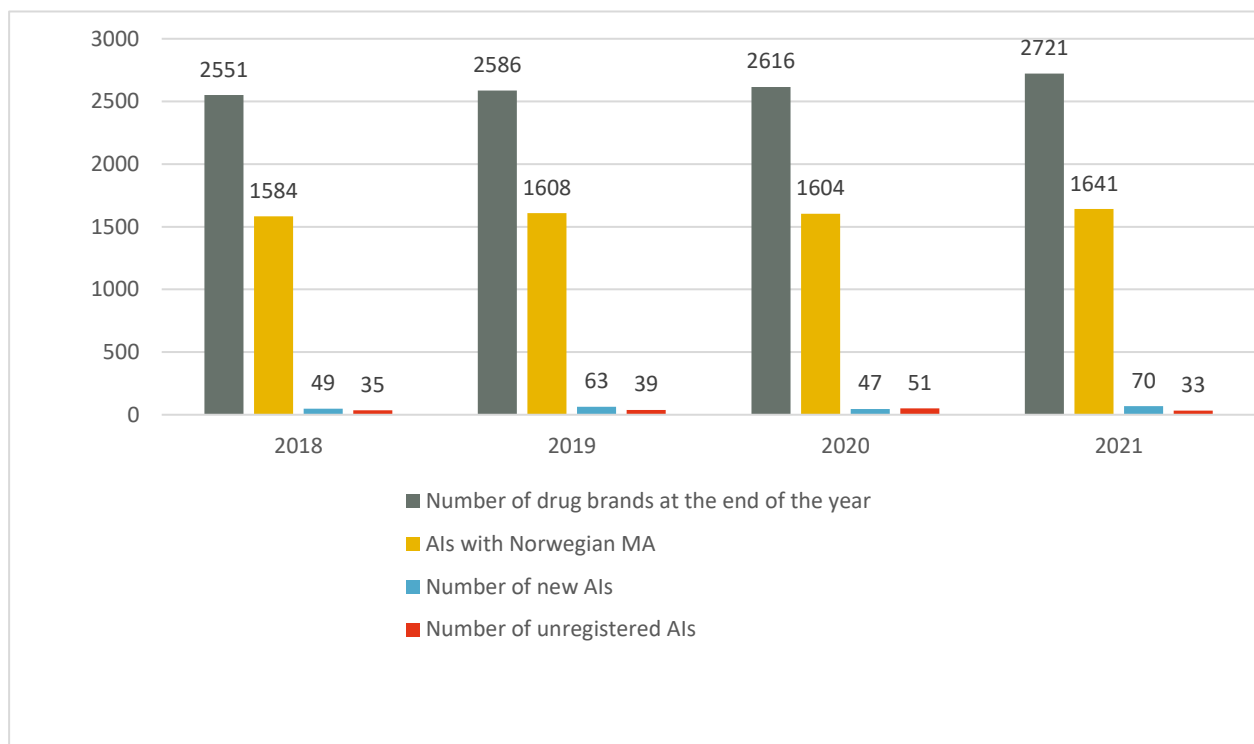
Source: NoMA.

2.2 Availability of and access to medicines

The number of approved medicines in Norway is increasing, cf. figure 2.4. As of 2021, there were 1,641 active ingredients (AI) registered. In 2021, 70 new AIs have been registered, while 33 have been unregistered. The AIs are distributed across 2,721 different brand names, including all strengths, package sizes and dosage forms.

Figure 2.4:

Norway – Number of approved active ingredients and drug brands 2018–2021.



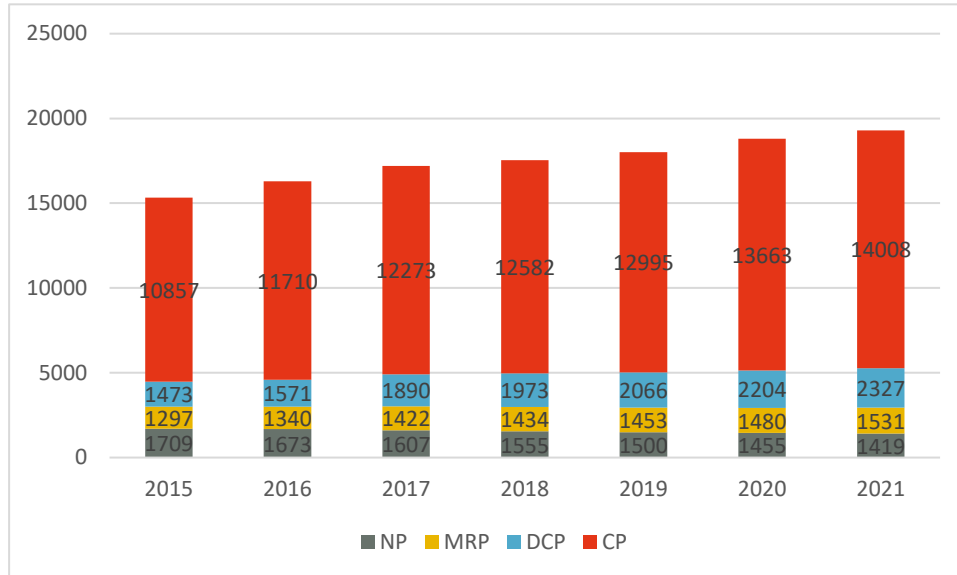
Source: NoMA.

«Unregistered AIs» are active ingredients without approved Marketing Authorisations (MA). The registered and unregistered AIs and drug names are distributed on 19,285 approved MAs in 2021. Of these, 14,008 have been approved via Central Procedure, 2,327 via Decentral Procedure, 1,531 via Mutual Recognition Procedure and 1,419 via National Procedure, cf. figure 2.5.

Norway

Figure 2.5:

Norway – Number of Marketing Authorisations at the end of the year – per procedure 2015 – 2021.



Source: NoMA.

The time it takes from a new medicine is granted a MA, until it is actually 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 34 days in 2021. Three applications took more than 90 days (maximum processing time).¹² In 2019, the average time for applications for general reimbursement was 66 days (including generics). 91% of those applications were processed within 180 days.¹³

2.3 Development of the pharmaceutical sales

The number of prescriptions in Norway has been steadily increasing in the past years, cf. table 2.2. Between 2019 and 2021, prescription volume increased 5.6%, while prescription value increased 15.6%.

Along with prescriptions, spending on pharmaceuticals has been growing in the past years. Between 2020 and 2021, the spending on pharmaceuticals has increased by 4.4% (adjusted for population

¹² Annual report 2021, NoMA.

¹³ Annual report 2019, NoMA.

growth).¹⁴ Particularly novel drugs for treatment of cancer, rheumatic diseases, blood clots and rare diseases, have contributed to a higher cost. In addition, the ageing population contributes to an increased use of pharmaceuticals.

Table 2.2:

Norway – Annual prescriptions in community pharmacies 2005, 2010, 2019 and 2021.

Prescriptions	2010	2015	2019	2021
No. of prescriptions (in volume)*	39,492	47,425	53,898	56,952
Prescriptions in value (PRP) in NOK**	13,199	16,888	20,700	24,176

*Prescription in volume = number of items prescribed, excluding sales of veterinary medicines.

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

PRP = pharmacy retail price incl. VAT.

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. One year later 15% of the prescriptions were electronic. Further, 79% prescriptions were electronic in 2015, and 93% of the prescriptions were electronic in 2021. Accurate comparisons of the number of prescriptions are therefore not available. Excluding the use of multidoses (which are not available on e-prescription) and prescribers with no access to e-prescription, the share of e-prescriptions is close to 98%.¹⁵

The figures in table 2.2 also include “H-prescriptions”. These are prescriptions that are reimbursed by the Regional Health Authorities (RHA), cf. section 4.1. In 2021, 1% of the prescriptions were “H-prescriptions”. The medicines on “H-prescriptions” are rather costly, and their value (PRP) in 2021 was NOK 6.7 billion (€ 670 Mio.), almost 28% of the value of total prescriptions.¹⁶

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 “stepped 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.

¹⁴ NPA.

¹⁵ <https://www.apotek.no/statistikk/apotekstatistikk/kunden/e-resept>.

¹⁶ Farmalogg, NPA.

Important steps towards cost-containment for reimbursable medicines have been taken. One important step has been the establishment of The Norwegian Drug Procurement Organisation (Sykehusinnkjøp HF), centralizing procurement for the RHAs, as well as further interface management. For example financing of several medicines that often are dispensed in public pharmacies, but which are 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).

2.4 Pharmaceutical consumption

The sales volume measured in number of DDDs increased by 3.2% in year 2021, and 31% in the period 2010 – 2021, cf. table 2.3.

Table 2.3:

Norway – Annual pharmaceutical consumption 2010, 2015, 2019, 2021.*

Consumption* (mio.)	2010	2015	2019	2021
Total pharmaceutical consumption				
In packs	84.7	92.3	99.7	104
In DDD**	2581.6	2866.8	3114.5	3387.6
Pharmaceutical consumption in the in-patient sector				
In packs	n.a.	n.a.	n.a.	n.a.
In DDD	n.a.	n.a.	n.a.	n.a.
Pharmaceutical consumption in the outpatient sector				
In Packs	n.a.	n.a.	n.a.	n.a.
In DDD	n.a.	n.a.	n.a.	n.a.

DDD = defined daily doses

*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 74% of the substitutable market today.

Table 2.3:

Norway – Development of the generic shares in volume and value, 2010, 2021.

Generic share	Volume ¹		Value ²	
	2010	2021	2010	2021
Shares in % of total market (in-patient/ outpatient)	64	74	46	60
Shares in % of total outpatient market	n.a.	n.a.	n.a.	n.a.
Shares in % of outpatient re-imbursment market	n.a.	n.a.	n.a.	n.a.
Shares in % of outpatient off-patient market	n.a.	n.a.	n.a.	n.a.
Shares in % of the in-patient market	n.a.	n.a.	n.a.	n.a.

¹ Number of DDD.

² Expenditure expressed in PPP.

Source: LMI.¹⁷

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. The top AI in terms of expenditure in 2021 in the primary care sector, is an anticoagulant, cf. table 2.5. Off-patent medicines are those leading the list in terms of consumption, where the top-seller is a statin.

¹⁷ Facts & figures 2015 and 2022, LMI.

Norway

Table 2.5:

Norway - Top 10 active ingredients in volume and value in the care sector, 2021

Position	Top active ingredients used in the primary care sector, ranked with regard to consumption*		Position	Top active ingredients used in the primary sector, ranked with regard to expenditure	
1	C10AA05	Atorvastatin	1	B01AF02	Apixaban
2	B01AC06	Acetylsalicylic Acid	2	L01FF02	Pembrolizumab
3	C09Ca06	Candesartan	3	L04AX0	Lenalidomide
4	N02BE01	Paracetamol	4	N02BE01	Paracetamol
5	C08CA01	Amlodipine	5	A10BJ02	Liraglutide
6	R06AE07	Cetirizine	6	A10BJ06	Semaglutide
7	A11CC05	Cholecalciferol	7	L01FC01	Daratumumab
8	A02BC02	Pantoprazole	8	L01FF01	Nivolumab
9	R06AX27	Desloratadine	9	B01AF01	Rivaroxaban
10	C09AA05	Ramipril	10	J06BA02	Immunoglobulins, normal human, for intravascular adm.

* Ranked by DDD.

Source: Farmalogg, NPA.

The top two AIs in terms of consumption in the specialist care sector, cf. table 2.6, are used to treat inflammation, followed by two AIs utilized in opioid replacement therapy (the LAR-program). The top AI in terms of expenditure is a type of immunotherapy which stimulates the body's immune system to fight cancer cells.

Table 2.4:

Norway - Top 10 active ingredients in volume and value in the specialist care sector, 2021.

Position	Top active ingredients used in the specialist care sector, ranked with regard to consumption**		Position	Top active ingredients used in the specialist sector, ranked with regard to expenditure	
1	L04AB02	Infliximab	1	L01FF02	Pembrolizumab
2	L04AB04	Adalimumab	2	J06BA02	Immunoglobulins, normal human, for intravascular adm.
3	N07BC02	Methadone	3	L04AX04	Lenalidomide
4	N07BC01	Buprenorphine	4	L01FC01	Daratumumab
5	H02AB02	Dexamethasone	5	L01FF01	Nivolumab
6	N02BE01	Paracetamol	6	L04AA33	Vedolizumab
7	L04AC05	Ustekinumab	7	L04AA27	Fingolimod
8	L04AB01	Etanercept	8	L04AA40	Cladribine
9	B01AB04	Dalteparin	9	S01LA05	Aflibercept
10	A11CC05	Cholecalciferol	10	L04AC05	Ustekinumab

*Based on consumption or expenditure of drugs in the regional health enterprises/hospitals, including drugs used in hospitals, H-prescriptions and opioid replacement therapy (LAR - numbers are stipulated).

**Consumption is ranked by DDD.

Source: Sykehusapotekenes legemiddelstatistikk (SLS).

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. Eleven companies have production facilities in Norway. The largest companies are GE, Fresenius Kabi and Takeda.¹⁸

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 Norwegian Association of Pharmaceutical Manufacturers (LMI). It represents research-orientated companies, often also with a generic's portfolio, and small-medium sized Norwegian biotech companies. In addition, all pharmaceutical companies specialising in aquacultures are members.

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 NCU 8 billion (€ 800 Mio.) in 2021.¹⁹

In 2018, the pharmaceutical industry in Norway invested approximately NOK 1 billion in science and development.²⁰ The industry has approximately 4,500 (LMI members) employees and contributes to the

¹⁸ <https://www.lmi.no/tall-og-fakta-2022/>

¹⁹ <https://www.lmi.no/tall-og-fakta-2022/>

²⁰ <https://www.lmi.no/tall-og-fakta-2018/>

accumulation and diffusion of relevant scientific knowledge in hospitals and private business involved in science.²¹

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 table 2.7.

Table 2.5:
Norway – Wholesalers, 2022.

Company	Market share (%)	Ownership
Apotek 1 Gruppen AS	33	Phoenix International Beteiligung GmbH
Alliance Healthcare Norge AS	41	AmerisourceBergen
Norsk Medisinaldepot AS	26	McKesson Corporation

Source: LMI.²²

In general, pharmacies get supplies from the wholesalers daily. 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 in 2015. Alliance Healthcare Norge AS also won the tender in 2021 for a new contract period of 4+2+2 years. Former wholesaler for hospitals and hospital pharmacies – Norsk Medisinaldepot AS, on the other hand, became the contracted wholesaler for H-prescription products in 2017.

Parallel trade wholesalers do not exist per se, but the major wholesalers engage in parallel export. Marketing authorisation is required for the sale of parallel imported medicinal products. In 2022 six companies submitted an application.

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.

²¹ <https://www.lmi.no/tall-og-fakta-2022/>

²² <https://www.lmi.no/tall-og-fakta-2022/>

2.7.3.1 Community pharmacies

The pharmacies' activities are regulated by the Norwegian Pharmacy Act and the associated regulations on pharmacies. The 1010 community pharmacies (as of October 2022) 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. 94% of the private pharmacies are owned by a wholesale company.²³ In addition, there is a chain of semi-independent pharmacies and a few independent pharmacies.

As of July 1 2022, there are approximately 5,231 inhabitants per community pharmacy.

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 are 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.

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. There are about 10 doctors with such a licence. The dispensing doctors are allowed to add a 10% extra mark-up on the fixed prices.²⁴ 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.²⁵ Public health nurses may prescribe contraceptive pills.²⁶

²³ NoMA. Evaluering av apotekavanse 2020. December 2020.

²⁴ Forskrifter om legers og veterinærers levering av legemidler m.v., mot betaling, § 5.

²⁵ The Norwegian Act on Medicinal Products § 17.

²⁶ Forskrift om rekvirering og utlevering av legemidler fra apotek, § 2-5.

2.7.3.3 Hospital pharmacies

Hospital pharmacies are owned by the Regional Health Authorities. The 33 hospital pharmacies are responsible for procurement of medicines, production of ready to use injection/infusion and pharmaceutical services including clinical pharmacy.²⁷

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.²⁸ 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 772 such outlets, mainly in grocery stores.²⁹ 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). The outlets keep in stock a small selection of over-the-counter (OTC) products and can dispense prescription medicines sent by the pharmacy. The legal basis for these outlets is Act on Medicinal Products § 16.

2.7.3.5 Other retailers

Grocery stores, gasoline stations, health stores, etc. are allowed to distribute a restricted list of OTC; these are known as medicines sold outside of the pharmacies (LUA). There are several thousand outlets that sell these medicines. 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.

²⁷ <https://www.apotek.no/statistikk/apotekstatistikk/apotek>. October 2022.

²⁸ Forskrift om grossistvirksomhet med legemidler, § 13.

²⁹ <https://www.apotek.no/Default.aspx?ID=9294>. January 2022.

Table 2.6:

Norway – Retailers of medicines 2010, 2015, 2019, 2021.

Retailers	2010	2015	2019	2021
No. of community pharmacies ¹	650	814	927	1010
– <i>Thereof:</i> <i>No. of private pharmacies²</i>	650	814	927	1010
– <i>Thereof:</i> <i>No. of public pharmacies</i>	0	0	0	0
No. of hospital pharmacies for outpatients	33	32	33	33
No. of dispensing doctors	n.a.	n.a.	n.a.	n.a.
No. of other POM disp., pharmacy outlets	n.a.	n.a.	770	772
Total no. of POM dispensaries				
No. of internet pharmacies*	n.a.	n.a.	15	16
No. of NPM disp., like drugstores	Several thousand	Several thousand	Several thousand	Several thousand

Disp. = dispensaries, NPM = non-prescription medicines, POM = prescription-only medicines

POM dispensaries are facilities that are allowed to sell POM to outpatients.

¹ Hospital pharmacies dispensing to outpatients are not included in this figure.

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

* Internet pharmacies must be registered with the NoMA.³⁰

Source: NoMA, NPA.

2.8 Pharmaceutical expenditure

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. chapter 5.1) and the development of costly medicines mainly prescribed by doctors in the specialist care sector.

³⁰ <https://legemiddelverket.no/import-og-salg/apotekdrift/registreringsordning-for-netthandel-med-legemidler/godkjente-utsalgssteder#klikk-her-for-%C3%A5-se-registrerte-nettapotek>.

Table 2.7:

Norway - Total pharmaceutical expenditure 2010, 2015, 2019, 2021.

Pharmaceutical expenditure*	2010	2015	2019	2021
TPE in bill. NOK**	18.6	24.3	30.2	35.9
– <i>thereof National Insurance Scheme</i>	9.4	11.6	11.7	13.8
– <i>thereof hospitals***</i>	3.9	5.9	10.6	12.6

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

*Estimated PRP.

**Including sales of products with approved marketing authorisation in Norway.

*** Includes out-of-hospital use.

Source: Norwegian Drug Wholesales Statistics and NorPD, NIPH, and Sykehusenes Legemiddelstatistikk, SLS.

2.9 Sources of funding

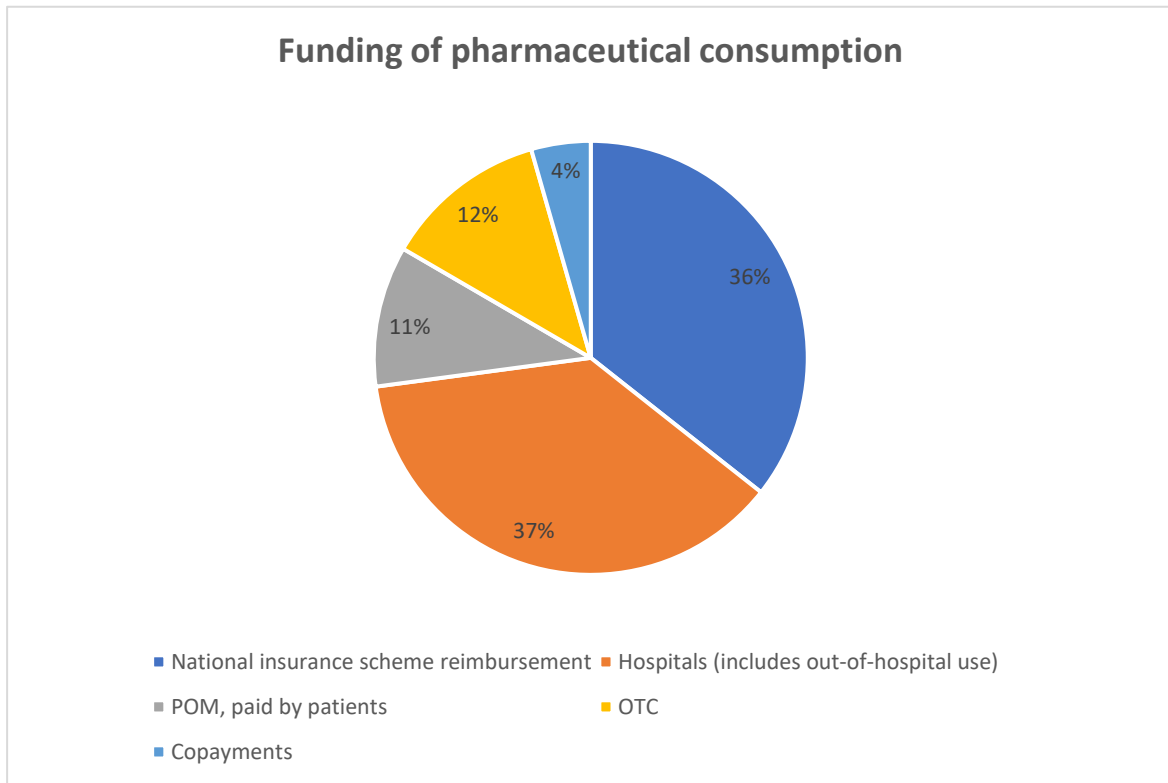
The Norwegian Directorate of Health decides which pharmaceuticals should be funded and reimbursed by the National Insurance Scheme (NIS), or the Regional Health Authorities, (cf. section 2.1).

Public funding of medicines accounted for 73% (NIS 36% and Hospitals 37%) of overall pharmaceutical spending in 2021, cf. figure. 2.6. Copayments and POM – paid by patients, account for 15%, while the remaining 12% is OTC-purchases of medicine.

In the four-year period 2017 – 2021, the funding by the NIS increased 12%, while funding of the specialist care (hospitals) increased 42%.³¹ Further, POMs paid by patients increased 10%, and copayments increased almost 20%.

³¹ Nominal values.

Figure 2.6
Norway – Split of funding of medicines, 2021.



Source: NIPH and NPA.

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

As mentioned, the definitions “out-patient” and “in-patient” are not adequate 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 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, was implemented in 2002. Before entering the Norwegian market, the Marketing Authorisation Holder (MAH) must apply for a maximum price with the Norwegian Medicines Agency (NoMA).

The Stepped price model (Trinnprismodellen) with generic competition was introduced in 2005 to reduce costs incurred by the National Insurance Scheme (NIS) and patients in relation to the use of generic medicines. Since august 2021 there has also been a stepped price model for biosimilars.

In the stepped price models – for generic or biosimilar medicines, 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 or biosimilar competition. The Stepped price model for generic medicines has been modified four times after its introduction with the aim of reducing medicine prices.

Table 3.1:

Norway – Ways of pricing of medicines at pharmacy level, 2022.

Pricing policies	(Non) prescription market		(Non) reimbursement market		Specific groups of medicine		
	POM	NPM (OTC)	Reim-bursable	Non-reim-bursable	Generics	Parallel imported	Others, specify: e.g. bio-similars
Free pricing	–	Yes	Yes, if individually approved OTC.	OTC	–	–	–
Statutory pricing	Yes	Yes, if reimbursable & on positive list*	Yes	POM	–	–	–
Price negotiations	No	No	No	No	No	No	No
Tendering	No	No	No	No	No	No	No

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

POM = prescription-only medicine, NPM = non-prescription medicine.

OTC drugs are usually not price regulated. There is no price notification in the statutory pricing system in Norway, and there is no regulation of prices at manufacturer level in Norway.

Source: NoMA.

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 or biosimilar competition arises for a substitutable medicine.

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.

Table 3.2:

Norway – Pricing procedures, 2022.

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	–	–
Managed-entry agreements	Yes	Pharmacy purchasing price	Defined by agreement

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

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

Source: NoMA.

The maximum price is set based on external reference pricing. According to Regulation on Medicinal Products, § 12-2, the price decision should consider 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, which is the case for example with ready-to-use adrenaline injections.

Each Marketing Authorisation Holder (MAH) is obliged, on request, to provide the NoMA the 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. Every autumn, the NoMA publishes a plan for next year's price revision.³² 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.

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 or biosimilar competition for a substitutable medicine arises. The NIS reimburses the stepped price, or in the case of non-reimbursable drugs, the patient pays it. 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.³³ The stepped price for a substance with generic or biosimilar competition is set as a percentage of the maximum PPP of the original medicine at the time it first was exposed to competition. The price is cut by two or three steps, cf. table 3.3.

For synthetic drugs there are two price-cuts.³⁴ The first price-cut takes place when generic competition arises. The second price-cut is implemented 18 months or more after generic competition has occurred. For biological drugs the first price-cut takes place when biosimilar competition arises.³⁵ Further price-cuts are implemented 6 months after competition has occurred. A third step is applicable 12 months or more after the implementation 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 or biosimilar competition.

There are specific cut rates for Atorvastatin and Simvastatin and Atorvastatin, 94% and 96%, respectively. The NoMA may on a discretionary basis decide lower cuts than the standard cut rates. This is for example

³² <https://legemiddelverket.no/offentlig-finansiering/maksimalpris#revurdering-av-maksimalpriser>.

³³ www.noma.no, October 2022.

³⁴ Until 1 January 2022, there were three price-cuts for synthetic drugs. The initial 35% price-cut was removed.

³⁵ Biological drugs were included in the stepped price model 1 January 2022.

sometimes done when the turnover of the substance is very low. Also, minimum stepped price per package (PRP) is NOK 55,40 (prescription group C), and NOK 79,10 for habit-forming/addictive prescription medications (prescription groups A and B).³⁶

Table 3.3:

Norway – Overview of the stepped price system (trinprismodellen), 2022.

Sales PRP, within a 12-month period during the two last years before generic competition was established.		< 100 Mio. NOK	> 100 Mio. NOK	
1 st step	Time of price-cut Start of generic competition	59%	81%	
Sales PRP \geq 18 months after start of 1 st step		> 15 Mio. NOK	> 30 Mio. & < 100 Mio. NOK	> 100 Mio. NOK
2 nd step	Time of price-cut \geq 18 months after start of 1 st step	69%	88%	90%
Sales PRP, within a 12-month period during the two last years before biosimilar competition was established.		< 100 Mio. NOK	> 100 Mio. NOK	
1 st step	Time of price-cut Start of biosimilar competition	25%	25%	
2 nd step	6 months after start of 1 st step	50%	70%	
Sales PRP \geq 12 months after start of 2 nd step		> 15 Mio. NOK	> 30 Mio. & < 100 Mio. NOK	> 100 Mio. NOK
3 rd step	Time of price-cut \geq 12 months after start of 2 nd step	60%	75%	80%

PRP = Pharmaceutical Retail Price.

Source: NoMA.

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.

³⁶ NoMA, 2022.

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

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).

It is prohibited to give discounts that are not established at the time of the sale of a medicinal product (Law on Medicinal Products § 6). The ban does not apply to discounts that result from an agreement between the public sector and the medicinal product's licensee to ensure public funding of the medicinal product, cf. chapter 3.4.6 Managed entry agreements.

All prices reported to the authorities should be reported as net-prices (Law on Medicinal Products § 6). 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. All POM medicines have a flat mark-up of 2 %. The fixed mark-up is NOK 29 (€ 2.9). 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 the use of inhalators for Asthma/CLD. Pharmacies are refunded NOK 84 (€ 8.4) for each training to patients.³⁷ A similar compensation was 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 235 (€ 23.5) for each information meeting. Both schemes are publicly funded and free of charge for patients. The aim of the meetings is to improve compliance.³⁸

³⁷ <https://www.helfo.no/regelverk/veiledning-i-apotek>

³⁸ <https://www.helfo.no/regelverk/veiledning-i-apotek>

Table 3.4:

Norway – Pharmacy mark-up scheme, 2022.

Pharmacy purchasing price	Maximum mark-up in % of pharmacy purchasing price
All POM packages	2%
	Fixed mark-up per package
All POM packages	NOK 29 (€ 2.9)
Additional for drugs requiring refrigeration	0.5%
Additional for addictive drugs/narcotics	NOK 19 / € 1.9

Source: NoMA.

The average pharmacy margin for POM included in the stepped price model was 66% in 2019. The whole-sale mark-up is not regulated. The average wholesaler margin was 44% in 2019.³⁹

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% (2022) 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% (2022) of the wholesalers purchasing price (ex-factory price). The tax is to be reported and paid to the NoMA by the Marketing Authorisation Holder.

There is a tax on sales in other retailers than pharmacies (LUA-avgift), such as grocery stores, petrol stations etc. (cf. section 2.7.3.5). The tax is 0.5% from 1st January 2023, reduced from 1.2% in 2022. 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.

³⁹ Evaluering av apotekavanse 2020, NoMA.

3.3.1 Reimbursement policies

In June 2016, the government described principles for priority-setting in a White Paper 34 (2015–2016) (1).⁴⁰ The Pharmaceutical Products Regulations, Sections 12 and 14, which regulates the pricing and reimbursement of medicines by the National insurance scheme, have 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 health benefit, 2) resource used 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 benefits to patients is reasonable. The cost-effectiveness ratio will be weighed against the severity of the relevant condition/disease. For more severe conditions, a higher cost-effectiveness ratio will be accepted.

- The health-benefit outcome should be measured in quality adjusted life years (QALYs).⁴¹
- Resource usage includes average pharmaceutical costs and other resource utilization in health and care services, compared to alternative treatment practices.
- Severity should be measured as absolute shortfall – loss of life-years in good quality for patients in the particular group as a result of not making the treatment under assessment available.
- 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). Over-the-counter (OTC) products are mostly not reimbursed.

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

⁴⁰ Prioriteringsmeldingen.

⁴¹ QALY are calculated by estimating the years of life remaining for a patient or a group following a particular treatment and weighting each year with a quality-of-life score (on 0–1 scale). The quality adjusted life year is a generic measure of disease burden, including both the quality and the quantity of life a person might gain as a result of a given treatment compared to alternative treatment options.

3.3.2 Reimbursement procedure

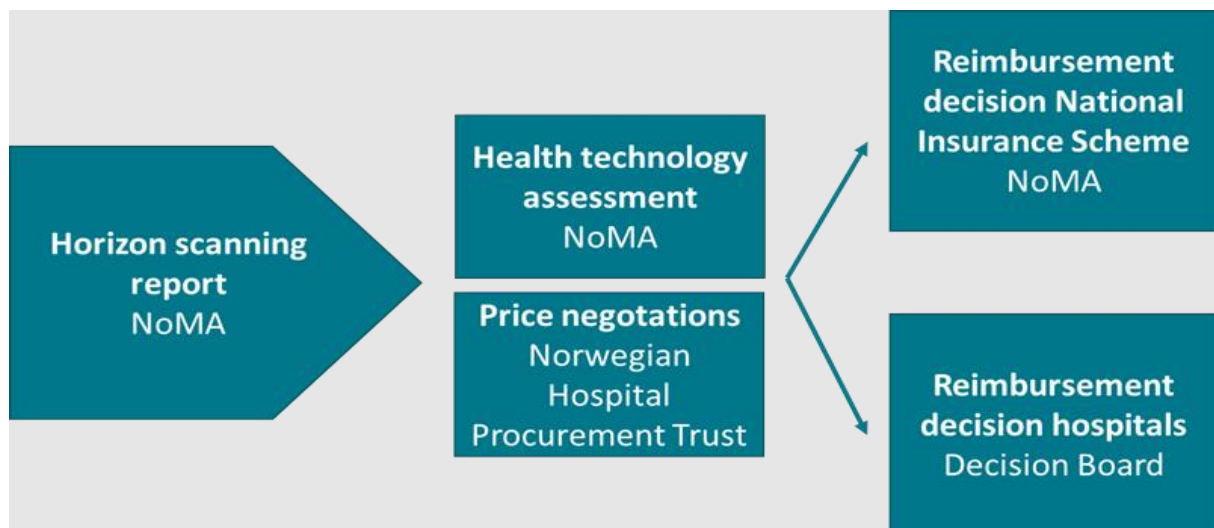
3.3.2.1.1 Decision making process

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 (HTAs). 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 prioritisation and decisions making. This is done to ensure that new technologies introduced are proven as safe and effective.

In 2021, the NoMA completed 94 HTAs, of which 27 on medicines financed by National Insurance scheme (NIS) and 67 on medicines financed by the hospitals.⁴²

Figure 3.1:

Norway – The decision-making process for reimbursement.



Source: NoMA.

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

⁴² <https://legemiddelverket.no/Documents/Om%20oss/%C3%85rsrapporter/%C3%85rsrapport%20for%202021.pdf>.

negotiations with the MAH. The Norwegian Drug Procurement Organisation (Sykehusinnkjøp HF) is responsible for price negotiations for medicines reimbursed by both hospitals and the National Insurance scheme (NIS).

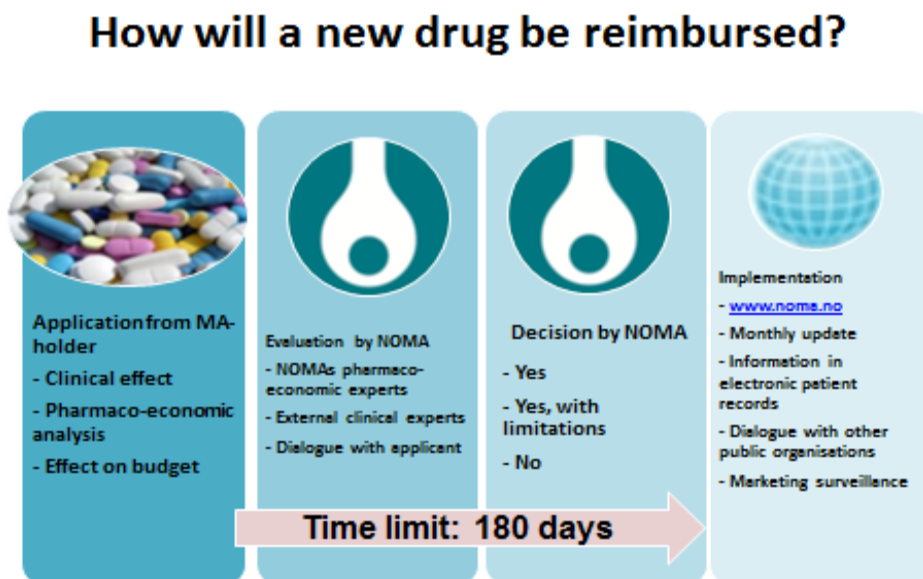
The NoMA is responsible for reimbursement decisions on behalf of the NIS. If the reimbursement decision is estimated to have an annual incremental fiscal impact above NOK 100 Mio. (€ 10 Mio.) by the fifth year after approval, the NoMA is not authorized to grant reimbursement.⁴³ In this case, provided that the application fulfils all prioritisation criteria, the NoMA will pass its appraisal on to the Ministry of Health and Care Services (HOD) which 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.

In 2021 there was one case – the medicine Rybelsus (semaglutide), which exceeded the limit of NOK 100 Mio. (€ 10 Mio.) and were submitted to the HOD.

For decisions regarding medicines paid by the Regional Health Authorities, cf. chapter 4.

Figure 3.2:

Norway – Reimbursement process in the primary care sector.



Source: NoMA.

⁴³ www.regjeringen.no/no/tema/helse-og-omsorg/legemidler/innsikt/finansiering-av-legemidler/id434582.
September 2021.

The time allocated to the NoMA for processing the reimbursement application is 180 days, cf. figure 3.2. Effective processing time may arise due to clock-stops, e.g. in case the NoMA needs further information to process an application. The median processing time in 2021 for medicines financed by NIS and by the hospitals, were 121 and 180 days, respectively.

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 Pharmaco-economic evaluation

A pharmaco-economic 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 guidelines: "Guidelines for the submission of documentation for single technology assessment (STA) of pharmaceuticals".⁴⁴

The guidelines require an explanation of the choice of comparison, the time frame for the analysis, data collection methods, analysis methods and costs. Pharmaco-economic evaluation is carried out for all 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. There is no official threshold. For severe conditions, high-cost effectiveness ratio may be accepted. Severity is measured as absolute QALY shortfall.

⁴⁴<https://legemiddelverket.no/Documents/English/Public%20funding%20and%20pricing/Documentation%20for%20STA/Guidelines%2018.10.2021.pdf>.

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 (cf. 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 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 2021, approximately 82.5% of the total NIS reimbursement expenditure of NOK 12.4 billion (€ 1.24 billion) arose from Schedule 2. Schedule 3 accounted for respectively 17.3% of total reimbursement. Reimbursement by schedule 4 was approximately 0.1% of total reimbursement.⁴⁵ The significantly lower reimbursement on schedule 4 in 2021, is due to a transfer of medicines to treat HIV and hepatitis C, from schedule 4 to H-prescriptions.

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 website⁴⁶ 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-11 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-

⁴⁵ The Norwegian Labour and Welfare Administration – NAV, 2022.

⁴⁶ www.noma.no, November 2022.

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, medicines and physiotherapy go under the ceiling for co-payments. In 2022, the ceiling is NOK 2,921 (€ 292).

When the cost ceiling has been reached within the calendar year, most of additional out-of-pocket expenses are reimbursed by the National Insurance Scheme (NIS), and any remaining treatment in that calendar year is therefore free of charge. In 2021 approximately 26.5% of the population age over 16, reached this ceiling.⁴⁷ There are several conditions that may exempt from paying co-payments. This is e.g. applicable for children under 16 years, treatment of contagious diseases or transfer between institutions. As a result of this, on average 90% of the expenses on schedules 2 and 3 are reimbursed by the NIS.

Table 3.5:

Norway – Reimbursement categories of medicines, 2023.

Reimbursement category	Reimbursement rate (%) ⁴⁸	Description
Schedule 2	50 / 100	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. An HTA-assessment will assess whether the three prioritisation criteria are fulfilled for the patient group.
Schedule 3	50 / 100	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.

⁴⁷ Prop. 1 S (2021 – 2022) – HOD and Statistics Norway.

⁴⁸ From 1st of January 2023, the reimbursement rate is 50% for schedule 2 and schedule 3. Until December 2022 the reimbursement rate was 61% for both schedules.

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 2021, NIS reimbursed NOK 10.2 billion (€ 1.02 billion) on schedule 2, for 2.75 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 3.5.

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 2021, NIS reimbursed NOK 2.15 billion (€ 0.21 billion) on schedule 3, for 207,541 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. No further application is necessary to obtain 100% reimbursement. Long-term treatment is not a prerequisite for Schedule 4.⁴⁹

In 2021, NIS reimbursed NOK 15 million (€ 1.5 million) on schedule 4, for 26,647 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.

⁴⁹ <https://lovdata.no/dokument/SF/forskrift/2007-06-28-814?q=blåresept>, August 2018.

3.3.3 Private pharmaceutical expenses

In 2021, 27% of the total pharmaceutical costs were directly covered by the patients, cf. section 2.9 figure, 2.6. This number is derived from non-reimbursed prescription-only medicines (11%), OTC medicines (12%) and patient co-payment of reimbursable medicines (4%).

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

Table 3.6:

Norway – Out-of-pocket payments for medicines, 2022.

Out-of-pocket payments	Amount	Vulnerable groups
Fixed co-payments	–	–
Percentage payments	50% (from 2023, c.f. table 3.5), max. NOK 520 (€ 52) per prescription.	Low-income pensioners and children under 16 are exempt
Deductibles	NOK 2,921 (€ 292)	–
Reference price system	Price difference between stepped price and maximum price if patient refuses generic substitution.	–

Source: Helfo, NAV.⁵⁰

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 NoMA 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.

⁵⁰ www.helfo.no, www.nav.no.

3.4.1 Generic substitution

Generic substitution has been allowed in Norway since 2001. According to The Norwegian Pharmacy Association's survey "Apotekbarometeret", 40% were positive and 44% were indifferent to this experience, whereas 15% had a negative experience.⁵¹

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, he or she 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 around 8% of the prescribed medicines.⁵² 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 International Non-proprietary Names (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.⁵³

Asthma/Chronical Lung disease inhalers have been included in the list of products that are generically substitutable in pharmacies.⁵⁴ Pharmacies may offer a training on new users for appropriate uses of inhalers.

3.4.2 Biosimilar substitution

The use of biosimilars has increased since 2006, in large part for H-prescriptions and medicines given patients at hospitals. Due to many years of experience the use of biosimilars, and switching between biological reference product and biosimilar, is considered safe.

⁵¹ <https://www.apotek.no/nyhetsarkiv/statistikk/folk-flest-foretrekker-a-fa-rad-ansikt-til-ansikt>. November 2021.

⁵² <https://legemiddelverket.no/offentlig-finansiering/medisinbytte-i-apotek/apotekets-og-legens-rolle-i-bytteordningen#reservasjon-mot-bytte>. April 2022.

⁵³ www.noma.no, October 2022.

⁵⁴ Salmeterol/fluticasone (Seretide) and formoterol/budesonide (Symbicort) were included in generic substitution and the stepped-price system in 2018.

Biosimilar substitution in pharmacies has been allowed in Norway since July 2021.⁵⁵ As of November 2022, three biological substances, reimbursed by the National Insurance Scheme, are substitutable in Norwegian pharmacies.⁵⁶ Two substances on H-prescription are also substitutable in pharmacies.⁵⁷

3.4.3 INN prescribing

Doctors are allowed, but not obliged, to prescribe by International Non-proprietary Names (INN). For many years, however, about 1% of all prescriptions were on INN. In 2022 a new system for electronic patient records was introduced in one of the health regions. This system facilitates INN prescribing. Due to this, the share of INN-prescriptions has risen to 5,4% in November 2022.⁵⁸

3.4.4 Other generic and biosimilar promotion

Pharmacies promote substitution for economic reasons. They do so by offering the generic or the biosimilar at a lower price than the original product. The use of generic and biosimilar medicines is promoted by the authorities for cost-containment reasons. The NoMA informs about substitution in pharmacies 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 and biosimilar substitution and the stepped price model, the NoMA assumes that the National Insurance Scheme (NIS) and patients save in all approximately NOK 2 billion (€ 200 mio.) every year. These savings are substantial in view of the fact that the NIS reimbursed medicines for NOK 12.0 billion (€ 1.2 billion) in 2021.⁵⁹

Generics and biosimilars 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/biosimilar 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 and biosimilar prescription that doctors would have to fulfil.

⁵⁵ The Pharmacy Act § 6–6.

⁵⁶ Insulin glargine, Insulin lispro and Teriparatide.

⁵⁷ Etanercept and Pegfilgrastim.

⁵⁸ Norsk helsenett.

⁵⁹ NPA. https://www.apotek.no/Files/Filer_2013/Engelske%20sider/Key%20figures%202021.pdf.

3.4.5 Clawbacks

Clawbacks are usually not used in Norway. Exceptions are managed-entry agreements with confidential prices (c.f. 3.4.6).

3.4.6 Managed-entry agreements

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

The first MEAs were entered in 2017, consisting of reimbursement agreements with two MA-holders to access the PCSK9 inhibitors Repatha and Praluent (the agreements have been renewed annually, last time in May 2021). In 2019 and 2020 MEAs were established also for three CGRP-inhibitors. The criteria for entering into MEAs 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 been requested, the Market Authorisation Holder (MAH) should follow the Norwegian guidelines for pharmaco-economic evaluation in connection with applications for reimbursement.⁶⁰

The Norwegian Knowledge Centre for the Health Services (NIPH) performs primarily health technology assessments (HTA) of medical devices and of other non-pharmacological methods. In addition the NIPH is responsible for conducting a full HTA of pharmaceutical group of products while NOMA mainly conducts Single HTA of pharmaceuticals. The Centre publishes all HTAs on the website: <https://www.fhi.no>.

⁶⁰ <https://legemiddelverket.no/english/public-funding-and-pricing>.

3.5.1 Prescription monitoring

The Norwegian Health Economics Administration – 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 Helfo’s 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”⁶¹. NIPH also produces an annual report based on the Norwegian Prescription Database (NorPD).⁶²

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”.⁶³
- Norwegian Pharmacy Association’s “Key figures”.⁶⁴

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

⁶¹ <https://www.fhi.no/contentassets/1b4b603c4ecf410588d584d5062cc9b8/legemiddelforbruket-i-norge-20172021.pdf>. September 2022

⁶² www.reseptregisteret.no. October 2022.

⁶³ <https://www.lmi.no/tall-og-fakta-2022/>

⁶⁴ <http://www.apotek.no/statistikk/2022>

application and sometimes performs such analysis as part of the processing. The NoMA has published guidelines for pharmaco-economic evaluations since 2002, with the latest revision in 2021.⁶⁵

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

⁶⁵ <https://legemiddelverket.no/Documents/English/Public%20funding%20and%20pricing/Documentation%20for%20STA/Guidelines%2018.10.2021.pdf>. October 2021.

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”. 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 2013–2014.⁶⁶ 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 system are (cf. figure 4.1):

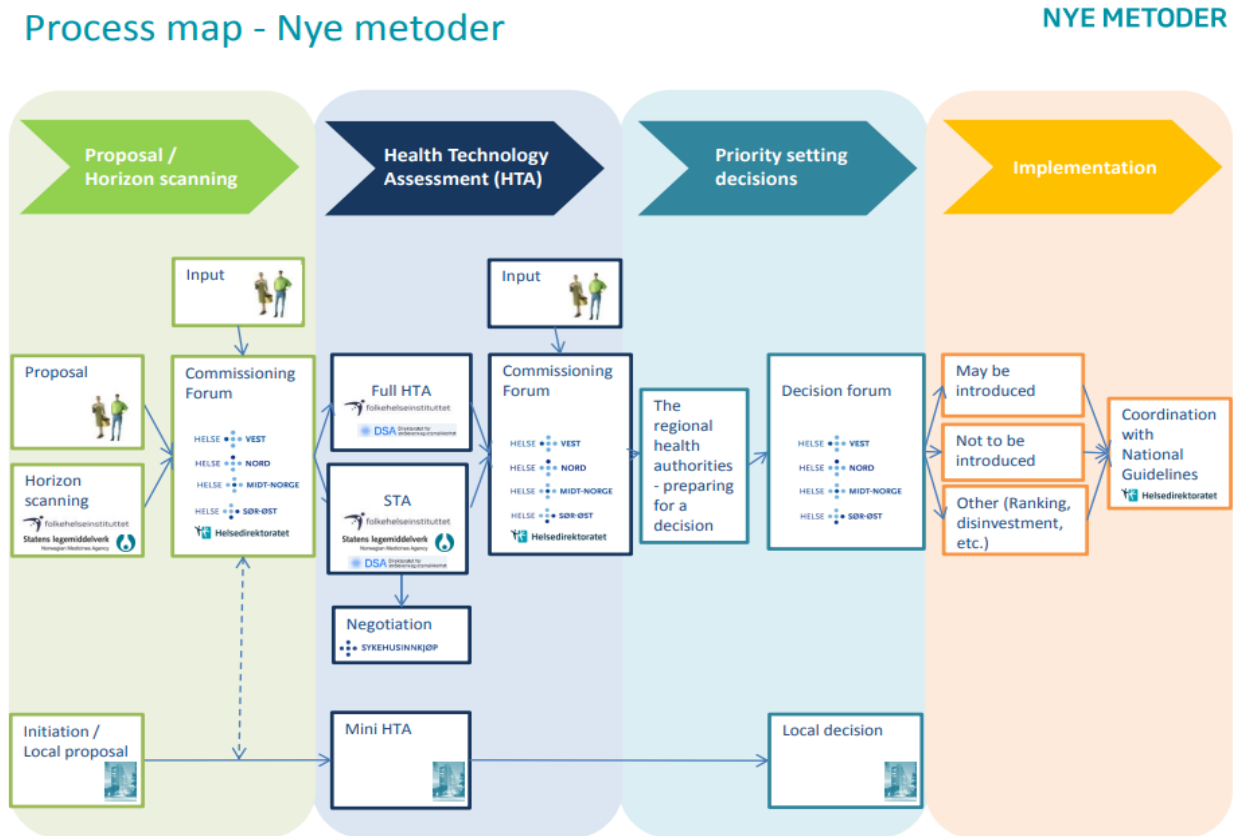
- Horizon scanning
- Health technology assessment
- Prioritisation and decision-making (Priority setting decisions)
- Implementation

The systematic introduction of new pharmaceuticals within the specialist health service follows the similar pathway as for medicines reimbursed by the National Insurance Scheme, reference to section 3.3. The NoMA issues 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, however, effectively, the NoMA carries out a HTA for all new pharmaceuticals and indications.

⁶⁶ <https://nyemetoder.no/english>, September 2018.

Figure 4.1:
Norway – Systematic assessment of new health technologies – Process map.



Source: nyemetoder.no.

The RHAs have established a Decision Forum, consisting of the CEOs of the 4 RHAs and two patient representatives, as well as one representative from the Directorate of Health. Only the CEOs have voting power. The Decision Forum utilizes the HTA to decide on if, and under which circumstances, a medicine will be used and thus reimbursed in the specialist care sector. The assessments also serve as an input to price negotiations. The Norwegian Drug Procurement Organisation (Sykehusinnkjøp HF) 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”.⁶⁷ 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” were used for TNF-inhibitors and MS-medicines. Since then numerous medicines have been transferred to H-prescriptions. About NOK 6.7 billion (€ 670 Mio.) were reimbursed in 2021.⁶⁸ Cf. section 5.1 for more information.

In 2004, the main responsibility for treatment of persons with substance use disorder was transferred from the municipalities to the health enterprises. However, persons with substance use disorder 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 enrolled 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 2021 medicines (methadone and buprenorphine) for NOK 276 Mio. (€ 27,6 Mio.) were handed out to users by the pharmacies.⁶⁹

4.2 Pricing and purchasing policies

The main pricing policy in Norwegian hospitals is tendering and negotiations for mainly new drugs that enters the market.

The Norwegian Drug Procurement Organisation 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 four years. All the wholesalers are distributing medicines on H-prescriptions to all 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 Norwegian Drug Procurement Organisation. There is no legal obligation for hospitals or hospital owners to publish the pharmaceutical prices or to notify the price to a competent authority.

⁶⁷ Doctors in specialist care are either employed by the hospital or private specialists contracted by the health enterprises.

⁶⁸ NorPD, NIPH.

⁶⁹ Farmalogg, NPA.

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 13 billion (€ 1.3 billion) on medicines between September 2021 and August 2022, including 25% value added tax.⁷⁰

The Norwegian Drug Procurement Organisation performs tenders on all pharmaceuticals financed by the hospitals. This is done on a yearly basis on therapy tenders and 2+1+1 years on generic/biosimilar tenders. 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 Norwegian Drug Procurement Organisation tenders and negotiations gave in 2021 a price reduction of 44% on average for the Norwegian hospitals, compared to the statutory maximum prices (for information on statutory prices c.f. section 3.2).⁷¹

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 Organisation (Sykehusinnkjøp HF), 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 medicines are procured through the Norwegian Drug Procurement Organisation. Hospitals purchase medicines according to public procurement regulations within their budget. The regional health authorities (RHAs) settle annual framework agreements through The Norwegian Drug Procurement Organisation and the hospitals' purchases are then considered to be in accordance with this agreement.

The Norwegian Drug Procurement Organisation has confidential prices on what hospitals pay for medicines. Prices are the same for all hospitals and are mostly confidential. The tenders are published in the Doffin⁷² and TED⁷³ database, due to legal provision.

⁷⁰ [www.sykehusinnkjop.no](https://sykehusinnkjop.no/Documents/Legemidler/Statistikktall/tall%20til%20nettsiden%20-%20oppdatert%20for%20august%202022.pdf), October 2022 <https://sykehusinnkjop.no/Documents/Legemidler/Statistikktall/tall%20til%20nettsiden%20-%20oppdatert%20for%20august%202022.pdf>

⁷¹ Sykehusinnkjøp HF.

⁷² <http://www.doffin.no>.

⁷³ <http://ted.europa.eu>.

The process is co-ordinated by the Norwegian Drug Procurement Organisation.

The assignment criteria are the following:

- Price
- Security of continuous supply/minimum storage
- 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 pay for the medicines handed out from pharmacies (for use in hospitals & H-prescriptions 50% each). 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.

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 Specialist groups

All tender processes are comprised of specialists from the Norwegian Drug Procurement Organisation and a group of experts in the tendering field. Each regional hospital trust selects their participants into the group. The group settle on all criteria and handle the whole process of tendering together. This imply making the documents, deciding on criteria and products that are equal, and arrange a seminar with users to help implement the tender.

4.5 Volume Control in the specialist care sector

4.5.1 Monitoring

The pharmacies and wholesaler give statistics on prices, expenditure per article and active substance. The hospital is the owner of the statistics. A computer system 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 Norwegian Drug Procurement Organisation annually by expenditure per active ingredient and expenditure per package per article. The statistics can be given by the Norwegian Drug Procurement Organisation on request.

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

5.1.1 Reform for better interaction between primary and secondary healthcare systems

The Government has been implementing a reform for better interaction between the primary and specialist healthcare systems between 2012 and 2015.⁷⁴ The reform gives incentives to the municipalities to prevent disease and injury in their population. For example, the municipalities will be obliged to provide emergency help and 24 hours-services for patients in need of treatment or observation.

Since 2012, co-payment from the municipalities is required for some treatments in specialist healthcare. Municipalities are required 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 the reason why there has been transferred a significant amount 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.⁷⁵

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

5.1.2 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

⁷⁴ <https://www.regjeringen.no/nb/tema/helse-og-omsorg/helse--og-omsorgstjenester-i-kommunene/samhandlingsreformen/status-samhandling/id708254/>, September 2018.

⁷⁵ <https://www.regjeringen.no/no/aktuelt/komm-pressemedling-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.

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 Hepatitis B and Hepatitis C.⁷⁶ In 2022 (12 last months to October 22), the RHAs reimbursed H-prescriptions for NOK 13 billion (€ 1,3 bill) incl. VAT (PPP).

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

Financing of medicines fulfilling these criteria, which currently are financed by the NIS will gradually be transferred to the RHAs. This means at 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.⁷⁷

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 are still subject to the individual agencies’ national regulations country-by-country.

⁷⁶ <https://sykehusinnkjop.no/legemidler#h-preparater>, September 2018.

⁷⁷ 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
- Reduce complexity in industry submissions

FINOSE is now accepting applications for joint assessment.

Nordic Pharmaceutical Forum

The Nordic Pharmaceuticals Forum (Nordisk Lægemedelforum) was established in 2015. The collaboration focusses on sharing knowledge and working towards common Nordic solutions. The Nordic Pharmaceuticals Forum is a collaboration of Finland, Norway, Denmark, Iceland and Sweden. The ministers of Health in Denmark and Norway signed in 2018 an agreement for collaboration in negotiations of expensive drugs. Iceland has later entered into the agreement. The Nordic countries (Finland, Norway, Denmark, Iceland and Sweden) have conducted two joint negotiations on two gene therapies (Zynteglo and Libmeldy). It is also a collaboration on tenders between the countries, mainly on older antibiotics between Denmark, Iceland and Norway. More information can be found here: www.sykehusinnkjop.no.

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6.2 Legislation

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The Health and Care Services Act – 2011

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The Norwegian Act on Medicinal Products – 1992

The Patients' Rights Act – 1999

The Specialist Health Care Services Act – 1999

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Forskrift om rekvirering og utlevering av legemidler m.m. – 2022

6.3 Web links

Relevant web links are included in the text.